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Original Article

Effects of Structured lifestyle Modification on Cardiovascular Risk Factors in Type-2 Diabetes Mellitus: A Randomized Controlled Trial

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ABSTRACT

Several clinical trials have shown that lifestyle modifications lower blood pressure, affect weight as well as lipid profile and lower risk factors for cardiovascular diseases. The study assessed the effect of structured lifestyle modification on cardiovascular risk factors amongst type 2 diabetic patients that attend the General Outpatient Clinic (GOPC) of Jos University Teaching Hospital (JUTH). The study was a randomized controlled trial on 352 participants at the GOPC of JUTH, from October 2015 to February 2016. The intervention offered was counselling on structured lifestyle modification in diet and exercise for a period of 12 weeks. The primary outcome measures were changes in blood pressure, weight and lipid profile. The data were analyzed using Epi Info version 3.5.3. There were significant differences between groups in favor of the intervention group; mean systolic blood pressure of -65 mmHg ($t = 5.344$; $p = 0.017$) and mean weight of -1.78kg ($t = 2.452$; $p = 0.015$). Structured lifestyle modification caused significant improvement on modifiable cardiovascular risk factors in patients with type 2 diabetes mellitus attending the general outpatient clinic of the Jos University Teaching Hospital.

Keywords: Lifestyle, Modification, Cardiovascular Risk Factors, Diabetes Mellitus, Exercise, Diet.

INTRODUCTION

Diabetes mellitus is a metabolic disorder of multiple aetiology, characterized by chronic hyperglycaemia and disturbances in the metabolism of carbohydrates, fats and proteins as a result of defects in insulin secretion, function and or both.[1] Risk factors for type 2 diabetes mellitus include impaired fasting glucose, impaired glucose tolerance, family history of diabetes mellitus, body mass index (BMI) greater than 25kg/m^2, sedentary lifestyle, hypertension, dyslipidaemia, history of gestational diabetes mellitus or large for gestational age infant, polycystic ovary syndrome, Black race, Latin Americans, Native

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Americans and Asian-Pacific islanders.[2] Peripheral resistance to insulin and pancreatic beta-cell dysfunction are the hallmarks of diabetes mellitus. The beta-cell dysfunction, which is worsened by chronic hyperglycaemia, is primarily responsible for its progression.[3]

The 2011 revised criteria by the Expert Committee on Diagnosis and Classification of Diabetes Mellitus, recommends the diagnosis of diabetes based on: Two fasting plasma glucose (FPG) levels of ≥126 mg/dL (7.0 mmol/L) or two 2-hours postprandial glucose (2hPPG) reading of ≥200 mg/dL (11.1 mmol/L) after a glucose load of 75g ,or two random glucose readings of ≥200 mg/dL (11.1mmol/L) or glycosylated haemoglobin of (HbA1c) ≥6.5% ,or a patient with classic symptoms of hyperglycemia with random plasma glucose of 200 mg/dL (11.1 mmol/L)[4,5]. The leading CVD risk factor is high blood pressure, to which 13% of global deaths is attributed, followed by tobacco use (9%), raised blood glucose (6%), physical inactivity (6%), and overweight and obesity (5%).[6]

Dyslipidaemia, an established risk factor for cardiovascular disease, is very common in patients with type 2 diabetes mellitus, affecting almost 50% of these patients.[7] Because of the increased cardiovascular risk of hyperglycaemia and hyperlipidaemia, lipid abnormalities should be aggressively detected and treated as part of comprehensive care in patients with diabetes mellitus. Improved control of cholesterol or blood lipids like low-density lipoprotein cholesterol (LDL-C) and triglycerides (TGs) in DM may greatly reduce cardiovascular complications by 20 to 50%,[1] with improved quality of life.[7]

Hypertension, defined as blood pressure ≥140/90 mmHg is an extremely common co-morbid condition in patients with diabetes mellitus, affecting 20-60% of them.[8] When a patient has both hypertension and diabetes mellitus, the risk of cardiovascular disease doubles.[9] Blood pressure control reduces the risk of cardiovascular disease among persons with diabetes mellitus. In general, for every 10 mmHg reduction in systolic blood pressure, the risk of complication from diabetes mellitus reduces by twelve percent.[1] Patients with diabetes should achieve a target blood pressure of less than 130/80 mmHg. Those with systolic blood pressure between 130 and 139 mmHg or whose diastolic blood pressure is between 80 and 89 mmHg are candidates for a three-month trial of lifestyle modification.[10] The seventh report of the Joint National Committee (JNC-7) on the prevention, detection, evaluation and treatment of high blood pressure recommends lifestyle modification for all patients with hypertension, which is a cardiovascular risk factor in patients with type 2 diabetes mellitus.[11,12]

