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IMPACT OF INFORMATIONAL CARE AND COMPLIANCE THERAPY ON TREATMENT OUTCOMES IN PATIENTS WITH TYPE 2 DIABETES MELLITUS

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Abstract

Background: Effective management of Type 2 diabetes mellitus (T2DM) emphasized patient education and adherence to treatment. This study evaluated the informational care and compliance therapy on glycemic control and treatment adherence among patients with T2DM.[1, 2,3]

Objective: To assess the effect of informational care and compliance therapy on glycemic parameters on medication adherence in patients with T2DM.

Methods: A randomized educational interventional study was conducted at Sohail Trust Hospital, Karachi, involving 100 patients with no-compliant T2DM. Participants were divided randomly into to intervention (n=50) and control (n=50). The interventional group was given standard treatment plus informational care and compliance therapy, while the control group was given standard care only. fasting blood sugar (FBS), and postprandial blood sugar (PPBS), and adherence (using the Mrisky-8 item scale) were measure at baseline, 6 weeks and 12 weeks. Data were analyzed using SPSS version 27 with independent t-tests, paired t-tests and chi-square tests. A p-value of < 0.005 was deemed statistically significant

Results: The Interventional group had significant decreased in FBS (from 141 mg/dL to 117 mg/dL) and PPBG (from 244 mg/dL to 179 mg/dL) ($p<0.001$), along with better adherence score (from 2.66 to 0.88). No significant changes were observed in the control group.

Conclusion: Informational care and compliance therapy significantly improve the glycemic control and treatment adherence among T2DM patients. These results suggest the adoption of educational interventions into normal diabetes care for better outcomes and complication prevention.

Keywords: Type 2 diabetes mellitus, informational care, compliance therapy, treatment outcome, glycemic control.

Introduction:

Type 2 diabetes mellitus (T2DM) is a growing global health concern, currently affecting 42 million people worldwide. According to the International Diabetes Federation (IDF), Pakistan had over 33 million cases in 2021 making it one of the top countries with the highest prevalence. This number is expected to rise to79.4 million by 2030, highlighting an urgent need for effective disease management strategies.[4-,6]

To achieve successful control over diabetes by evidence-based diabetes protocols of management, which include adherence to the medication, changes in diet plan according to the guidelines, and lifestyle modification[7,8]. In order to delay diabetes-related complications, adherence to the treatment is necessary to control the sugar levels[9].

Noncompliance is the common problem and has been found as a main source in progression of disease, and in chronic patients, it is the main reason for developing diabetes complications.

Many variables relate to poor compliance, particularly patient-related problems like forgetfulness, carelessness, lack of interest, and use of inconsistent prescriptions.

Moreover, extrinsic factors like no proper informational care given to the patient about the disease, unwanted effects of medications, financial limitations, limited access to visits to doctors, and not having self-blood monitoring tools are important indicators of non-adherence[10,11].

Research findings point to an optimum control on sugar levels significantly associated with a substantial level of treatment compliance, which sequentially can reduce the risk of brief and enduring diabetes sequelae.

The consequence of poor adherence may be severe as it reduces the blood glucose control and worsens the risk of microvascular and macrovascular complications, which include diabetes retinopathy, nephropathy, neuropathy, cardiovascular diseases (hypertension), cerebrovascular disease (stroke), and peripheral artery disease[12,13].

Therefore, dealing with non-compliance is a key element in enhancing the better treatment effects for the patient with T2DM, which in turn decreases the significant health consequences in the community of this prevalent disease[14,15].

Methodology

The educational interventional study was carried out in the Diabetes Outpatient Clinic at Sohail Trust Hospital Karachi from June to August 2024, after the approval of the Ethical Review Committee. Written and verbal consent was obtained from participants. OpenEpi software was used to estimate the sample size of 100 diagnosed cases of non-compliant type 2 diabetes mellitus. Participants were randomly assigned (1:1) into either an intervention group(n=50) or a control group (n=50) using a computer-generated randomization sequence. Allocation concealment was ensured using sequential numbered, sealed opaque envelops.

The control group received the standard treatment as usual following the current diabetes guidelines; on the other hand, the intervention group received standard treatment plus informational care and compliance therapy, aimed to increase understanding of the diabetes regimen and to promote medication compliance.

