



Taibah University
Journal of Taibah University Medical Sciences

www.sciencedirect.com



Original Article

Medication adherence and environmental barriers to self-care practice among people with diabetes: A cross-sectional study in a lifestyle clinic in eastern India

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Received 27 August 2022; revised 20 December 2022; accepted 18 January 2023; Available online 3 February 2023



المخلص

أهداف البحث: أجريت الدراسة لتقدير انتشار عدم الالتزام بالأدوية بين مرضى السكري من النوع 2 الذين يحضرون إلى عيادة نمط الحياة في المستشفيات التخصصية في غرب البنغال، الهند؛ لتحديد العوائق البيئية التي تحول دون ممارسات الرعاية الذاتية، بما في ذلك النظام الغذائي والتمارين الرياضية واختبار الجلوكوز والأدوية؛ وتحديد المحددات الاجتماعية والديموغرافية والبيئية لعدم الالتزام بالأدوية.

طريقة البحث: تم إجراء دراسة مقطعية بين مرضى السكري من النوع 2 الذين هم على أدوية مرض السكر عن طريق الفم في عيادة نمط الحياة في مستشفى تعليمي في عام 2021. تمت مقابلة المشاركين في العيادة باستخدام استبانة منظومة باللغة المحلية. تم تقييم الالتزام بالأدوية من خلال مقياس موريسكي للأدوية بينما تم تقييم الحواجز البيئية من خلال مقياس تقييم الحاجز البيئي.

النتائج: من بين 178 مشاركا، تم العثور على مستوى عالٍ من الالتزام حسب مقياس موريسكي للأدوية (درجة 8) بين 3 (1.7%) من المشاركين، والالتزام المتوسط (درجة 6 إلى 7.75) بين عدد (37.6%)، مستوى ثقة 95%، 30.3%، 44.9% من المشاركين. كان انتشار عدم الالتزام بنسبة 60.7% (مستوى ثقة 95%، 53.4%، 68.0%). كان متوسط الدرجة الإجمالية لنتيجة الحاجز 134. تم توزيع جميع مكونات الحواجز البيئية بالتساوي بين المتغيرات التنبؤية باستثناء درجة النظام الغذائي التي كانت أقل بين الذكور (متوسط الفرق 1.3، مستوى ثقة

95%، 0.04، 2.5) والأشخاص الحاصلين على تعليم عالٍ (متوسط الفرق 1.8، مستوى ثقة 95%، 0.6، 3.1).

الاستنتاجات: وجدت الدراسة ضعف الالتزام بأدوية سكر الدم عن طريق الفم في هذه الفئة من السكان. تسود العوائق التي تحول دون ممارسة الرعاية الذاتية والالتزام بالأدوية في جميع الطبقات الاجتماعية والاقتصادية. يشكل التقيد الضعيف بالأدوية تحديا كبيرا للأطباء وخبراء الصحة العامة لتحقيق هدف العلاج.

الكلمات المفتاحية: الحاجز البيئي؛ التحكم في نسبة السكر في الدم؛ نمط الحياة؛ الرعاية الذاتية؛ الالتزام بالعلاج؛ داء السكري من النوع 2

Abstract

Objective: The study was conducted to estimate the prevalence of non-adherence to medications among patients with type 2 diabetes attending a lifestyle clinic in a tertiary care hospital in West Bengal, India; to identify the environmental barriers to self-care practices, including diet, exercise, glucose testing and medication; and to identify the socio-demographic and environmental determinants of medication non-adherence.

Methods: A cross-sectional study was performed among the patients with type 2 diabetes taking oral hypoglycemic drugs and attending a lifestyle clinic of a teaching hospital in 2021. The participants were interviewed in clinical settings via a structured questionnaire in the local language. Medication adherence was assessed with Morisky Medication Adherence Scale-8 (MMAS), and environmental barriers were assessed with the Environmental Barrier Assessment Scale (EBAS).

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Peer review under responsibility of Taibah University.



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Results: Among 178 participants, a high level of adherence (MMAS score 8.0) was found among 3 (1.7%) participants, and moderate adherence (MMAS score 6.0 to 7.75) was found among 67 (37.6%; 95% CI 30.3%, 44.9%) participants. The prevalence of non-adherence was 60.7% (95% CI: 53.4%, 68.0%). The overall mean barrier score was 134 (SD 13). All environmental barrier components were distributed equally among the predictor variables except the diet score, which was lower among men (mean difference 1.3; 95% CI: 0.04, 2.5) and people with higher education (mean difference 1.8; 95% CI: 0.6, 3.1).