Exercise is beneficial in individuals with diabetes mellitus with observed increase in circulating HDL-C and reductions in systolic and diastolic blood pressures.[13] The American Diabetes Association (ADA) recommends that people with diabetes mellitus should be advised to perform at least 150 minutes per week of moderate-intensity aerobic physical activity (50-70% of maximum heart rate). In the absence of contraindications, people with type 2 diabetes mellitus should be encouraged to perform resistance training three times per week.[13]

Studies have shown that lifestyle interventions can produce long term weight loss and improvement in fitness with sustained beneficial effects on CVD function in individuals with type 2 diabetes mellitus.[14] Intensive lifestyle interventions provide great reduction in the occurrence of hypertension, along with a modest reduction in CVD risk factors. Management of all CVD risk factors is therefore necessary in individuals with diabetes mellitus.[15] Achieving this goal requires a comprehensive, coordinated, patient-centred approach.

Despite the advances made in the prevention and management of cardiovascular diseases, people with diabetes mellitus continue to have alarmingly high morbidity and mortality secondary to cardiovascular disease. The increasing number of people with type 2 diabetes mellitus globally is of serious public health concern.[16] Epidemiologic studies have identified diabetes mellitus as an independent risk factor for cardiovascular disease which amplifies the effects of other common risk factors, such as smoking, hypertension and hypercholesterolaemia.[1]

Assessment of cardiovascular risk in routine clinical practice helps to identify low and high-risk individuals, motivating high-risk individuals to modify their lifestyle or adhere to medical therapy. It may also help to monitor responses to the interventions and in prognostication.

MATERIALS AND METHODS

Study Design

The study was a randomized controlled trial carried out at the general outpatient clinic of the Jos University Teaching Hospital, located in Jos North Local government area of Plateau State. The participants were patients with type 2 diabetes mellitus who met the inclusion criteria and gave written informed consent. The study followed the Consolidated Standards of Reporting Trials (CONSORT) guideline as seen in the flow chart on figure 1.

Setting

Participants included type 2 diabetes mellitus patients aged 25 years and above, who have consistently been on follow-up at the general outpatient clinic for a minimum of three months. Data was collected between October 2015 and February 2016.

Study Population and Sampling Strategy

Three hundred and fifty-two (352) participants were voluntarily recruited into the study after a written informed consent using systematic random sampling technique. The main eligibility criteria were blood pressure of ≥140/90 mmHg and body mass index (BMI) of ≥25 kg/m^2. Exclusion criteria were (1) patients on lipid lowering agents, which could alter the serum lipids; (2) patients taking weight loss medications like Orlistat and Sibutramine; (3) patients who did not give consent; (4) type 2 diabetic patients on treatment with insulin due to erratic response to medication when on some form of moderate intensity exercise; and (5) patients with co-morbidity such as heart failure, renal disease and chronic liver disease. The sample size for the study was calculated using the formula for comparing two proportions in a randomized controlled trial. This was based on the objective of the study to compare improvement in the proportion of type 2 diabetes mellitus patients with cardiovascular risk factors following a structured lifestyle modification as the intervention. Using a power of 80% and confidence interval of 95% statistical standard value in a normal population distribution of 0.05 was used. The participants were randomized using Microsoft excel computer generated random numbers, into intervention and control groups with one hundred and seventy-six (176) participants in each study group.

Participants were assigned to either of the groups by means of previously sealed opaque numbered envelopes, which were only opened at the time of treatment allocation. Those with odd numbers were allocated to group A (intervention group) while those with even numbers to group B (control group).

Intervention

All patients in the intervention group were assessed on readiness for change using the health behaviour trans-theoretical model and were at readiness for change stage.[18] They were counselled and advised concerning diet, alcohol, smoking and exercise using a structured format. They were given written diet and exercise instructions in either English or Hausa and asked to keep an exercise, diet and sleep diary. Reminder was sent through text messages once a week to these patients. Examples of a diet plan and local food groups were provided. Those in the control group were only given the usual educational counselling as it was always provided during routine visits.

