# Effectiveness of Colour-Coded Diabetes Monitoring Chart on Glycemic Control Among Adults with Diabetes Mellitus: A Community Trial in Rural South India

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# A B S T R A C T

**Background:** Uncontrolled diabetes remains a major challenge, especially in developing countries, necessitating low-cost interventions. The objectives of this study were to assess, among adults with diabetes mellitus, (1) the effectiveness of colour-coded diabetes monitoring chart on glycemic control, (2) the change in knowledge and practice related to the control of diabetes, and (3) the perceptions regarding the use of the chart.

**Methodology:** This community trial was conducted from Oct 2021 to Dec 2024 in Jokatte (Intervention site) and Madani Nagar (Control site) rural areas of Mangalore, India. A total of 180 adults with diabetes (90 per site) were recruited. The intervention arm was given the colour-coded diabetes chart designed by the authors to be used for one year. Statistical analyses were performed using SPSS Ver27.

**Results:** The intervention led to a 0.58% reduction in HbA1c after adjusting for covariates. Additionally, there were significant improvements in knowledge and practices related to diabetes management. The participants had favourable perceptions of the chart, with most desiring to continue using it.

**Conclusion:** The colour-coded diabetes chart significantly improved glycemic control and enhanced diabetesrelated knowledge and practices. This low-cost chart can be utilized in both government settings such as PHCs as well as private clinics.

**Keywords:** Diabetes Mellitus, Diabetes Control, Glycemic Control, Community Trial, Intervention, Colour Chart, Diabetes Knowledge, Self-Care Practices

## ARTICLE INFO

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# **INTRODUCTION**

Diabetes mellitus is a chronic metabolic disorder characterized by elevated levels of blood glucose with disturbances of carbohydrate, fat, and protein metabolism due to deficiency or resistance to insulin.<sup>1</sup> Over time, it can lead to microvascular complications such as neuropathy, nephropathy, and retinopathy, as well as macrovascular complications such as cardiovascular disease, stroke and peripheral artery disease.<sup>2</sup> The estimated global prevalence of diabetes mellitus among adults is 10.5%, which is expected to increase to 11.3% by 2030 and 12.2% by 2045.<sup>3</sup> In India, diabetes mellitus is a significant public health concern, with an estimated prevalence of 11.4% among adults.<sup>4</sup>

The vast majority of diabetes cases are of Type 2 diabetes, which is characterised by resistance to insulin or relative deficiency of it.<sup>1</sup> In Type 1 diabetes, there is damage to the pancreatic cells resulting in the pancreas producing little or no insulin by itself.<sup>1</sup> As diabetes is a chronic disease and humankind has not yet found a wonder drug to cure it permanently. the current management is focused on maintaining blood glucose levels in the normal range with the help of medication and lifestyle modification.5 Achieving optimal glycemic control remains a challenge, particularly in low and middle-income countries. Studies from India reported that adequate diabetic control was achieved by 23%-50% of diabetic patients.<sup>6-8</sup> There are various reasons for poor diabetic control in India, such as poor awareness of the disease, difficulty accessing treatment and follow-up, inadequate adherence to recommendations, irregular blood glucose monitoring, financial constraints and social barriers.9

Given that poor awareness, inadequate adherence, and insufficient blood glucose monitoring contribute to suboptimal diabetes control, targeted strategies are needed to address these issues. A way forward towards addressing these issues could be by devising a tool that can bring about behaviour change in diabetes patients. This can be done by creating and using an interactive diabetes monitoring chart similar to the existing World Health Organization (WHO) growth chart that is used for monitoring growth in children.<sup>10</sup> Cost-effective strategies for managing diabetes and other medical conditions have been explored in previous studies.<sup>11-16</sup>

A longitudinal diabetes monitoring chart may be created in the form of colour-coded zones (red, yellow and green) representing different glycemic levels, along with the advice/action plan for each colourcoded zone. The action plan would include advice on medication and lifestyle modification. The mechanisms by which these charts could bring about glycemic control include the visual impact of the colourcoded zones, such as the red zones, which alert the patient to take corrective action, as well as the information provided in the chart, which enhances and reinforces patient knowledge on diabetes control. Psychologically the chart provides a target (the green zone) to achieve, with the means to reach it clearly outlined in the accompanying advice. Additionally, if the monitoring chart is seen by the treating physician, they may put additional efforts into helping the patient achieve glycemic control.

A prior study on glycemic control using a colour zone diabetes monitoring chart (without printed advice) in outpatient geriatric patients was carried out in Bengaluru, which showed promising results.<sup>17</sup> However, there are no studies in India or abroad which have attempted to create an interactive colour-coded diabetes monitoring chart and tested its effectiveness in community settings. This study intends to create and test such a chart among adults having diabetes in community settings.

If proven effective, the chart could serve as a costeffective tool aligned with the appropriate technology principle of primary healthcare.<sup>18</sup> It will then have a mass application and may be given and explained to all diabetic patients in Government settings by the medical officer and in private by the medical practitioner. Due to its simplicity and ease of use, the chart can be distributed to diabetic patients at the village level by trained ASHA workers, who can also assist them in monitoring their blood glucose levels. Thus, this chart holds promise to empower diabetic patients and foster behaviour change, resulting in better diabetes control.

The objectives of the study were to assess, among adults with diabetes mellitus residing in the selected study areas, (1) the effectiveness of a colour-coded diabetes monitoring chart on glycemic control (HbA1c and trend of fasting blood sugar), (2) the change in knowledge and practice related to the control of diabetes in the intervention and control arm, and (3) the perceptions regarding the use of colourcoded diabetes monitoring chart in the intervention arm.