Data was collected at baseline, six weeks, and twelve weeks for fasting blood sugar (FBS) and postprandial blood sugar (PPBS), and adherence score was calculated by using the Morisky 8-item scale. The chi-square test was used for quantitative data to analyze the frequency distribution, and independent t-tests were applied for quantitative data to compare means between the control and case groups, and paired t-tests were applied to assess the mean changes within the group over time. Statistical analysis was performed using SPSS version 27. A p-value of < 0.005 was considered statistically significant.

Results:

Among the 100 participants, the control group consisted of 19 males and 31 females, while the intervention group had 17 males and 33 females. The mean age of participants was 54.14 ± 12.35

years in the control group and 53.60 ± 12.50 years in the intervention group. The duration of diabetes was 8.57 ± 6.76 years for the control group and 7.57 ± 5.56 years for the Intervention group. Self-Monitoring of Blood Glucose (SMBG) was reported at 2.94 ± 0.37 times per day in the control group and 2.84 ± 0.51 times per day in the Intervention group. The SMBG baseline frequency score is more than 2 in both cases, which means these patients check their blood glucose once a week (three categories were made; category 1 checks their blood sugar daily, 2 checks thrice a week, and 3 checks once a week). Average postprandial blood glucose (PPBG) levels were 226 ± 79 mg/dL in the control group and 244 ± 74 mg/dL in the intervention group, while average fasting blood glucose (FBG) levels were 131 ± 28 mg/dL in the control group and 141 ± 44 mg/dL in the intervention group. We can appreciate that the level of glucose is high in both groups at baseline assessment. Adherence scores were 2.88 ± 1.64 for the Control group and 2.66 ± 1.58 for the Intervention group which shows low compliance, as the score is more than 2 according to the Morisky adherence scale (0 means high adherence, 1-2 means moderate adherence, and >2 means low adherence). (Table 1).

Table-1 (Comparison of Demographic and Clinical Variables Between Control and Intervention Groups)

Variable	**Control (Mean ± STD)**	**Intervention (Mean ± STD)**	**P-value**
Male	19	17	0.76
Female	31	33	
Age	54.14 ± 12.35	53.60 ± 12.50	0.828
Duration of Diabetes	8.57 ± 6.76	7.57 ± 5.56	0.422
SMBG Baseline Frequency	2.94 ± 0.37	2.84 ± 0.51	0.266
Average PPBG	226 ± 79	244 ± 74	0.239
Average FBG	131 ± 28	141 ± 44	0.176
Adherence Score	2.88 ± 1.64	2.66 ± 1.58	0.498

(None of the baseline characteristics show statistically significant differences between the control and interventional groups (all p-values > 0.05). This suggests that the two groups are well-matched)

After analyzing and comparing different diabetes-related factors between the control and case groups, no statistically significant differences were observed. 36 participants in the control group and 38 participants in the case group reported a positive family history of diabetes, while 14 in the control group and 12 in the case group had no such history. The p-value of this comparison was 0.648, indicating no significant difference between the groups.

When it comes to diabetes-related complications, both groups showed identical distribution; 45 individuals in each group reported having complications, while 5 individuals in each group had non, with a p-value of 0.63, further supporting the lack of significant difference.

Compliance with oral antidiabetic and insulin also revealed no significant disparity; in the control group, 44 were compliant, and in the case group, 39 were compliant. Meanwhile, 6 in the control group and 11 in the case group were non-compliant, with a significant *p*-value of 0.183.

Dietary compliance shows similar trends. There was no significant difference between the groups, as indicated by a p-value of 0.86.

Physical activity levels were also identical in both groups, with 8 participants in each group engaging in physical activity and 42 were not participating. The p-value for this comparison was 1.00, clearly indicating no difference.
Overall, all p-values in these comparisons exceeds the 0.05 threshold, signifying that none of the examined factors shoed a statistically significant difference between the case and control groups. (Table-2)

Table 2 Comparison of Diabetes-Related Factors Between Control and Interventional Groups

Variable	Groups	Frequency	p-value
Family history of diabetes			0.648
yes	Control	36	
	Case	38	
No	Control	14	
	Case	12	
Diabetes related complications			
yes	Control	45	0.630
	Case	45	
No	Control	5	
	Case	5	
Oral Antidiabetics and Insulin compliance			
yes	Control	44	0.183
	Case	39	
No	Control	6	
	Case	11	
Diet compliance			0.86
yes	Control	20	
	Case	12	
No	Control	30	
	Case	38	
Physical Activity			1.00
yes	Control	8	
	Case	8	
No	Control	42	
	Case	42	

