

Effect of Lifestyle Modification Intervention on Diabetes Mellitus Treatment Outcomes in Tuberculosis Patients with Diabetes Mellitus in Southwest Nigeria

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Abstract

There is an observed poor treatment outcome of Diabetes mellitus (DM) in patients with Tuberculosis and Diabetes (TBDM) comorbidity due to interference of drugs used in the treatment of Tuberculosis (TB) with first-line drugs used in the treatment of DM. Insulin does not interact with TB drugs, but it is not accessible and affordable to low-resource communities due to high cost. Hence a lifestyle-based intervention, which this study evaluated to determine its effect on Diabetes control in these individuals. It is a quasi-experimental intervention with two groups of 25 participants each as experimental and control cohorts, enrolled from Tuberculosis Healthcare centers in Lagos and Oyo states. The questionnaires were administered after the baseline Glycated hemoglobin (HBA1c) has been measured, repeated after 12 weeks, and analyzed with SPSS software. In the control cohort, the difference in the means of HBA1c was statistically significant at 95%CI: 1.1(0.2 – 2.1; $p < 0.05$), indicating a worsening of blood glucose control. The difference in the means of educational scores was not significant 95%CI: -0.04(-2.8 – 2.7; $p < 0.05$), showing no uptake. In the intervention group, the difference in the means of the HBA1c was statistically significant 95%CI: -2.4(-3.1 – 1.6; $p < 0.05$), indicating improvement in glucose control. The difference in the means of the educational and behavioral score was significant statistically 95%CI: 40.6(37.7 – 43.6; $p < 0.05$) indicating uptake of behavioral changes. The intervention with educational and behavioral lifestyle modifications improved the blood glucose control as an adjunct to the conventional treatment with drugs compared to the control group.

Keywords: Behavioral change, Lifestyle, Treatment, Tuberculosis-Diabetes comorbidity.

Introduction

Diabetes Mellitus (DM), an important chronic metabolic disease characterized by failure of the system to maintain glucose homeostasis in the body leading to hyperglycemia. It is raising serious public health concern as it impacts negatively on quality of life. It is a disease prevalent in the developed nations but has assumed epidemic proportions in the developing countries of the world, exhibiting the health in transition model characterized by globalization and gradual assimilation of western lifestyle including adoption of sedentary lifestyle among

rural communities in sub-Saharan Africa thought to be the precursor to observed changes in metabolic integrity responsible for the disease [1, 2, 3]. Diabetes is estimated to affect 462 million people worldwide in 2017 representing 6.28% of world population and caused 1 million deaths per year and the 9th leading cause of mortality in the world, with a prevalence rate of 6059 per 100,000 which is estimated to rise to 7079 per 100,000 by 2030 [4]. Most of the individuals predicted to be affected are said to be in the developing countries due to increasing rate of the disease caused by globalization, adoption of

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Western sedentary lifestyle, provision of easy communication system and adoption of western non fiber processed caloric dense diet [5, 1, 6]. Diabetes is a component of Non- Communicable Diseases (NCD), which contributes about 71% of all deaths globally killing up to 41 million people annually and 77% of these deaths occur in Low- and Medium-Income Countries (LMIC) with low resources [5, 2, 7, 8].

Tuberculosis is an age long highly infectious disease that affects all age groups across the globe. It primarily affects the lungs with cough, fever, night sweat and weight loss. It is highly infectious and spreads through droplets from person to person and is endemic in many parts of the world. Immune depression is one the main factors that helps the causative organism, mycobacterium tuberculosis accesses the human body escaping the body's immune mechanisms. It establishes its presence in the lungs by destroying the tissues due to immune reaction of the body and forms a cavity with copious sputum production.

Global burden of this infection showed that more than two billion people are infected with TB worldwide and about five to ten percent will develop active TB in their lifetime, and yearly infection rate of ten million people with a death rate of two million deaths per annum [9, 10]. Although the disease has a universal distribution involving both low- and high-income countries, Asia and Africa had the highest number of cases with 87% of new cases in 2019 found in 30 high TB burden countries of which 8 of them contributed to the two thirds of the world TB burden, with Nigeria as the 6th of these 8 countries and the highest in West Africa subregion [10].

There is also a bidirectional interaction between TB and Diabetes because the latter increases the chances of susceptibility to TB infection by 3 folds in a similar way HIV increases the susceptibility to TB infection because of immunosuppression [11]. This means that in TB endemic areas of the world, there is a preponderance of people with diabetes infected

with Mycobacterium tuberculosis and exhibiting complicated treatment trajectory and poor outcomes with likely development of Drug resistance- MDR –TB, making any eradication program very difficult [12, 13]. There is also increase in the progression of Latent TB infection (LTBI) to active TB infection in Diabetics more than in non – diabetics since the reactivation of LTBI depends on the immunity status of individuals, which is weakened in Diabetics [12,13].

