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Digital Nutrition Counseling and its Impact on Diabetics and Prediabetic Individuals in the Developing Country

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Abstract

Digital health care services claim to assist personalised patient care. Web-based programs and apps are relatively low-cost with the potential for broad reach. Digital nutrition therapy that monitors or provides recommendations on diet is effective in managing Diabetes. However, there is less evidence on how the integration of personalized nutrition recommendations impacts glycemic control among individuals with diabetes and prediabetes. The objective of the study is to assess the quality and effectiveness of the Mfine Diabetes care program in improving glycaemic levels among diabetes and prediabetes individuals. One hundred and seventy-two adults: 112 males and 60 females (mean age 48.1±12.3) with Type II diabetes and prediabetes who enrolled and completed 3 three-month paid diabetes care programs through MFine application between November 2021 to December 2022 were included. User characteristics and their associations with diabetes management were analysed retrospectively. Information regarding the participant's age, gender, height, weight, comorbidities or history of illness, medication details with dosage and usual dietary intake were collected. Participants who followed the program were compared to their baseline measures taken before the intervention, to assess any improvement or decline in the lab values (Hb_{A1c}, FBS, ABG), and diabetic medication post-program completion. The before-after lab test design was used to evaluate changes in outcomes over time. The mean BMI of the study group was 28.6±2.9 kg/m^2. Of them 138 patients were diabetic with (mean initial Hb_{A1c} 8.96±1.93, FBS 179.7±67, and ABG 186.1±61.0 mg/dl) and 34 patients were prediabetic individuals with (mean initial HbA1, 6.27±0.13, FBS 154.1±54.1 mg/dl, and ABG 172.5±49.9) at initial consultation. After following program for 3 months with therapeutic carbohydrate restriction/four pillars consideration (Diet, physical activity, sleep and stress management) there was a significant difference ($p<0.000$) among the participants with final blood glucose levels of diabetic (mean final Hb_{A1c} 6.48±0.72, FBS 122.2±30.1, and ABG 130.4±32.0) and prediabetic individuals (mean final HbA1, 5.25±0.24, FBS 102.7±14.5 mg/dl, and ABG 116.2±20.3 mg/dl). Also, there was a change in medication dosage among this population (36% of individuals have been recommended to reduce the medication dosage, and 26% of individuals were advised to stop medication upon carbohydrate restriction) post-program completion. Digital nutrition counselling and monitoring interventions with Mfine application targeting prediabetes and Type II diabetes are effective for improving glycaemic levels (Hb_{A1c}, FBS, ABG). There was a significant improvement in their glycemic levels and a decrease in body weight and BMI. Thus, this digital therapeutic program can be considered an effective tool for improving glycaemic control in people with diabetes and pre-diabetes individuals.

Keywords: Diabetes, Diabetes Care Program, Digital-Nutrition, Glycemic Control, Mfine App, Meal Images, Monitoring, Nutrition Therapy, Prediabetes

Abbreviations: BMI: Body Mass Index; CRDs: Carbohydrate-Restricted Diets; CRD: Carbohydrate-Reduced Diet; Hb_{A1c}: Haemoglobin A1c; DCP: Diabetes Care Program; T2DM: Type II Diabetes; FBS: Fasting Blood Glucose; ABG: Average Blood Glucose.

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1. Introduction

According to 2021 International Diabetes Federation (IDF) statistics, there are 537 million adults (20-79 years) living with diabetes (1 in 10). This number is predicted to rise by 643 million by 2030 and 783 million by 2045. Over 3 in 4 adults with diabetes live in low- and middle-income countries and it is responsible for 6.7 million deaths in 2021. 541 million adults have Impaired Glucose Tolerance (IGT), which puts them at risk of Type II diabetes[1-4]. However, prediabetes is an intermediate state of hyperglycaemia with glycaemic parameters above normal but below the diabetes threshold[5]. Early diagnosis and intervention of prediabetics and their cluster of risk factors can prevent cardiovascular events and complications of diabetes such as diabetic retinopathy, neuropathy, and nephropathy[6]. Physical inactivity and nutritional transition along with increased consumption of refined carbohydrates, and processed foods, led to the increased prevalence of diabetes in India[7].