# METHODOLOGY

This community trial was carried out from Oct 2021 to Dec 2024 in the rural areas of Jokatte and Madani Nagar, located in the Dakshina Kannada District of Karnataka, India. The trial registration number is CTRI/2022/07/044213. Jokatte has an estimated population of 7,470, whereas Madani Nagar has a population of 3,350. These sites were selected due to their socio-demographic similarities and the presence of medico-social workers of the Institute who assisted in quality data collection. The sample size was calculated based on a study by Fathima FN et al. conducted among diabetic patients attending the geriatric outpatient department, which observed a  $\beta$ coefficient of 0.265% for the reduction in glycated haemoglobin.17 G power software was used for sample size computation. Assuming a  $\beta$  coefficient 0.265% change in HbA1c with the study factor, the

colour-coded diabetes monitoring chart, the minimum number of participants required to detect a clinically significant reduction of 0.265% in HbA1c level with 95% power and 5% level of significance is 72 (36 each in intervention and control arm). After accounting for a design effect of 2 and a 25% attrition rate, the effective sample size for the study was 180 (90 each in the intervention and the control arm).

Randomization was done using a "tossing a coin" method, with Jokatte designated as the intervention area and Madani Nagar as the control area. A sampling frame of eligible participants residing in these areas was created. A total of 180 participants (90 from Jokatte and 90 from Madani Nagar) were selected through simple random sampling using computer-generated numbers. Participants from Jokatte were assigned to the intervention arm and those from Madani Nagar to the control arm. Inclusion criteria consisted of diabetic individuals aged 18 years and older who were residing in the study areas. Individuals who were critically ill, bilaterally visually impaired, colour-blind, pregnant, or planning to relocate within the next year were excluded.

The study tools consisted of questionnaires, colourcoded diabetes monitoring charts, glucometers, a haemoglobin analyser, non-elastic measuring tapes and digital weighing scales. A semi-structured pretested questionnaire designed by the authors was used which consisted of four parts. The first part had questions on socio-demographic information and clinical profile of diabetes mellitus, the second part was on baseline information on knowledge and practices related to diabetes control and documentation of participant's HbA1c levels, the third part was a table for the recording of monthly fasting blood sugar readings for 12 months, and the fourth part was on post-intervention information on knowledge and practices related to diabetes control, documentation of participant's HbA1c levels and perceptions regarding the chart.

The colour-coded diabetes monitoring chart was developed by the authors considering guidelines given by the World Health Organization, the International Diabetes Federation, the US Centre for Disease Control and Prevention, the American Diabetes Association, the Indian Council of Medical Research and the Indian National Programme for Non-Communicable Diseases. On the front side, the chart has colourcoded zones (green, yellow and red colour) showing blood sugar levels on the y-axis and time in monthly intervals on the x-axis (Figure 1). The back side consists of advice/action plans for blood sugar levels in the green, yellow, and red colour zones. The questionnaire and chart were validated by five independent experts in the fields of diabetes, medicine and public health. Fasting blood sugar levels were measured using the Accu-Chek Active glucometer (Model GB) and Accu-Chek Active test strip (manufactured by Roche Diabetes Care, a division of Hoffmann-La Roche Limited). HbA1c testing was performed with the Bio-Rad D-10 glycated haemoglobin analyser using high-performance liquid chromatography (HPLC). The measuring tape used was a non-elastic, extra-long (2 meters) type, and the weighing scale was an Agaro electronic scale (Model No WS-502).

The operational definitions used in the study have been described in a prior publication.<sup>19</sup> A participant was considered to have diabetes mellitus if they had ever been diagnosed with the condition by a doctor, regardless of whether treatment was being taken. Good knowledge of normal blood sugar levels was defined as the participant knowing the correct values. Knowledge of the frequency of blood sugar testing was considered good if the participant knew that testing should be done at least once a month. Good knowledge of the use of HbA1c test was defined as knowing that it measures blood sugar control over a few months. Knowledge regarding doctor visits was considered good if the participant knew that consultations should occur at least once every six months. Good knowledge of the duration of medication was defined as knowing that diabetes medication must be taken for life. Knowledge of the diabetic diet was considered good if the participant correctly answered all four questions related to the diabetic diet, some knowledge if two or three were answered correctly, and poor knowledge if only one or none were correct. A participant was considered to have good knowledge of the role of exercise in diabetes control if they knew that it helps in controlling blood sugar levels. Good knowledge of recommended exercise was defined as knowing that at least 30 minutes of physical activity is required daily. Participants were considered to have good knowledge of the effects of tobacco and alcohol consumption if they knew that impair blood sugar control. Similarly, thev knowledge of the relationship between obesity and diabetes control was considered good if the participant knew that obesity negatively affects blood sugar levels.

For diabetes-related practices, blood sugar testing was considered regular if it was done at least once a month. Doctor follow-up was considered regular if at least two visits occurred in a year. Good compliance with the doctor's advice was defined as following all or most of the instructions given. Medication intake was considered regular if the participant missed no doses or up to five doses in a month. A participant was considered to be following a diabetic diet if they adhered to all dietary instructions given by their doctor. Regular physical activity was defined as engaging in at least 30 minutes of activity on five or more days per week. Tobacco consumption was defined as the daily use of tobacco products in any form (smoking or chewing), and alcohol consumption was defined as consuming alcohol at least once a week. Meditation was considered to be practised if the participant engaged in meditation, prayer, or mind-focused yoga activities for a total duration of at least 15 minutes per day, either in a single session or across multiple sessions.