The first line drugs for the treatment of TB negatively affects the affordable oral diabetic drugs. Rifampicin causes hyperglycemia and worsening of the blood glucose level by inducing cytochrome enzymatic catabolism of Sulfonylureas and Biguanides thereby making them less active. It also inhibits the release of insulin and increases intestinal absorption of glucose. All of these actions lead to hyperglycemia and this effect is amplified by Isoniazid which antagonizes the action of the sulfonylureas, thereby making the control of diabetes difficult [12,14]. In effect the first line drugs used in the treatment of TB lowers the potency of the affordable drugs used in the treatment of DM in low – resource communities thereby worsening the disease.

Insulin therapy is the drug used in the treatment of this comorbid condition of TBDM, but it is expensive and not within reach of low-resource communities with poor health infrastructure and inadequate or low health insurance coverage, hence the need for an alternative community based and affordable treatment model, which was the proposed use of behavioral change intervention as an adjunct to the affordable first line drug treatment with Sulfonylureas and Biguanides [12, 15, 16].

This study was an interventional study that explored how the independent variables of knowledge of blood glucose monitoring, drug adherence, participation in structured exercise and healthy Mediterranean diet affected the dependent variable (outcome) of blood glucose control in TBDM comorbidity. They were

encouraged to change from unhealthy to healthy diet and sedentary to structured exercise lifestyle through applying change theories. These theories are Health Belief Model (HBM), Social Cognitive Theory (SCT) and Diffusion of Innovation Theory (DIT). These theories and their constructs formed the nucleus for the design of the behavioral change teachings and the questionnaires that measured the uptake of the behavioral changes [17, 18,19, 20, 21]. The literature supported the use of HBM as the underpinning theory in educational intervention to promote self-care in type 2 diabetics [22]. Another study showed that HBM was used as a theoretical framework in determining the determinants of self-care in diabetics and concluded that HBM was efficient in determining the determinants of self-care among diabetics and recommended it as a framework in designing and implementing educational interventions in diabetes control programs [23]. It is known that when individual's belief system is understood and facilitated in HBM, behavioral change is initiated, and the behavior change may be adding a behavior like starting an exercise program or substituting a behavior like in food substitution in diet or extinction of a behavior as in cessation of smoking [24]. The improvement in self-care would positively improve diabetic control which was measured at the end of the study. The objective of the intervention was to determine the immediate-post impact of the lifestyle modification intervention program on Blood glucose control among participants in this study.

A model that underpinned the whole design and evaluation, which encompassed all these theories was the PRECEDE-PROCEED Model developed by Dr. Lawrence Green as an effective tool for development of health promotion programs was adapted for intervention/experiment for the first time in the treatment of TBDM comorbidity. [25, 26]. The constructs of this model – predisposing factors, reinforcing and enabling factors with the behavioral change theories of HBM, SCT and

DIT were the basis for the design of the questionnaires that measured the behavior changes that formed the independent variables in the experiment. [25, 27, 28, 29].

Materials and Methods

This experiment was a structured quantitative quasi-experimental study that measured the response of participants that was used as data which facilitated in answering the research question of the impact of lifestyle modification on diabetes treatment outcome in TBDM comorbidity. It employed lifestyle intervention as an adjunct to the treatment of DM in TBDM comorbidity in the experimental cohort. The control group had the normal first line DM drugs and no structured lifestyle change treatment. The questionnaires measured the uptake of the lifestyle changes and was administered at the beginning of the intervention in both cohorts and repeated after 3 months, which measured the independent variables while the HBA1c was measured at the beginning of intervention and after 3 months as the dependent variable. There were two groups of participants located at Lagos and Ibadan as experiment and control cohorts respectively with 25 patients in each group. The sample size of the participants was calculated from the following formula below:

$$N = \frac{(Z\alpha + Z\beta)^2 \times Pp0(1-Pp0)}{(Pp1 - Pp0)^2} \quad (1)$$

Where, $Z\alpha$ and $Z\beta$ have Confidence levels of 95% = 1.96 Z score for type I Error, and $Z\beta$ is power at 80% to avoid Type II Error which 0.84.

$Pp0$ - the prevalence of DM blood sugar at pre-intervention is 0.5,

$Pp1$ - the prevalence of DM blood sugar level at post-intervention is 0.8.

The margin of difference between pre-and post-intervention prevalence is $(Pp1 - Pp0)^2$.

$$= (1.96 + 0.84)^2 \times 0.5 \times (1-0.5) / (0.8 - 0.5).$$

$$= 1.96/0.09.$$

$$= 22 \text{ participants minimum.}$$

(15% buffer was added to account for attrition with a final sample size of 25 participants per group).

