LA TECNOLOGIA
oggi ... e domani

Milano, 7 giugno 2025

Asst Grande Ospedale Metropolitano Niguarda

I sistemi per Automated Insulin Delivery

La conta dei carboidrati: è ancora necessaria?

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S.C. Diabetologia - ASST Sette Laghi

Il sottoscritto Nicholas Chiari dichiara di NON aver ricevuto negli ultimi due anni compensi o finanziamenti da Aziende Farmaceutiche e/o Diagnostiche.

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Nutrition therapy in diabetes: an overview

Carbohydrate intakes in diabetes management

- A wide range of carbohydrate intakes are acceptable, provided recommendations relating to dietary fibre, sugars, saturated fats and protein intakes are met. ⊕⊕⊕⊖ Moderate
- Very low carbohydrate intakes, such as with ketogenic diets, are not recommended. ⊕⊕⊕⊖ Moderate
- Foods naturally high in dietary fibre should be encouraged. ⊕⊕⊕⊕ High
- Dietary fibre intake should be at least 35 g per day (4 g per 1000 kJ). ⊕⊕⊕⊖ Moderate
- Fibre-enriched foods and fibre supplements should be considered when sufficient intakes cannot be obtained from diet alone. ⊕⊕⊕⊖ Moderate
- Diets with a low glycaemic index or low glycaemic load can be recommended, provided their composition is consistent with overall diet recommendations for dietary fibre, sugars, saturated fats and protein. ⊕⊕⊕⊖ Moderate
- Intakes of free or added sugars should be below 10% of total energy intake. ⊕⊕⊕⊖ Moderate
- Non-nutritive sweeteners (NNS) can be used to replace sugars in foods and beverages. ⊕⊕⊕⊖ Moderate
- Carbohydrate counting may be a useful approach to determine mealtime insulin dose. ⊕⊕⊕⊖ Moderate

Dietary fat intakes in diabetes management

- Dietary fats should mainly come from plant-based foods high in both mono- and polyunsaturated fats, such as nuts, seeds and non-hydrogenated non-tropical vegetable oils. ⊕⊕⊖⊖ Low
- Saturated- and *trans*-fat intakes should comprise <10% and <1% of total energy, respectively. ⊕⊕⊖⊖ Low
- When reducing saturated fats, replacement should be mainly with plant-based polyunsaturated fats containing both *n*-6 and *n*-3 fatty acids, and monounsaturated fats as found in nuts, seeds and non-hydrogenated non-tropical vegetable oils. ⊕⊕⊖⊖ Low

Protein intakes in diabetes management

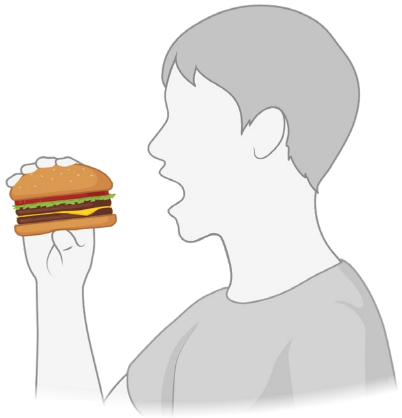
- For weight-stable, normal-weight people with diabetes a protein intake of 10-20% total energy is recommended for people under the age of 65 years with an estimated glomerular filtration rate (eGFR) >60 ml/min per 1.73m^2. Higher intakes (15-20% total energy) are recommended for those aged 65 years or older. ⊕⊕⊖⊖ Low
- For people with type 2 diabetes who have overweight or obesity with an eGFR >60 ml/min per 1.73m^2 a protein intake of 23-32% may be recommended in the short term (up to 12 months) in the context of a weight-loss diet. ⊕⊕⊖⊖ Low
- For people with moderate diabetic nephropathy (stage 3a: eGFR <60 but >45 ml/min per 1.73m^2) a protein intake of 10-15% is recommended. ⊕⊕⊖⊖ Low

Carbohydrate counting is a way of **adjusting insulin dose to the amount of carbohydrate in a meal**. The goal of carbohydrate counting in the treatment of type 1 and type 2 diabetes with a basal-bolus insulin regimen is to **allow flexibility in meal choice** by adjusting insulin dose to food intake without a negative effect on metabolic control and health outcomes. Carbohydrate counting has been associated with **improved HbA1c** in adults, **with no detrimental effect on severe hypoglycaemia or quality of life**.

Diabetologia. 2023 Jun;66(6):965-985.

Core elements

Carbohydrate counting focuses on carbohydrate as the primary nutrient affecting the postprandial glycemic response and **assumes a linear correlation between the amount of carbohydrates consumed and insulin dose**.



Postprandial glycemic response and insulin requirement depend on the **amount of carbohydrate in the meal** rather than the type of carbohydrate consumed.

1:X

Bolus insulin is calculated from the total amount of carbohydrate consumed at each meal and the insulin-carbohydrate ratio (ICR varies among individuals and is defined as **the number of grams of carbohydrate that are covered by 1 unit of insulin**).

Nutrients. 2024 Sep 26;16(19):3249.

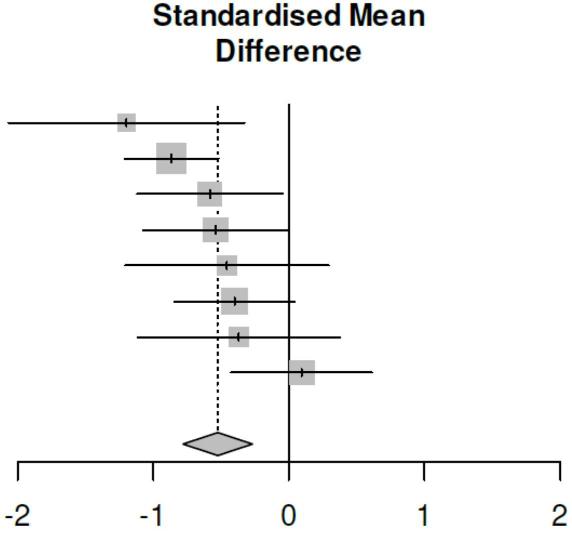
Cureus. 2023 Nov 18;15(11):e48998.

Lancet Diabetes Endocrinol. 2022 Jan;10(1):58-74.

