ARE CARBOHYDRATE COUNTING APPS USEFUL FOR PEOPLE WITH DIABETES? OPINIONS OF DIETITIANS AND DIABETOLOGISTS.

Anam Gubitra

Student M.Sc., Department of Food Science and Dietetics

Dr. Shobha Udipi, Mrs Sheryl Salis

Department of Food Science and Dietetics

SVT College of Home Science

Mumbai, India.

Abstract : The objective of this study was to gauge the importance of carbohydrate counting as a tool for management of diabetes mellitus and its practice and use of apps for carbohydrate counting by professionals in India. Carbohydrate counting used in counselling for diabetes patients has helped in achievement of dietary management goals. The study is designed to record the opinions of diabetologists and dietitians on the usage of carbohydrate counting apps. The information would be useful for developing technology applications to help the medical professionals in counselling and patients to manage their diets.

IndexTerms **- Diabetes, Carbohydrate counting, Apps, Dietitians, Diabetologists.**

I.INTRODUCTION

1.DIABETES

1.1 PREVALANCE OF DIABETES

Diabetes mellitus has afflicted more than 422 million people worldwide. [Kitajima, et.al., 2016]. According to Wild et al.2009, the prevalence of diabetes would double globally in 2030 with a maximum increase in India. In India, the steady migration of people from rural to urban areas, the economic boom, and corresponding change in life-style would be factors affecting the level of diabetes. [Kaveeshwar, et.al, 2014]. However, the advances in management programmes and tools in India may not be keeping up with the increase in the prevalence of the disease.

1.2 PATHOPHYSIOLOGY OF DIABETES

Diabetes mellitus is described a group of metabolic diseases characterized by elevated blood glucose levels termed as hyperglycaemia, resulting from metabolic or genetic defects in insulin secretion, insulin action, or both. [American Diabetes Association,2009] Type 1 and Type 2 diabetes are the most common forms of the disease, other forms such as gestational diabetes and MODY (Maturity Onset Diabetes of the Young) also exist.

Several pathogenic processes are involved in the development and complication of diabetes. Autoimmune destruction of the β-cells of the pancreas, insulin deficiency, abnormalities that result in resistance to insulin and insulin action, [American Diabetes Association,2009] abnormalities in carbohydrate, fat, and protein metabolism, deficient insulin action results with or without diminished insulin resistance by the tissues. [Borschuk, 2015.] Symptoms of hyperglycemia commonly noted in people with diabetes are polyuria, polydipsia, polyphagia. Long term, poorly managed diabetes is often complicated by microvascular complication of diabetes like, retinopathy that is characterised by loss of vision, nephropathy that may cause death due to renal failure, peripheral neuropathy that is proven to increase the risk of foot ulcers, Charcot joints and limb amputations and autonomic neuropathy causing gastrointestinal, genitourinary, and cardiovascular symptoms as well as sexual dysfunction. Diabetes is the leading cause of blindness, kidney failure, amputations, heart failure and stroke. [Bidasee, et al.,2004.]. Thus, timely management of diabetes is of utmost importance to prevent or delay complication of the diabetic state.

1.3. MANAGEMENT OF DIABETES

Management of diabetes is essential to retard progression and prevent complications of diabetes.

1.3.1 DIETARY INTERVENTION

Dietary intervention is the backbone of management of diabetes, it is well noted that carbohydrate counting is the most important tool in the management of post prandial glycaemic response when insulin therapy is used and may also be useful without insulin administration. Carbohydrate counting is an established approach used by patients with Type 1 Diabetes Mellitus to improve their glycemic control. The concept of carbohydrate counting has been practiced since 1920s, but it gained popularity amongst medical professionals after being used in meal planning approaches in the Diabetes Control and Complications Trial. In the trial, carbohydrate counting was found to be effective in meeting glycemic control and allowed flexibility in food choices. [Gillespie et al, 98] This method has been widely accepted and used since 1993, when its usefulness was demonstrated in the United States. [Kawamura, 2007].

