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A Cross-sectional Study of Adherence to Lifestyle Modifications among Ambulatory Type 2 Diabetic Nigerians in a Resource-poor Setting of a Primary Care Clinic in Eastern Nigeria

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Authors' contributions

This work was carried out in collaboration between all authors. Author GUPI did the study design and wrote the protocol. Authors GOCO, ANN and CICE did the statistical analysis and literature searches while analyses of study was by author GUPI. All authors read and approved the final manuscript.

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ABSTRACT

Background: Despite the evidence that lifestyle modifications (LSMs) play important role in glycaemic control, adherence to healthy lifestyles has been variable in Nigeria and this has great impact on the success or failure of pharmacological care.
Aim: The study was designed to determine adherence to LSMs among ambulatory type 2 diabetic Nigerians in a resource-poor setting of a primary care clinic in Eastern Nigeria.
Study Design: This was a primary care clinic-based cross-sectional study done on consecutively sampled 120 adult type 2 diabetic patients who were on management for diabetes mellitus for at

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least 3 months at the primary care clinic of a tertiary hospital in Nigeria.

Place and Duration of Study: The study was carried out at the primary care clinic of a tertiary hospital in South-Eastern Nigeria from April 2011 to December 2011.

Methodology: Instrument of data collection was pretested, structured and interviewer-administered questionnaire. Each item of lifestyle was scored on a five points Likert scale ordinal responses of always, most times, sometimes, rarely and none. Adherence to lifestyle modifications was assessed in the previous 12 months for alcohol and tobacco use and 7 days for physical activity, dietary fruits, vegetables, fats and oil consumptions. Each of the domains of lifestyle was given a score of one point for healthy lifestyle and zero point for unhealthy lifestyle. Type 2 diabetic patients who scored 6 points in all the evaluated domains were adherent. Awareness of LSMs and Specific adherence to lifestyle factors were also determined.

Results: The awareness and overall adherence rates to LSMs were 88.3% and 22.5% respectively Specifically, adherence was highest with the non-tobacco use (100.0%) followed by adequate dietary vegetables consumptions (96.7%) and non-use of alcohol (90.8%). Other adherence rates were consumptions of adequate dietary fruits (51.7%), dietary fat and oils (23.3%) and physical activity (22.5%). Adherence was significantly associated with young age <40 years (p=0.039).

Conclusion: The awareness of LSMs was high but was not translated to comparative adherence. The adherence to non-tobacco use was rated highest and physical activity the lowest. Young age <40 years was significantly associated with adherence. Targeting the domains of inadequate adherence for improvement is a primary care imperative especially in resource-poor settings where there are limited options for healthy living.

Keywords: Adherence; adult type 2 diabetics; LSMs; Nigeria; primary care.

1. INTRODUCTION

Type 2 diabetes mellitus is the commonest metabolic disorder in Nigeria [1-4] and other parts of the world [5,6]. The prevalence has been rising at an alarming rate in the last two decades particularly in nations in socio-economic and demographic transition [6,7]. This carries with it a concomitant rise in diabetic complications resulting in decrease quality of life [2,4,8]. These complications include cardiovascular diseases, blindness, renal failure, lower limb amputations and erectile dysfunction in men among others [9,10]. These complications significantly contribute to morbidity and death among the type 2 diabetic patients [3].

The management of type 2 diabetics can be burdensome and can distort personal, family and social dynamics and lifestyles [1,11]. The changing lifestyles as a result of urbanization and westernization might influence outcome of type 2 diabetic care [1,12]. Evidence from research has shown that goal glycaemic control involves factors other than medication adherence [1,12-14]. Among these factors are adherence to recommended lifestyles. Lifestyle modification is therefore a non-pharmacological care plan towards diabetes self management efforts generally and glycaemic control to target specifically [15,16].

Lifestyle refers to the pattern of an individual behavioral choices and practices with respect to daily activities that are related to elevated or reduced risk of type 2 diabetes mellitus or serve as adjunct to its treatment [17]. Major lifestyles shown to lower blood glucose include weight reduction in overweight or obese diabetics, regular physical activities, social habits such as moderation or cessation of alcohol consumption and cessation of smoking, adequate dietary fruits and vegetable consumption and reduction of saturated fat intake [16-18]. Adherence with lifestyle modifications is defined conceptually as the degree to which the type 2 diabetic patient actively participate with prescribed lifestyles and involves partnership between the diabetic patient and the clinician [1,13].

