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Impact of Lifestyle Change Intervention on Tuberculosis Treatment Outcome in Tuberculosis Patients with Diabetes Mellitus Comorbidity in South West Nigeria

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Abstract

It is well documented in the literature that there is poor treatment outcome in patients with Tuberculosis and Diabetes (TBDM) comorbidity due to the observed interference of drugs for Tuberculosis (TB) treatment on anti-diabetic drugs and elevated glucose level reduces the efficacy of anti- tuberculosis drugs leading to poor TB treatment outcome, and that insulin therapy is not affected by this drug interaction. Importantly, access to Insulin is a challenge due to its prohibitive out-of-pocket cost. The only alternative sustainable treatment for TBDM patients in resource-limited communities is lifestyle-based intervention. This study evaluated the impact of lifestyle intervention on TB treatment outcomes in patients with TBDM comorbidity. This study is a quasi-experimental intervention involving two cohorts of 25 TBDM patients each, as control and experimental cohorts. Their enrolment was from Tuberculosis patients from health facilities in Lagos and Oyo states. The questionnaires were administered before the commencement of the Intervention and at 8 weeks. The sputum Acid Fast Bacillus (AFB) was checked, and chest x-ray (CXR) done before Intervention and Sputum AFB at 8 weeks. The Control group showed no difference in the means of the sputum AFB 95%CI: 0.12(- 0.12 – 0.36; p>0.05), which was an indication of poor treatment outcome. The difference in the means of the sputum AFB in the intervention group was statistically significant 95%CI: -0.8(-0.9 - -0.6; p<0.05). The intervention with educational and behavioral lifestyle modifications significantly improved the outcome of treatment of TB in TBDM comorbidity.

Keywords*: Behavioral change, Tuberculosis, Diabetes, comorbidity, Treatment outcome.*

Introduction

Tuberculosis (TB) is a chronic infection that primarily affects the respiratory system and is caused by bacteria known as Mycobacterium tuberculosis, which is an acid-fast bacillus (AFB).

About two billion people are affected worldwide, and five to ten percent of these will develop active TB in their lifetime and ten million infections per year with two million deaths per year demonstrates the global burden of the disease and impact on human capital [1,2]. All the countries of the world are affected with predominance of the infection in Asia and Africa with eighty percent of new cases in 2019 found in the thirty high TB-burden countries of which eight countries accounted for two-thirds of the total world burden, and these are India, Indonesia, China, Philippines, Pakistan, Nigeria, Bangladesh, and South Africa in that order with Nigeria the being the 6th country [1].

Diabetes mellitus (DM) is a chronic metabolic disorder caused by relative or total lack of insulin or its inaction in the target tissues resulting in hyperglycemia and its clinical consequences and it poses a serious public health concern of wide impact to quality

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of life. It is prevalent in developed nations and has assumed epidemic dimensions in the developing nations attributable to adoption of western lifestyle and undergoing health in transition model [3,4,5].

Those living with DM are more prone to contracting TB than in the general population [6]. Diabetes is a single risk factor for TB and those with DM were three times more likely to have TB than non-diabetics with odd ratio (OR) of developing TB is 2.44 – 8.33 higher than in non- diabetics [7].

In a review by Sahakya et al, it was observed that TB patients with Diabetes had treatment failure and death more than those without Diabetes [8]. Diabetes negatively impacts TB patients by reducing the immune response to infection of these patients [9].

The first line drug Rifampicin in the treatment of TB increases the blood glucose level by inducing the metabolism of the Sulfonylureas and Biguanides through induction of Cytochrome enzymes; inhibits the release of insulin and increases the absorption of glucose, while Isonaizide another first line drug directly antagonizes the action of the Sulfonylureas, which results in hyperglycemia and difficulty in diabetic control [10,6]. This problem of drug interference further compounds the problem of TB treatment in Diabetics because as stated above, the primary drugs used in TB treatment reduce the potency of the commonly used drugs in the treatment of Diabetes that are affordable to patients in low resource communities, thereby worsening the Diabetes.