From counting to control: improving glycemia

Study	Carbohydrate Counting Total	Mean	SD	Control Total	Mean	SD	SMD	95%-CI	Weight
Schmidt et al. 2012	22	8.10	0.4000	8	8.90	1.1000	-1.20	[-2.07; -0.33]	6.7%
DAFNE Study Group 2002	69	8.40	1.2000	72	9.40	1.1000	-0.86	[-1.21; -0.52]	20.1%
Trento et al. 2011	27	7.20	0.9000	29	7.90	1.4000	-0.58	[-1.12; -0.05]	13.2%
Laurenzi et al. 2011	28	7.61	0.6400	28	7.94	0.5600	-0.54	[-1.08; -0.01]	13.3%
DeAlbuquerque et al. 2014	14	8.39	2.2800	14	9.62	2.9100	-0.46	[-1.21; 0.30]	8.4%
Goksen et al. 2014	52	7.58	0.9700	32	8.01	1.2000	-0.40	[-0.85; 0.04]	16.2%
Enander et al. 2012	14	7.60	1.1000	14	8.00	1.0000	-0.37	[-1.12; 0.38]	8.5%
Donzeau et al. 2020	27	7.82	0.8700	30	7.74	0.8200	0.09	[-0.43; 0.61]	13.7%
Random effects model	**253**			**227**			**-0.52**	**[-0.78; -0.27]**	**100.0%**

Heterogeneity: $I^2 = 41.2\%$, $\tau^2 = 0.0529$, $p = 0.1034$



In daily clinical practice, the goal is to maintain good long-term disease control, prevent chronic complications from DM, and reduce the frequency of hypoglycemia and/or hyperglycemia to improve overall quality of life. Carbohydrate counting (CC), when used as a strategy to calculate prandial insulin doses in adults with type 1 diabetes mellitus, has consistently been associated with **improved glycemic control** compared to standard dietary approaches. <u>This benefit has been demonstrated across both short-term</u> (e.g., 3 months) <u>and long-term follow-up periods</u>, suggesting the durability of its effectiveness. CC is generally considered a safe approach, as current evidence **does not consistently indicate an increased risk of hypoglycemia or weight gain**. Moreover, total daily insulin requirements appear to remain comparable between those using CC and those receiving conventional care, further reinforcing its safety profile.

J Hum Nutr Diet. 2022 Dec;35(6):1030-1042.

Arch Endocrinol Metab. 2018 Jun;62(3):337-345.

Nutrients. 2024 Jul 9;16(14):2183.

Healthcare (Basel). 2023 Mar 24;11(7):934.

Prioritizing quality of life

	W-BQ12	Diabetes treatment satisfaction questionnaire (DTSQ)			Cardiovascular risk factors			
			Perceived frequency† of:					
Group	Total wellbeing*	Total satisfaction*	Hyperglycaemia	Hypoglycaemia	Weight (kg)	Total cholesterol (mmol/l)	HDL cholesterol (mmol/l)	Triglycerides (mmol/l)
Immediate DAFNE:								
Baseline	20.94 (5.8)	22.88 (6.2)	3.57 (1.4)	2.04 (1.2)	80.5 (16.7)	5.2 (0.9)	1.5 (0.4)	1.5 (0.9)
6 months	24.34 (5.7)	31.58 (3.9)	2.90 (1.4)	2.16 (1.3)	81.5 (16.9)	5.1 (0.8)	1.6 (0.4)	1.4 (0.7)
Delayed DAFNE:								
Baseline	21.09 (5.8)	23.21 (5.8)	3.60 (1.6)	2.12 (1.4)	77.4 (13.4)	4.9 (0.8)	1.5 (0.5)	1.5 (0.9)
6 months	21.37 (5.5)	22.82 (6.0)	4.03 (1.3)	2.40 (1.3)	77.3 (13.4)	5.0 (1.0)	1.5 (0.3)	1.5 (0.9)
Difference between groups at six months								
Mean (95% CI)	2.98 (1.06 to 4.89)	8.75 (7.02 to 10.48)‡	–1.13 (–1.59 to –0.67)	–0.23 (–0.68 to 0.21)	4.18 (–0.90 to 9.27)	0.15 (–0.16 to 0.45)	0.09 (–0.01 to 0.22)	0.12 (–0.41 to 0.17)
Statistical values	*t*=3.1, P<0.01	*t*=–10.3, P<0.0001	*t*=–4.88, P<0.0001	*t*=–1.0, P=0.31	*t*=1.6, P=0.11	*t*=0.95, P=0.34	*t*=1.46, P=0.14	*t*=0.83, P=0.41

We found a **significant improvement in <u>psychological wellbeing</u> and <u>satisfaction with treatment</u>** at six months and a **significant decrease in <u>perceived frequency of hyperglycaemia</u>** (**perceived frequency of <u>hypoglycaemia</u> did not change significantly** in either group across the trial). Twelve months after training psychological wellbeing had continued to improve to a mean of 24.7 (P<0.0001). Treatment satisfaction remained significantly higher, with a 12 month mean of 31.0 (P<0.0001).

BMJ. 2002 Oct 5;325(7367):746.

Prioritizing quality of life

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Despite **increased dietary freedom** (as shown by responses to the *“freedom to eat as I wish”* item in the audit of diabetes-dependent quality of life), we observed **no deterioration in cardiovascular risk factors**. These results are encouraging and suggest that people with established diabetes, when taught appropriate skills, will intensify management of their diabetes.

BMJ. 2002 Oct 5;325(7367):746.

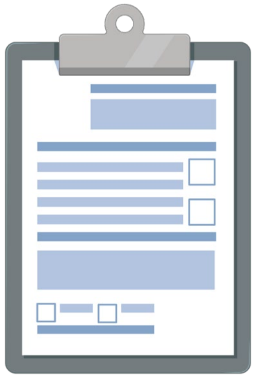
How it works?