In Nigeria, changes in lifestyle due to modernization influence the management of type 2 diabetes [4,12]. However, type 2 diabetes mellitus is associated with increased risks of chronic diseases like cardiovascular diseases in the presence of unhealthy lifestyles [1,4,12]. For effective management of type 2 diabetes, it is imperative that holistic approach be adopted taking into consideration prescribed lifestyles amidst other diabetic management constraints in the study area [19-21]. However, little is known about adherence to LSMs among Nigerians with type 2 diabetes mellitus in primary care settings. Of great concern is that primary care clinicians in

the study area, though aware of LSMs and its clinical benefits in the management of type 2 diabetes haven't made it a routine to assess for their adherence. This has led to missed opportunities for health education, health promotion and health maintenance among the type 2 diabetic Nigerians. It is hoped that the findings of this study would help to bridge this gap and also generate data for a better understanding of the concept of adherence to LSMs among type 2 diabetic patients in primary care. This study invariably underscores the relevance of inquiring for adherence to LSMs amidst other reinforcement mechanism in management of type 2 diabetic patients. It is against this background that the authors were motivated to determine adherence to LSMs among ambulatory type 2 diabetic Nigerians in a primary care clinic in South-Eastern Nigeria.

2. MATERIALS AND METHODS

2.1 Ethical Consideration and Patients Consent

Health Research and Ethics Committee of the hospital gave approval for the study. Respondents included in the study gave informed consent.

2.2 Study Design and Setting

This clinic-based cross sectional study was done on 120 type 2 diabetic patients between April 2011 and December 2011 at the department of Family Medicine of Federal Medical Centre Umuahia, Abia state, South-Eastern, Nigeria.

2.3 Selection Criteria

Adult diabetic patients aged ≥18 years who gave informed consent, had been on outpatient treatment for diabetes mellitus for at least 3 months in the clinic were included in the study. This was to ensure that the study population were on prescribed management. Critically ill patients, diabetic hypertensives, diabetic patients who were on insulin medication were excluded from the study.

2.4 Sample Size Determination

Sample size was estimated from the formula [1,22] for calculating minimum sample size for studying population <10,000. Thus $n_f = n/1+(n/N)$ where nf= desired sample size when population

< 10,000; n=desired sample size when the population is more than 10,000, N=estimate of the population size=200 adult diabetic patients based on annual primary care ambulatory type 2 diabetic patients' attendance records who were managed and provided with continuity of care at the department of Family Medicine in 2010 [1]. These 200 adult diabetic patients excluded other ambulatory diabetic patients referred to and being followed up in other medical outpatients' clinics in the Medical Centre in 2010. The diabetic hypertensives were also excluded from this recorded number.

To calculate for n=desired sample size when the population > 10,000 using the formula $n = Z^2 pq/d^2$ where Z=Standard normal deviation usually set at 1.96 which corresponds to 95% confidence interval, p=Proportion of the population estimated to have a particular characteristic. In view of the absence of similar study on lifestyle modifications among ambulatory type 2 diabetic Nigerians in primary care setting the authors therefore assumed that 50% of the adult ambulatory type 2 diabetic patients would adhere to lifestyle modifications at 95% confidence level and 5% margin of error [22]. The assumption was likely to maximize the estimated variance and indicated a representative sample size for the study [1,22]. This gave a sample size estimate of 384; thus q=1.0 - p=1.0- 0.5=0.5, d=degree of accuracy set at 0.05. Hence N= $(1.96)^2$ x 0.5x0.5/ $(0.05)^2$. Therefore, n=384.

For the population < 10,000 and substituting in the formula $n_f = n/1+(n/N)$ where n=384; N=200. Thus n_f=132. This gave a sample estimate of 132 patients. However, selected sample size of 120 adult diabetic patients was used based on the duration of the study.

2.5 Sampling Method

The selection of the study population was done consecutively using every ambulatory adult type 2 diabetic patient who presented to the primary care clinicians on each consulting day during the study period and who met the inclusion criteria. This sampling method was judgementally chosen by the authors based on the fact that the researchers believed that those selected were likely to be representative of the study population.