When the blood glucose is not strictly controlled, TB treatment outcome is poor leading to treatment failure, deaths, and development of drug resistance. In a longitudinal study in India, it was observed that poor glycemic control in TBDM comorbidity was associated with poor TB treatment outcome of delayed sputum conversion [21], increase in chest x-ray cavitation, development of MDR – TB, increase in relapse after treatment and death [11].

The drug that can effectively control the blood glucose of diabetics with TB is insulin, which is expensive and unavailable to patients in poor resource communities. So, there is a need to treat these patients in these communities having TBDM comorbidities with an affordable and available and affordable method that will improve the TB treatment outcome and operate at the community level. Although the treatment of TB in the world through the Directly Observed Treatment Short course (DOTs) is either free or heavily subsidized, but the treatment of DM is not subsidized and in developing countries with poor health care facilities, controlling blood glucose with insulin in TB patients will be an uphill task [6]. The patients pay out-of-pocket due to poor health care financing where only five percent of the population has health insurance cover [12]. Although insulin is the preferred drug for achieving strict blood glucose control, it is expensive or unavailable especially in the low resource communities [6]. The objectives of the intervention are to design a lifestyle modification (Health Education and Behavioral change) intervention program that will be effective and acceptable in our environment for TB patients with Diabetes at the community level, as an adjunct to the use of oral hypoglycemic agents and evaluate the effects of lifestyle behavioral modification intervention - blood glucose monitoring, medication adherence, consumption of healthy diet, and regular exercise, would have on TB treatment outcome in TBDM comorbidity.

The PRECEDE model used in health promotion was the underpinning guide for the health behavioral theories of change, Health Believe Model, Social Cognitive Theory and Diffusion of Innovation Theory used in the intervention. This was the first time the PRECEDE model was used in experiment/intervention as the constructs of these theories formed the independent variables to measure the uptake of the behavioral change intervention among the participants, and this health promotion framework was adapted for a secondary prevention in this project, which is the first time it was used for the treatment of a disease in a comorbid state of TBDM.

Materials and Methods

This Research was approved by the Nigerian Institute of Medical Research (NIMR) Institutional Research Board (IRB), and a structured quantitative study that generated data from participants that helped to answer the research question of the effect of lifestyle changes on TB treatment outcome in TBDM comorbidity. It was a quasi-experimental study that used lifestyle changes as a treatment to the experimental cohort. The other cohort had the usual treatment of TB without the lifestyle treatment intervention. Questionnaires were designed to measure the uptake of the lifestyle treatment using the Precede-Proceed Model of Health promotion and the constructs of the HMB, SCT and DIT, and it measured the uptake of these constructs in predisposing, reinforcing, and enabling factors as the independent variables. Sputum conversion was the dependent variable that was measured.

This intervention was a behavioral study design with two cohorts of participants drawn from tuberculosis centers selected randomly in Southwest Nigeria. One Center was for Intervention, while the other was for the control or comparison group, and each had 25 participants calculated from the following equation as sample size below.

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

Where, Zα and Zβ have Confidence levels of 95% = 1.96 Z score for type I Error, and Zβ 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 $(Pp1 – Pp0)^2$.

$= (1.96 + 0.84))^2$ x 0.5 x (1-0.5)/ (0.8 – 0.5)

= 1.96/0.09

= 22 participants minimum.

A 15% buffer will account for attrition with a final sample size of 25 participants per group of control and intervention cohorts. One Center was for Intervention, while the other was for the control or comparison group.

The participants were either newly diagnosed TB patients with DM or TB patients newly diagnosed with DM. They were enrolled in the program by simple random sampling into the two centers after obtaining both verbal and written consent from the participants. The inclusion criteria were Diabetes confirmation (FBG ≥ 126 mg/dl or ≥ 7.0 mmol/L. HBA1c ≥ 6.5%); positive sputum TB; radiological evidence of PTB and weight of 40 kg and above. The exclusion criteria were weight lower than 40 kg; HIV positive; re-treatment/ failed treatment; extrapulmonary Tuberculosis (EPTB); TB patients without Diabetes; patients on Insulin and patients with other chronic illnesses and on other medications.