Researchers have been documenting the use of mobile phones as Behaviour Change Communication (BCC) tools for encouraging physical activity and healthy diets, combating depression, quitting smoking, and managing diabetes and other Non-Communicable Diseases (NCDs), while on the one hand, the proliferation of Information and Communication Technologies (ICTs), more profusely that of mobile phones, is blamed in part for physical inactivity and associated lifestyle diseases[8]. The advances in mobile technology have led to the concept of mobile health (mHealth) and the use of mobile phones as an important platform for the delivery of health communication interventions. Multiple studies have shown the successful use of mHealth in managing various health conditions[9,10]. Digital health technologies that incorporate nutrition education and monitoring have gained increasing popularity in changing and managing dietary choices[11-13]. Several calorie-counting apps developed in various countries are available in the mobile play stores claiming to help in weight management and diabetes management. However, the number of studies that analysed their quality and effectiveness is very limited in developing countries, and very few such studies have been done in India. This study aimed to analyse the quality and effectiveness of diabetes care programs in glycaemic control delivered through MFine application in an Indian scenario and to get an understanding of the short-term effects of a modified lifestyle in diabetes management.

The objective of the study is to assess the quality and effectiveness of the Mfine Diabetes care program in improving glycaemic levels among diabetes and prediabetes individuals. The primary outcome of the study was to analyse the changes in the Haemoglobin A1c (Hb_{A1c}) levels, FBS, ABG and medication changes after completion of the program as compared to those in the baseline. The study focused on evaluating the effect of a therapeutic carbohydrate-restricted diet and the short-term effects of a modified lifestyle by using the changes in the body weight of study individuals after program completion.

2. Methodology

A prospective observational study of individuals who took consultation and followed the program for 3 months was included in the study. During the programme, patients were counselled via video calls with both diabetologists and Clinical dieticians and were educated with weekly follow-ups, daily meal plate guiding pictures and their food plate images with the Mfine application.

Mfine Mobile/web application has a user-friendly interface that helps curate user databases like anthropometric measurements (height and weight) and the system calculates the Body Mass Index for them. They can log their details with the help of AI for adding details like - medical conditions, 24-hour dietary details, physical activities, and medication details. They can also upload their medical test report in the application - the system database records this information in the participant's profile. Users are provided access to evidence-based educational Content like blogs and videos created by experts like Doctors, Clinical Dietitians, etc. Users get personalized medical and dietary prescriptions and weekly exercise session access throughout the program (3 months).

The Diabetic Care Program (DCP) is a technology-enabled personalized program for 3 months amalgamating various specialities like diabetologists, clinical dietitians, fitness experts, and dedicated health coaches to continuously monitor and support participants and improve their health by providing personalized guidance. The Program is designed so that two Full-body blood tests are included at the beginning and one towards the end of the program. As part of the continuous monitoring in the program, DCP emphasizes the significance of sharing meal images for assessing the micro and macronutrients

and vitals like Fasting blood Sugar levels and Post Prandial Blood Sugar in the application. The weight of participants was recorded at the baseline (enrolment) and the end of the study (after 3 months). Participants' data like age, gender, physical activities, food preference, and medical history were collected in the application during the enrolment in DCP. Participants were given unlimited access to their coaches through the Mfine app, and on-demand dietician consultations during the program.

2.1 Study Design

A prospective observational study was performed with a convenient sampling technique. Among the total enrolled patients, (n=172) patients who completed 3 3-month paid diabetic care program on the Mfine application were selected for the study from November 2021 to December 2022. The clients were recruited from various locations across India who themselves enrolled for the program.

The study aims to evaluate the effectiveness of the digital Diabetes care program delivered through the Mfine application on individuals who have diabetes and prediabetes, using initial and final lab tests (consisting of Hb_{A1c}, Fasting and ABG) as a part of the program. All participants who followed the program were compared to their baseline measures taken before the intervention, to assess any improvement or decline in the lab values, post program completion. The before-after design was used to evaluate changes in outcomes over time, providing insight into the intervention's effectiveness on the participants.

2.2 Sample Collection

The sample was collected through the Mfine application via video call during the DCP consultations by certified and trained Clinical Dieticians and Diabetologists who were onboard with Mfine as practising doctors. Mfine is an AI-driven Online platform aggregating various multi-specialties to improve individuals' overall health and wellness. There are more than 84+ Specialties aligned in the application. The platform functions as a tool to help people check their health status by utilizing the built-in BP and Heart Rate monitor.

Care managers were assigned to each client. Their primary role was to coordinate with the respective senior dietician, doctors, and clients to get the sessions scheduled, pick up queries from clients in between the sessions get them addressed and share self-help materials timely. The self-help materials consisted of relevant healthy nutrition tips like high protein, fibre and healthy recipes, videos, podcasts, and guiding meal images.