2.6 Study Procedure

Data collection tool was designed by the authors to suit Nigerian setting through robust review of

appropriate literature on lifestyle modifications [17,23-35]. The specific domains of lifestyle factors examined were dietary fruits and vegetables consumption and use of dietary saturated fats and oils, physical activity profile, alcohol and tobacco use.

Adherence to each of the specific domain of lifestyle factor was given an ordinal score thus: adherence to physical activity=1 point, adherence to alcohol consumption=1 point, adherence to tobacco use=1 point, adherence to dietary fruits consumption=1 point, adherence to dietary vegetables consumption=1 point and adherence to the use of dietary fats and oils=1 point. Adherence to each domain of lifestyle was scored in a five points Likert scale ordinal response of: All times=5 points, most times=4 points, sometimes=3 points, rarely=2 points and none=1 point. The physical activity was assessed by inquiring how often the respondents engaged in physical activities in the previous 7 days. Those who engaged in physical activities all times and most times were considered adherent while those who engaged in physical activities sometimes, rarely and none were considered non-adherent. Subject's occupational; transport, leisure-related and other activities of daily living were taken into account in assessing for the physical activity. Alcohol consumption was assessed in the previous 12 months preceding the study. Patients who consumed alcohol sometimes, rarely and none were adherent while those who use alcohol all times and most times were non-adherent. Tobacco use was evaluated with respect to the use of smoked and smokeless tobacco in the previous 12 months. Patients who responded none were considered adherent while those who responded all times, most times, sometimes and rarely were considered non-adherent. The dietary fruits consumption was evaluated by asking how many days in the previous 7 days did the respondents eat fruits. Those who responded all times and most times were adherent while those who responded sometimes, rarely or none were non-adherent. The dietary vegetables consumption was evaluated by asking how many days in the previous 7 days did the respondents eat vegetables. Those who responded all times and most times were adherent while those who responded sometimes, rarely or none were non-adherent. The question on dietary saturated fats and oils consumption was inquired in the previous 7 days and those who responded all times and most times are considered non-adherent while those who responded sometimes,

rarely and none were adherent. The dietary fats and oils were classified into saturated and unsaturated oils and fats based on the type of oils and fats available in Nigeria.

The information on physical activity and dietary measurements was based on previous 7 days physical activity and dietary recall methods. This method was expected to give required information on physical activity and dietary assessment based on the feasibility and the Nigerian practice population setting. The researchers explained briefly the concept of the study and made vigorous effort to maximize honest response in order to minimize the potential for information bias especially response acquiescence, social desirability response, floor and ceiling responsorial effects.

The questionnaire was pretested at the primary care clinic using five non diabetic patients. The pre-testing of the questionnaire lasted for two days. The respondents for the pre-testing of the questionnaire were selected haphazardly from the clinic. The pretesting was done to find out how the questionnaire would interact with the respondents and ensured that there were no ambiguities. However, no change was necessary after the pre-test as the questions were interpreted with the same meaning as intended. The questionnaire instrument was interviewer-administered. Language used was English Language. However, local languages were used to interpret the questions to patients who could not understand the medical terms in the questionnaire.

2.7 Operational Definitions of Terms

Researchers defined young adult patients as those aged 18 years to 40 years and old adults as those ≥ 40 years. Lifestyle modification refers to the diabetic patients' behavioural daily choices and practices as regards physical activity, alcohol and tobacco use, dietary fruits, vegetables, fats and oils consumptions. Adherence to LSM by diabetic patients means the extent to which the type 2 diabetic patient's behaviour with respect to following dietary regimen and executing other lifestyle changes coincides with clinical prescriptions. Overall adherence to LSM referred to the score of 6 points in all the six specific sections of LSMs assessed while non-adherence refers to the score less than 6 points. Specific adherence to LSM refers to adherence to specific lifestyle factor as defined by the 5 points Likert ordinal

score described for each specific domain of lifestyle factor in the methods section and scored as: all times=5 points, most times=4 points, sometimes=3 points, rarely=2 points and none=1 point. Awareness of LSM refers to positive responses to the questions on lifestyle factors such as advice by a health professional to stop smoking, start or do more physical activity, little or no alcohol, eat fruits and vegetables always and eat less saturated fats and oils. Primary care refers to the clinical care provided by physicians specifically trained for comprehensive first contact and continuing care for undifferentiated patients including early detection, management of the patient, health promotion and maintenance.