Participants at the TB centers with confirmed TB were screened for DM and recruited if confirmed to be diabetic, given consent forms to read, ask questions and endorse. Fifty people were recruited from the centers at Ibadan, Lagos, and the suburbs of Oyo state. The participants (25) in the control group who had TB and DM (TBDM) had no intervention but had their usual diabetic care from the clinics and the questionnaires administered at commencement of the study, and sputum for AFB collected at the beginning of the study and after 8 weeks (about 2 months).

The participants in the experiment/intervention group who had both TB and DM (TBDM) were engaged in a monthly education on educational and behavioral changes. Before the Intervention, questionnaires were administered to these participants, after written and verbal consent were obtained. The baseline data for all participants with the positive sputum AFB and Chest x-ray was recorded. The teachings followed a uniform guideline on Diabetes and complications, the causes, and how to manage it, including teaching on the effect on organs of the body when uncontrolled. The trained health care personnel taught the participants in experimental cohorts the reason for lifestyle modification. The participants received lectures on the benefits of good blood sugar control and what constituted a healthy diet, which was adapted to our local diet. The diet that was adopted and implemented consisted of vegetables, fruits, complex carbohydrates, grains, and protein. The food menu that was used as the sample to be adjusted according to individual need and affordability is shown in Table 1. They were encouraged to reduce the intake of fatty, salty, and sugary food products and to increase the intake of fibrous diet such as whole grain, green vegetables, and fruits – typical Mediterranean diet with medium to low index glycemic foods. The rationale for the above was explained to the participants thus: Balanced diet helps in glycemic control, and weight reduction especially if is tilted to low and medium glycemic index diet, which reduced the blood sugar by delaying absorption of glucose from the intestine. The plate diagram in "Figure 1" showed that half of the plate should be non-starch vegetables (Green leaves, Ugu, Ewedu, Okoro, Bitter leaf, Cabbage etc.), quarter protein and another quarter starch/grains, which was well understood by the participants and was applied by them in their local meals. They followed a dietary principle that was taught that they ate small frequent meals up to 5 times a day. Glycemic index was explained to them as the rate of release of glucose to the body when people ate food hence the basis for the food to avoid or eat in small quantities or eat liberally.

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

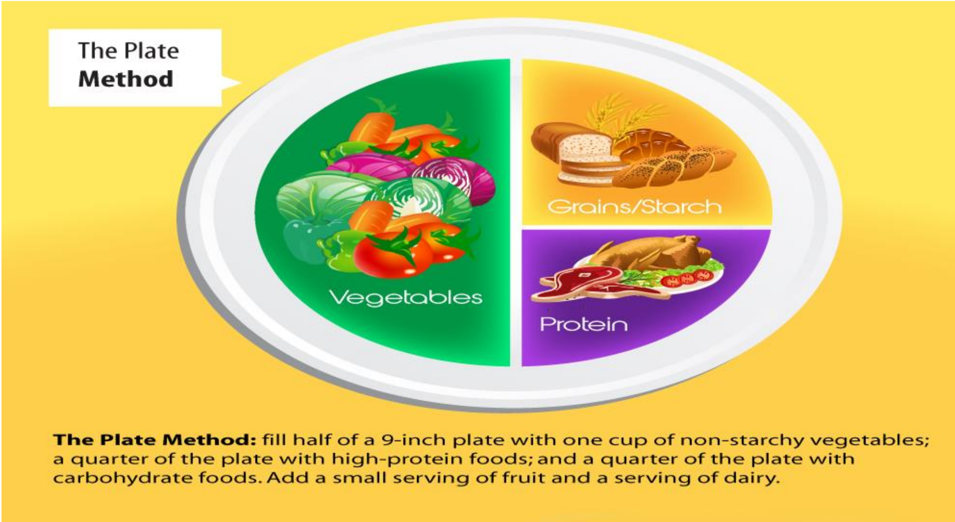

Figure 1. The Plate Method for Meal Planning [22, 23]