Nutritional tool

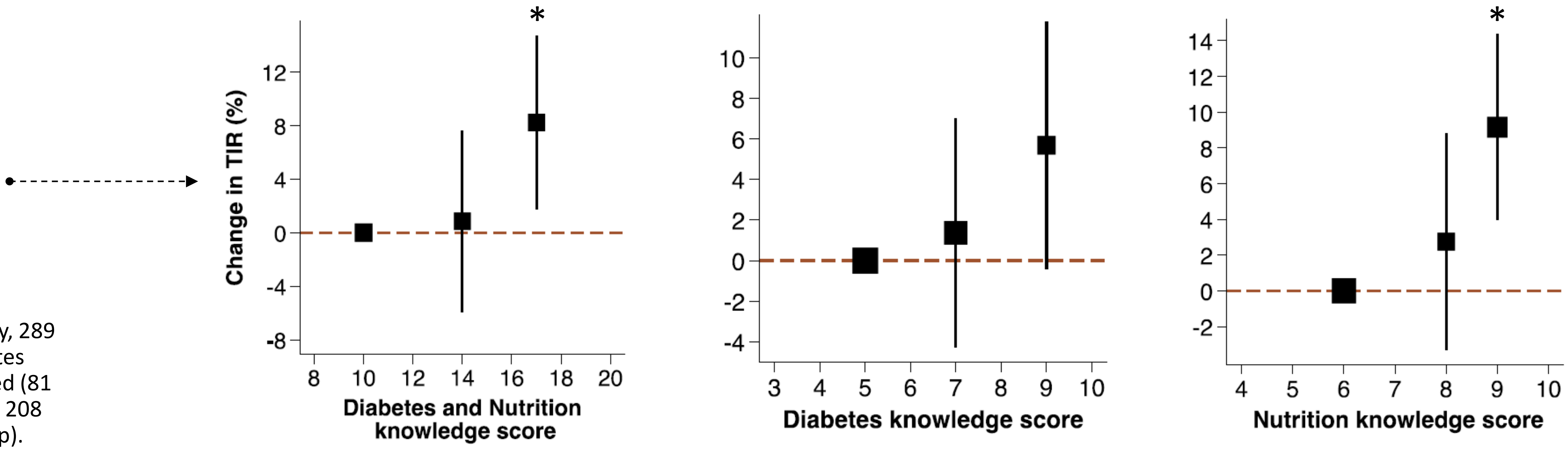
There is a consensus on the beneficial role of **carbohydrate counting as a <u>key component</u> of nutritional education in diabetes management**. Educational programs are essential to <u>enhance nutritional literacy</u> and guide patients toward healthier decisions.

Nutrients. 2024 Jul 9;16(14):2183.

Missing skills, missed opportunities



In this cross-sectional study, 289 participants with diabetes mellitus type 1 are included (81 with an insulin pump and 208 without an insulin pump).



In participants with T1D, a combined **diabetes and nutrition knowledge** score of ≥16/20 points **increased the TIR significantly by +9%** when compared with participants with a score of ≤12/20 points adjusted for age, diabetes duration and diabetes complications. When assessing both questionnaires separately, no significant association was seen between TIR and the diabetes knowledge score in participants with T1D. However, participants with T1D with a **nutrition knowledge score of ≥9/10 points had a significant increase in TIR of +9.2%** when compared with participants with a nutrition knowledge score of ≤7/10 points adjusted for age, diabetes duration and diabetes complications. Hence, **a better nutrition knowledge was also associated with a higher TIR in participants with type 1 diabetes**.

Diabet Med. 2025 Feb 28:e70018.

How it works?

Nutritional tool

There is a consensus on the beneficial role of **carbohydrate counting as a key component of nutritional education in diabetes management**. Educational programs are essential to enhance nutritional literacy and guide patients toward healthier decisions.

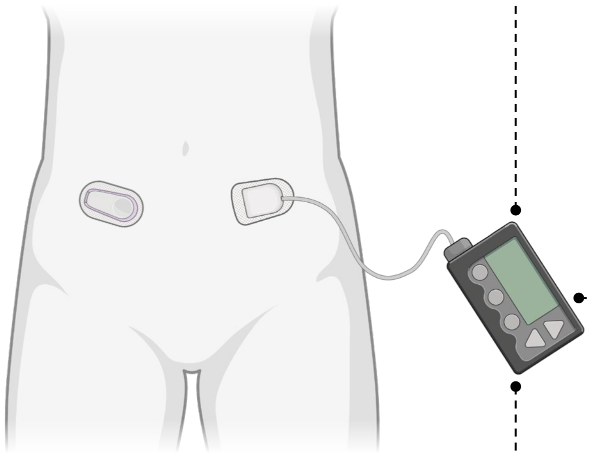
Non only carbohydrates!

Meal composition should be addressed, as high amounts of fat and/or proteins can have (with significant differences among individuals) an impact on glycemic control. This impact may require adjustment of insulin dosage and/or duration of insulin delivery.

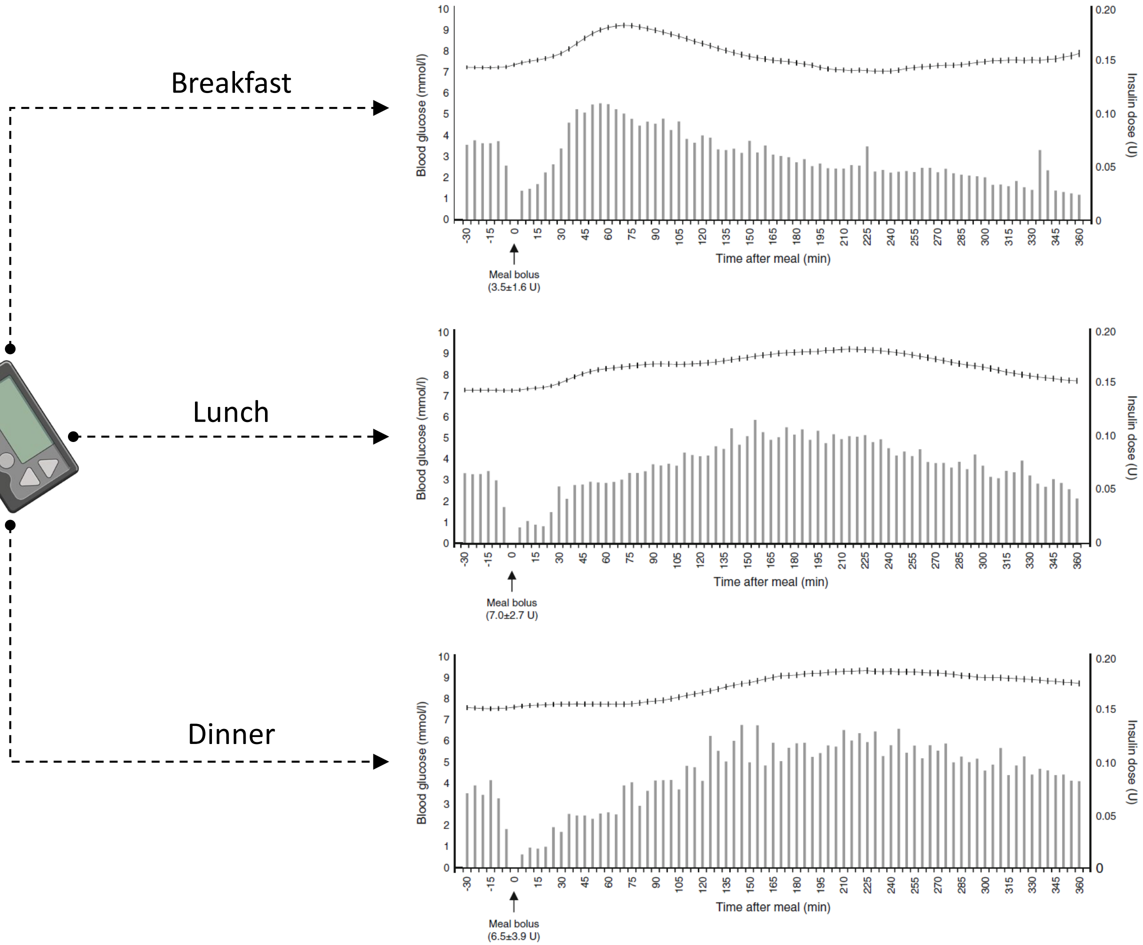
Nutrients. 2024 Jul 9;16(14):2183.