2.3 Virtual Access to the Clinical Dietitian

A dedicated Dietetic team monitors the participants throughout the study. Patients were given customized dietary prescriptions based on their progress. The senior dietitians were in touch with the participant through the application-based video conference and depending upon the discussion, a new dietary prescription was generated. Regular check-ins were initiated to keep track of the progress made by the participants.

2.4 Nutritional Screening and Assessment

To evaluate nutritional status, each participant was initially screened and assessed at the time of initial assessment by Care Team (CT) Dietician and Senior Consultant Dietician during the consultation as a part of the Mfine protocol. The assessment includes interpretation of anthropometric, biochemical (laboratory), clinical and detailed dietary history.

2.5 Dietary Approach

Therapeutic carbohydrate restriction (<130gm of dietary carbohydrate) is the primary nutrition therapy applied for the targeted individuals in the study. It was observed that levels of carbohydrate tolerance vary between individuals and even in one person over time. For example, a Very low-carbohydrate Ketogenic Diet (VLCKD) is defined as one comprised of 20 to 50 g/d carbohydrate, is advised for individuals who have sufficient protein intake per/kg body weight. The advised therapeutic restriction of total carbohydrates was 110-130 gm/day, 50 to 70 gm/day and 20-50 gm/day as per the patient's body weight and daily protein intake satisfaction. The main principle of the CRD was to eliminate carbohydrate-rich foods once or twice a day at breakfast and dinner, or breakfast and lunch. Table 1 shows the list of foods that the subjects were instructed to restrict/avoid.

2.6 Meal Plate Assessment

The Users' progress is checked by assessing the meal images shared by them after the personalized dietary

Table 1. Carbohydrate-rich foods instructed for restriction

Type of Foods	Foods to restrict
Staple foods	All cereals and millet like Rice, bread, corn, wheat spaghetti, noodles made of wheat
Fruits	Pears, apples, oranges, peach, grapes, melon, watermelon, banana, custard apple, mango, sapota, pineapple, etc.
Vegetables	Carrot, beetroot, potato, sweet potato, taro root and yam, pumpkin
Sugar	Confectioneries, table sugar, jaggery, honey
Beverages	Drink containing sugar, glucose and fructose, and milk

prescription provided by the senior dietitian. A team of dietitians and health coaches constantly monitored the participants' updates and evaluated them by giving the right suggestions to improve their meals and correct their macronutrient intake. The Mfine Web Dashboard can be accessed by professionals like doctors and clinical dietitians to access the information and interpret the same for tracking the progress of the users. It was used for interacting with the users to clear their doubts and set short-term goals for them. This will help the Clinical dietitians to curate the Diet plan in the next consultation.

2.7 Virtual Access to the Diabetologist

A dedicated Diabetologist and team monitors the participant throughout the program. The senior Diabetologist gives consultation to the user through a system video call and provides the medical prescription for improving the health goal of the user. The participant will have access to put forward queries and feedback in the chat section and on-demand consultation for further assistance.

2.8 Weekly Wellness Sessions by the Certified Health Coach

The DCP offers weekly group exercise sessions for the participants enrolled in the program to generate a community feeling and to motivate everyone to embrace their fitness journey without fear or tension. The health coach also provides personal guidance during the virtual session that is conducted through the Zoom platform. The recorded version of this exercise session is shared with all the users enrolled in the program so that they can refer to the same and continue the fitness journey.

2.9 Inclusion and Exclusion Criteria

2.9.1 Inclusion

Patients diagnosed with diabetes and prediabetes were included in the study (Hb_{A1c} levels >6.5%, >5.6% respectively). Adults aged ≥18 years voluntarily enrolled and completed a paid 3-month, diabetes program through the Mfine platform, having a smartphone and willing to utilize the mobile app were included in the study.

2.9.2 Exclusion

Chronic diabetic patients who required hospitalization, patients with severe sensory deficits (visual, auditory, or motor) which would affect digital consultation, presence of severe complications (e.g., end-stage chronic kidney failure, chronic liver disease), history of unstable angina pectoris or stroke within the past 6 months, and history of surgical procedures, which can affect the ability to follow a dietary regimen were excluded.

Informed consent was signed by everyone who took part allowing data to be used for research. Their participation in the program and the standard of care were not impacted by their refusal to sign an informed consent form.