2.8 Statistics

Data analysis was done using software Statistical Package for Social Sciences (SPSS) version 13.0, Microsoft Corporation, Inc. Chicago, IL, USA for calculation of percentages for categorical variables. Bivariate analysis involved the use of Chi-Square for testing the significance of associations between categorical variables. The level of significance was set at $p<0.05$.

3. RESULTS

Of the one hundred and twenty type 2 diabetic patients studied, twenty seven (22.5%) (27/120) were adherent to all the domains of LSMs while ninety three (77.5%) (93/120) were non-adherent (Table1).

One hundred and six (88.3%) (106/120) out of 120 respondents were aware of LSMs for type 2 diabetes while fourteen (11.7%) (14/120) were unaware of LSMs for type 2 diabetes mellitus (Table 2).

Frequency of adherence to specific domain of lifestyle modifications showed that one hundred and twenty were adherent to non-use of tobacco (100.0%) (120/120), one hundred and sixteen (96.7%) (116/120) were adherent to consumption of dietary vegetables and one hundred and nine (90.8%) (109/120) were adherent to non-use of alcohol. Other adherence to specific domains of lifestyle modifications are shown in Table 3.

Bivariate analysis of the basic socio-demographic variables as related to adherence to lifestyle factors showed that young age < 40 years (x^2=4.01, p-value=.039) was statistically

significant while other demographic variables were not statistically significant (Table 4).

Table 1. Frequency of adherence to all domains of LSMs among type 2 diabetic patients. (N=120)

Variable	Number	Percentage
Adherence to LSMs		
Yes	27	22.5
No	93	77.5

Table 2. Awareness of LSMs for type 2 diabetic among the study participants. (N=120)

Variable	Number	Percentage
Awareness of LSMs		
Yes	106	88.3
No	14	11.7

Table 3. Frequency of adherence to specific domains of LSMs among the type 2 diabetic patients (N=120)

Variable	Number	Percentage
Adherence to		
Non-use of tobacco	120	100.0
Consumption of dietary vegetables	116	96.7
Consumption of alcohol	109	90.8
Consumption of dietary fruits	62	51.7
Consumption of dietary fats and oils	28	23.3
Physical activity	27	22.5

4. DISCUSSION

The overall adherence rate to lifestyle modifications among the type 2 diabetic Nigerians in the study was 22.5%. The finding of this study has corroborated previous reports on inadequate adherence to LSMs among type 2 diabetic patients in Nigeria [1,21]. And in other parts of the world such as Egypt [36]. The inadequate adherence to LSMs among the study population is probably due to health beliefs about diabetes in a milieu of poor knowledge and attitude to the diabetic medical condition [19-21] amidst complementary and alternative medicine use [37]. It is therefore not enough to prescribe LSMs during clinical encounter with diabetic patients in the study area but regular determination of the level of adherence should

Table 4. Association between adherence to LSMs and basic demographic variables of the study participants (N=120)

Variable age (years)	Adherence		x^2	p-value
	Yes number (%)	No number (%)		
18-39	18(66.7)	5(5.4)		
≥40	9(33.3)	88(94.6)	4.01	.039*
Sex				
Male	12(44.4)	33(35.5)		
Female	15(55.6)	60(64.5)	7.15	.196
Marital status				
Single	4(14.8)	2(2.2)		
Married	15(55.6)	60(64.5)		
Separated or divorced	2(7.4)	2(2.2)		
Widowed	6(22.2)	29(31.1)	5.12	.793
Education				
Primary and less	8(29.6)	20(21.5)		
Secondary and more	19(70.4)	73(78.5)	8.05	.061
Occupation				
Trading	3(11.1)	44(47.3)		
Public/civil servants	10(37.1)	20(21.5)		
Farming	6(22.2)	4(4.3)		
Clergy	5(18.5)	3(3.2)		
Drivers	0(0.0)	4(4.3)		
Artisans	0(0.0)	2(2.2)		
Retired	3(11.1)	16(17.2)	5.77	.207

=Significant

be considered for diabetic patients in primary care settings. Clinicians attending to adult type 2 diabetic Nigerians should therefore ask specific questions during clinical consultation in order to discern overt or covert LS limitations requiring modifications. The primary care strategies to improve quality of life and reduce the risk of cardiovascular events should focus not only on blood glucose control with anti-diabetic medications but also on the benefits of lifestyle interventions [21,38].