Data Collection and measurements

Instruments of data collection were the questionnaire, weighing scale (HANSON®), flexible non-stretch measuring tape, mercury sphygmomanometer (Accoson®), Littmann® Stethoscope, wall-mounted stadiometre and Accu-chek® Active glucometer. Socio-demographic data as well as history of alcohol ingestion and cigarette smoking were taken from the participants. Blood pressure, waist circumference, hip circumference, height and weight were taken. Body mass index (BMI) was then calculated. Each subject's blood pressure was measured two times in the sitting position on the left arm using a mercury sphygmomanometer after five minutes of rest, with five minutes between measurements. First appearance and disappearance (phase V) of Korotkoff's sounds heard with the aid of a Littmann's stethoscope were used to define systolic and diastolic blood pressures respectively in millimetres of mercury (mmHg). An average of the two readings was used as the subject's blood pressure. Body weight in kilograms (kg) was recorded while standing motionless on a bathroom weighing scale. The scale was calibrated using a standardized weight. Height was measured while standing erect against a vertical stadiometre to the nearest 0.1cm. The stadiometre was positioned on a flat surface. The participant was without shoes or head gear, stood erect with hands by the sides and heels touching the wall. Body mass index (BMI) was then calculated as weight in kilograms divided by height in metres squared (kg/m^2). Overweight was taken as BMI of 25.0-29.9 kg/m^2 and obesity as BMI $\geq$30 kg/m^2. Obesity grade I was taken as BMI of 30-34.9 kg/m^2, grade II as 35.0-39.9 kg/m^2 and grade III as $\geq$40.0 kg/m^2.[17]

The waist circumference (WC) was measured midway between iliac crest and lowermost margin of ribs at maximum expiration. Normal values for men was taken as $\leq$102 centimeters and women $\leq$88 centimetres.[17] The hip circumference was measured at the widest portion of the buttocks. The waist-hip-ratio (WHR) was then calculated. The WHR of 0.90 and 0.85 was taken as normal for males and females respectively.[17] Blood sample was obtained under sterile technique for estimation of serum lipids and analyzed with Jet UV/vis 752 spectrophotometer machine in the chemical pathology laboratory of the authors' institution. Participants were instructed to fast for at least eight hours overnight before the venepuncture, and compliance was ascertained by an interview before collection of samples.

Data Analysis

Descriptive analyses were conducted for all sociodemographic and disease-related variables. Data generated was analyzed using Epi Info version 3.5.3 (Centres for Disease Control and Prevention, Atlanta, Georgia, USA).[19] Chi-square test and student t-test were used at confidence interval (CI) of 95%. Data was analyzed on an intension to treat basis. Continuous variables were expressed as means ± standard deviations, or medians with interquartile range (IQR). Categorical variables were presented as proportions and compared using the Chi-squared tests or Fisher's exact test as appropriate. Means were compared using unpaired Student's t-tests. A p-value of < 0.05 was considered significant in all analysis.

Ethical Consideration

The study's ethical approval was obtained from the Jos University Teaching Hospital 'Ethics Committee'. The data set was anonymized by transcribing names into initials and serial numbers to maintain confidentiality.

RESULTS

Figure 1 shows the profile of participants in the study; the total of 352 were randomized, comprising of 176 for each control and intervention group. Of the 176-control group, 8 participants were lost to follow up, and 168 completed the study, in the intervention group, 9 participants were lost to follow up, and 167 completed the study. The baseline characteristic of the participants is shown in table 1, the female ratio was generally higher (66.0%) than male (34.1%). The mean age of the participants in the intervention group was 51.64±7.91, control group 50.87±6.74, age category 50-59year had the highest participants; intervention group (46.0%), control group (46.5%), with no statistical difference in the association, p=0.227. Table 1 showed that randomization was effective because there were no significant differences in the sociodemographic characteristics in the two groups. There was significant differences between groups: mean systolic blood pressure -6.5mmHg (t = 5.344; p = 0.017), mean weight -1.78kg (t = 2.452; p = 0.015), mean HDL-C 0.17mmol/L (t= 3.053; p = 0.002) and mean TG -0.31mmol/L (t = 3.619; p = 0.04), as shown in Figure 2, table 2 and table 3, respectively. Overall, significant improvements in healthy lifestyle habits were notable in the intervention group (p <0.05).