These participants were enrolled by simple random sampling into the control and experimental centers and were mainly TB patients newly diagnosed with DM and others were DM patients newly diagnosed of TB. Verbal and written consent were obtained from participants prior to actual enrolment. The inclusion criteria were confirmed diabetes (FBG ≥ 126 mg/dl or ≥ 7.0 mmol/L. HBA1c $\geq 6.5\%$), positive sputum AFB, Chest X-ray confirmation of TB and weight of 40 kg and above. The exclusion criteria included weight ≤ 40 kg, HIV positive, having been treated for TB previously, Tuberculosis not in the lungs (Extrapulmonary TB); Having TB without Diabetes; Diabetic patient on Insulin and medications for other chronic illnesses. The TB centers were selected randomly at Lagos, Ibadan and rural areas in Oyo state where confirmed TB patients were screened for DM and those confirmed were given consent forms to endorse and were recruited. The participants in the control cohort had the normal TB and Diabetes medications and care from the clinics with administration of questionnaires at the beginning and after 3 months with the blood glucose measurements (Glycated hemoglobin – HBA1c). The participants in the intervention cohort had series of structured teaching on lifestyle modification about behavioral change techniques every month using a designed module and food menu. It followed a uniform guideline on knowledge and complications of Diabetes, management, and effects on organs with motivational interviewing technique having the application of change theories in the background. The reason for lifestyle modification was elucidated with the merits of maintaining a target blood sugar and the make-up of a healthy diet with local affordable content. They learnt how to check their blood sugar at home and design exercises

that will suit their environment and the importance of medication adherence in order to achieve a target blood glucose level. A modified Mediterranean diet was designed, which had vegetables, fruits, complex carbohydrates, grains, and protein as the main components. The food menu was designed to take into cognizance the local dishes that were affordable to the participants and adjusted according to individual's preferences Table 1. They were taught about reduction of certain foods like fat, salt and sugar and related products but encouraged to eat non-starchy vegetables freely, whole grain and fruits while taking with moderation complex carbohydrates like yam and derivatives, potatoes, bread preferably whole wheat, oatmeal, beans, and derivatives like Amala, pounded yam, unripe plantain, rice (unpolished or brown rice preferably)– modified Mediterranean diet with medium to low glycemic index foods. The participants understood the rationale for this pattern of meal and that encouraged them to practice it. They also understood the need and health benefits of a balanced diet, which helps in reduction of weight and control of blood glucose especially when low and medium glycemic index foods were consumed. This led to a delay in absorption of glucose from the intestine. The plate diagram in “Figure 1” was used to demonstrate portion control and it worked well because it was easy to practice. The portions that made up the meal was non-starch vegetables (Green leaves, Ugu, Ewedu, Okoro, Bitter leaf, Cabbage etc.) occupying half of the plate, protein quarter of the plate and starch/grains another quarter. They were taught about eating small frequent meals and they imbibed it as a principle. The reason for avoiding certain food was explained to them as the rate of release of sugar from food.

Table 1. Meal Plan that was Implemented during the Intervention

Meal plan	Suggestions
Breakfast	Fresh fruits, Oatmeal, boiled egg or 1 slice of brown/white bread with vegetable oil spread, Green or black tea/coffee. (No jam, sugar, honey or juice). Drink up to 1L of water or more.
Lunch	Half cup of rice and beans (a typical cup contains 100 g of rice), + vegetables + salad without cream. Or yam flour (amala)/unripe plantain flour (the size of the person’s fist) and vegetable soup. Chicken or fish Eat small quantity up to 3 times a day
Snacks	Roasted unripe plantain (Bole) + roasted groundnut or crackers biscuits with green tea
Dinner	“moimoi” (Bean cake) or EKO and Pepper soup or Akara and Pap (Corn meal) or Beans + Potatoes/cocoyam with fish/chicken sauce
General guide	Reduce portions size and eat in small amounts. Avoid second serving and eat slowly and mindfully

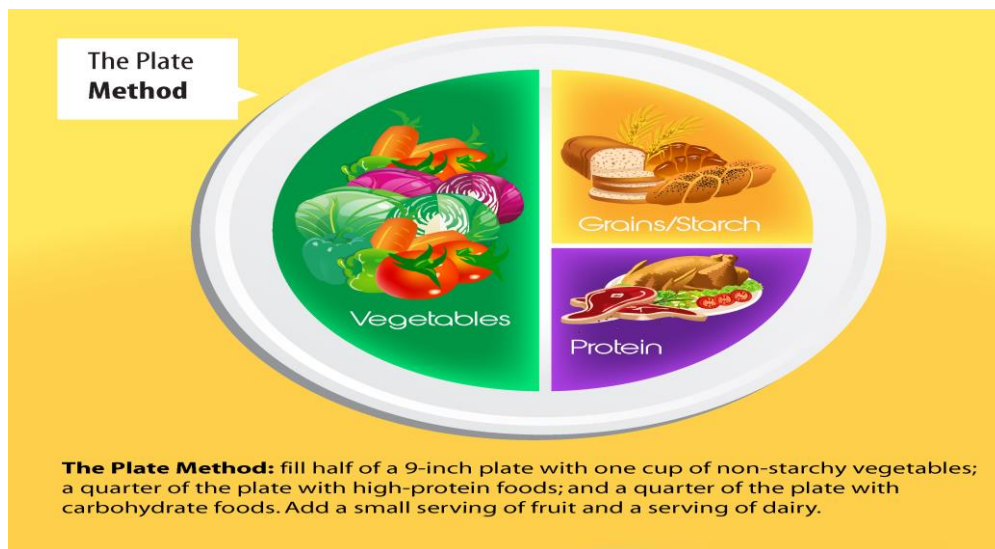


Figure 1. The Plate Method for Meal Planning [30, 31]