How to design exercises that the participants at home undertook was taught. Participants were motivated to adhere to the regular brisk walk for at least 30 minutes per day or 10, 000 steps per day for at least 3 times a week to break out in sweat. They understood that Physical activity reduces the blood glucose level and improves the response of anti - diabetic drugs by diverting the blood to the muscles and enhancing insulin sensitivity. Some of the exercises that were taught to participants as beginners included arm stretching (“Figure 2”), brisk walking, dancing, gardening, walk to destination instead of using public transport when the distance was less than half kilometer, stop at a bus stop to their destination and walk through, involve in house chores, sports, cycling, games, and use of staircases instead of elevators. They were taught to take small measurable and positive actions [24] and chose the activity type that suited them and be consistent. They increased the duration of the exercise at their own pace to meet the target set by each participant for oneself.

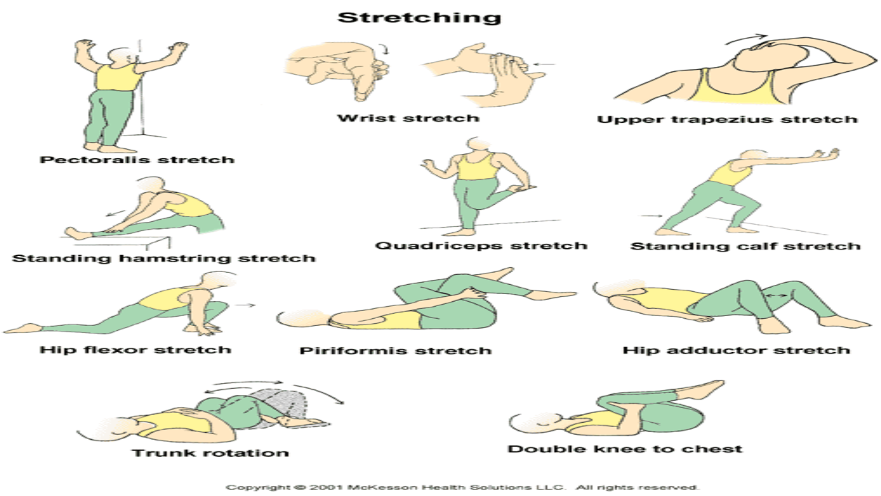

Figure 2. Types of Stretch Exercises and Duration of Exercise

No	Items	Duration and Time
1	Proper Warm-up	5-10 minutes of aerobic exercise
2	Stretching	5-10 minutes after warm up session
3	Cool down	5-10 minutes after exercise

The participants learnt how to measure their blood sugar with a Glucometer at home, and the importance of medication adherence was emphasized. After eight weeks, the sputum of all the participants was cultured for Acid-fast-Bacilli (AFB) using GeneXpert machine and results recorded. Questionnaires were administered, and responses recorded by the field workers at the end of 8 weeks.

The data was analyzed by inductive analysis by subjecting it to analytic/inferential statistical analysis, but before this, the questionnaires were cleaned and transformed by feeding into SPSS software. The Data on the Likert scale was fed into the SPSS, summed up and median/mean calculated. The values at the beginning of the study were compared with the values after 8 weeks in the two cohorts.

The mean differences measured were subjected to analytical/inferential statistical analysis that tested the hypothesis and established the strength of association. Test of significance at $p < 0.05$ was done to either reject or fail to reject the Null hypothesis. The hypothesis was tested by analyzing the difference in treatment outcome in control at the beginning and after 8 weeks (about 2 months) for sputum AFB clearance taking the significant level to be $p < 0.05$ at CI – 95%, to reject or fail to reject the Null hypothesis. The dependent variables of the treatment outcome (sputum clearance at eight weeks) in the two cohorts and their means compared (baseline and after 8 weeks) for any significant difference using paired t-test in SPSS.

Result

The participants from the control cohort showed mean age of 44 years with minimum age of 24 years and maximum of 63 years. The females (68%) were more than the males (32%), predominantly Yoruba (73%) and half of them married (52%) and thirty nine percent (39.1%) divorced, separated, or widowed. The majority had secondary education and above (71.5%) and either self- employed or traders (81%) "Figure 3".