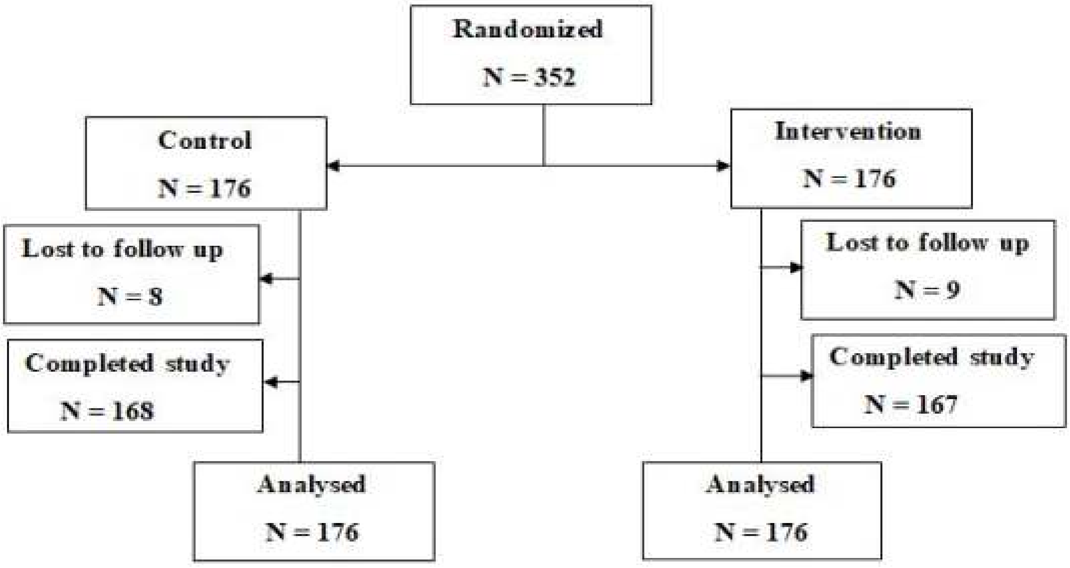

Figure 1. The profile of the Structured lifestyle Modification on Cardiovascular Risk Factors in Type-2 Diabetes Mellitus patients presenting at an Out-patient clinic