The participants learnt and practiced simple home-based exercises which included regular brisk walks for at least 30 minutes per day or 10,000 steps per day for at least 3 times a week. They should break out in sweat. They understood that Physical activity reduced the blood glucose level by improved response of anti-diabetic drugs, diverting the blood to the muscles and increasing insulin sensitivity with reduction of adipose tissues that masked insulin receptors. Some of the home-based exercises

were illustrated in “Figure 2” – stretching exercises and the duration of each component in the exercise shown in Table 2. Others were brisk walking, house chores, sports, cycling, games, and use of staircases instead of elevators, dancing, gardening, walk home for distances less than a kilometer. They were taught to take small measurable and positive actions after setting goals that were achievable [32] and consistent. The duration of the exercise should be increased stepwise at one’s pace.

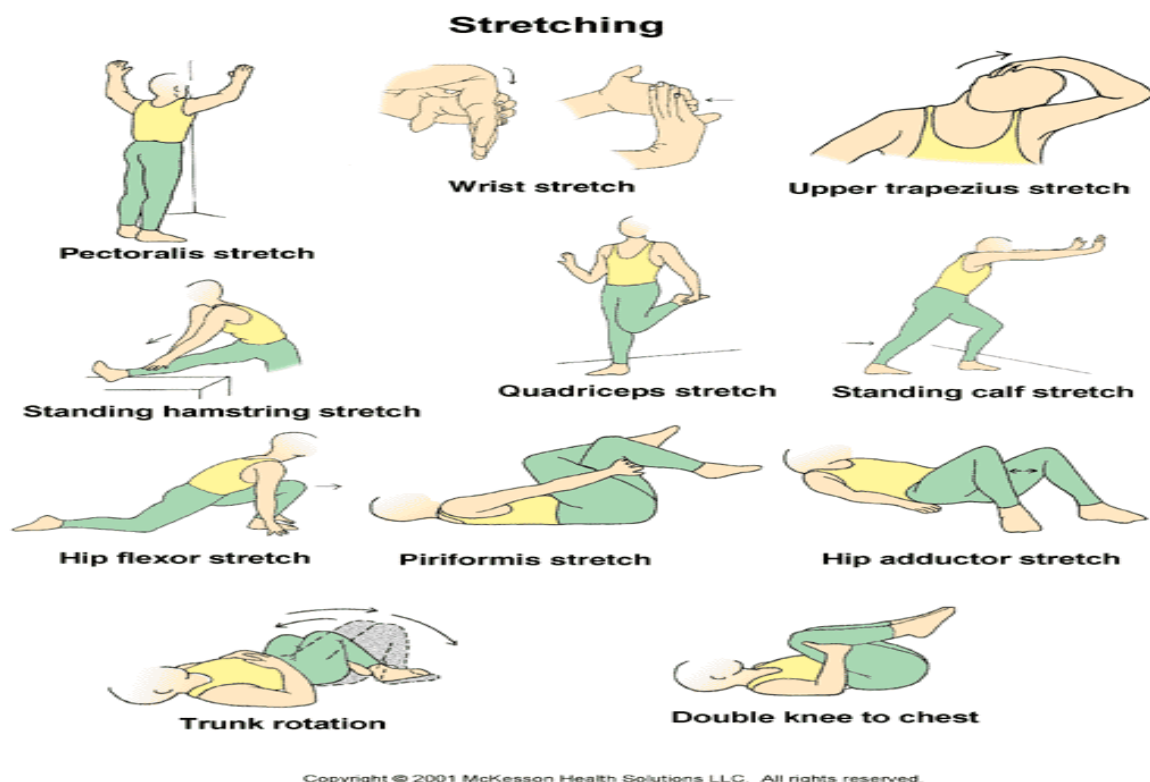


Figure 2. Types of Stretch Exercises

Table 2. Duration of Different Components/Items involved in Exercise

No.	Items/components	Duration and time
1	Proper warm- up	5 - 10 minutes of Aerobic Exercise
2	Stretching	5 - 10 minutes after warm-up exercise
3	Cool down	5 - 10 minutes after exercise

They were taught and learnt how to use the Glucometer at home for a pin prick estimation of blood glucose. They learnt about the importance of meeting blood glucose targets by adhering to the prescribed drugs and keeping appointment with the managing Physician. The HBA1c was measured, and questionnaires response collected after 3 months of intervention by the trained field workers. The questionnaires were cleaned and fed into the SPSS software for statistical analysis of the data. The mean values of the data from the HBA1c levels at baseline and after 3 months were compared for strength of association for the control and experiment groups. The mean differences were subjected to statistical analysis to test the significance of the differences if any to either reject or fail to reject the Null hypothesis at $p \leq 0.05$. The baseline values of the

lifestyle changes uptake and HBA1c were compared with the values after 3 months intervention for the two cohorts. The paired t-test in SPSS was used to compare the means at confidence interval of 95% and $p \leq 0.05$.