1.3.1.1 CARBOHYDRATE COUNTING

Carbohydrate counting used in dietary therapy for diabetes is based on the concept that the postprandial rise in blood glucose levels is due to ingested carbohydrates. Inaccurate carbohydrate counting is frequent and associated with higher glucose fluctuations in people with Type 1 diabetes mellitus. [Brazeau, et al, 2013]

Carbohydrate counting is known as a nutrient focused management plan, it is a method of calculating ingredients and insulin, allowing flexibility of food choices, shows improved blood glucose control, and is empowering to patients. Understanding the need to adjust insulin for meals, knowing one's own pre- and post-meal blood glucose targets, using pattern management skills, and calculating bolus and basal insulin doses would help people with diabetes to be successful in using this meal planning system. [Kulkarni et al, 2003] Prevention of complication of the diabetic state, prevention of fluctuations in blood glucose levels and near normal HbA1c levels are attained when carbohydrate counting and insulin therapy are combined. [Dias, et.al.,2010] However, in India carbohydrate counting for management of diabetes in unpopular due to lack of awareness, guidance and absence of appropriate guiding tools.

1.4 MANAGEMENT OF DIABETES IN INDIA

Few studies in India concentrate on care and management of diabetes, it is indicated that 50 to 60% of diabetic patients did not achieve the glycemic target of HbA1c below 7%. [Venkataraman, et al, 2009]. Awareness and understanding of the disease and its management has been below average among Indian patients, leading to delayed recognition and hence unsuccessful prevention and management of complications. Global guidelines for the management of diabetes though available, may not be cross culturally applicable. In India less than one-third of the doctors use clinical guidelines in their practice, the reason for the same was reported to be poor knowledge and the non-applicability of western guidelines in the Indian context. [Hasan et al, 2012.]. Thus, the need for an Indian tool that makes practicing carbohydrate counting feasible and accessible to professionals and the patients is evident.

1.5.1.1. CARBOHYDRATE COUNTING APPS

Insulin administration with quantified carbohydrate intake can be complex, and subject to literacy and numeracy skills. Hence, m-health to guide and help with the same is a promising endeavour. App-based insulin calculators are proven to improve glycemic control by helping people with diabetes efficiently quantify insulin and carbohydrate intake. While many apps for this purpose may be available, there is limited data evaluating their efficacy, safety, and usability and need for research in this context is evident. While current literature quotes improvements in quality of life and glycemic control after use of these apps, larger trials would be needed for monumental results. Higher standards and regulations need to be set for app developers to ensure safety and efficacy of such programmes. Eiland et al 2018 quotes, “Although the ability to automatically calculate bolus insulin dosages addresses a critical need of MDI (Multiple Daily Insulin Injections) treated individuals, this technology has raised concerns about efficacy of treatment and the protection of patient safety”. [Eiland et al,2018]

Carbohydrate counting apps have been proven to benefit people with diabetes managing their insulin doses with dietary intervention in the form of carbohydrate estimation. However, utmost care needs to be taken to eliminate any source of error. Guidance tools to help people calculate the insulin; carbohydrate ratios and provide information on carbohydrate content of foods can make the management of diabetes easy for people with diabetes and benefit professionals counselling these patients. In India health care professionals often stated that time constraints as a major issue in using carbohydrate counting while counselling the patients. A tool guiding patients and professionals, making carbohydrate counting easy and quick could be beneficial and popular, if developed with established data and in accordance with health care standards and norms followed by medical professionals. The lack of Indian data and resources about the same is also a pressing issue. It is important to gauge if such an app would be used in the practical setting, the possible advantages of such an app, safety or precautions to be taken while developing

and in use of such apps. The development of such an app could be followed by research conducted to estimate the need of the app and features that users deem necessary in such apps.

In this context, the study examines usefulness of carbohydrate counting apps by interviewing medical health professionals namely dietitians and diabetologists who counsel people with diabetes. It was envisaged that interviews with these professionals would help gauge the need for, usefulness, acceptance of and market for carbohydrate counting apps in addition to the requirements and demands of an ideal carbohydrate counting app in the Indian scenario.

I. RESEARCH METHODOLOGY

The study is a qualitative study.

To record opinions of dietitians and diabetologists about carbohydrate counting, the need and use of apps an interview guide was used, consisting of the following questions

- What is your opinion on carbohydrate counting?
- Do you recommend it to your patients?
- If yes, which of your patients do you recommend carbohydrate counting to?
- How many people use carbohydrate counting in their daily lives?
- What difficulties do patients commonly face regarding carbohydrate counting?
- Have you come across any tools to make carbohydrate counting easy?
- Do you use/ recommend any tool?
- Is there a tool with Indian data available?
- Have you come across an app for carbohydrate counting?
- Have you actively used a carbohydrate counting app?
- Do you think there is a need for an app with Indian data?