Front Clin Diabetes Healthc. 2023 Aug 29;4:1243237.

Beyond carbs



Overall, dietary records included 1.264 meals (398 breakfasts, 441 lunches and 425 dinners).



A higher glycaemic load was a predictor of decreased postprandial TIR, driven by a **main contribution of simple sugars**.

No relationship between post-lunch TIR and meal composition was observed. The increased food variety may have attenuated the effects of individual nutrients through complex dietary interactions.

Dinner showed the worst postprandial control compared with the other meals, with a glucose response increasing up to 6 h after the meal. This was generally the meal **highest in protein**, **fat** and **foods with a high glycaemic index**.

Diabetologia. 2022 Jan;65(1):79-87.

How it works?

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Nutritional literacy

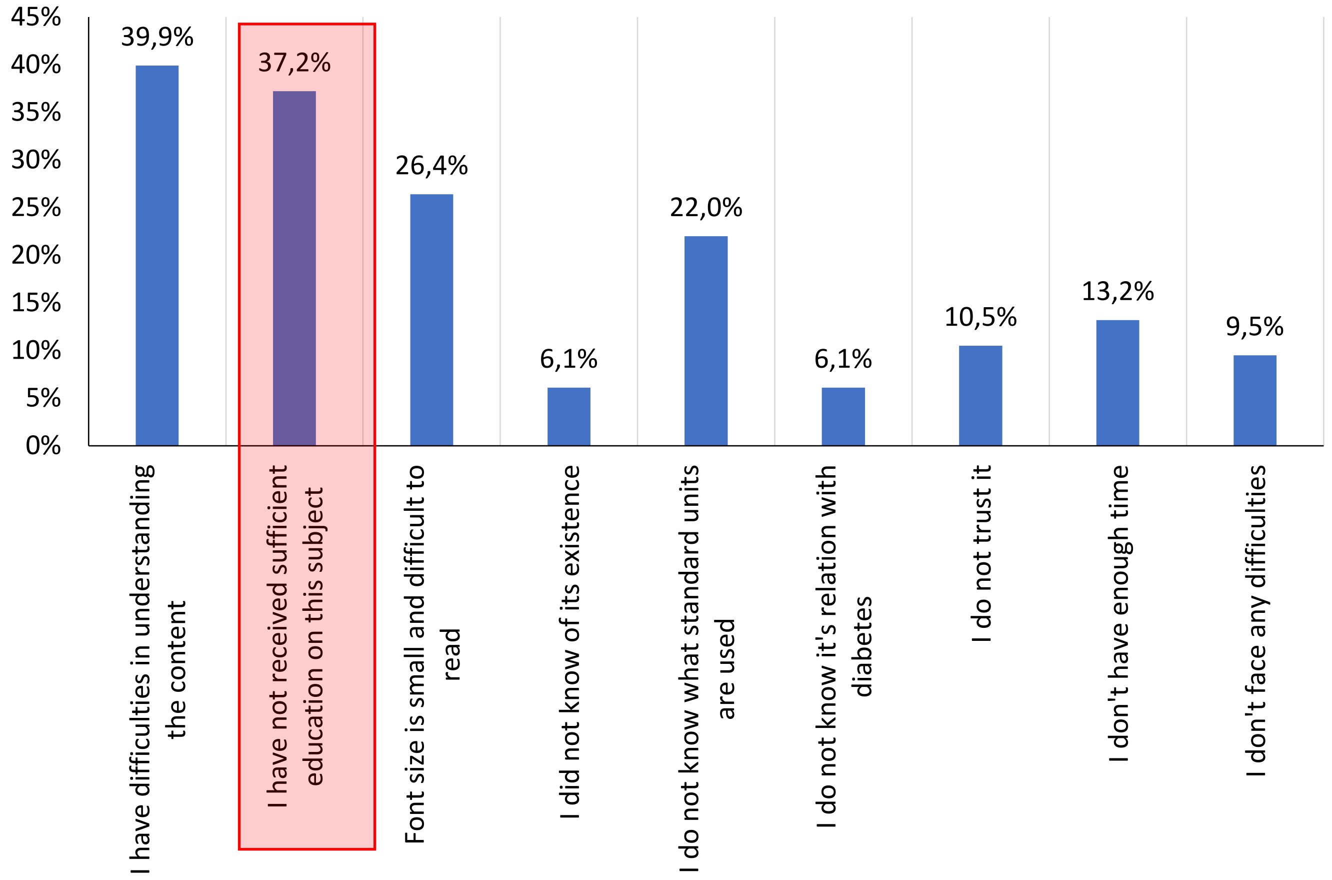
Patients and healthcare providers must work together to **improve patients' nutritional literacy**, particularly with regard to food labeling, food composition, food selection, and portion sizing, which are fundamental to daily meal planning.

Nutrients. 2024 Jul 9;16(14):2183.

Front Clin Diabetes Healthc. 2023 Aug 29;4:1243237.

Read it right

The majority of participants (39.9%) reported having trouble interpreting the content on the nutrition labels, and some of the participants (**37.2%**) reported **<u>not having attended any educational sessions on the topic</u>. Only 9.5%** of the participants said that **reading food labels was not difficult** for them. <u>There is a need to educate patients about food labels to help them in choosing healthy meals</u>.



J Family Med Prim Care. 2023 Feb;12(2):264-269.