Result

The mean age of control cohort participants from the control cohort was 44 years with a range of 24 to 63 years. Sixty eight percent of the participants were females and the males 32% and the predominant tribe was Yoruba (73%), with the married people (52.2%) greater than the other categories (47.8%). All the participants had formal education and seventy one percent (71%) had secondary education and above. Majority were either self-employed or traders (81%), none was unemployed while the

housewives and retirees made up to 9.6% (Figure 3).

The sociodemographic characteristics of the intervention group followed the pattern found in the control cohort with a female preponderance.

The percentage of the participants with secondary education (56%) was lower than in the control group (71.5%). This was expected as the experiment was done in the rural communities “Figure 4”.

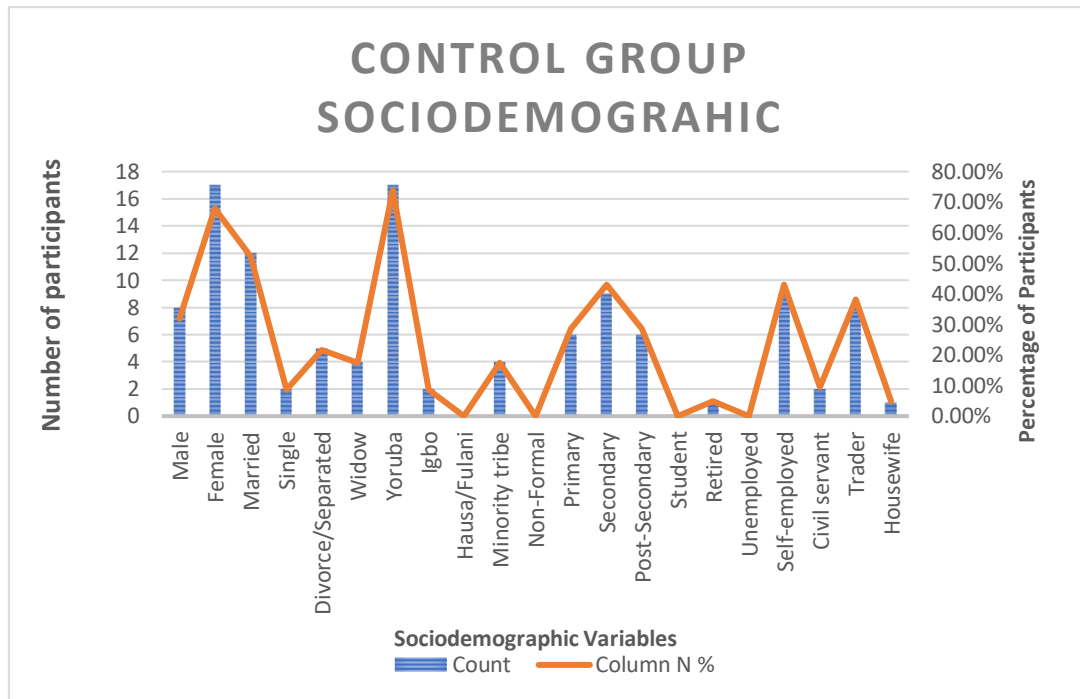


Figure 3. Control Group Sociodemographic Data to show Distribution of the Social and Demographic Variables of the Study Population