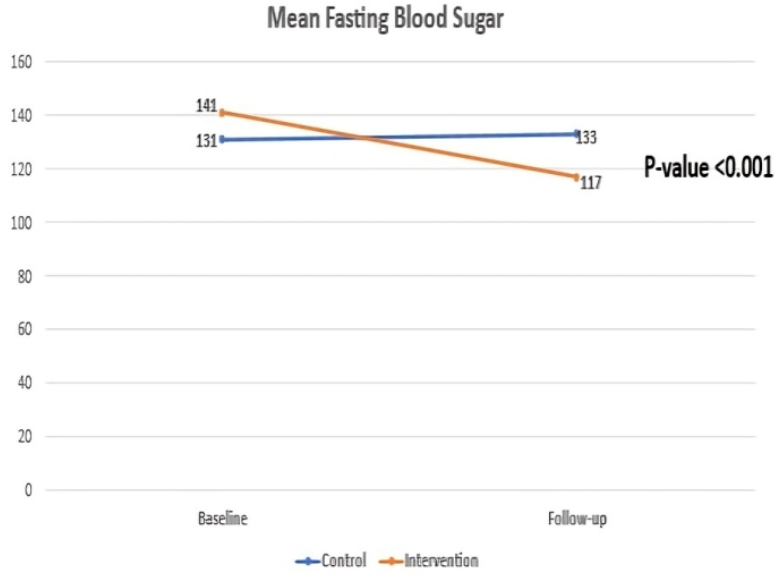
Table 3 compares the values of baseline to follow-up for the control and interventional groups for fasting blood sugar (FBS), postprandial blood sugar (PPBG), and adherence score. The result shows the considerable difference between two groups.
In the interventional group, the fasting blood sugar levels significantly reduced from 141 mg/dL at baseline to 117 mg/dL at follow-up, as shown in Graph-1, but there was no significant change in fasting sugar levels in the control group during the same period. Likewise, in the intervention group, a remarkable drop in PPBG was noticed; levels dropped from 244 mg/dL to 179 mg/dL, as shown in Graph 2. These changes were statistically significant, with a p-value less than 0.001. As indicated by Graph 3, the intervention group not only showed significant improvement in control of blood sugar but also in adherence to the treatment, can be witnessed from the results, 2.66 to 0.88 ($p < 0.001$).

These results strongly support the interventions improving the patient's behavior with relation to medication compliance in addition to blood glucose management.
On the other hand, in the control group, adherence scores and glycaemic variables like FBS and PPBG showed little change, highlighting the important role of educational interventions performed in achieving the positive results.

Table-3 (Comparison of Mean Differences in Blood Sugar Levels and Adherence Scores from Baseline to Follow-up)

Variable	Baseline (Mean ± STD)	Follow-up (Mean ± STD)	Mean Difference	P-value
Fasting Blood Sugar				<0.001
Control	131 ± 28	133 ± 29	-1.70	
Intervention	141 ± 44	117 ± 28	24.54	
Postprandial Blood Sugar				<0.001
Control	226 ± 79	233 ± 64	-7.0	
Intervention	244 ± 75	179 ± 60	64.66	
Adherence Score				<0.001
Control	2.88 ± 1.65	2.82 ± 1.66	0.060	
Intervention	2.66 ± 1.59	0.88 ± 0.90	1.70	

Graph 1: (Changes in Fasting Blood Glucose (FBG) Levels in Control and Intervention Groups)