Carb counting: an essential skill


DOCUMENTO DEL GRUPPO
DI STUDIO INTERSOCIETARIO
AMD - SID - SIEDP
"TECNOLOGIA E DIABETE"

MICROINFUSORI DI INSULINA - *Caratteristiche del paziente ideale*

Selezionare correttamente il paziente è compito cruciale e talora difficile. Le indicazioni cliniche non sempre sono sufficienti per garantire il successo della terapia; pertanto, è essenziale una adeguata valutazione del paziente, che idealmente dovrebbe avere le seguenti caratteristiche:

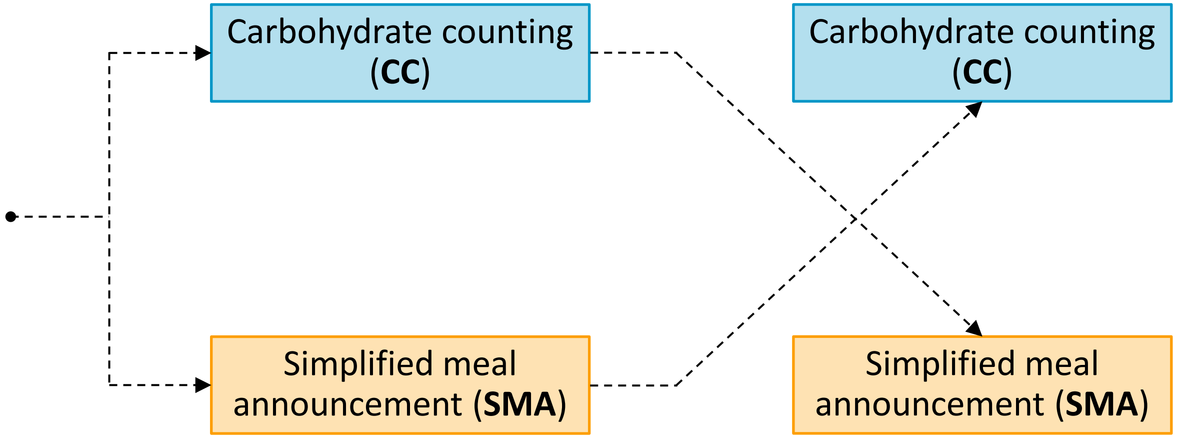
- essere motivato e desiderare di raggiungere e mantenere un buon controllo del diabete
- essere disponibile al cambiamento
- avere aspettative realistiche nei confronti della CSII
- accettare di eseguire ≥ 4 glicemie capillari al giorno
- accettare lo strumento ed essere in grado di apprendere l'uso e la gestione della pompa
- **conoscere e applicare il calcolo dei carboidrati**
- dimostrare stabilità emotiva

SISTEMA INTEGRATO - *Caratteristiche del paziente ideale*

Il paziente ideale per utilizzare un microinfusore integrato o associato ad un dispositivo per CGM deve avere **le stesse caratteristiche del paziente ideale per l'uso della CSII** e inoltre deve essere:

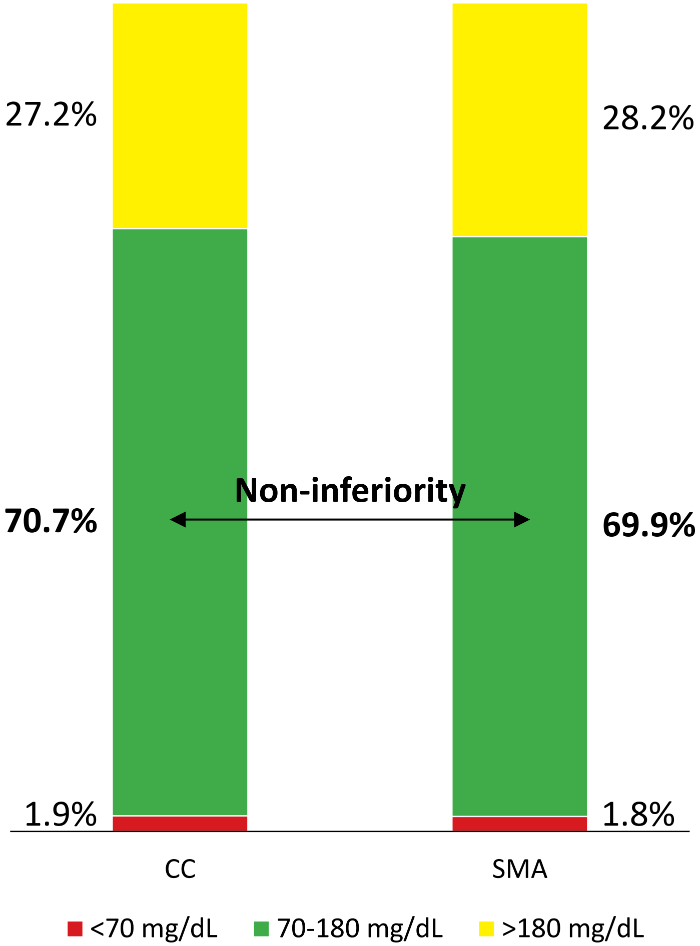
- in grado e disposto a usare il CGM per un tempo ≥ 70 %
- adeguatamente istruito sull'uso dello strumento
- consapevole del significato del "lag-time" e delle frecce di tendenza

Counting or not?



Two-centre, randomised crossover, non-inferiority trial in 46 participants (aged 12-20 years) with T1D. Participants underwent two 3-month periods using HCL system to **compare SMA** (individualised carbohydrate meal sizes) **with CC** (carbohydrate counting).The **primary endpoint** was the proportion of time glucose was in **target range** (70-180 mg/dL) **<u>with a non-inferiority margin of 5 percentage points</u>**.

In the intention-to-treat analysis, **time in range** (mean±SD) was **69.9±12.4% with SMA** and **70.7±13.0% with CC** (estimated mean difference -0.6 percentage points, demonstrating non-inferiority).



Diabetologia. 2025 Feb;68(2):295-307.

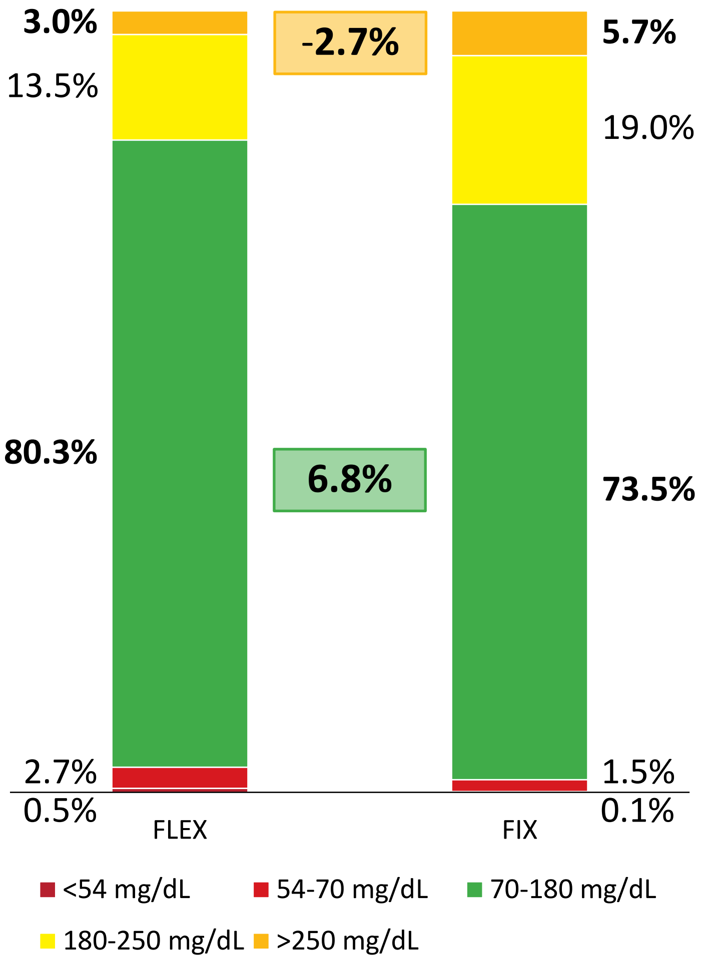
Counting or not?