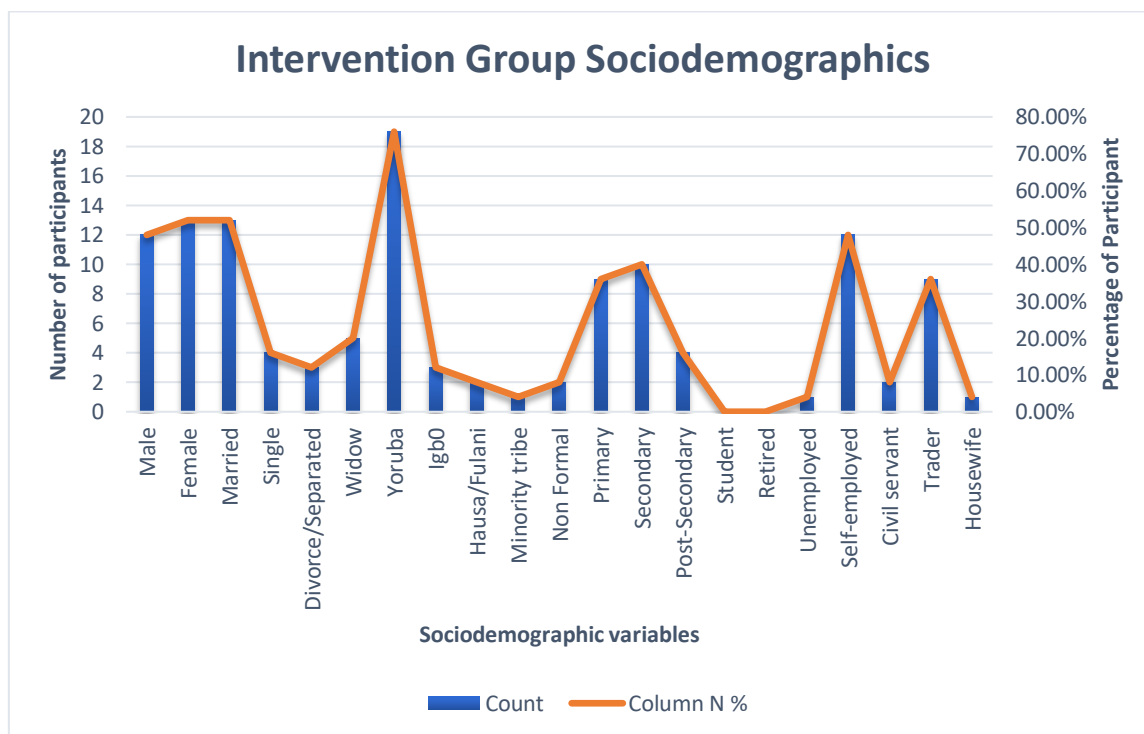


Figure 4. Experiment Group Sociodemographic Data to show Distribution of the Social and Demographic Variables of the Study Population

Table 3. Control Cohort Result of the Comparison of the Mean Scores at Enrolment and after 12 Weeks to Determine Statistical Significance in the Mean Differences – Paired Samples Test

	Paired Differences						t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		Upper			
				Lower	Upper				
Pair 1	Value of HBAlc in percentage at 3 months After Treatment - Value of HBAlc in percentage before Treatment	1.1920	2.31749	.46350	.23539	2.14861	2.572	24	.017
Pair 2	Sum of Behavior and Education score after treatment - Sum of Behavior and Education scores before Treatment	-0.04	6.74216	1.34843	-2.82303	2.74303	-.030	24	.977

∞

Table 4. Intervention Cohort Result of the Comparison of the Mean Scores before and after Experiment to Determine Statistical Significance in the Mean Differences – Paired Samples Test

	Paired Differences						t	df	Sig. (2-tailed)
	Mean Diff	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		Upper			
				Lower	Upper				
Pair 1	Value of HBAlc in percentage 2-3 months after intervention - Value of HBAlc in percentage at the beginning of intervention	-2.40000	1.77623	.35525	-3.13319	-1.66681	-6.756	24	.000
Pair 2	Sum of Behavior and Education scores 2-3 months Treatment - Sum of Behavior and Education scores before Intervention	40.68000	7.13396	1.42679	37.73525	43.62475	28.512	24	.000

Table 3 is the result of the comparison of the mean scores of the HBA1c (dependent variable) in the cohort group at the commencement of the experiment and after a 12-week period. There was a significant increase in the HBA1c value of 1.19 which was statistically significant - 95%CI: 1.1(0.2 – 2.1; $p < 0.05$) and it rejected the Null hypothesis. This increase meant a worsening of blood glucose control. The other result was that of the independent variable which was the comparative values of the uptake of the lifestyle changes. There was no significant change in the means at the commencement of the study and after 3 months in the control group - 95%CI: -0.04(-2.8 – 2.7; $p < 0.05$) hence it failed to reject the Null hypothesis, despite exposure of the participants to the usual clinic teachings about lifestyle changes in their respective clinics.

Table 4 compared the variable means in the experiment group. The mean difference between the HBA1c at the beginning of the intervention and after 3 months showed a significant reduction of 2.4% which meant a better blood glucose control - 95%CI: -2.4(-3.1 – 1.6; $p < 0.05$), hence rejecting the Null hypothesis. The independent variable of lifestyle modification change uptake measured by the behavioral scores mean at the start of the experiment and after 3 months showed a significant difference - 95%CI: 40.6(37.7 – 43.6; $p < 0.05$), which rejected the Null hypothesis and showed that the lifestyle behavior of the participants changed significantly after 3 months of the intervention.

Discussion

The double dilemma encountered by patients with TBDM comorbidity cannot be overemphasized. The diabetes is worsened on treating TB in these patients with the first line drugs – Rifampicin and Isoniazid. These drugs undermine the activities of the blood glucose lowering drugs primarily used to manage

diabetes (Metformin and Sulfonylureas), thereby worsening the disease condition. The other medication that is an alternative to these first line affordable diabetic drugs is insulin, which is expensive and not within the reach of the low- and middle-income earners in the rural communities [12]. These communities in Nigeria are under insured with less than 5% of them having one form of health insurance policy or another [15].