Conclusion: The study indicated poor adherence to OHA in this population. Barriers to self-care practice and medication adherence were observed across all socio-economic strata. Poor medication adherence poses a major challenge to clinicians and public health experts in achieving treatment goals.

Keywords: Environmental barrier; Glycemic control; Lifestyle; Self-care; Treatment adherence; Type 2 diabetes mellitus

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Introduction

Type 2 diabetes mellitus (DM) is a lifestyle disorder in which insulin resistance leads to abnormally high blood glucose levels.¹ Lifestyle practices such as unhealthy diets, or a lack of adequate exercise and physical activity, can precipitate insulin resistance.² The cornerstone of the management of DM includes non-pharmacological management by self-care practices and pharmacological management. Self-care practices include regular monitoring of blood glucose levels, adherence to medication, controlling dietary intake and regular exercise to achieve dietary goals.^{3,4} Thus, pharmacologic and non-pharmacological management improves glycemic control and ameliorates complications of DM.⁵

Both globally and in India, the burden of diabetes is increasing rapidly. Unfortunately, the global burden of disease estimates suggest that the absolute number of people with diabetes has increased by almost threefold in the past

three decades.⁶ With an estimated 72 million cases in 2017, India carries approximately 50% of the world's diabetes burden. By 2025, alarmingly, the figure is expected to double.⁷

Most people who have diabetes in India have type 2 or non-insulin-dependent diabetes mellitus. A lack of patient adherence to therapeutic regimens may be a reason for the inability to achieve glycemic control in India, although the medications are provided free of cost in government hospitals.⁸ According to the U.S. Food and Drug Administration, "Medication adherence, or taking medications correctly, is generally defined as the extent to which patients take medication as prescribed by their physicians." Adherence involves factors such as filling prescriptions, remembering to take medications at the proper time and understanding the directions.⁹

India launched the National Programme for Prevention and Control of Cancers, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) in 2010. The program's main objectives are to prevent and control common NCDs, including diabetes, by providing early diagnosis and management, and behavior and lifestyle changes.¹⁰ Evidence of lifestyle modification through NPCDCS is currently inadequate. However, contemporary evidence suggests that the program is nascent and requires substantial improvement in lifestyle modification delivery.^{11,12} Hence, baseline information is needed to support lifestyle modification among people with diabetes. Evidence is lacking in the eastern region of India. Therefore, we conducted this study to estimate the prevalence of non-adherence to medications among patients with type 2 diabetes attending a lifestyle clinic in a tertiary care hospital in Kalyani, West Bengal. We also aimed to identify the environmental barriers to self-care practices, including diet, exercise, glucose testing and medication. Furthermore, we examined the socio-demographic and environmental determinants of medication non-adherence.

Material and methods

Study design

This was a questionnaire based cross-sectional study.

The study was conducted between May 2020 and June 2020.

We studied patients with type 2 diabetes attending the lifestyle clinic of a tertiary care teaching Hospital in Nadia district, West Bengal. We included patients diagnosed with type 2 diabetes who were 30 years of age or above, and had

received oral hypoglycemic agents (OHA) for treatment for at least a year. We excluded those who denied consent and had taken OHA for less than a year.

Sample size

Assuming a 40% prevalence of adherence to anti-diabetic drugs, 20% relative prevalence, and 10% non-response rate, we estimated a required sample size of 165.

Sampling technique

According to the register of the previous 1 year period, 750–800 patients attended the clinic every week. On the basis of the inclusion criteria, we recruited the first 20 patients presenting each week. Thus, we expected to achieve the necessary sample size in 8 weeks.

Study tools

We conducted interviews with a semi-structured questionnaire with three parts. The first part consisted of socio-demographic and clinical questions. The second part evaluated adherence to OHA with Morisky Medication Adherence Scale-8 (MMAS), which had been translated into the local language.¹³ This questionnaire contained eight items with a score ranging from 0 to 8. The first seven questions involved dichotomous responses (yes/no) and addressed common reasons for missing medications. A five-point Likert scale was used for the eighth question regarding how often patients had difficulty in remembering whether they had taken their medication. Each question was assigned a value of 1 or 0 except the eighth question, which was graded on a scale of 0, 0.25, 0.5 and 1.0. The final score was categorized into high adherence (MMAS score = 8), moderate adherence (MAMS 6.00–7.75), and poor or non-adherence (MAMS <6.0). The third part of the questionnaire assessed barriers to self-care, including diet, exercise, glucose testing and medication, through the Environmental Barrier Assessment Scale (EBAS), which had been translated into the local language.¹⁴ This questionnaire had 60 items with four subscales: diet, exercise, glucose testing and medication. Each question had five options: never, rarely, sometimes, often and always. The options were scored from 5, for a response of never, to 1, for a response of always. A lower score indicated a higher barrier.