Precise carbohydrate counting (**Flex group**)

Simplified meal announcement by preset of three personalized fixed carbohydrate amounts (**Fix group**)

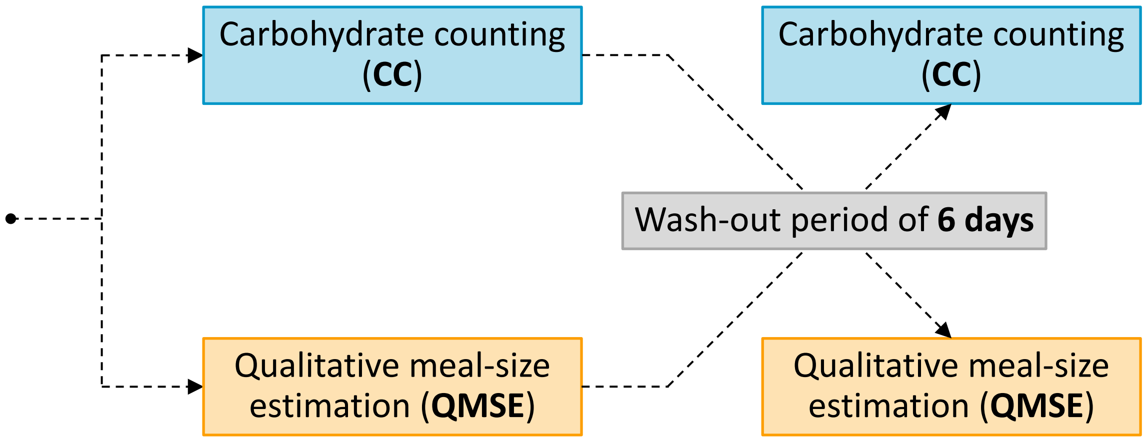
This randomized controlled trial included 34 participants (age 12-18 years) with T1D. Participants were randomly assigned to the **fix group** (simplified meal announcement by preset of three personalized fixed carbohydrate amounts) or the **flex group** (precise carbohydrate counting) and followed for 12 weeks. Between-group d**ifference in time in range** (TIR) was the **primary endpoint**.

In adolescents using an AHCL system was found a **significant 6.8% TIR difference in favor of the flex group** during the study phase, as well as a **significant -2.7% difference of time >250 mg/dL**.



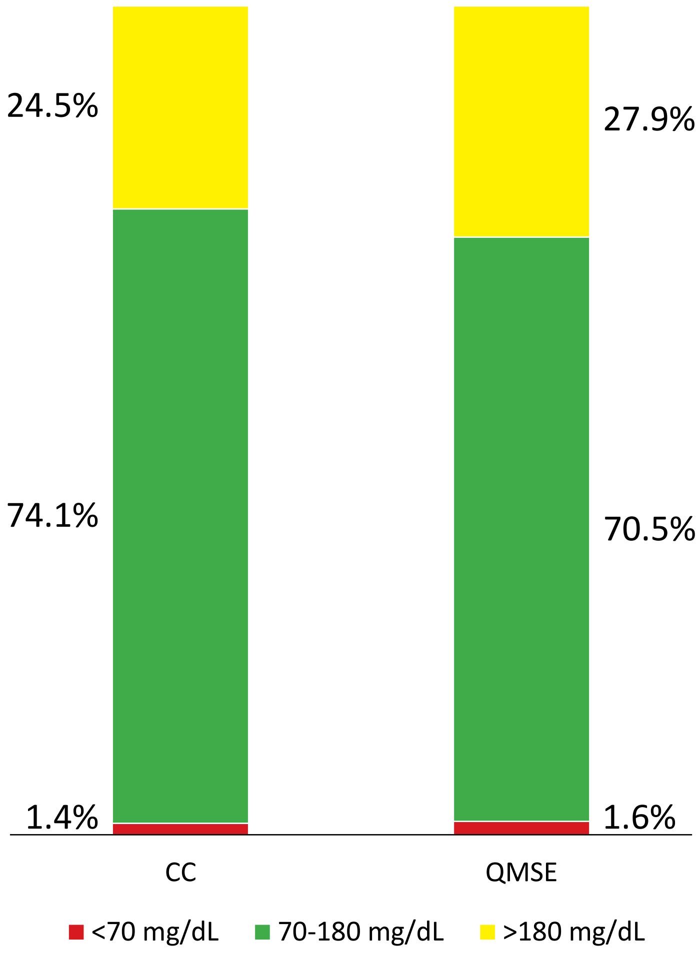
Diabetes Care. 2023 Mar 1;46(3):544-550.

Counting or not?



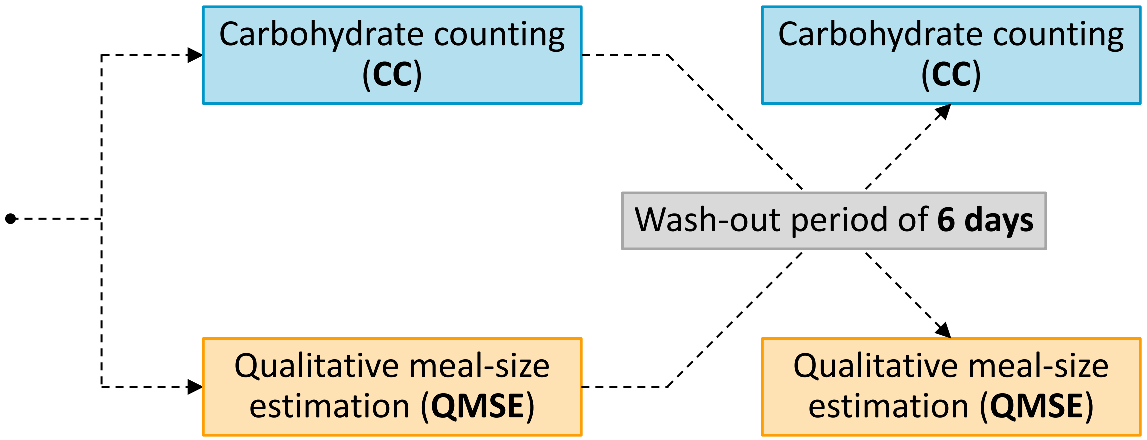
Two-center, randomized, crossover, noninferiority trial to compare 3 weeks of automated insulin delivery with 1) **CHO counting** and 2) **qualitative meal-size estimation** in adults with type 1 diabetes. The primary outcome was time in range 70-180 mg/dL, **<u>with a predefined noninferiority margin of 4%</u>**. A total of 30 participants completed the study.