The dependent variable measured in the intervention was the blood glucose level using the HBA1c level as indicator of the control of diabetes, as a lower level depicted a better control. “Figure 5” compared the HBA1c levels in the control cohort with the intervention group. There was an increase of the mean value of the HBA1c by 1.19 (8.74 to 9.93) in the control group after 3 months of treatment compared to the value at baseline, while the HBA1c decreased in the experiment group by 2.4 (11.28 to 8.88). The control group showed a worsening of the blood glucose control despite treatment with the sulfonylureas and metformin, whereas the control of blood glucose level improved in the intervention cohort with treatment with same drugs – metformin and sulfonylureas.

“Figure 6” compared the behavior change uptake in the control cohort compared with the intervention group. The control group bar chart showed no significant change in the height of the bars – 90.32 and 90.36, baseline and after 3 months. There was no significant uptake despite the usual clinic counseling in their respective clinics. In the experiment group, the uptake at baseline was about 60 and after 3 months it rose to about 100 which showed that there was uptake of the behavioral changes in this group. This study was based on the use of the health promotional framework PRECEDE – PROCEED for a quasi-experiment employing its constructs to measure behavior changes with behavioral theories underpinning it.

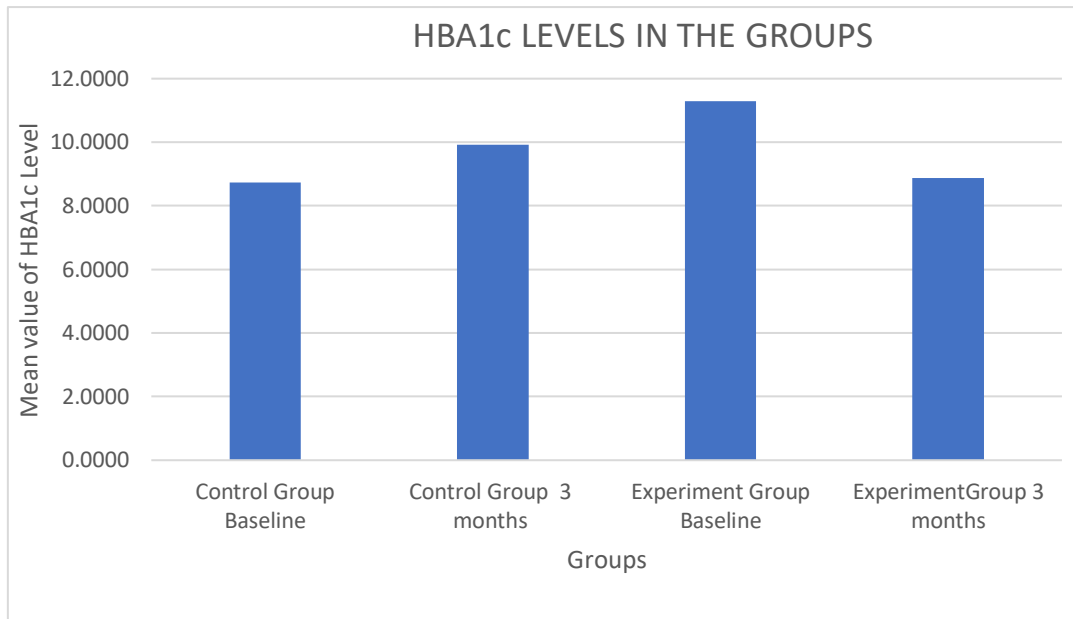


Figure. 5. Comparison of Experimental & Control Groups Blood Glucose Control Mean HBA1c Levels