Data collection

We collected data from the participants after they provided informed consent. On each data collection day, we screened patients with diabetes attending the lifestyle clinic according to the inclusion and exclusion criteria described above. We recruited approximately the first 20 patients meeting the inclusion criteria each week. We

interviewed the recruited participants at a dedicated area within the clinic.

Statistical analysis

We entered the data in Microsoft Excel and performed analysis in SPSS version 21.0 (IBM Corp. Released 2012. IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp). We expressed categorical variables as proportions with 95% confidence intervals (CIs) and continuous variables as means with standard deviations (SDs) and medians with interquartile ranges. We estimated the mean differences between groups with 95% CIs and performed statistical analysis with unpaired t-tests. We calculated correlation coefficients to verify the relationships between two continuous variables. To determine the predictors of poor adherence, we conducted univariate analysis followed by multivariate analyses to calculate the adjusted odds ratios (ORs) with 95% CIs. A p-value <0.05 was considered significant for all statistical tests.

Results

We recruited 178 participants with type 2 diabetes who were taking oral hypoglycemic agents. The mean age of the participants was 53.9 years (SD 11.6 years; Table 1). The majority were men (n = 100, 56.2%), belonged to the Hindu religion (n = 134, 75.2%), had at least secondary education (n = 148, 83.1%) and were gainfully employed (n = 97, 54.5%). The mean age of diabetes onset was 48 years (SD 9.6). High adherence was found among 1.7%

Table 1: Socio-demographic details

Variables	Frequency
Age in years (mean, SD)	53.9 (11.6)
Sex (%)	
Male	100 (56.2)
Female	78 (43.8)
Religion (%)	
Hindu	134 (75.2)
Muslim	43 (24.2)
Christian	1 (0.6)
Education	
Primary (0–4)	30 (16.9)
Secondary (5–10)	84 (47.2)
Higher secondary (11–12)	37 (20.8)
Above higher secondary	27 (15.2)
Occupation	
Homemaker/not working	81 (45.5)
Working	97 (54.5)
Family income in 1,000 (median, IQR)	10 (7 to 20)
Age of diabetes onset (mean, SD)	48 (9.6)
Duration of diabetes (median, IQR)	5 (3 to 8)

Table 2: Distribution and predictors of the environmental barrier scores for diet, exercise, glucose testing and medication