2.10 Ethical Clearance

The study was approved by the Ethical Committee (ethics approval number: DCGI Reg. No. ECR/141/Indt/KA/2013/RR-19). The Indian Medical Council's regulations were strictly followed. In compliance with the telemedicine standards published by the Indian government in 2020, consent was obtained for the Mfine application. Everyone who took part was voluntarily enrolled on the Mfine diabetic care programme. When a case is created, the AI in Mfine quickly converts client names to a numeric code, maintaining client confidentiality. Therefore, no one else at Mfine or outside of the company knows the names or details of the clients except the consulting doctor and the medical staff.

2.11 Statistical Analysis

SPSS Windows version 24.0 was used for statistical analysis. Mean and SD and 95% Confidence Interval values were calculated for quantitative and normality characteristics variables, and median and IQR were calculated for non-normal variables. Percentages were calculated for qualitative variables. Mean values of

Hb_{A1c}, FBS, ABG, BMI, Initial and Final Body weight, and carbohydrate restriction were compared by initial and post-program completion using paired T-test/ Wilcoxon signed-rank test performed. A chi-square test was performed to study the association of Hb_{A1c} Carbohydrate restriction. Effect size was calculated for diabetic, pre-diabetic and total initial and final values of Hb_{A1c}, FBS and ABG. The level of significance was considered as 0.05.

3. Results and Discussion

The present study investigated the efficacy of a digital nutrition therapy provided through DCP which was delivered via Mfine application. As part of the continuous monitoring included in the program, DCP emphasizes the significance of sharing meal images and vitals like Fasting blood Sugar levels and Postprandial Blood Sugar in the application. The participants who were enrolled in the program from various parts of India were asked to share the meal images daily to track the intake of macro and micronutrients. Participants were given unlimited access to their coaches through the application and via telephone, and on-demand dietician consultations for the entire duration of the program. All participants were asked to share their meal images after getting a customized diet plan from their dietician.

A total of 172 patients out of 702 were recruited for the study. Five hundred and thirty patients were excluded because of various reasons like incomplete data, did not follow the diet as advised, did not complete 3 months of the program etc. (Figure 1).

3.1 General Characteristics of Patients

Of the total participants, 172 members included and completed 3 months of the program. They are between the age groups of 27 to 74 (mean age 48.1±12.3) years. The study population consisted of 112 males and 60 females (Table 2).

In the study, the subjects were categorised as diabetes and pre-diabetes individuals as shown in Table 3.

Among 172 subjects, 141 of the individuals had one or more co-morbidities. 55 individuals had been diagnosed with dyslipidaemia, 36 of them were hypertensive and 29 of them had thyroid-related issues (hyper or hypo thyroid) as shown in (Figure 2).

A paired sample t-test was conducted to evaluate the efficacy of the digital nutrition therapy intervention on the diabetic parameters in the Mfine Diabetes care program. Table 4 showed that the average parameters at baseline of Hb_{A1c} (8.43±2.04), FBS (174.7±65.58 mg/dl) and ABG (183.4±59.14 mg/dl) were higher than the average parameters of Hb_{A1c} (6.24±0.81), FBS (118.3±28.77 mg/dl) and ABG (127.6±30.55 mg/dl) after the program intervention.

This demonstrates that following programme intervention, the Hb_{A1c}, FBS, and ABG levels were significantly reduced., t=17.861 (171), 12.908 (171), 12.915 (171), p=0.000 (two-tailed) and reduced parameters on NPar Test (Wilcoxon Signed Ranks Test) indicate improvement in glycaemic parameters. The effect size is large (Cohen's d= 1.36) for Hb_{A1c}, indicating the large impact of the DCP intervention on the program clients (Tables 5 and 6).

The study highlighted that digital Nutrition therapy delivered by DCP was effective in reducing the glycemic