Even though the qualitative meal-size estimation led to a high time in range and low time in hypoglycemia, it still **degraded time in range by 3.6%** compared with CHO counting, and noninferiority with a predefined margin of 4% was not confirmed.



Diabetes Care. 2023 Jul 1;46(7):1372-1378.

Counting or not?



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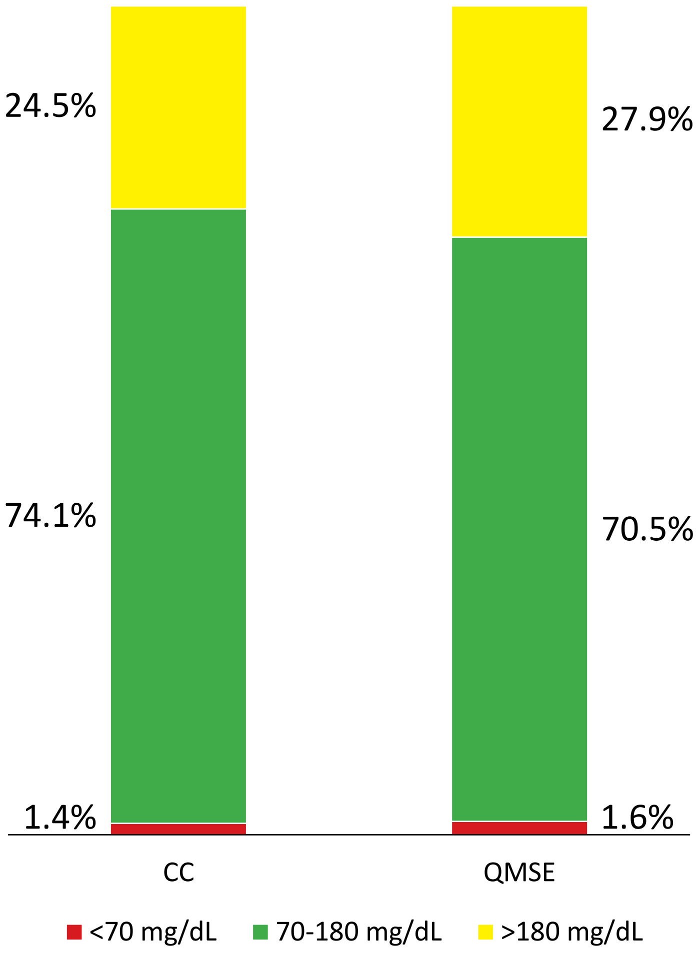
During the night, the **TIR was 77.7% with CHO counting and 72.7% with qualitative meal-size estimation** (P=0.014).



Diabetes Care. 2023 Jul 1;46(7):1372-1378.

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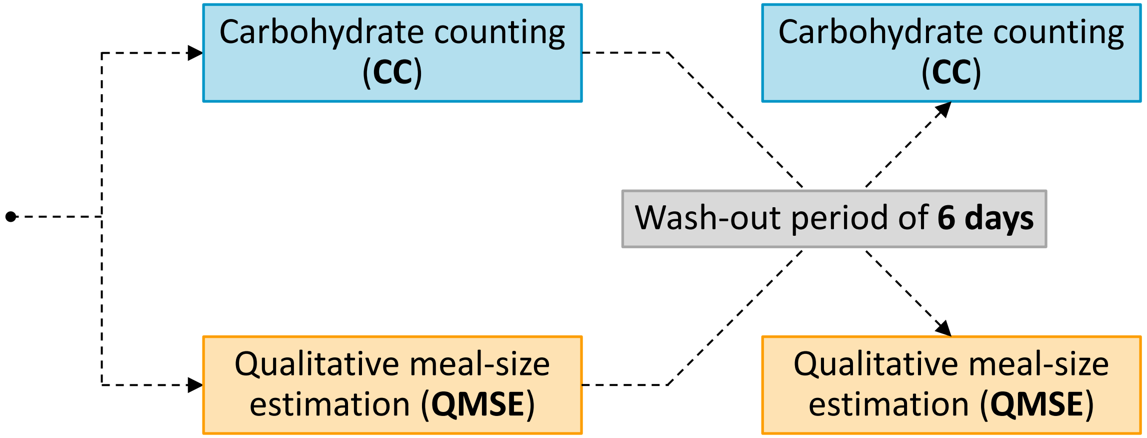

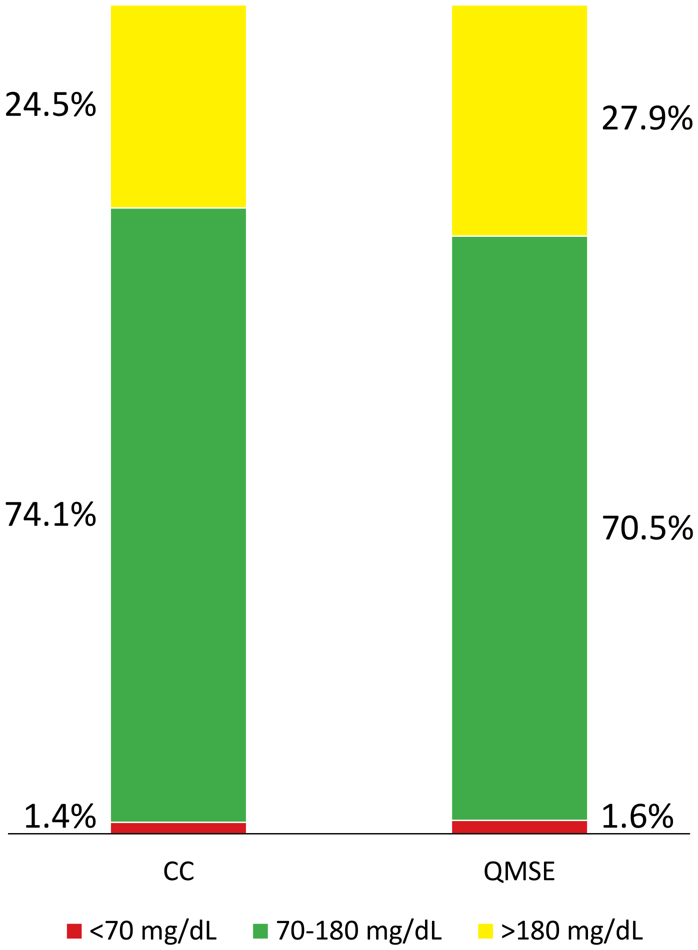

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The **time in tight range** (TITR), defined as the percentage of time spent in target glucose range of 70-140 mg/dL, was **51.1% with CHO counting** and **46.6% with qualitative meal-size estimation** (-4.5%; P=0.012).