Predictors of environmental barrier	Mean score (SD)	Mean difference in score	95% CI (lower boundary, upper boundary)	p-value
<i>Diet score (mean 45, SD 4.2)</i>				
Age >40 years	44.8 (4.0)	-0.2	-2.0, 1.6	0.8
Male sex	45.5 (4.2)	-1.3	-2.5, -0.04	0.04*
Hindu religion	44.5 (4.3)	-1.2	-2.6, 0.3	0.1
Low education (up to secondary)	45.5 (4.4)	1.8	0.6, 3.1	0.04*
Working at home	45.4 (4.9)	1.0	-0.2, 2.3	0.1
Family income (<10,000)	45.2 (3.7)	0.8	-0.4, 2.0	0.2
Age of onset of DM ≤40 years	44.9 (4.9)	0.2	-1.2, 1.6	0.8
Duration of DM	44.8 (4.3)	0.1	-1.2, 1.3	0.9
Presence of any comorbidity	46.3 (4.4)	-1.7	-3.7, 0.4	0.1
<i>Exercise (mean 32, SD 5.0)</i>				
Age >40 years	32.2 (5.2)	0.7	-1.5, 2.9	0.5
Male sex	31.6 (2.0)	-1.2	-2.6, 0.3	0.1
Hindu religion	32.4 (5.5)	1.3	-0.5, 2.9	0.15
Low education (up to secondary)	32.3 (6.0)	0.5	-1.0, 2.0	0.5
Working outside home	32.6 (7.0)	1.0	-0.5, 2.5	0.2
Family income (<10,000)	31.6 (2.1)	-1.1	-2.6, 0.3	0.1
Age of onset of DM ≤40 years	32.6 (6.5)	0.6	-1.1, 2.3	0.5
Duration of DM	31.9 (4.8)	-0.4	-1.9, 1.1	0.6
Presence of any comorbidity	31.9 (4.0)	-2.4	-4.8, 0.1	0.06
<i>Glucose testing (mean 29.0, SD 4.1)</i>				
Age >40 years	29.2 (4.3)	0.8	-1.0, 2.7	0.8
Sex	26.6 (2.6)	-0.9	-2.1, 0.3	0.14
Hindu religion	29.0 (4.6)	-0.3	-1.7, 1.2	0.7
Low education (up to secondary)	29.4 (4.7)	1.0	-0.3, 2.2	0.13
Working outside home	29.3 (5.4)	0.4	-0.8, 1.6	0.5
Family income (<10,000)	28.6 (2.5)	-0.9	-2.1, 0.3	0.2
Age of onset of DM ≤40 years	28.9 (4.8)	-0.1	-1.5, 1.2	0.8
Duration of DM	28.8 (3.2)	-0.6	-1.8, 0.7	0.4
Presence of any comorbidity	28.8 (3.6)	-2.1	-4.1, -0.06	0.04*
<i>Medication (mean 27.8, SD 2.5)</i>				
Age >40 years	27.9 (2.6)	0.6	-0.6, 1.7	0.3
Sex	27.6 (2.3)	-0.6	-1.4, 0.1	0.1
Hindu religion	27.7 (2.7)	0.4	-1.3, 0.5	0.4
Low education (up to secondary)	28.0 (2.6)	0.5	-0.3, 1.3	0.2
Working outside home	27.8 (2.0)	0.1	-0.7, 0.9	0.8
Family income (<10,000)	27.9 (2.1)	0.1	-0.7, 0.8	0.8
Age of onset of DM ≤40 years	27.5 (3.1)	-0.4	-1.3, 0.5	0.4
Duration of DM	27.7 (2.7)	-0.4	-1.2, 0.3	0.3
Presence of any comorbidity	27.8 (2.4)	-1.0	-2.2, 0.3	0.1

* Statistically significant

(n = 3) participants, and moderate adherence was found among 37.6% (n = 67, 95% CI: 30.3, 44.9%) of participants. The prevalence of non-adherence was 60.7% (n = 108; 95% CI: 53.4%, 68.0%).

The overall mean barrier score was 134 (SD 13). All components of the environmental barriers were distributed equally among the predictor variables except the diet score (Table 2). The barrier for diet was lower among men (mean

difference 1.3; 95% CI: 0.04, 2.5) and people with higher education (mean difference 1.8; 95% CI: 0.6, 3.1). The presence of any comorbidities tended to decrease the environmental barriers for diet (mean score reduction 1.7; 95% CI: -0.04, 3.7), exercise (mean score reduction 2.4; 95% CI: -0.1, 4.8), glucose testing (mean score reduction 2.1; 95% CI: -0.06, 4.1) and medication (mean score reduction 1.0; 95% CI: -0.3, 2.2).