Figure 1A: Front side of colour-coded diabetes monitoring chart used by the intervention arm

#### ADVISE FOR CONTROL OF DIABETES MELLITUS

#### ADVISE ON DOCTOR VISITS AND MEDICINES BASED ON BLOOD SUGAR LEVEL

GREEN COLOUR	YELLOW COLOUR	RED COLOUR
(Blood sugar: 80 to 130 mg/dl)	(Blood sugar: 131 to 180 mg/dl)	(Blood sugar: >180 mg/dl)
Your blood sugar level is normal	Your blood sugar level is high	Your blood sugar level is very high
- Continue to take your medicines regularly	- If 2 consecutive blood sugar readings are high,	- You need to visit the doctor and take the
- Visit the doctor once in 6 months or as advised	then you need to visit the doctor and take the	advised medicines regularly
by your doctor	advised medicines regularly	- Check your fasting / after-food blood sugar
- Check your fasting / after-food blood sugar	- Check your fasting / after-food blood sugar	regularly as advised by your doctor or at
regularly as advised by your doctor or at least	regularly as advised by your doctor or at least	least once a week if you are not on insulin
once a month if you are not on insulin	once in 15 days if you are not on insulin	- Check your long-term diabetes control by
- Check your long-term diabetes control by	- Check your long-term diabetes control by doing	doing an HbA1c test once in 3 months.
doing an HbA1c test once in 6 months. HbA1c	an HbA1c test once in 3 months. HbA1c level of	HbA1c level of < 7 indicates good diabetes
level of < 7 indicates good diabetes control	< 7 indicates good diabetes control	control

#### GENERAL ADVICE FOR ALL DIABETES PATIENTS

DIET	BODY WEIGHT
<ul> <li>Consume diet as advised by your doctor</li> <li>Consume 4-6 smaller meals rather than 2-3 big meals</li> <li>Consume your meals at regular time and do not skip meals</li> <li>Consume more of vegetables and fruits</li> <li>Consume more of pulses such as beans, lentils and chickpeas</li> <li>Reduce white rice, white bread and replace it with whole wheat chapati and whole wheat brown bread</li> <li>Avoid refined sugar products such as sweets, cakes, biscuits and</li> </ul>	<ul> <li>Your body weight should be within normal BMI limits of 18.5 to 23</li> <li>Calculate your BMI using the formula BMI = weight (kg's) height? (meters)</li> <li>Waist circumference should be &lt; 90 cm's for men and &lt; 80 cm's for women (To measure your waist circumference, stand and place a measuring tape around your waist, just above hip bones)</li> </ul>
<ul> <li>Avoid roinks</li> <li>Avoid processed foods such as chips, French fries, chocolates and popcorn</li> </ul>	EXERCISE - Do 30 minutes of exercise daily such as brisk walking/ jogging/ cycling/ sports which involves continuous physical activity
SMOKING AND ALCOHOL - If you are a smoker or alcoholic, then quitting it will result in better control of blood sugar	<ul> <li>Start with 10 to 20 minutes exercise per day as per your capacity and then increase it to 30 minutes per day</li> <li>If your BMI&gt;23, then 2 sessions of exercise may be done till BMI becomes normal</li> </ul>

#### Figure 1B: Back side of colour-coded diabetes monitoring chart used by the intervention arm

Ethical approval for the study was obtained from the Yenepoya Ethics Committee 1 (YEC-1/2022/036 dated 16.06.2022). Permission to conduct the study was obtained from the District Health Officer and heads of the local panchayaths (Jokatte panchayath for the Jokatte area and Munnur panchayath for the Madani Nagar area). Support for the study was sought from the Medical Officers of Primary Health Centres, ASHA workers and Anganwadi workers serving the study areas. The study plan for the intervention and control arm is shown in Flow Chart 1. Four healthcare workers (two for each site) were recruited and trained for data collection. The initial house visit was conducted to register diabetic patients for the study. Participants were provided with information about the study in the local language, along with the participant information sheet. They were given an opportunity to discuss and clarify any doubts. Written informed consent was obtained in the local language from those advice on medication, doctor visits, lab investigations, diet, addictions, exercise and weight management. In the control arm, the standard advice for diabetes control similar to the intervention arm was given.

Follow-up visits were conducted monthly for 12 months. Prior to each visit, a phone call was made to the participants to schedule an appointment for the next day and remind them to fast overnight. On the day of the house visit, fasting blood sugar was measured early in the morning using an Accu-Chek glucometer and recorded. In the intervention arm, the participants were asked to mark their blood glucose levels on the chart. They were then guided to follow the advice/action plan on the back of the chart according to the corresponding colour zone. If a participant was illiterate, a bystander was asked to assist them with using the chart. In the control arm, the fasting blood glucose levels were informed to the participants.

At the last visit of 12 months, a post-intervention test questionnaire was administered, and information was collected in both arms. Blood samples for HbA1c were collected and transported to the central lab of Yenepoya Medical College Hospital for analysis. The perceptions of the participants in the intervention arm regarding colour-coded diabetes chart were documented using a questionnaire. In both arms, the participants were given post-intervention standard advice for diabetic control.