Diabetes Care. 2023 Jul 1;46(7):1372-1378.

Nutrition knowledge is the common thread

Randomized Controlled Trial > Diabetologia. 2025 Feb;68(2):295-307.
doi: 10.1007/s00125-024-06319-w. Epub 2024 Nov 19.

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

Randomized Controlled Trial > Diabetes Care. 2023 Jul 1;46(7):1372-1378.
doi: 10.2337/dc22-2297.

A Randomized Crossover Trial to Compare Automated Insulin Delivery (the Artificial Pancreas) With Carbohydrate Counting or Simplified Qualitative Meal-Size Estimation in Type 1 Diabetes

Randomized Controlled Trial > Diabetes Care. 2023 Mar 1;46(3):544-550.
doi: 10.2337/dc22-1692.

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

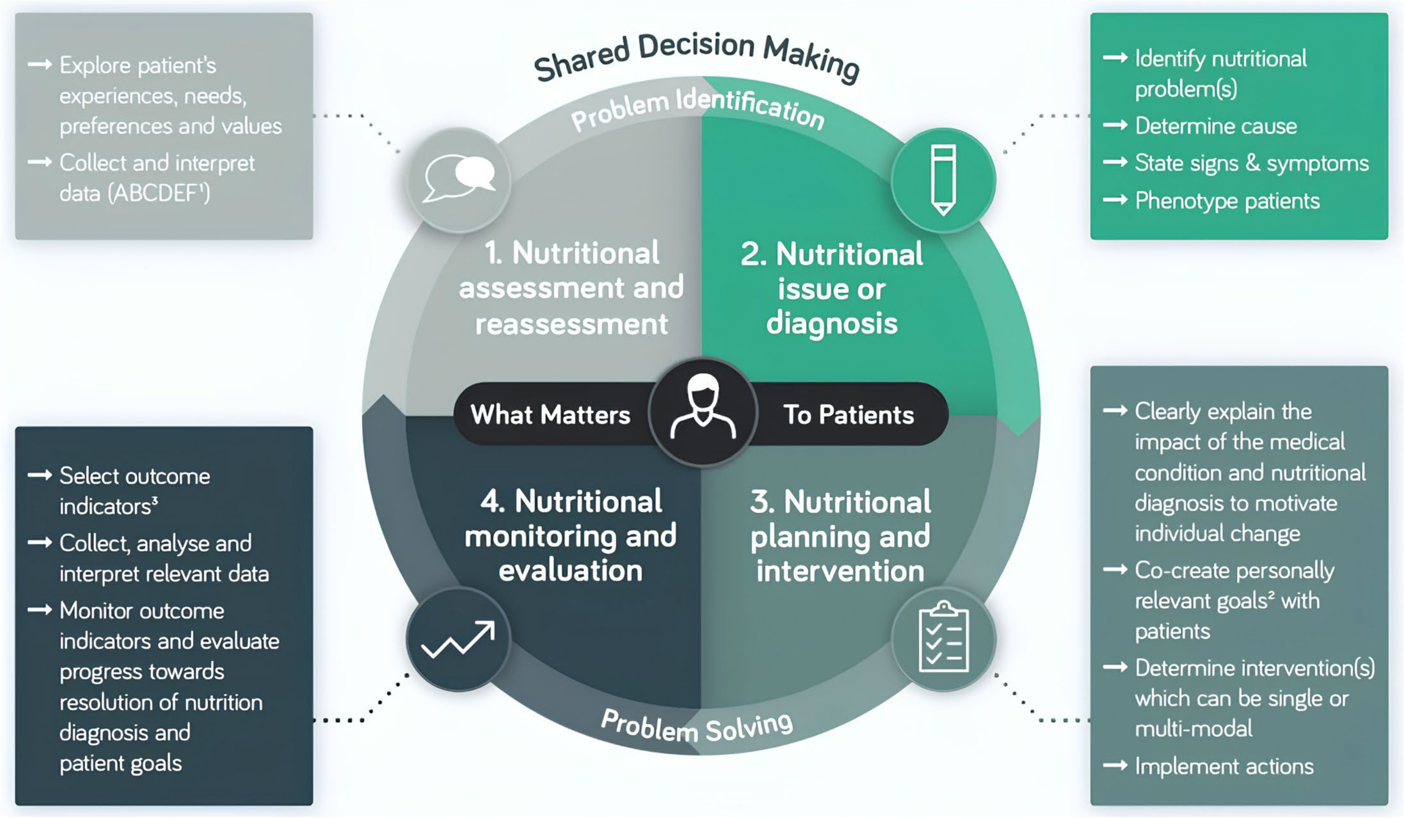
Nutritional knowledge

It could be a <u>**slippage into unhealthier eating as a result of using the closed-loop**</u>. Specifically, some participants reported increased snacking and portion sizes and consumption of fatty, energy-dense foods (e.g. pizza) <u>because of the perceived ability of the closed-loop to deal with errors in carbohydrate counting and automatically address small fluctuations in blood glucose</u> resulting from snacking or delayed absorption of fatty foods. Since participants may become deskilled as a result of using a closed-loop system, <u>**users may benefit from ongoing training in carbohydrate counting to help ensure effective diabetes management**</u>.

Diabet Med. 2019 Jun;36(6):753-760.

Conclusions

Regardless of the technology progress that reduce the patient's involvement in therapeutic decisions, <u>education remains crucial for the successful initiation and management of insulin pumps therapy.</u> Alongside technical education and support, **<u>the knowledge of carb counting is the fundamental to the success of insulin pumps therapy success, even with AHCL systems</u>**.



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LA TECNOLOGIA oggi ... e domani

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Asst Grande Ospedale Metropolitano Niguarda

Thank you