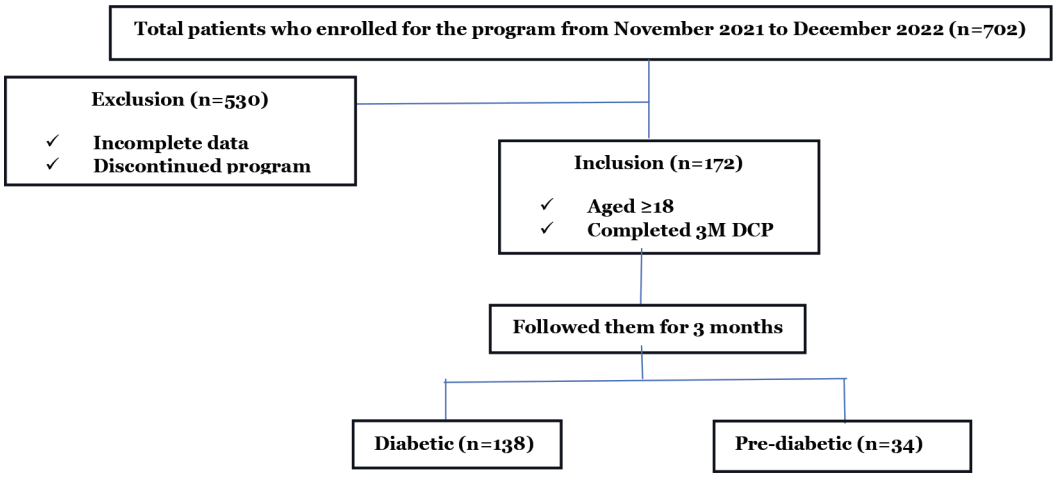

Figure 1. Flow diagram of patients selected for analysis. DCP – Diabetes Care Program.

Table 2. Characteristics of the study population

Gender	Number of Participants (%)	Mean Age ± SD	Age in Years (Range)
Male	112 (65)	46.3±12.2	28-73
Female	60 (35)	51.5±11.9	27-74
Total	**172 (100)**	**48.1±12.3**	**27-74**

The results of the study (Table 2) indicated that the average age of the clients who enrolled on the program was (48.1±12.3) years, and most of the clients were between the ages of 27-74 yrs. This shows the rapid growth of digital technologies[14], which offers improvement in public health, particularly in disease prevention and health promotion.

Table 3. Characteristics of diabetic and pre-diabetic individuals

[redacted]

levels (Hb_{A1c}, FBS, and ABG) of individuals who enrolled and followed the program (p-0.000) among diabetic and pre-diabetic groups (Tables 3–5), was a higher percentage of clients — in particular, pre-diabetic individuals — have returned to normal levels. These results are in line with those of comparable research that has examined the low carbohydrate diet[15-17] and app-based interventions to improve diet, physical activity and sedentary behaviours can be effective[18,19].

3.2 Changes in Hb_{A1c} Levels After Program Completion

A significant mean reduction in Hb_{A1c} levels by 2.19% (SD 1.61%) (p<0.001) was observed in all the participants—from a baseline mean of 8.43% (SD 2.0%) to 6.24% (SD 0.81%) after the program (Table 3). 42.4% (73/172) reached the recommended target of Hb_{A1c} 6% showed an average Hb_{A1c} reduction of 1.7% (SD 1.38) (p<0.001).

3.3 Changes in Weight After Program Completion

The participants showed a significant mean weight reduction by 4.8 (SD 5.78) kg from a pre-program mean weight of 76.5 (SD 13.81) kg to 71.8 (SD 13.04) kg after the program (p<0.001). Weight reduction was observed in 88.3% (152/172) of the participants, with 59.9% (103/172) having weight loss of ≥4% and with 40.1 % (69/172) having weight loss of % <4%.

3.4 Therapeutic Carbohydrate Restriction and Hb_{A1c} Reduction

A significant mean reduction in Hb_{A1c} levels by 2.12% (SD 1.3) (p-0.000) was observed in all the participants who followed 110-130gm of carbohydrate (n= 118/172) —

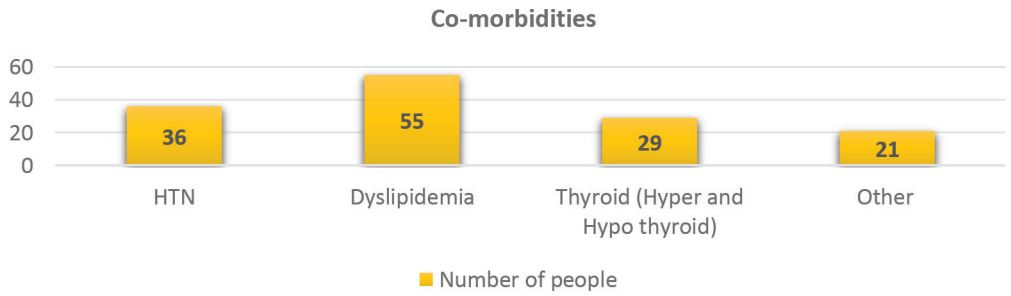

Figure 2. Several co-morbidities.