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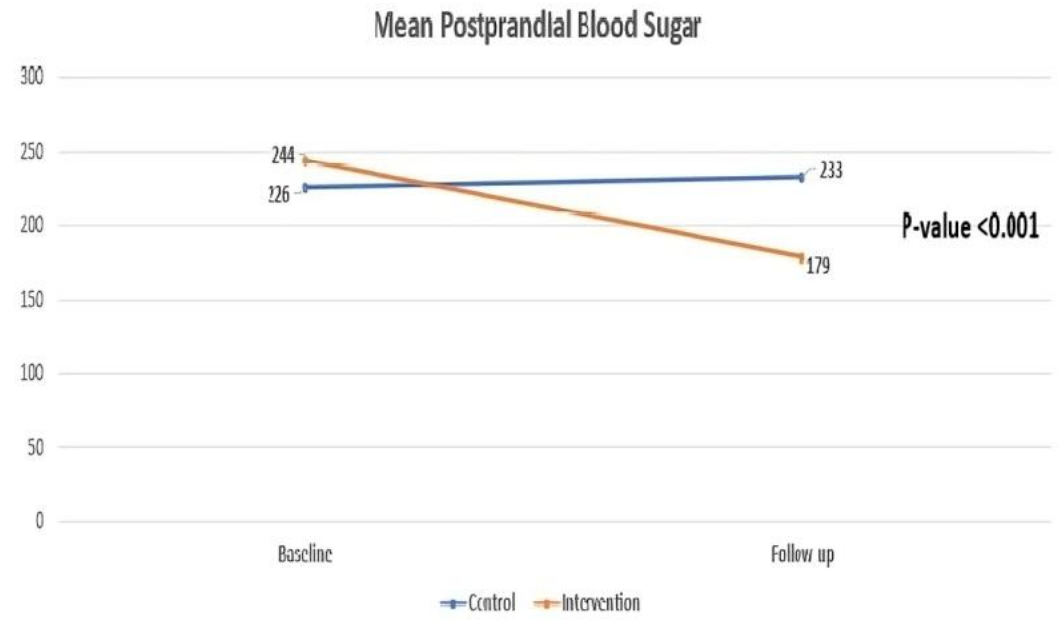
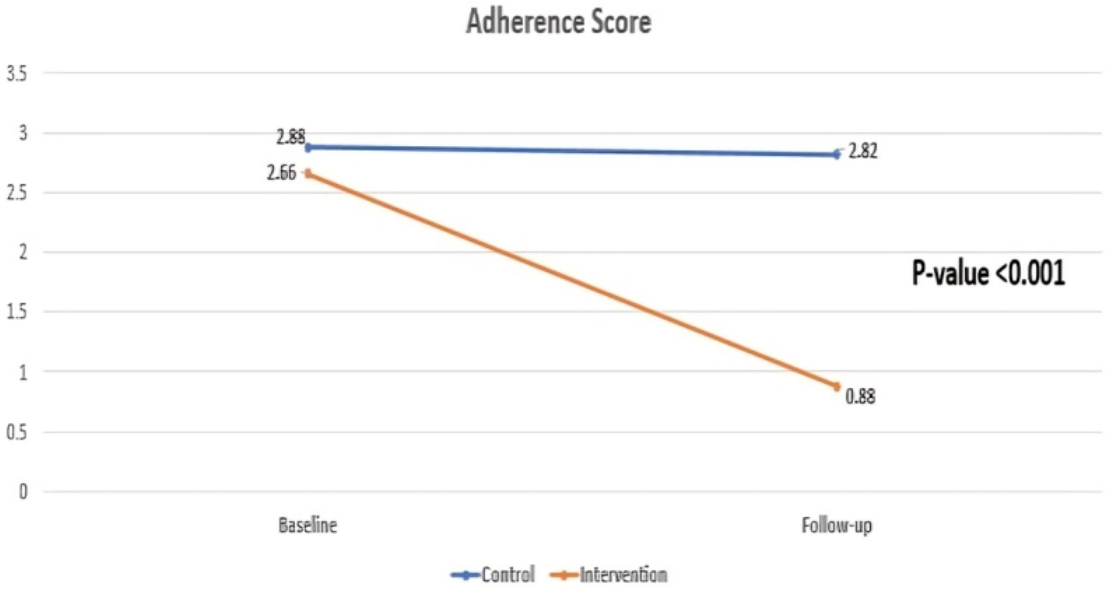
Graph 2: (Changes in Postprandial Blood Glucose (PPBG) Levels in Control and Intervention Groups)



Graph 3: (Changes in Adherence Scores in Control and Intervention Groups)



Discussion:

The study was carried out to see the impact of informational care and compliance therapy on treatment outcome in patients with type 2 diabetes mellitus (T2DM) and gives useful knowledge into optimizing diabetes management protocols. The research findings emphasize the essential requirement of improving patients' education and treatment compliance for diabetes management in a country where diabetes is a significant global health challenge.

The findings of both the intervention and control groups showed significant differences. In the intervention group, the individuals received the informational care about the disease and management and compliance therapy, which showed valuable improvements in both fasting and postprandial blood glucose levels.

Particularly, the decline in FBS from 141 mg/dL to 117 mg/dL, and the reduction in PPBG from 244 mg/dL to 179 mg/dL. This appreciable decrease reflected the impact of informational care and compliance therapy in diabetes mellitus management and improved health outcomes[16].

The control group did not show any noticeable changes in blood glucose levels, demonstrating the significance of patient education towards achieving improved health outcomes.

Moreover, the improvement in adherence scores within the intervention group—from an average of 2.66 to 0.88 on the Morisky scale—further emphasizes the importance of compliance therapy.