The awareness of LSM was 88.3% but adherence to its practice was 22.5%. This gap in practice of LSMs is a cause for concern considering the enormous negative impact of unhealthy lifestyles on diabetic management. Information based on knowledge is power and this knowledge needs to be delivered as part of primary care package for these diabetic patients. If type 2 diabetic patients are aware of the metabolic and diverse benefits of lifestyle modifications, then it becomes easier to educate and counsel them on LSMs. This posits that interventional programs geared towards translating awareness of LSMs to adherence is a quality of care imperative among type 2 diabetic patients in primary care practice in the study area. There is therefore the need to make the type 2 diabetic patients committed to adjusting their lifestyles to the recommended lifestyles that have been proven to be safe, effective and patient centred.

This study has demonstrated that adherence to no smoking had the highest adherence of 100.0%. Although the practice of smoking generally varies socio-environmentally, adherence to no smoking among the type2 diabetic patients in this study could be adduced that some of the respondents who were previous smokers quit smoking not necessarily due to their diabetic condition or fear of diabetes-related risks but for other reasons such as religious reasons [1,21]. In addition no smoking among the female diabetic patients who constituted larger proportion of the study population could be ascribed to socio-cultural reasons as the Nigerian society detests smoking especially among the females. Cessation or abstinence

from smoking is beneficial to the patients, the clinicians, health delivery system and the Nigerian nation. The detrimental impacts of smoking on diabetes mellitus have been reported in previous studies [39,40]. According to these reports, smoking decreases insulin absorption and worsens atherogenic progression by increasing peroxidation of lipoprotein cholesterol and decreasing the antioxidant levels. Physicians should be made aware about these subtleties because they can affect patient management with covert smoking habits or who are exposed to second hand cigarette smoke. Interventional strategies should be adopted in primary care to ensure that type 2 diabetic patients who didn't smoke avoid smoking while those who cease from smoking didn't recourse to it.

Dietary vegetables consumption had second highest adherence among the type 2 diabetic patients. This finding could be a reflection of the Nigerian family diet in which vegetables are predominantly served as part of the daily meals while fruits are eaten by choice as snacks. In addition, there is high cost of fruits in the study area [41]. However, there is need to encourage type 2 diabetic patients to adjusting their lifestyle to the recommended dietary vegetable consumption that have been proven to be beneficial among the diabetics. In this regard, translating adherence practice to the desired health action that could promote healthy consumption of dietary vegetables among the type diabetic patients should be improved.

Alcohol had the third highest adherence. This finding could be due to the awareness of the effect of alcohol on anti-diabetic medications especially the pressor effect which discourages these patients from indulging in alcohol ingestion [42,43]. In addition, type 2 diabetic patients in the study area had limited social interactions amidst widespread notions that alcohol makes anti-diabetic medications ineffective. More so, some type 2 diabetic patients avoided alcohol due to financial constraints involved in procuring alcohol in addition to anti-diabetic medications. Furthermore, the interactions of type 2 diabetic patients in search of healing with conventional religious organizations were likely to lead to abstinence from alcohol consumption. Adherence to alcohol use should therefore be part of the primary care concerns in resource-poor settings especially among non-adhering type 2 diabetic patients.

Physical activity had the lowest adherence rate in this study. This finding is in consonance with the reports that physical activity is inadequate among type 2 diabetics [36,44]. Adherence to recommended physical activity among the type diabetic patients is therefore critical and indispensable part of the management because of its beneficial effects [44,45]. According to these recommendations, physical activity improves blood glucose and enhances cardiovascular health. Appreciating the role of physical activity among type 2 diabetic patients would sensitize primary care clinicians to see every encounter with type 2 diabetic patients as an opportunity to render therapeutic and prophylactic physical activity. The relevance of physical activity in type 2 diabetics is an important management challenge that should be modified during consultation in primary care. Screening for physical activity profile and initiation and implementation of necessary measures would help these patients improve their quality of care and cardiovascular health.