Data confidentiality was maintained throughout the study. The hard data forms were securely stored in a lockable cabinet, and the electronic data files were kept in a password-protected computer accessible only to the research authors. Data entry was done on Microsoft Excel and statistical analysis was conducted using SPSS (version 27.0 IBM, New York, USA). A per-protocol analysis was performed. Categorical variables are presented as percentages and continuous variables are reported as means with standard deviations. The pre- and post-intervention change in mean HbA1c and monthly fasting blood sugar (FBS) were assessed as the measures for the effectiveness of the colour-coded diabetes monitoring chart. Similarly, the relative change in knowledge and practice related to diabetes control pre- and post-intervention was assessed. Statistical tests such as chi-square, McNemar, t-tests and linear regression were used for analysis. A p-value of less than 0.05 was considered statistically significant.



Flow Chart 1: Study plan for intervention and control arm

# RESULTS

A total of 180 participants were recruited for the study, with 90 participants in each arm (intervention and control). The sociodemographic and diabetes profiles of the participants are presented in Table 1. No significant differences were observed between the intervention and control groups in terms of age, gender, education, or mean HbA1c.

At the end of 12 months of follow-up, there was an attrition of six participants in the intervention arm and five participants in the control arm. The mean HbA1c decreased by 0.52% in the intervention arm, while in the control arm it increased by 0.15%, and this difference was statistically significant (Table 2).

A linear regression analysis of the effect of the intervention on HbA1c controlling for baseline HbA1c, age, gender, socio-economic status and duration of diabetes revealed a B Coefficient of -0.58 (p-value = 0.014). In the intervention arm (N=84), the proportion of participants with controlled diabetes increased from 20.2% at baseline to 31.0% post-intervention, which was statistically significant when applying the McNemar test (p-value = 0.049). In the control arm (N=85), it increased from 27.1% to 30.6% (p-value = 0.607). The trend in mean monthly fasting blood sugar levels in the two groups is depicted in Figure 2. A two-way repeated measure ANOVA (Greenhouse-Geisser) showed a significant difference in the trend lines with a p-value of 0.042.

Table 1: Baseline sociodemographic and diabetes profile comparison of participants in intervention and control arm (N=180)

Variables	Total (N=180) (%)	Intervention arm (N=90) (%)	Control arm (N=90) (%)	χ² value	df	p- value
Age groups in years						
31 - 40	10 (5.5)	5 (5.5)	5 (5.5)	2.614	4	0.624
41 - 50	43 (23.9)	24 (26.7)	19 (21.1)			
51 - 60	59 (32.8)	32 (35.6)	27 (30.1)			
61 - 70	50 (27.8)	22 (24.4)	28 (31.1)			
> 70	18 (10)	7 (7.8)	11 (12.2)			
Age in years (mean ± SD)	57.0 ± 10.3	55.8 ± 9.8	58.1 ± 10.7	-	-	0.137
Gender						
Male	70 (38.9)	39 (43.3)	31 (34.4)	1.496	1	0.221
Female	110 (61.1)	51 (56.7)	59 (65.6)			
Education		( · · · )				
Not literate	21 (11.7)	9 (10)	12 (13.3)	10.193	5	0.07
Less than primary school	17 (9.4)	6 (6.7)	11 (12.2)	10.170	0	0.07
Primary school completed	49 (27.2)	26 (28.9)	23 (25.6)			
Secondary school completed	39 (21.7)	25 (27.8)	14 (15.6)			
High school completed	37 (20.6)	20 (22.2)	17 (18.9)			
PUC / Diploma / Graduate	17 (9.4)	4 (4.4)	13 (14.4)			
Occupation	17 ().+)	- ()	15 (14.4)			
Officials/Professionals/Technicians	9 (5)	7 (7.8)	2 (2.2)	7.364	3	0.061
Clerks/Operators/Elementary	49 (27.2)	30 (33.3)	2 (2.2) 19 (21.1)	7.304	5	0.001
Housewife	89 (49.5)	39 (43.3)	50 (55.6)			
Retired		14 (15.6)	19 (21.1)			
Socio-economic status	33 (18.3)	14 (15.0)	19 (21.1)			
	07 (52 0)	44 (40 0)		1.811	1	0.178
Below poverty line	97 (53.9)	44 (48.9)	53 (58.9)	1.011	1	0.170
Above poverty line	83 (46.1)	46 (51.1)	37 (41.1)			
Religion	45 (25)	21 (22.2)	24(2(7))	2 000	2	0.224
Hinduism	45 (25)	21 (23.3)	24 (26.7)	2.989	Z	0.224
Islam	124 (68.9)	66 (73.4)	58 (64.4)			
Christianity	11 (6.1)	3 (3.3)	8 (8.9)			
Duration of diabetes group in years	04 (45 0)	4 ( (1 = 0)		44000		0.000
<1	31 (17.2)	16 (17.8)	15 (16.7)	16.877	4	0.002
1 to 5	76 (42.2)	32 (35.6)	44 (48.9)			
6 to 10	48 (26.7)	35 (38.9)	13 (14.4)			
11 to 15	15 (8.3)	4 (4.4)	11 (12.2)			
> 15	10 (5.6)	3 (3.3)	7 (7.8)			
Duration of diabetes in years (mean ± SD)	6.3 ± 5.7	5.7 ± 4.5	6.8 ± 6.7	-	-	0.215
Health care provider						
Government	21 (11.7)	7 (7.8)	14 (15.6)	2.642	1	0.104
Private	159 (88.3)	83 (92.2)	76 (84.4)			
Comorbidities						
Present	49 (27.2)	20 (22.2)	29 (32.2)	2.271	1	0.132
Absent	131 (72.8)	70 (77.8)	61 (67.8)			
HbA1c (mean ± SD)	8.49 ± 1.91	8.71 ± 1.99	8.28 ± 1.81	-	-	0.135
Diabetes mellitus						
Controlled	44 (24.4)	19 (21.1)	25 (27.8)	1.083	1	0.298
Uncontrolled	136 (75.6)	71 (78.9)	65 (72.2)			