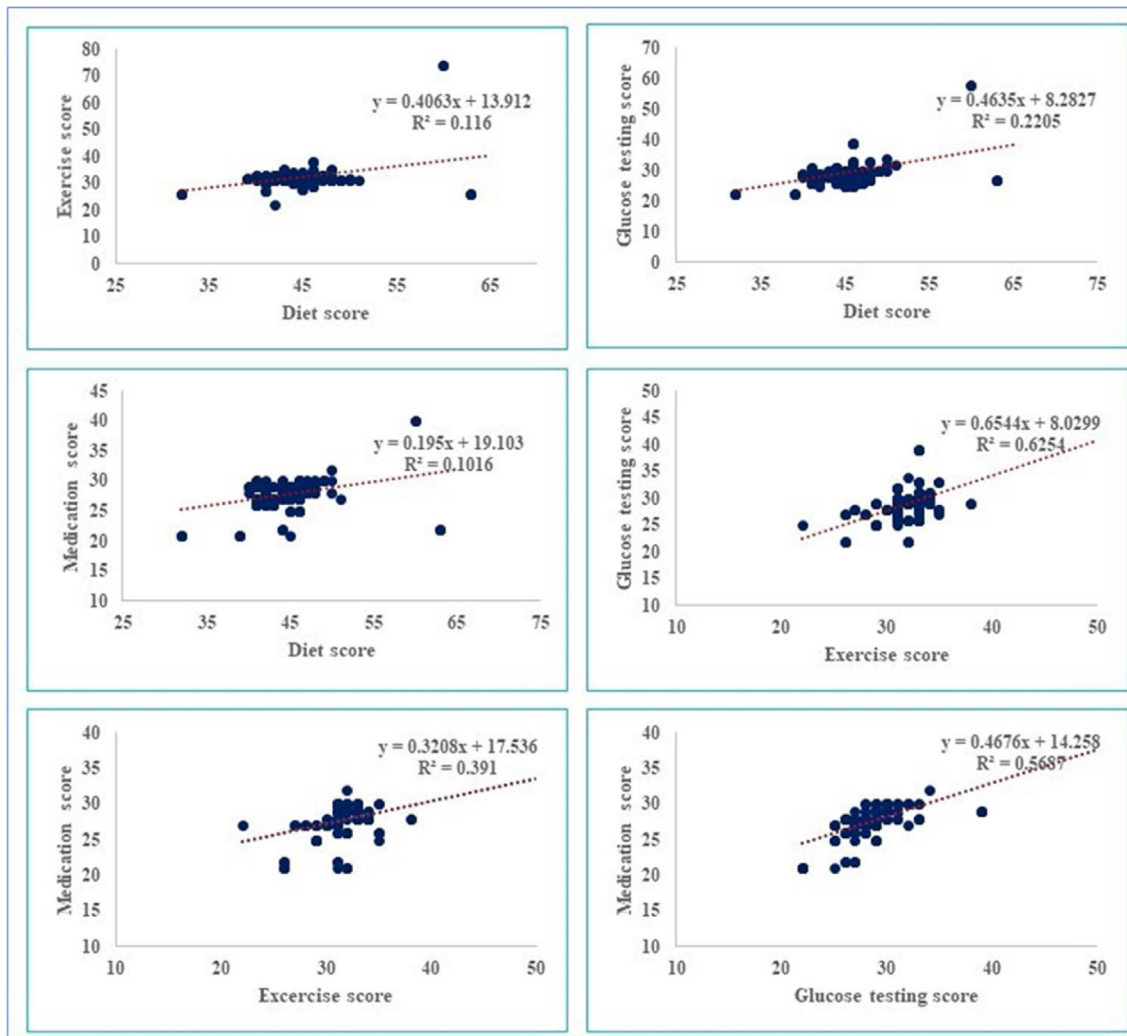


Fig 1: Inter-relationship of the environmental barrier scores.

We found strong inter-relationships among all self-care components. The relationship between the diet score and the other three barrier scores was relatively weaker and explained only 10–22% of the change. The relationship was high for environmental barrier score for exercise, glucose testing and medications, and explained 39–62% of the change (Figure 1).

In univariate analysis, none of the variables were significantly associated with non-adherence to diabetic medications (Table 3). With the logistic regression model, we did not find a significant relationship between non-adherence and environmental barriers to diet (OR: 1.02; 95% CI: 0.9–1.1), exercise (OR: 0.95; 95% CI: 0.86–1.06), glucose testing (OR: 1.0; 95% CI: 0.87–1.18) or medication (OR: 1.05; 95% CI: 0.88–1.27).

Table 3: Predictors of non-adherence to diabetes medication

Variables	Frequency		Odds ratio (95% CI: LB, UB)	p-value
	Non-adherent group (%) (n=108)	Adherent group (%) (n=70)		
Age (years)				
≤40 years	18 (78.3)	5 (21.7)	2.6 (0.9, 7.7)	0.07
>40 years	90 (58.1)	65 (41.9)		
Sex				
Male	63 (63)	37 (37)	1.2 (0.7, 2.3)	0.5
Female	45 (57.7)	33 (42.3)		
Religion				
Hindu	81 (60.4)	53 (39.6)	1.0 (0.5, 1.9)	0.9
Others	27 (61.4)	17 (38.6)		
Education				
≥12th	39 (60.9)	25 (39.1)	1.0 (0.5–1.8)	1.0
<12th	69 (60.5)	45 (39.5)		
Working status				
Outside home	59 (60.8)	38 (39.2)	1.0 (0.5–1.8)	1.0
Within home	49 (60.5)	32 (39.5)		
Family income (INR)				
<10,000	56 (60.2)	37 (39.8)	1.0 (0.5–1.8)	0.9
≥10,000	52 (61.2)	33 (38.8)		
Age of onset of DM				
≤40 years	30 (65.2)	16 (34.8)	1.3 (0.6–2.6)	0.5
>40 years	78 (59.1)	54 (40.9)		
Duration of DM				
≤5 years	60 (60)	40 (40)	0.9 (0.5–1.7)	0.8
>5 years	48 (61.5)	30 (38.5)		
Presence of comorbidities				
Yes	12 (70.6)	96 (59.6)	1.6 (0.5, 4.8)	0.4
No	5 (29.4)	65 (40.4)		