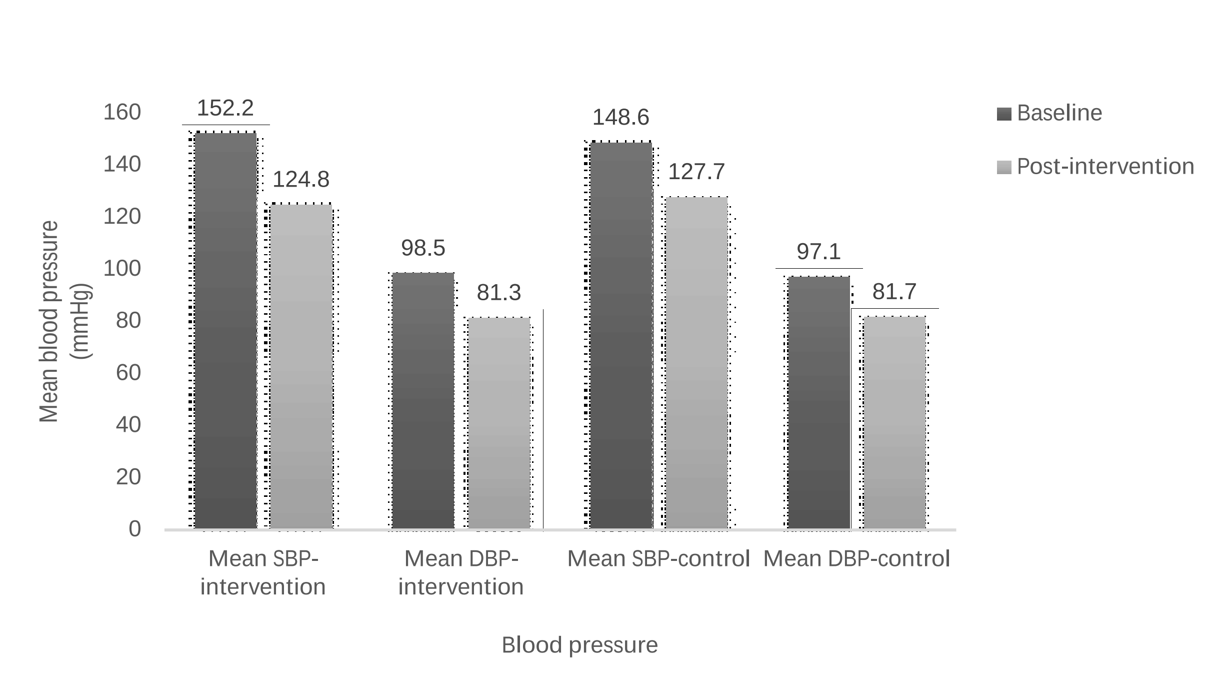

Figure 2: Comparison of changes in blood pressure of participants in both groups

Table 1: Sociodemographic characteristics of Structured lifestyle Modification on Cardiovascular Risk Factors in Type-2 Diabetes Mellitus patients

Demographic characteristic	Intervention n(%) N= 176	Control n(%) N=176	χ2	*p*-value
Sex				
Male	61(34.7)	59(33.5)	0.198	0.656
Female	115(65.3)	117(66.5)		
Mean age	51.64±7.91	50.87±6.74		
Age group				
≤40	8(4.5)	9(5.1)	3.910	0.227
40-49	37(21.0)	36(20.5)		
50-59	81(46.0)	82(46.5)		
60-69	36(20.5)	38(21.6)		
≥70	14(8.0)	11(6.3)		
Religion				
Christianity	104(59.1)	106(60.2)	3.892	0.273
Islam	72(40.9)	70(39.8)		
Level of education				
Non-formal	66(37.5)	68(38.6)	3.892	0.273
Primary	64(36.4)	60(34.1)		
Secondary	15(8.5)	16(9.1)		
Tertiary	31(17.6)	32(18.2)		

Table 2: Change in anthropometric parameters of participants in both groups at 12 weeks

Anthropometric parameter	Intervention	Control	t-test	*p*-value
Mean weight (kg)				
Initial weight	77.27±12.35	77.13±14.62	0.597	0.551
Weight at 12 weeks	74.80±12.15	76.44±13.99		
Change in mean weight	-2.47	-0.69	2.452	0.015
Mean BMI (kg/m^2)				
Initial BMI	29.16±4.57	29.73±5.15	1.139	0.256
BMI at 12 weeks	27.68±4.51	28.80±4.87		
Change in mean BMI	-1.48	-0.93	1.610	0.254
Mean waist circumference (cm)				
Initial waist circumference	97.34±11.75	98.17±12.83	0.635	0.526
Waist circumference at 12 weeks	96.50±11.59	97.65±12.28		
Change in mean waist circumference	-0.84	-0.52	0.906	0.365
Mean waist-hip-ratio (cm)				
Initial waist-hip-ratio	0.94±0.07	0.94±0.07	0.098	0.922
Waist-hip-ratio at 12 weeks	0.93±0.07	0.94±0.07		
Change in mean waist-hip-ratio	-0.01	0.00	0.365	0.715

Table 3: Differences in lipid profile of participants in both groups at 12 weeks

Serum lipids	Group Intervention	Control	Change	t-test	*p-value*
Mean TC (mmol/L)					
Initial TC	4.71±1.03	4.69±1.06	0.02	0.117	0.907
TC at 12 weeks	4.34±0.95	4.51±1.05			
	-0.37	-0.18	-0.19	1.610	0.108
Mean HDL (mmol/L)					
Initial HDL	1.81±0.91	1.83±0.98	0.02	0.194	0.846
HDL at 12 weeks	2.06±0.53	1.75±0.50			
Change in mean HDL	0.25	-0.08	0.17	3.053	0.002
Mean TG (mmol/L)					
Initial TG	2.47±1.17	2.50±1.20	0.03	0.333	0.740
TG at 12 weeks	2.15±1.17	2.49±1.25			
Change in mean TG	-0.32	-0.01	-0.31	3.619	0.04
Mean LD(mmol/L)					
Initial LDL	2.61±0.90	2.61±0.97	-0.00	0.019	0.985
LDL at 12 weeks	2.66±0.80	2.58±0.90			
Change in mean LDL	-0.05	-0.03	-0.02	1.602	0.110

DISCUSSION

Several studies investigating the effect of lifestyle modification on cardiovascular risk factors have been done elsewhere.[20, 21,22] It is in line with this that the study sought to determine the effect of structured lifestyle modifications on cardiovascular risk factors among adults with type 2 diabetes mellitus in this environment.