Table 2: Pre- and post-intervention mean HbA1c levels in intervention and control arm (N=169)

Arm	Ν	Post-intervention HbA1c (mean ± SD)	Pre-intervention HbA1c (mean ± SD)	Difference in HbA1c (mean ± SD)	t value	p-value
Intervention	84	8.19 ± 1.93	8.71 ± 1.99	-0.52 ± 1.72	-2.724	0.007
Control	85	8.43 ± 2.17	8.28 ± 1.83	$0.15 \pm 1.48$		



Figure 2: Trend of mean monthly fasting blood sugar in the intervention and control arm (N=169)

Knowledge	Post-intervention (%)	Pre-intervention (%)	OR (95% CI)	p-value
Normal blood sugar levels				
Good Knowledge	78 (92.9)	25 (29.8)	30.68 (11.83-79.57)	< 0.001
Poor Knowledge	6 (7.1)	59 (70.2)	Reference	
Frequency of blood sugar testing				
Good Knowledge	79 (94)	65 (77.4)	4.62 (1.64-13.05)	0.002
Poor Knowledge	5 (6)	19 (22.6)	Reference	
Use of HbA1c test				
Good Knowledge	72 (85.7)	11 (13.1)	39.82 (16.51-96.1)	< 0.001
Poor Knowledge	12 (14.3)	73 (86.9)	Reference	
Frequency of doctor visits				
Good Knowledge	75 (89.3)	66 (78.6)	2.27 (0.95-5.4)	0.059
Poor Knowledge	9 (10.7)	18 (21.4)	Reference	
Duration of diabetes medication				
Good Knowledge	78 (92.9)	73 (86.9)	1.90 (0.68-5.57)	0.201
Poor Knowledge	6 (7.1)	11 (13.1)	Reference	
Diabetic diet				
Good Knowledge	68 (81)	48 (57.1)	7.08 (1.49-33.79)	0.014
Some knowledge	14 (16.6)	26 (31)	2.69 (0.52-14.04)	0.24
Poor Knowledge	2 (2.4)	10 (11.9)	Reference	
Exercise effect on diabetes control				
Good Knowledge	78 (92.9)	65 (77.4)	3.80 (1.43-10.08)	0.005
Poor Knowledge	6 (7.1)	19 (22.6)	Reference	
Recommended exercise				
Good Knowledge	67 (79.8)	38 (45.2)	4.77 (2.41-9.45)	< 0.001
Poor Knowledge	17 (20.2)	46 (54.8)	Reference	
Effects of tobacco consumption				
Good Knowledge	68 (81)	56 (66.7)	2.13 (1.05-4.32)	0.035
Poor Knowledge	16 (19)	28 (33.3)	Reference	
Effects of alcohol consumption				
Good Knowledge	67 (79.8)	62 (73.8)	1.39 (0.68-2.88)	0.361
Poor Knowledge	17 (20.2)	22 (26.2)	Reference	
Obesity relation with diabetes co				
Good Knowledge	59 (70.2)	39 (46.4)	2.72 (1.44-5.14)	0.002
Poor Knowledge	25 (29.8)	45 (53.6)	Reference	

Table 3: Diabetes control knowledge among participants in the intervention arm (N=84)

Table 4: Diabetes control knowledge among participants in the control arm (N=85)
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Knowledge	Post-intervention (%)	Pre-intervention (%)	OR 95% CI)	p-value
Normal blood sugar levels				•
Good Knowledge	35 (41.2)	17 (20)	2.80 (1.41-5.55)	0.003
Poor Knowledge	50 (58.8)	68 (80)	Reference	
Frequency of blood sugar tes				
Good Knowledge	72 (84.7)	60 (70.6)	2.30 (1.09-4.89)	0.027
Poor Knowledge	13 (15.3)	25 (29.4)	Reference	
Use of HbA1c test				
Good Knowledge	45 (52.9)	38 (44.7)	1.39 (0.76-2.54)	0.283
Poor Knowledge	40 (47.1)	47 (55.3)	Reference	
Frequency of doctor visits				
Good Knowledge	67 (78.8)	64 (75.3)	1.22 (0.59-2.5)	0.584
Poor Knowledge	18 (21.2)	21 (24.7)	Reference	
<b>Duration of diabetes medicat</b>				
Good Knowledge	77 (90.6)	78 (91.8)	0.86 (0.30-2.49)	0.787
Poor Knowledge	8 (9.4)	7 (8.2)	Reference	
Diabetic diet				
Good Knowledge	3 (3.5)	9 (10.6)	0.31 (0.08-1.23)	0.094
Some knowledge	47 (55.3)	44 (51.8)	0.98 (0.52-1.84)	0.941
Poor Knowledge	35 (41.2)	32 (37.6)	Reference	
Exercise effect on diabetes co				
Good Knowledge	54 (63.5)	51 (60)	1.16 (0.63-2.2)	0.636
Poor Knowledge	31 (36.5)	34 (40)	Reference	
Recommended exercise				
Good Knowledge	37 (43.5)	43 (50.6)	0.75 (0.41-1.38)	0.357
Poor Knowledge	48 (56.5)	42 (49.4)	Reference	
Effects of tobacco consumption	on			
Good Knowledge	54 (63.5)	55 (64.7)	0.95 (0.51-1.78)	0.873
Poor Knowledge	31 (36.5)	30 (35.3)	Reference	
Effects of alcohol consumptio	n	-		
Good Knowledge	46 (54.1)	40 (47.1)	1.38 (0.73-2.43)	0.357
Poor Knowledge	39 (45.9)	45 (52.9)	Reference	
Obesity relation with diabete				
Good Knowledge	45 (52.9)	49 (57.6)	0.83 (0.45-1.51)	0.537
Poor Knowledge	40 (47.1)	36 (42.4)	Reference	