Table 4. Comparison between the means of pre and post-program scores of DCP (n=172)

Measuring Factors		Mean	SD	Paired Differences					t	df	Sig.(2-tailed)	Cohen's Effect Size
				Mean Difference	SD	Std. Error Mean	95% Confidence Interval of the Difference					
							Lower	Upper				
Hb_{A1c}	Initial	8.43	2.04	2.19	1.60	0.12	1.94	2.43	17.86	171	0.00	1.36
	Final	6.24	0.81									
FBS	Initial	174.7	65.58	56.35	57.25	4.36	47.73	64.97	12.90	171	0.00	0.98
	Final	118.3	28.77									
ABG	Initial	183.4	59.14	55.80	56.66	4.32	47.27	64.33	12.91	171	0.00	0.98
	Final	127.6	30.55									

Table 5. Comparison between the means of pre and post-program scores and effect size as measures of efficacy of the Diabetic population (n=138)

Measuring Factors		Mean	SD	Paired Differences					t	df	Sig. (2-tailed)	Effect size (Cohen's d)
				Mean Difference	SD	Std. Error Mean	95% Confidence Interval of the Difference					
							Lower	Upper				
Hb_{A1c}	Initial	8.96	1.93	2.47	1.66	0.142	2.19	2.76	17.44	137	0.00	1.49
	Final	6.48	0.72									
FBS	Initial	179.7	67.3	57.57	58.34	4.96	47.74	67.39	11.59	137	0.00	0.99
	Final	122.2	30.1									
ABG	Initial	186.1	61.0	55.67	58.88	5.01	45.76	65.59	11.10	137	0.00	0.95
	Final	130.4	32.0									

Table 6. Comparison between the means of pre and post-program scores and effect size as measures of efficacy of pre-diabetic population (n=34)

Measuring Factors		Mean	SD	Paired Differences					t	df	Sig.(2-tailed)	Effect size (Cohen's d)
				Mean Difference	SD	Std. Error Mean	95% Confidence Interval of the Difference					
							Lower	Upper				
Hb_{A1c}	Initial	6.27	0.13	1.02353	0.31436	0.05391	0.91384	1.13322	18.985	33	0.000	3.326
	Final	5.25	0.24									
FBS	Initial	154.1	54.1	51.42059	53.15029	9.11520	32.87557	69.96560	5.641	33	0.000	0.968
	Final	102.7	14.5									
ABG	Initial	172.5	49.9	56.3235	47.3669	8.1233	39.7965	72.8506	6.934	33	0.000	1.189
	Final	116.2	20.3									

from a baseline mean of 8.48% (SD 1.49%) to 6.36% (SD 0.61%). For participants who have been advised for 50 to 70gm of carbohydrate restriction (n=47/172), the mean reduction in Hb_{A1c} levels was 2.5% (SD 2.1) (p-0.000) —from a baseline mean of 8.6% (SD 3.0%) to 6.0% (SD 1.14%). Similar results were obtained with the restriction of 20-50 gm (n=7/172), the mean reduction in Hb_{A1c} levels was observed by 1.0% (SD 0.2) (p-0.000) — from a

baseline mean of 6.3% (SD 0.16%) to 5.2% (SD 0.2%) after the program (Table 7 & 8).

The program clients also reported statistically significant levels of reduction (Hb_{A1c}, FBS and ABG) post-program completion (digital DCP intervention Table 5). There is a reduction of 2.48% in diabetes and a 1.02% reduction in Hb_{A1c} among pre-diabetics. The overall reduction of Hb_{A1c} among the total sample (n=172) was found to be 2.19, (p-.000). Hence the Null hypothesis was rejected, and the research hypothesis has been accepted. The effect size for the total sample (1.21) was also statistically found to be large indicating a large positive impact of DCP on the overall symptoms of the clients enrolled in the program. These results of our study are consistent with previous meta-analyses conducted on diet, physical activity and health interventions, which have demonstrated their potential to improve overall health outcomes[20-23]. Web-based programs and apps are relatively low cost with the potential for a broad reach, however, sustained engagement is a key factor constraining effectiveness[24]. The use of web-based programs and smartphone apps will continue to proliferate as health information services are used by the public[25].

Mfine's Diabetes care program can be highly beneficial to people with T2DM for improving glycemic control. Mfine is a multi-speciality online platform powered by AI that aims to enhance people's overall health and wellness. The application relates to more than 84 different specialities. The DCP is a technology-enabled, individualised programme that brings together a range of specialities such as diabetologists, dietitians, fitness experts, and committed health coaches to help people continuously monitor and support themselves and improve their health by receiving customised advice. By using the BP and heart rate monitor that is already included in the platform, users can use it as a tool to check their state of health. Especially in developing countries like India, virtual access to interdisciplinary field experts can significantly improve patient care.