Whenever needed, additional questions about the same were asked to encourage sharing of opinions in depth.

Ethics Committee Approval: Ethics Committee approval from Inter System Biomedica Ethics Committee Mumbai was obtained before for the study.

Sample Size and Selection of Sample: Purposive sampling was used as a technique for the study to identify Dietitians and Diabetologists. The sample size was finalised in consultation with a statistician. The following sample size was proposed:

Sample size: 60 (20 Diabetologists and 40 Dietitians)

Table. 3.1 INCLUSION AND EXCLUSION CRITERIA

Inclusion criteria:	Exclusion Criteria:
Practising Dietitians.	Practicing diabetologists with Ayurveda, Yunani, Homeopathy background.
Practising Diabetologists with allopathy background.	Unawareness of carbohydrate counting apps.
More than 5 years of experience.	
Practicing in Mumbai.	

On beginning the scheduling of interviews, it was found that Carbohydrate Counting as a tool of management for diabetic patients was not practiced in government or municipal establishments in view of time constraints and large number of patients who need to be guided.

It was seen that the use of counselling of carbohydrate counting was extremely time consuming and made it difficult for professionals in government and municipal establishments to practice. The same reason among others was also quoted by many professionals practicing in private establishments for not counselling patients or using carbohydrate counting as a tool of management of the diabetic state in people with diabetes.

Hence, the sample of professionals was restricted to private establishments:

20 dietitians and 10 diabetologists.

Each group was divided into 2 categories:

1.With 5-10 years' experience in a private establishment.

2.With more than 10 years' experience in private establishment.

1.1 STUDY METHOD

Participants were contacted at their establishments and interviews were set up via phone calls. The dietitians and diabetologists who agreed to be a part of the study were given the participant information sheet and consent form. Interviews were taken in person and answers given were recorded.

In depth interviews of 32 professionals were conducted.

1. 12 dietitians with 5-10 years' experience in private establishments.
2. 10 dietitians with more than 10 years' experience in private establishments.
3. 5 diabetologists with 5-10 years' experience in private establishments.
4. 5 diabetologists with more than 10 years' experience in private establishments.

1.2 ANALYSIS

From the Information collected from dietitians and diabetologists, qualitative analysis was done to understand the usefulness of carbohydrate counting apps, the importance of carbohydrate counting as a tool of management of diabetes and the need to develop as a mobile application.

I. RESULTS AND DISCUSSION

The study indicated that the practice of carbohydrate counting counselling by diabetologists and dietitians was not common in Mumbai. Dietitians and Diabetologists from government or municipal establishments did not recommend carbohydrate counting or counsel patients about its practice and benefits, due to time constraints and large amounts of patients coming in each day which made it difficult for them to explain the details of efficient carbohydrate counting, hence they avoided recommending it altogether. Medical professionals from government establishments also stated that low educational and economic status of their patients were reasons for not recommending carbohydrate counting.

On eliminating these participants and including only those who had practiced counselling patients on carbohydrate counting in the study, the following results were obtained.

Table 4. ALL PARTICIPANTS SHARED THE SAME OPINION.

SUBJECT (n=32)
Carbohydrate counting is essential and successful tool of management when insulin therapy is used.
They recommended carbohydrate counting to Type 1 DM patients on insulin therapy.
There is a need for an Indian carbohydrate counting app.

4.1 OPINIONS ON CARBOHYDRATE COUNTING

The results showed that all participants felt that carbohydrate counting was an essential and successful tool of management in diabetes when insulin therapy was used.

"Extremely successful as an approach when coupled with insulin therapy"

-One of the dietitians with more than 10 years' experience.

3 dietitians with 5-10 years' experience, 2 dietitians with more than 10 years' experience, 3 diabetologists with 5-10 years' experience and 2 diabetologists with more than 10 years' experience stated that the effects of carbohydrate counting on fluctuating glucose levels were evident soon after initiation of its regular practice. 5 dietitians with 5-10 years stated that carbohydrate counting gave patients "flexibility" regarding their diet. They explained that with carbohydrate counting it was easy for patients to self adjust their insulin levels according to their carbohydrate intake and vis a versa allowed them to be flexible with their diet without fluctuating glucose levels. Explaining the same 1 dietitian with 5-10 years' experience and 1 dietitian with more than 10 years' experience also described carbohydrate counting as "empowering for the patients." 1 dietitian with 5-10 years' experience, 1 dietitian with more than 10 years' experience and 1 diabetologist with 5-10 years' experience also expressed their concern regarding the same empowerment carbohydrate counting gave patients, explaining that some patients may excessively and repeatedly manipulate their carbohydrate intake and insulin therapy via carbohydrate counting which may have adverse effects on their health in the long run.