The adherence to lifestyle modifications was significantly higher in young adults patients compared to old adult patients. Although the factors responsible for this higher adherence among young adults' patients are variable but this could be ascribed to the fact that young adult diabetic patients were likely to be physically active and have social interactions that enhance their attitude and practice of lifestyle modifications for their diabetic conditions. More so, the young adult patients in the study area were likely to enjoy wider patient companion to the hospital and dependent on their family members for diabetic care. This companionship to the hospital invariably leads to supervision and monitoring of prescribed lifestyles by their family members who were more proximal to them. However, due to their dependent living the young adult diabetic patients may not afford the cost of alcohol or tobacco in addition to the cost of diabetic treatment. The young adult diabetic patients, by virtue of understanding that their diabetic condition requires lifelong management were likely to adhere to prescribed lifestyle modifications. The presence of a healthy lifestyle among young adult diabetic patients should mandate the clinician to encourage and motivate improvement in prescribed lifestyle which will impact on the success of other diabetic therapeutic interventions. The primary care physicians should be aware of this disposition in other to tailor lifestyle interventions to accommodate the needs of young adult diabetic patients amidst other diverse diabetic care resources.

4.1 Study Implications

Nigeria is currently experiencing rapid industrialization, westernization and urbanization which have the tendency of leading to changes in lifestyles with implications for type 2 diabetic cares. Despite the publications of relevant clinical trials on the benefits of lifestyle modifications among type 2 diabetic patients, adherence to these lifestyle factors still remain suboptimal in primary care settings particularly in resource poor settings where there are limited options for healthy living. The magnitude of poor adherence to lifestyle modifications in resource poor Nigerian primary care environment is better imagined than seen amidst societal belief on the causes of type 2 diabetes mellitus and this will have negative effects on the achievement of therapeutic outcome. Appreciating the gap in adherence to lifestyle modifications and narrowing them will enable type 2 diabetic Nigerians benefit timely from recommended lifestyle interventions. This study will therefore sensitize primary care physicians in the study area to routinely evaluate for lifestyle factors during clinical consultations with type 2 diabetic patients and will help to prevent missed opportunities for counselling, health education, health promotion, risk reduction and health maintenance on healthy lifestyles.

4.2 Study Limitations

The authors recognized the following limitations: First and foremost, the reliability of the qualitative responses on adherence to specific dimensions of lifestyles was subject to systematic error since some patients couldn't clinically provide true responses to adherence to lifestyle factors. However, effort was made to minimize this threat by pre-testing the questionnaire. In addition, research assistants received training and instruction on standard interview procedure and respondents were assured of anonymity. Furthermore, socio-cultural background could explain the rarity of some of the behavioural lifestyle factors among the respondents. In order to minimize recall biases the questions were structured in a manner that will enable the researcher obtain information relevant to the objectives of the study. This objectivity was also maintained by not fielding misleading questions. The researchers ensured that questions were not ambiguous or presented to the respondents in such a way as to communicate different meanings that could generate inaccurate and inconsistent responses.

More so, this study was not an all inclusive study on lifestyle factors for diabetic management but on some selected common lifestyles such as physical activity, alcohol and tobacco use, dietary consumption of fruits, vegetables, fats and oils. The assessment for the lifestyle factors was not quantitative as regards the cardiovascular relevance of Likert ordinal scores for specific domains of lifestyle factors.

Finally the limitation imposed by the relative small sample size for the study is recognized. However, this was the number of patients seen within the duration of the study. Moreover, the sample for the study was drawn from family medicine clinic of the hospital. Hence, the findings of this study may not be general conclusions regarding diabetic patients attending medical outpatient clinics of the department of internal medicine of the hospital.

4.3 Strength of the Study

This research is the first study in primary care to highlight lifestyle modifications among ambulatory type 2 diabetic Nigerians in primary care clinics.

5. CONCLUSION

The awareness of lifestyle modifications was 88.3% but was not translated to comparative adherence (22.5%). The adherence to non-tobacco use was rated highest and physical activity the lowest. Young age <40 years was significantly associated with adherence. Targeting the domains of inadequate adherence for improvement is a primary care imperative especially in resource-poor settings where there are limited options for healthy living.

6. FUTURE RESEARCH STUDIES

Future research directions are recommended on quantitative assessment of lifestyle factors among ambulatory type 2 diabetic patients in the study setting in order to further explore the effects of adherence to lifestyle modifications on glycaemic control. This will provide valuable robust clinic-epidemiological data for comparative purposes.

CONSENT

All authors declare that 'written informed consent was also obtained from respondents included in the study.

ETHICAL APPROVAL

Ethical approval was obtained from the Ethics Committee of the hospital.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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