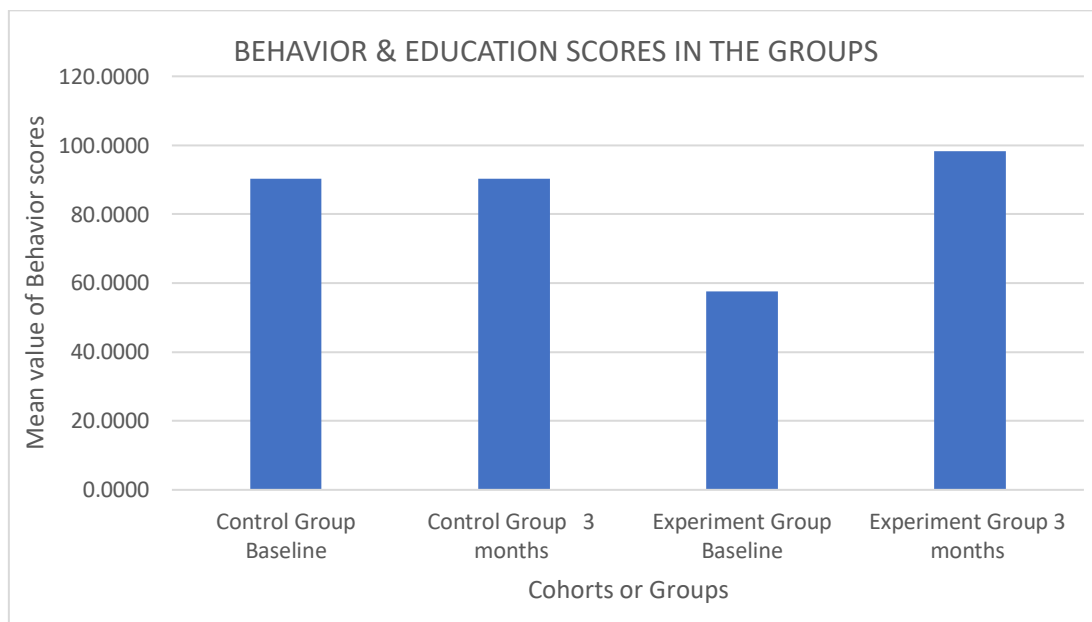


Figure. 6. Comparison of Experimental & Control Groups Mean Behavior & Education Uptake Score

This result followed the same pattern as some studies in literature. One study measured the HBA1c levels of some middle-aged women that were involved in postural corrective exercise for about 20 weeks with a significant HBA1c reduction [33]. Another study showed that exercise and diet reduced blood glucose significantly and found out that there were cellular and molecular mechanism responsible for the effect of exercise on target organs leading to blood glucose reduction, in line with this

study design and results [34]. In a study by Yang et al, a new hormone Irisin was discovered to be responsible for the conversion of the white fat to brown fat which can be metabolized and can only be secreted during exercise, and this was in line with the result in this study [35]. The LOOK AHEAD ILI (Intensive Lifestyle Intervention) study showed a reduction in the HBA1c [36]. A study showed the superiority of intensive lifestyle intervention over healthy lifestyle teaching in producing HBA1c reduction and

supported our findings in this report [37]. The study on the use of digital lifestyle intervention on Diabetes self-management showed a reduction in HBA1c over a period of three months in conformity with the findings in this study. [38]. Merino, J in the clinical review of evidence supporting diet as means of controlling Diabetes stated that Diet is a fundamental principle in the management of Diabetes mellitus. It went further to develop the concept of precision nutrition which was an overflow from population based dietary plan [39]. This was what was adopted in this research as the diet was individualized from a planned diet using our local menu as the population of study was rural. In a meta-analysis on the effect of carbohydrate restriction on the control of DM, it was found out that reduction in the dose of carbohydrate by 10% resulted in a 0.2% reduction of the HBA1c over a period of 6 months [40]. This study agrees with this study as the reduction in the carbohydrate intake among the participants as part of the dietary plan contributed to the reduction of HBA1c in the experiment group. A researcher found out that using a theory-based approach in teaching lifestyle modifications resulted in a better diabetic control [41], which was in line with the framework of this study. It was found in a study that diet has same effect of reducing blood glucose compared to that of Bariatric bypass surgery, and this study used diet as one of the tools to reduce the blood glucose in the TBDM participants [42]. This study followed the higher female than male prevalence of Diabetes [43].

There was under coverage in enrolment because some people usually patronize traditional healers and religious worship centers for healing. In this study only interested ones enrolled and this excluded those not interested hence selection bias. Certain categories of patients were excluded to eliminate confounders like those on chronic disease medications which showed survivorship enrolment bias. Non-responders were replaced in the study and there was recall bias in filling out the questionnaires

during the study. All these may limit generalization of results.

To reduce the above limitations this study has to be carried out with a larger population to include other TBDM patients in other non-governmental centers like private health facilities, Herbal homes and religious worship centers. Other regions in Nigeria apart from the Southwest should have this study done, which will increase the power and enable extrapolating the finding to the general population and used as a national data. Another study on this subject of TBDM should last up to 6 months to determine all other indices of poor outcome especially drug resistance, relapse, and death. The lifestyle modification used in this study should be adopted as an integral part of the care plan of TBDM patients especially in the low resource communities as part of a public health intervention for a better control of their blood glucose, which will result in a better treatment outcome. It is simple and easily adapted to any community whether rural or urban as a public health solution to TBDM treatment failure.

Conclusion

The objective of this study has been achieved. The lifestyle modification suitable for the low resource communities was designed and implemented in this study. This paper was based on a study where the PRECEDE framework originally designed for health promotion was configured to an experimental tool and integrating other behavior theories. This paper has shown that anti TB drugs affect the oral hypoglycemic drugs, which adversely affect the control of blood glucose. This was demonstrated in the control cohort where the HBA1c increased after 3 months instead of decreasing showing worsening of the diabetic control- 95%CI: 1.1(0.2 – 2.1; $p<0.05$). The use of lifestyle intervention as an adjunct to the normal diabetic treatment in TBDM comorbidity had a positive outcome with a reduction in the HBA1c level within twelve weeks as demonstrated in the intervention group - 95%CI: -2.4(-3.1 – 1.6:

p<0.05).

This experiment clearly lowered the blood sugar level which showed a better management of Diabetes in TB patients with Diabetes than without the intervention among the participants.

Conflict of Interest

There is no conflict of interest in this study.

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