Table 7. Carbohydrate restriction and Hb_{A1c} reduction

CHO	Hb_{A1c}	Paired Differences							Sig. (2-tailed)
		Mean difference	SD	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper	Minimum	Maximum	
110-130gm/day	Initial	8.48	1.49	0.13	8.21	8.75	6.00	13.60	0.000
	Final	6.36	0.62	0.05	6.24	6.47	4.8	7.7	
50-70gm/day	Initial	8.63	3.01	0.43	7.74	9.51	6.0	14.50	0.000
	Final	6.09	1.14	0.16	5.76	6.43	4.6	8.8	
20-50gm / day	Initial	6.30	0.16	0.06	6.14	6.45	6.0	6.50	0.000
	Final	5.22	0.22	0.08	5.02	5.43	5.1	5.7	

Table 8. Changes in blood parameters

Parameters		Mean	SD	Paired Differences					t	df	Sig. (2-tailed)	Effect size (Cohen's d)
				Mean Difference	SD	Std. Error Mean	95% Confidence Interval of the Difference					
							Lower	Upper				
Hb_{A1c}	Initial	6.27	0.13	1.02	0.31	0.05	0.91	1.13	18.985	33	0.000	3.326
	Final	5.25	0.24									
FBS	Initial	154.1	54.1	51.42	53.15	9.11	32.87	69.96	5.641	33	0.000	0.968
	Final	102.7	14.5									
ABG	Initial	172.5	49.9	56.32	47.36	8.12	39.79	72.85	6.934	33	0.000	1.189
	Final	116.2	20.3									

Further, the program is focused on Hb_{A1c} levels as the outcome of lifestyle modification can help in achieving goals in a measured way. The weekly glucose and daily real-time meal image monitoring-based analysis of the program helped in providing a personalized approach, while the assessment of Hb_{A1c}, FBS, and ABG levels at the beginning and end helped in understanding the program results in a resource-efficient and clinically effective manner.

After the 3-month programme, the participants' Hb_{A1c} levels had significantly decreased by 2.19%. According to clinical research, a 1% decrease in mean Hb_{A1c} levels correlates to a 14% decrease in the risk of myocardial infarction, a 21% decrease in the risk of diabetes-related death, and a 37% decrease in the risk of microvascular complications[26]. Another study among Americans with T2DM found that 1% lower Hb_{A1c} levels were associated with 2% lower costs for total healthcare due to all causes and 13% lower costs for diabetes-related care[27]. The program was effective in improving glycemic control in participants with different baseline Hb_{A1c} levels, 42.4% (73/172) reached the recommended target of Hb_{A1c} 6% and showed an average Hb_{A1c} reduction of 1.7% (SD 1.38) ($p<0.001$).

The participants in our study also showed a significant ($p<0.00$) average reduction in weight by 4.7 kg after 3 months of the program. These results were like those reported in studies on other programs using digital diabetes care for people with T2DM, showing a mean weight reduction of 2.04kg[28,29].

In most therapeutic settings, a reduction in symptoms together with a reduction in medication is considered as a sign of effectiveness. In the study, of 11 patients on medication in the VLCKD arm who finished the study, 5 reduced or discontinued one medication and 2 discontinued all medications. Of the 13 patients on the moderate carbohydrate diet, only 1 discontinued a sole medication. Similarly, another study found that 17 of 21 patients with Type II diabetes reduced or discontinued diabetes medication upon carbohydrate restriction[30]. This result is a general feature of carbohydrate restriction in Type II diabetes[31-34]. In the current study in people who followed the carbohydrate restriction. Table 4 shows a total of (n=37, 26%) individuals in which 143 individuals discontinued and (n=52, 36%) individuals in which of (n=143) individuals diabetic medication dosage has been reduced upon carbohydrate restriction.

Twelve studies reported medication changes at 3-6 months and six at 12-24 months. There was a greater reduction in medication use for participants on carbohydrate-restricted diets compared with high-carbohydrate diets at every time point. Carbohydrate restriction either reduced the dosage of oral medications and/or insulin or saw an elimination of medication for participants across all studies that reported on medication outcomes[35].

Our results demonstrated that the Mfine Diabetes care program significantly improved glycemic control in participants with various medication histories and that lifestyle modification can be a significant factor in improving glycemic control in participants who are not taking any anti-diabetic medications.