"Sometimes when patients have too much power or control over their condition, they may learn to exploit that power. They think they know more than the doctors."

- One of the Diabetologists with 5-10 years' experience.

2 dietitians with 5-10 years' experience and 2 dietitians with more than 10 years' experience said that it was often difficult for the patients to understand carbohydrate counting, however with continuous counselling and support most were able to practice it efficiently and observe its positive health effects. 1 dietitian with 5-10 years' experience and 1 dietitian with more than 10 years' experience said that carbohydrate counting was "time consuming" as it took a while to counsel patients about it, for patients to understand it and took up time from patients' daily routine while practicing it. For the same reasons 1 dietitian with more than 10 years' experience felt that carbohydrate counting was "not practical". 1 diabetologist with 5-10 years' experience and 2 diabetologists with more than 10 years' experience stated that carbohydrate counting was "unpopular in India" despite its proven effectiveness, they agreed that awareness about it as a tool of management of the diabetic state was increasing but also expressed that larger steps needed to be taken to increase its practice within the diabetic population and also professionals.

4.2 CARBOHYDRATE COUNTING: RECOMMENDING AND COUNSELLING

All participants stated that they recommended carbohydrate counting to their patients. 1 dietitian stated that they "always" recommended it to Type 1 Diabetes Mellitus patients, due to its well-established success in managing fluctuating glucose levels with insulin administration. 1 dietitian with 5-10 years' experience stated, "but not often" as it was "time consuming", 4 dietitians with more than 10 years' experience 1 diabetologists with 5-10 years' experience also stated time constraints as the reason for recommending it rarely. 1 dietitians with more than 10 years' experience shared that even though they always recommended it to patients in the past it was not always followed up on by the patients, hence they started to selectively recommend it to those who they felt had a better understanding of their disease, condition and management, those who they on counselling felt would be able to understand and practice regularly and efficiently. 2 diabetologists with more than 10 years' experience said that they recommended it but asked their dietitian colleague to counsel their patients about carbohydrate counting rather than doing it themselves due to limited knowledge about the intricacies of carbohydrate counting and its practice.

All participants recommended carbohydrate counting to Type 1 Diabetes patients on Insulin therapy. 1 dietitian with 5-10 years' experience, 4 dietitians with more than 10 years' experience, 2 diabetologists with 5-10 years' and 2 diabetologists with more than 10 years' experience also recommended it to patients with Type 2 Diabetes Mellitus who were "health conscious", "motivated to improve their health". 2 dietitians with 5-10 years' experience and 2 diabetologists with more than 10years' experience also recommended it to women with Gestational Diabetes Mellitus. 1 dietitian with more than 10 years experience also recommended it to patients with Chronic Obstructive Pulmonary Disorder and those on ketogenic diets. Patients with Oral Hypoglycemic Agents' failures, those with history of uncontrolled or unmanaged diabetes, those on Mixed Dose Insulins, those with Insulin pumps were most often those who were recommended and practiced carbohydrate counting.

"Typically, carbohydrate counting is used only in Type 1 patients or those with complete OHA failures, those on MDIs, premixed insulin and insulin pumps. It is extremely successful in Type 1, in Type 2 portion control is more important."

- One of the dietitian with more than 10 years' experience.

2 dietitians with 5-10 years' experience, 1 diabetologists with 5-10 years' experience and 2 diabetologists with more than 10 years' experience stated that they kept in mind the patient's economic status, educational background while recommending carbohydrate counting. 2 dietitians with 5-10 years' experience said that they recommended carbohydrate counting only when the patient was able to cook for himself or had a dedicated cook available so that the carbohydrates consumed were efficiently counted.