Table 5: Diabetes control practices among participants in the intervention arm (N=84)

Practice	Post-intervention (%)	Pre-intervention (%)	OR (95% CI)	p-value
If blood sugar is high on 2 or more of		The man vention (70)	01 (75 / 01)	p value
Visit doctor	75 (89.3)	71 (84.5)	1.53 (0.61-3.79)	0.36
Do nothing or try other measures	9 (10.7)	13 (15.5)	Reference	0100
Follow up with the doctor		10 (10:0)	11010101100	
Regular	77 (91.7)	71 (84.5)	2.01 (0.76-5.33)	0.153
Irregular	7 (8.3)	13 (15.5)	Reference	
Compliance with doctors advise		()		
Good compliance	64 (76.2)	52 (61.9)	2.26 (1.14-4.46)	0.045
Poor compliance	20 (23.8)	32 (38.1)	Reference	
Medication intake				
Regular	79 (94)	70 (83.3)	3.16 (1.08-9.22)	0.028
Irregular	5 (6)	14 (16.7)	Reference	
Diet				
Follow diabetic diet	19 (22.6)	11 (13.1)	2.27 (0.85-6.1)	0.104
Follow to some extent	49 (58.3)	52 (61.9)	1.24 (0.58-2.64)	0.583
Do not follow diabetic diet	16 (19.1)	21 (25)	Reference	
Physical activity				
Regular	28 (33.3)	14 (16.7)	2.50 (1.2-5.19)	0.013
Irregular	56 (66.7)	70 (83.3)	Reference	
Tobacco consumption				
No	6 (7.1)	9 (10.7)	0.64 (0.22-1.89)	0.417
Yes	78 (92.9)	75 (89.3)	Reference	
Alcohol consumption				
No	3 (3.6)	3 (3.6)	1.00 (0.19-5.10)	1
Yes	81 (96.4)	81 (96.4)	Reference	
Meditation				
Yes	75 (89.3)	79 (94)	0.53 (0.17-1.65)	0.264
No	9 (10.7)	5 (6)	Reference	
BMI				
BMI <23	24 (28.6)	15 (17.9)	1.84 (0.89-3.83)	0.101
BMI ≥23	60 (71.4)	69 (82.1)	Reference	

Practice	Post-intervention (%)	Pre-intervention (%)	OR (95% CI)	p-value
If blood sugar is high on 2 or more of	ccasions			
Visit doctor	77 (90.6)	74 (87.1)	1.43 (0.55-3.76)	0.465
Do nothing or try other measures	8 (9.4)	11 (12.9)	Reference	
Follow up with the doctor				
Regular	75 (88.2)	76 (89.4)	0.89 (0.34-2.31)	0.808
Irregular	10 (11.8)	9 (10.6)	Reference	
Compliance with doctors advise				
Good compliance	56 (65.9)	50 (58.8)	1.35 (0.73-2.52)	0.342
Poor compliance	29 (34.1)	35 (41.2)	Reference	
Medication intake				
Regular	74 (87.1)	67 (78.8)	1.81 (0.79-4.10)	0.153
Irregular	11 (12.9)	18 (21.2)	Reference	
Diet				
Follow diabetic diet	7 (8.2)	10 (11.7)	0.74 (0.25-2.18)	0.588
Follow to some extent	45 (52.9)	40 (47.1)	1.19 (0.63-2.26)	0.578
Do not follow diabetic diet	33 (38.9)	35 (41.2)	Reference	
Physical activity				
Regular	39 (45.9)	36 (42.4)	1.15 (0.63-2.12)	0.643
Irregular	46 (54.1)	49 (57.6)	Reference	
Tobacco consumption				
Yes	9 (10.6)	8 (9.4)	1.14 (0.42-3.11)	0.798
No	76 (89.4)	77 (90.6)	Reference	
Alcohol consumption				
Yes	6 (7.1)	7 (8.2)	0.85 (0.27-2.63)	0.773
No	79 (92.9)	78 (91.8)	Reference	
Meditation				
Yes	67 (78.8)	65 (76.5)	1.15 (0.56-2.36)	0.713
No	18 (21.2)	20 (23.5)	Reference	
BMI				
BMI <23	15 (17.6)	17 (20)	0.86 (0.39-1.85)	0.695
BMI ≥23	70 (82.4)	68 (80)	Reference	

Table 6: Diabetes control practices among participants in the control arm (N=85)

There was a marked improvement in participants' knowledge of diabetes control in the intervention arm. Significant improvement was seen in the understanding of normal blood sugar levels, frequency of blood sugar testing, use of HbA1c test in diabetes monitoring, diabetic diet, benefits of exercise, including recommended exercise, and the effect of tobacco consumption and obesity on diabetes control (Table 3). In the control arm, significant improvement in the knowledge was noted for normal blood sugar levels and frequency of blood sugar testing (Table 4). Each correct answer in the knowledge assessment was awarded 1 point, with a maximum possible score of 12. The mean knowledge score in the intervention group increased from 7.41 to 10.37, reflecting an improvement of 2.96 points. In the control group, the mean score rose slightly from 6.55 to 6.88, an improvement of 0.33 points. A t-test comparing the mean knowledge score improvements between the two groups showed a statistically significant difference, with a p-value of less than 0.001.