The result corresponds with research by Cramer (2004), who found a strong association between greater patient outcomes in the management of diabetes and greater compliance rates[17].

The significant difference in adherence suggests that informational care motivates the patient to engage actively in the treatment plan and also additionally enhances their awareness about illness.

Complex medication regimens, memory problems, and lack of proper knowledge of illness are the some of the major factors of non-adherence. The intervention focuses on these obstacles by giving informational care about diabetes mellitus and the necessary tools that they need to comply with treatment to better manage the illness. As it is highlighted in the study on "Management of Hyperglycemia in T2DM," personalized interventions are vital to increase the patients' knowledge to take care of their health for better self-management and to control the sugar levels.[18]

Although the study provides strong support for the intervention, it is important to take into account the results and their wider implications. Integration of compliance therapy and informational care in routine management may change the way T2DM is treated by professionals. Besides giving informational care, and compliance improves the health outcome and also reduces the health care burden by lowering the chances of illness-related complications.[19]

A randomized control trial approach was used in the research methodology, which gives relevance to the results. More research is required to investigate the long-term possibility of these improvements, as suggested by Davies et al., which will help to understand the better results to maintain long term for the effects of informational care and compliance therapy.[20]

Conclusion.

The present research provides a number of significant findings regarding the treatment of diabetes. Essentially, to reduce the enduring complications like neuropathy and cardiovascular diseases by controlling the fasting blood sugar and postprandial sugar levels. Furthermore, patients' better compliance with treatment gives the improved results to maintain the sugar level in the long term. Moreover, the patient's education is vital to allowing people to effectively manage the diabetes, which thereby minimizes emergency visits and hospitalization as well. Implementing informational care and compliance therapy into the routine treatment modalities of diabetes may provide extended effectiveness, which in turn improves the quality of life and decreases the health care burden. Lastly, by focusing on these treatment approaches in community health programs, significantly lessen the diabetes-related consequences, resulting in health care expenses and better health outcomes.

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Recommendations

- To promote the introduction of informational care and compliance therapy across different healthcare settings to improve compliance among patients.
- Combining these protocols in existing clinical practice protocols to have good control of sugar levels and reduce adverse effects.
- Highlight the awareness about the importance of treatment compliance, healthy changes in daily dietary plans and lifestyle modification for ongoing diabetes care.
- Giving additional guidance to the health care professionals on how to provide informational care and optimize the compliance therapy.
- Further, longitudinal studies are required to assess the long-term maintenance of these interventions for better management of diabetes and its complications.

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Authors' contributions

Please indicate here the specific contribution made by each author to the manuscript as specified above under 'Authorship Responsibility, Criteria, and Contributions'.

1. Dr. Aneel Kumar (Supervisor & Corresponding Author): Study Design & Oversight: Conceptualized the research framework and methodology. Manuscript Preparation: Authored the introduction, discussion, and conclusion sections. Ethical Oversight: Secured ethical approval and ensured adherence to ethical standards. Correspondence: Managed all communications related to the study.

2. Dr. Anum: Literature Review: Conducted comprehensive reviews of existing research on diabetes management. Methodology Development: Assisted in designing the intervention protocols for informational care and compliance therapy. Data Collection: Coordinated the collection of baseline and follow-up data from participants. Manuscript Drafting: Contributed to drafting the methodology and results sections.

3. Muhammad Umer: Literature review. Participant Recruitment: Assisted in recruiting participants and obtaining informed consent. Data Entry: Managed the entry of collected data into the study database. Follow-up Coordination: Coordinated follow-up appointments and data collection at 6 and 12 weeks.

4. Umeed Ali: Data Collection: Conducted interviews and administered the Morisky 8-item adherence scale. Monitoring Compliance: Assisted in monitoring participant adherence to the intervention protocols. Data Analysis Support: Provided support in analyzing adherence scores and glucose level data.

5. Dr. Suresh Goreja: Provided support in manuscript drafting, contributed in result section, helped in discussion writing in recommendations

6. Dr Raja Khetpal: Helped in manuscript writing, formatting the results, contributed in writing recommendations

7. Dr. Syed Sanwer Ali: Contributed in methodological design of the study, sample size determination and double-blinding sampling technique for data collection.

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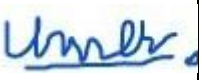
3	Muhammad Umer	MBBS	Umerarifahmed73@gmail.com	03302764614		0009-0006-5698-0855	25/11/25
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