3 dietitians with 5-10 years' experience, 4 dietitians with more than 10 years' experience, 2 diabetologists with 5-10 years' experience and 3 diabetologists with more than 10 years' experience said the "few" people followed carbohydrate counting after counselling. 2 dietitians with 5-10 years' experience, 2 dietitians with more than 10 years' experience, said that "few" people followed carbohydrate counting after counselling. 1 dietitian with more than 10 years' experience, said all Type 1 DM patients followed carbohydrate counting after being counselled by them. 2 dietitians with 5-10 years' experience shared that all patients on insulin pumps that were counselled them followed carbohydrate counting. 1 dietitian with 5-10 years' experience commented that around 20 percent diabetic patients practiced carbohydrate counting in their

daily lives on being counselled by a dietitian. 2 dietitians with 5-10 years' experience said that all juvenile diabetics on being counselled by a patient practiced carbohydrate counting in their daily lives. Most dietitians and diabetologists were unable to comment when asked how many people practiced carbohydrate counting in their daily lives after they were recommended/counselled about it.

4.3 DIFFICULTIES FACED WHILE PRACTICING CARBOHYDRATE COUNTING

Table 4.3.1 OPINION OF DIETITIAN AND DIABETOLOGISTS ON DIFFICULTIES FACED BY PATIENTS WHILE COUNTING CARBOHYDRATES.

OPINION	**NO. OF DIETITIANS (n=22)**		**NO. OF DIABETOLOGISTS (n=10)**	
	5-10 years' experience (n=12)	more than 10 years' experience (n=10)	5-10 years' experience (n=5)	more than 10 years' experience (n=5)
Difficult to understand	4	5	4	2
Misunderstanding portion sizes	4	1	-	2
Lack of information on carbohydrate content of locally eaten cooked foods	2	2	1	1
Weighing and measuring foods	1	1	-	2
Confusion when eating out	1	-	1	-
Read and understand food labels	2	1	-	-
Calculating insulin in regard to carbohydrate content of foods consumed and vis a versa	2	-	-	-

When asked about the difficulties patients faced while practicing carbohydrate counting, many felt that patients found the concept of carbohydrate counting "difficult to understand", it would be a tedious process that required efficient counselling unless which patients were often confused about carbohydrate counting as they may not have heard about it from elsewhere, the counselling is the first introduction to carbohydrate counselling hence should be made "simple" and "well explained" so that every patient is able to understand it. Some dietitians and diabetologists said that "understanding portion sizes" was difficult for patients. Dietitians said that calculating insulin in regard to carbohydrate content of foods consumed and vis a versa was confusing and difficult for some patients. Dietitians felt that patients found it difficult to read and understand food labels. Dietitians and diabetologist said that it was difficult for patients to understand the nutritional content specially the carbohydrate content of locally eaten cooked foods, while nutritional content of raw foods is clear to few people. The nutrient composition of cooked foods is still confusing for a lot of patients owing to the large amount of misleading information available over the internet as well as the diverse ways of cooking the same food across the country. Dietitian and diabetologist said that "eating out" was difficult for patients as the carbohydrate content of meals cooked at restaurants and food establishments was unclear and patients were confused about the insulin to be hence administered as well. It was stated that most impromptu contact with doctors were regarding the same.

"Confusion when eating out is very common, when thickeners, sugar substitutes are used glucose response is different hence confusion, there is lack of understanding among patients and information about commonly eaten recipes is unavailable. I get most calls from patients at odd timings asking me that we have eaten XYZ food from a restaurant now how much insulin should I inject."

-One of the diabetologist with 5-10 years' experience

Dietitians and diabetologists shared that "weighing and measuring foods" was difficult for patients, it was a tedious task to do every day for every meal, patients often "grew tired" of it and it was also stated as one of the biggest reasons for noncompliance.

4.4 CARBOHYDRATE COUNTING TOOLS

Table 4.4.1. CARBOHYDRATE COUNTING TOOLS PROFESSIONALS USED IN THEIR PRACTICE.