The practice of the participants on diabetes control also improved in the intervention arm but to a lesser extent as compared to the knowledge improvement. Significant improvement in compliance with doctors' advice, medication intake and physical activity was noted in the intervention arm (Table 5). No significant changes in diabetes-related practices were noted in the control group (Table 6). Each correct practice was awarded 1 point, with a maximum possible score of 11. In the intervention arm, the mean practice score increased from 7.17 to 7.95, reflecting an improvement of 0.79 points. In the control arm, the mean practice score rose slightly from 7.06 to 7.26, an improvement of 0.2 points. A t-test comparing the mean practice score improvements between the two groups revealed a statistically significant difference, with a p-value of 0.012.

Table 7: Participants' perceptions of the colour-coded diabetes monitoring chart (N=84)

Variable	Participants (%)				
Usefulness of chart in understanding blood sugar levels					
Very useful	60 (71.4)				
Moderately useful	24 (28.6)				
Usefulness of chart in tracking blood sugar levels					
Very useful	58 (69)				
Moderately useful	26 (31)				
Usefulness of written advice on the chart					
Very useful	30 (35.7)				
Moderately useful	39 (46.4)				
Slightly useful	12 (14.3)				
Not useful	3 (3.6)				
Ease of use of chart*	8.6 (± 0.9)				
Usefulness of the chart*	8.9 (± 0.8)				
Future use of chart					
Definitely continue using it	70 (83.3)				
Most likely continue using it	13 (15.5)				
Not yet decided	1 (1.2)				

\*Rated on a Likert scale of 10 and expressed as mean (± SD)

Participants in the intervention arm had an overall favourable perception of the diabetes monitoring chart. Approximately 70% reported that the chart was very useful for understanding and tracking their blood sugar levels (Table 7). Additionally, 82% found the written advice on the chart to be very or moderately helpful. Concerning future use, nearly all participants indicated they would definitely or most likely continue using the chart.

# **DISCUSSION**

This study was conducted to assess the effectiveness of a colour-coded diabetes chart on glycemic control of patients. A total of 180 participants were recruited, with 90 each in the intervention and control arms. Overall, the socio-demographic and diabetic profile of the participants in the two arms were similar.

The intervention of the use of a colour-coded diabetes monitoring chart for one year resulted in a reduction of HbA1c by 0.52%, whereas in the control arm, HbA1c increased by 0.15%. Regression analysis controlling for other factors revealed an HbA1c improvement of 0.58% as a result of the intervention. Similar findings were reported by Fathima FN et al., where the use of coloured diabetes charts for one year by senior citizens resulted in an HbA1c reduction of 0.27%.<sup>17</sup> Another study by Chawla R et al., conducted over three months using a digital therapeutic intervention app focusing on self-monitoring of blood glucose and digital consultations with a doctor, dietician and exercise coach, resulted in an HbA1c reduction of 0.84%.<sup>20</sup>

The present study also looked at the trend of FBS in both arms. In the intervention arm, FBS decreased for the first four months, followed by an increase over the next few months, and then a decline after the ninth month. At the 12<sup>th</sup> month, there was a reduction of 12.4 mg/dl in FBS compared to baseline. The FBS trend was variable in the control arm, with an increase in the FBS of 5.8 mg/dl at the 12<sup>th</sup> month compared to baseline. The difference in the mean FBS trends in the two arms was statistically significant. A similar finding was noted in the study of Chawla R et al., where there was a reduction of 8.4 mg/dl in FBS.<sup>20</sup> In another study by Pot GK et al., conducted in the Netherlands over six months, with an intervention focused on nutrition, physical activity, and stress management, found an FBS reduction of 21.6 mg/dl.21

The improvement in glycemic control in the intervention arm can be attributed to two key factors. First, the colour-coded zones of blood sugar levels on the front side of the diabetes chart helped patients understand whether their blood sugar was under control or not. Second, effective glycemic control requires not just awareness but also appropriate action. The reverse side of the chart supported this by providing a structured action plan, offering clear guidance on steps to take when blood sugar levels were high, as well as advice for maintaining control when levels were within the normal range.

A study by Stratton IM et al. reported a 37% reduction in microvascular complications, a 14% decrease in myocardial infarction, and a 21% reduction in diabetes-related deaths for every 1% reduction in HbA1c.<sup>22</sup> In the present study, a 0.58% reduction in HbA1c was achieved in the intervention arm, with the proportion of patients achieving controlled diabetes increasing from 20% to 31%. This represents a substantial improvement from a public health perspective, with the potential to reduce complications for millions of diabetic patients.

The use of colour-coded diabetes monitoring chart led to a significant improvement in knowledge related to diabetes control. Similar findings were noted in RCTs on educational intervention and counselling conducted by Geetha K et al. in Tamil Nadu, Kumar M in Gujarat and Malathy R et al. in Tamil Nadu, where they noted improvement in the knowledge of participants.<sup>23-25</sup> In the present study, there was a notable improvement in knowledge regarding normal blood sugar levels. Typically, patients rely on doctors or lab technicians to inform them if their blood sugar is normal after testing. However, the study chart not only helped patients recognize normal blood sugar levels but also reinforced this knowledge every time it was used. Even if patients didn't know the exact levels, they could still understand if their blood sugar was under control due to the colour coding. An improvement in knowledge about the frequency of blood sugar testing was also noted. Interestingly, knowledge of normal blood sugar levels and frequency of testing also improved significantly in the control group. This may be attributed to the fact that monthly blood sugar testing by field workers made patients more eager to know whether their levels were normal, thereby enhancing their knowledge in this area.