3.5 Changes in Diabetic Medication After Program Completion

Of the 172 total patients, 143 were taking various diabetes medications, whereas 29 patients were in the pre-diabetic stage and thus not taking any medication. Among 143 participants, a total of (n=37, 26%) were recommended to discontinue their medication upon carbohydrate restriction diet on post-program completion. Similarly, (n=52, 36%) individuals' diabetic medication dosage has been reduced post-program completion Table 9.

3.6 Reduction and Elimination of Medication

Medication reduction or discontinuation is a significant influence that observed in the current study in people who followed the carbohydrate restriction. Table 8 shows a total of (n=37, 26%) individuals in which 143 individuals discontinued and (n=52, 36%) individuals in which of (n=143) individuals diabetic medication dosage has been reduced upon carbohydrate restriction.

4. Strengths and Limitations of the Study

This study's strength is its use of a commercial program to analyze data in contexts that are like real-world circumstances. Participants from different ages, states in India, treatment plans, and baseline Hb_{A1c}, FBS, ABG, values were included in these preliminary findings of the study. The nonrandomized design, lack of a control group,

Table 9. Changes in diabetes medications of (n=143) participants with Type II diabetes and pre-diabetes who underwent 3 months of DCP intervention

Patient Number	Daily Dose- At DCP start	Daily Dose - after 3M
Medications Discontinued (n=37 of 143 originally on medication)		
3	GALVUSMET 50/500MG TAB	none
17	GLYCOMET SR TAB 500mg	none
7	JALRA TAB 50mg	none
3	JANUMET FILM-COATED TAB	none
6	JARDIANCE 25MG TAB	none
1	TENZULIX M 500MG TAB	none
Medications Reduced (n= 52 of 143)		
4	BASAGLAR KWIKPEN 3ML INJ+ glycomet 500mg	GALVUSMET 50/500MG TAB (2), GLYCOMET SR TAB 500mg (2)
5	Fiasp 100 IU/ml Penfill+GLYCOMET SR TAB 500mg	GALVUSMODIFIED-RELEASE TAB 50mg (1), TENZULIX M 500MG TAB (1), GLYCOMET SR TAB 500mg (2), Tab Galvusmet 50/500, Tab zoryl 1mg (1)
5	GALVUSMET 50/500MG TAB	GLYCOMET SR TAB 500mg (4), Tab Teniva 20mg (1)
4	GLYCOMET SR TAB 500mg	JARDIANCE 25MG TAB (2), Tab Teniva 20mg (2)
2	HUMALOG KWIKPEN PRE-FILLED PEN 100IU/1mL+glycomet 500mg	GALVUSMET 50/500MG TAB
2	JALRA TAB 50mg	JARDIANCE 25MG TAB
3	JANUMET 50/1000MG TAB	GLYCOMET SR TAB 500mg (2), JARDIANCE 25MG TAB (1)
2	OBIMET SR TAB 500mg	GLYCOMET SR TAB 500mg (2)
3	Tab Galvusmet 50/500, Tab zoryl 1mg	Tab Galvusmet 50/500 (2), Tab zoryl 1mg (1)
1	Tab Teniva 20mg	JARDIANCE 25MG TAB (1)
11	TENZULIX M 500MG TAB	GALVUSMET 50/500MG TAB (2), GLYCOMET SR TAB 500mg (1), JALRA TAB 50mg (1), JARDIANCE 25MG TAB (6), JARDIANCE 50MG TAB (1)
3	VOLIBO TAB 0.3mg	JARDIANCE 25MG TAB (2), GLYCOMET SR TAB 500mg (1)
1	ZITA MET PLUS 20/500MG TAB	OBIMET SR TAB 500mg
6	ZOMELIS MET 50/1000 MG TABLET	GALVUSMET 50/500MG TAB (4), GLYCOMET SR TAB 500mg (1), JARDIANCE 25MG TAB (1)

self-selection bias, and referral bias all contributed to the study's limitations. The participants' glycemic outcomes after completing the program for 3 months are considered in this study. To fully understand the efficacy of this digital diabetes care program, more research will be needed with a larger sample size, control groups, and longer duration periods.

5. Conclusion

Digital nutrition counselling and monitoring interventions with Mfine application targeting Pre-diabetes and Type II diabetes are effective for improving glycaemic levels (Hb_{A1c}, FBS, ABG). There was a significant improvement in their glycaemic levels, as well as a decrease in their body weight and BMI. As demonstrated from the meal image monitoring provided, the information about food consumption helped to deliver timely suggestions and tailored nutrition therapy that improved patient outcomes. Thus, this digital therapeutic program can be considered an effective tool for improving glycaemic control in people with diabetes and pre-diabetes individuals.

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