TOOLS		**NO. OF DIETITIANS (n=22)**		**NO. OF DIABETOLOGISTS (n=10)**	
Name	5-10 years' experience (n=12)	more than 10 years' experience (n=10)	5-10 years' experience (n=12)	more than 10 years' experience (n=10)	more than 10 years' experience
Carbohydrate counting by Sheryl Salis [Medtronic]	Book	4	1	-	-
Hand measures	Teaching method for portion size	2	-	-	2
Pictures of food	Teaching method for portion size	-	2	-	-
Self curated exchange list	Nutrient information document	-	1	-	-
San Jose's CHO counting of traditional South Asian foods	Online nutrient information document	-	-	1	-
Standardised cups and spoons	Teaching method for portion size	-	1	-	-

Most dietitians and diabetologists had not come across any tool that explained or made carbohydrate counting easy for patients or professionals. They knew about carbohydrate counting only from what they had learnt as students and heard from professional conferences. Some dietitians used the book "Carbohydrate counting by Sheryl Salis [Medtronic]' to understand carbohydrate counting and used it in their practice to explain it better to the patients. The reasons stated for using this book were "It is easy to understand ", "Language used is simple" and "Ample graphic representation makes counselling easy using it. 1 diabetologist previously used "San Jose's CHO counting of traditional South Asian foods" to understand and explain carbohydrate counting to patients. The reason for using the online tool was the "inclusion of Indian recipes" and the reason for discontinuing use was noticing that "patients got confused" because of this tool as it used American measures to quantify foods.

Few dietitians and diabetologists used hand measures to teach patients about carbohydrate counting. They counselled patients about the portion of food containing certain amount of carbohydrate relating it to the amount that fit in their hand. 1 dietitian curated an exchange list of foods containing 10g of carbohydrates and used the same to counsel patients. Few dietitians used pictures of foods to explain portion sizes regarding carbohydrate content to patients, while 1 dietitian used standardised cups and spoons for the same reason.

4.5 CARBOHYDRATE COUNTING APPS

Most participants had not actively used or recommended to their patients a carbohydrate counting app. Unauthentic information used by app makers and complicated manner of apps and high data entry were the main reasons as to why the medical professionals refrained from using or recommending these apps. 11 dietitians with 5-10 years' experience, 9 dietitians with more than 10 years' experience, 4 diabetologists with 5-10 years' experience and 5 diabetologists with more than 10 years' experience had not come heard or used any apps for carbohydrate counting. 1 dietitian with 5-10 years' experience, stated that they had information a few apps but not used or recommended them as they found the apps "efficient". 1 dietitian with more than 10 years' experience, had used "Fitterfly" and "Bon Appetit" the reasons stated for the use were the "use of Indian values of nutrient content from IFCT". 1 diabetologists with 5-10 years' experience said that they had heard about a few apps from patients but did not use them or encourage their patients to use them as they were "unsatisfied by the quality of information provided by these apps".

All participants agreed that there was a need of a carbohydrate counting app that need to be developed using authentic Indian information catering to the Indian diabetic population.

"An Indian Carbohydrate Counting App is the call of the moment."

- One of the diabetologists with 5-10 years' experience

"It is very important to develop an app in India that will explain the concept of carbohydrate counting and also guide patients how to go about it."

- One of the diabetologists with more than 10 years' experience.

DISCUSSION

This study confirmed the interest among dietitians and diabetologists about carbohydrate counting and carbohydrate counting apps although practice of carbohydrate counting counselling by diabetologists and dietitians was not common in Mumbai, consequently knowledge and use of apps for the same was uncommon. All participants agreed that carbohydrate counting is essential and a successful tool of management when insulin therapy is used, it empowered patients and gives them flexibility regarding their diet. Dietitians and diabetologists recommended carbohydrate counting to Type 1 DM patients on insulin therapy. The reason for its uncommon practice despite the knowledge of its benefits among professionals and patients is its complex and time-consuming nature. Difficult to understand, misunderstanding portion sizes, lack of information on carbohydrate content of locally eaten cooked foods, weighing and measuring foods, confusion when eating out, difficult to read and understand food labels, calculating insulin in regard to carbohydrate content of foods consumed and vis a versa, were the main barriers seen among patients while practicing carbohydrate counting. Most of the respondents were unable to comment on the usefulness of already available carbohydrate counting apps due to lack of awareness of these. However, majority of the participants showed interest in using such an app for carbohydrate counting if it meant saving time and credibility of the app was established. The limitations of this study are the limited sample size (n=32), the recruitment process that was restricted by the limited number of professionals who practiced counselling patients on carbohydrate counting, the inclusion criteria and limited number of professionals that agreed to be a part of the study. These restrictions hamper the representativeness of the data and its generalizability. Nevertheless, this study confirms the existence of the need for an Indian carbohydrate counting app. Future research will be based on a larger sample size, include other professional groups as well as patients, and also broaden the use of qualitative methods for data collection.

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