A majority of participants in the intervention arm were initially unaware of HbA1c, but this knowledge improved significantly post-intervention. Understanding the importance of HbA1c testing equips patients to better manage long-term blood sugar control. Knowledge of a diabetic diet was tested by asking four relevant questions. Although it was a brief assessment of dietary knowledge, it showed significant improvement post-intervention. The diabetes counselling trial by Malathy R et al. also found significant improvement in knowledge of diabetes diet in the intervention arm.<sup>25</sup> The participants in the intervention arm of the present study also gained better knowledge of not only the exercise benefits on diabetes but also the type of exercise that is required. A study by Ihekoronye et al. in Nigeria on pharmacistled health education also observed improved exercise knowledge in the intervention arm.<sup>26</sup>

The intervention arm showed improved knowledge regarding the negative impact of tobacco on diabetes

control. This is a significant finding, given the widespread use of tobacco in India. Without awareness of its detrimental effects, individuals with diabetes may continue tobacco consumption, hindering their glycemic management. Additionally, it was concerning to note that many participants were initially unaware of the link between obesity and poor diabetes control. The chart addressed this gap by providing information on the negative effects of obesity on glycemic control and offering guidance on achieving recommended BMI and waist circumference. Similar improvements were noted in the study by Ihekoronye et al.<sup>26</sup>

Next, the study assessed if the improvement of knowledge translates into improved practices. A significant improvement in diabetes management practices was observed in the intervention arm, however, the improvement was less pronounced than that observed in knowledge. This is plausible as knowledge acquisition is easier, but practice change needs more multidimensional efforts. Similar practice improvements were reported by Geetha K et al. and Kumar M.<sup>23,24</sup> AlQahtani in Saudi Arabia noted a negative correlation between diabetes self-care practices and HbA1c levels.<sup>27</sup>

Participants in the intervention arm showed significant improvements in compliance with the doctor's advice, medication and physical activity. These improvements highlight that when people are made aware of their blood sugar levels and provided with a practical action plan, then a considerable proportion of them will follow the action plan in order to achieve control. Following the doctor's advice and consuming medicines is relatively easy, hence, the majority of participants were able to achieve this part of the action plan. However, dietary changes and physical activity require more effort. The improvement in physical activity in the intervention arm, even though modest, was still significant compared to the baseline. The dietary improvement was not significant, indicating more efforts, such as tailored advice by the doctor/dietician, and reinforcement may be required. The study by Ihekoronye et al. noted similar improvement in medication adherence.26

A study by Celli A et al. in the USA focusing on intensive lifestyle intervention resulted in a significant reduction in body weight.<sup>28</sup> In contrast, the present study was able to see an overall reduction in the BMI of the participants, however, it was not statistically significant. It is important to note that the present study employed a simple, practical chart provided directly to the patient, unlike the aforementioned study which required extensive resources such as dieticians, doctors and exercise coaches.

An important finding of the study was the favourable perception of the intervention arm participants towards the colour-coded diabetes monitoring chart. About two in three participants found the chart very helpful in understanding and tracking their blood sugar levels. A vast majority felt the written information to be useful; however, few participants gave feedback that simpler information would be more useful, especially related to the BMI part. Overall, the chart was very highly rated for its ease of use and usefulness. A critical measure of any tool's success is whether participants are willing to continue using it in the future. In this case, the colour-coded chart demonstrated strong acceptance, with all but one participant expressing a desire to continue its use.

The colour-coded diabetes chart significantly reduced blood sugar levels, improved knowledge and practices, and garnered wide acceptance from participants. While many RCTs have demonstrated improved diabetes control through intensive lifestyle or digital interventions which often require significant manpower, funding, technology, and extensive training, these approaches can be unsustainable at a community level over time. In contrast, the present study offers a sustainable and scalable solution that does not rely on such resources and can be easily implemented across Indian communities. This intervention should be considered as part of a multi-pronged strategy to address uncontrolled diabetes in the country.

### **STRENGTHS AND LIMITATIONS**

The study has a few limitations. First, patientreported practices may have been influenced by social desirability bias, potentially leading to overreporting of correct practices. Second, the sample size was limited due to the logistical challenges of conducting monthly follow-ups over one year. Despite these limitations, the study has notable strengths. It was community-based, enhancing its real-world applicability, and the diabetes control was assessed using the gold-standard HbA1c test, conducted in an accredited laboratory, ensuring reliability and accuracy.

## **CONCLUSION**

The colour-coded diabetes chart proved effective in reducing blood sugar levels while enhancing patients' knowledge and self-care practices for diabetes control. Participants found the chart easy to use and beneficial, with most expressing a desire to continue using it. Similar to the growth chart, this tool can be implemented in both government healthcare settings, such as primary health centres, and private clinics. Given its practicality, cost-effectiveness, and sustainability, the colour-coded diabetes chart represents a valuable addition to a comprehensive approach to diabetes management.

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**Availability of Data:** The data that supports the findings of the study are available from the corresponding author upon reasonable request.

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