Discussion

In this study, we estimated that three-fifths of the diabetic population was not adherent to anti-diabetic medications. Non-adherence was observed among almost all socio-demographic groups. Environmental barriers pertaining to diet, exercise, glucose testing and medicine might affect glycemic control. Inter-relationships were observed among these barriers, which were positively correlated. Men with diabetes, low education levels and any comorbidities tended to have more environmental barriers, particularly regarding the diet component.

Most of the available literature in India on diet, exercise and medication non-adherence in diabetes has been hospital based. Medication adherence has been reported to vary from 16.6% to 44% in different parts of the country in the past decade.^{15–19} In the present study, we estimated moderate to high adherence in nearly two-fifths of the population. The burden was similar to that indicated by other hospital-based evidence. In contrast, a community-based study in rural parts of southern India has estimated an adherence of 45.4%.²⁰ The difference in adherence might be attributable to poor glycemic control, thus increasing hospital visits among the non-adherent population.

Globally, diabetes self-care is a difficult non-pharmacological component of diabetes.^{21–25} Lack of dietary control, regular physical exercise, glucose testing, and medication adherence are common in India.^{26–29} We found that environmental barriers were common in our setting, particularly among people with low levels of formal education. Most of the prior Indian studies have identified

similar findings coupled with inadequate counselling from the health care system.³⁰ Although a substantial proportion of people with diabetes do not refrain from performing physical exercise or following desirable diets, limited evidence is available regarding the environmental barriers affecting these practices. However, summary findings from multiple studies have indicated the interaction of multiple factors, most prominently low education level, cultural practices, and inadequate time and economic constraints.³⁰

Poor medication adherence was distributed evenly among all socio-demographic strata in our study. Evidence from other Indian studies suggests that patients' perceptions, low socioeconomic status, and the presence of other comorbidities and micro- and macro-vascular complications are the key factors underlying poor adherence.^{31,32}

A large community-based study from the southern part of the country has estimated a prevalence of low adherence to diabetic medication of 45.4%. The authors have identified illiteracy, poor satisfaction with governmental health facilities, lack of knowledge regarding the effects of poor adherence and a lack of transportation to health facilities as the key factors underlying poor adherence.²⁰

Limitations: The study lacked adequate power to precisely determine the predictors of environmental barriers and non-adherence to anti-diabetic medications.

Conclusion

Both pharmacological management and non-pharmacological management are crucial for achieving

diabetes management goals. We observed poor adherence to OHA in the study population. Barriers to self-care practices and medication adherence were observed in all socio-economic strata. Healthcare providers, including counselors, must explain non-pharmacologic management to patients and the caregivers. An individual-level approach may be necessary to understand the specific challenges to complying with self-care practices and medication adherence.

Source of funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Conflict of interest

The authors have no conflict of interest to declare.

Ethical approval

This work was approved by the appropriate institutional ethics committee of the College of Medicine & JNM Hospital, Kalyani, Nadia, WB, India (ref no: F-24/PR/COMJNMH/IEC/20/563, dated September 23, 2020).

Authors' contribution

All six authors affirm that they contributed sufficiently to be considered for authorship and have also verified an absence of plagiarism. KS, AG and DS conceived and designed the study, conducted research, gathered research materials, collected and tabulated data and wrote the initial draft. SB and CKD analyzed and interpreted data. SC wrote the final draft, and provided logistic support and research materials. Finally, all authors critically reviewed and approved the final draft, and hence are responsible for the content and similarity index of the manuscript.

Acknowledgment

Mr. Raju Dasgupta, Statistician cum Assistant Professor Department of Community Medicine, COMJNM&H, Input in analysis and software handling.

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How to cite this article: Ghosh A, Banerjee S, Dalai CK, Chaudhuri S, Sarkar K, Sarkar D. Medication adherence and environmental barriers to self-care practice among people with diabetes: A cross-sectional study in a lifestyle clinic in eastern India. *J Taibah Univ Med Sc* 2023;18(5):909–916.