The results from the study showed that prevention through structured lifestyle modification produced favorable effects on cardiovascular risk indicators in patients with type 2 diabetes mellitus within a twelve-week period. In this study, there were more females (66%) than males. Yavari and colleagues also documented a higher proportion of female participants compared to males in a study among type 2 diabetic patients.[23] The similarity may be because both studies were carried out in primary care settings.

From this study, there was a statistically significant difference in weight between the intervention and control groups. The findings are consistent with the study by Balducci *et al* in Italy, which examined the effect of supervised aerobic and resistance training plus structured exercise counselling.[24] The study found that the interventions produced significant improvement in weight and body mass index in the intervention group compared to the control group.[24] It is also consistent with the meta-analyses by Wing *et al*, Alpert et al and Chen et al who found significantly greater reductions in weight in the intervention groups compared to the control groups.[14,21,25] The large sample sizes compared to this study may account for the similarities.

There were changes in the body mass index in both groups, although the reduction observed was not statistically significant post-intervention despite reminders on diet and exercise. This was unlike the report by the Action for Health in Diabetes (Look AHEAD), in a hospital-based study among type 2 diabetic patients where the mean weight loss in the intervention group versus the control group was statistically significant, in the body mass index .[21] Chen *et al* and Balducci *et al* also reported statistically significant improvements in BMI of participants in the intervention group.[25, 24] The inability to detect significant difference in BMI between the two groups may be because of the relatively short twelve-week duration of this study which was inadequate to demonstrate a difference compared to the other studies.

Our result showed that structured lifestyle modification produced a statistically significant increase in the HDL-C of participants in the intervention group, and this emphasized the benefits of exercise in the intervention group resulting in the increased concentration of HDL-C with reductions in systolic and diastolic blood pressures.[13]

The triglycerides level also showed a statistically significant change which conforms to the study by Balducci *et al* in Italy.[24] who also found a statistically significant difference in the HDL-C and TGs in the intervention group.[24] It also agrees with the findings of Yavari et al, Wing et al and Alpert et al, who all found statistically significant changes in HDL-C and TGs in the intervention groups compared to the control groups.[14,21,23.]

Limitations encountered in the course of this study included a disproportionate male to female ratio. The short duration of the study was another limitation that might have been inadequate to detect more differences in other variables between groups. Physical activity was assessed by questionnaires which depended on self-reported data rather than objective indices and may have been subject to recall reporting bias. Due to cost and resource limits, only fasting blood glucose level and serum lipid profile tests were done. HbA1c, which is recommended to evaluate the overall glycaemic control over eight to twelve weeks could not be carried out.

This study evaluated the cumulative benefit that can be expected from structured therapeutic lifestyle changes and concluded for both groups that improvement in cardiovascular risk factors requires maximizing the effectiveness of lifestyle interventions.

CONCLUSION

This study shows that additional cardiovascular risk factors are common and on the increase among patients with type 2 diabetes mellitus, and structured lifestyle modification counselling is beneficial. Structured lifestyle modification caused significant improvement on modifiable cardiovascular risk factors in patients with type 2 diabetes mellitus attending the general outpatient clinic, of the Jos University Teaching Hospital.

Counselling if done properly will improve adherence to medications and lifestyle modifications. It is also important to make available, exercise, physical activity and healthy eating tips, in form of posters and handbills, to all patients at each appointment visit within the waiting area of the hospital. The study recommends further research with longer follow-up period on assessment of blood pressure, weight and lipid profile reductions with appropriate lifestyle modification counselling. Also, HbA1c could be checked as a marker of good glycaemic control over such a long period. Other lifestyle issues like effects of stress and objective measurement of duration of sleep hours are important aspects for future research.

Competing interest: The authors declared no conflict of interests.

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