The intervention group showed similar sociodemographic characteristics to that of control group as shown in "Figure 4", except that the people with secondary education were lower in this cohort (56%) compared to 71.5% in the control group. This was due to the rural nature of the communities of the control group of Oyo state compared with the urban city of Ibadan and Lagos where the control experiment was carried out.

Table 2 showed the statistical analysis of the Control cohort dependent variables of the difference in the means of the sputum AFB concentration at baseline and after two months of medication which showed no statistical difference 95%CI: 0.12(- 0.12 – 0.36; $p>0.05$) and it failed to reject the null hypothesis hence no significant conversion of the sputum AFB from positive to negative after 2 months of treatment which is an indicator of poor treatment outcome. The difference in means of the educational scores before and after treatment showed no statistical significance 95%CI: -0.04(-2.8 – 2.7; $p<0.05$), which failed to reject the null hypothesis. This means that there was no difference between the two means and no uptake of teaching on lifestyle changes by the participants despite the exposure to the conventional lifestyle teaching from the health care facilities they were receiving treatment.

Table 3 showed the paired t– test statistics of the intervention group.

The difference in means of sputum AFB before and after intervention was (0.2 – 1.0 = -0.8), which was statistically significant 95%CI: -0.8(-0.9 - -0.6; $p<0.05$); hence it rejected the null hypothesis and showed a reduction in the AFB seen in the sputum after 8 weeks of treatment, which meant better treatment outcome.

It also showed the mean difference of the educational and behavioral scores of (98.3 – 57.6 = 40.6), which was significant statistically 95%CI: 40.6(37.7 – 43.6; $p<0.05$) to reject the null hypothesis. This showed that the teaching was effective, and the participants learned and practiced lifestyle modifications during the Treatment.

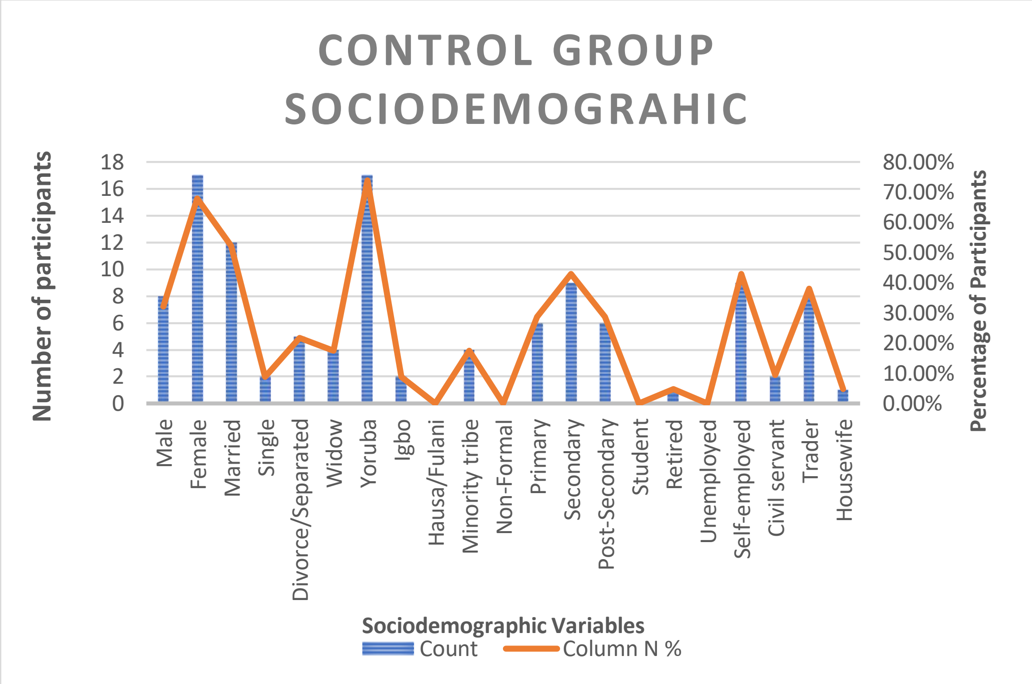

Figure 3. Control Group Sociodemographic Data to show Distribution of the Social and Demographic Variables of the Study Population

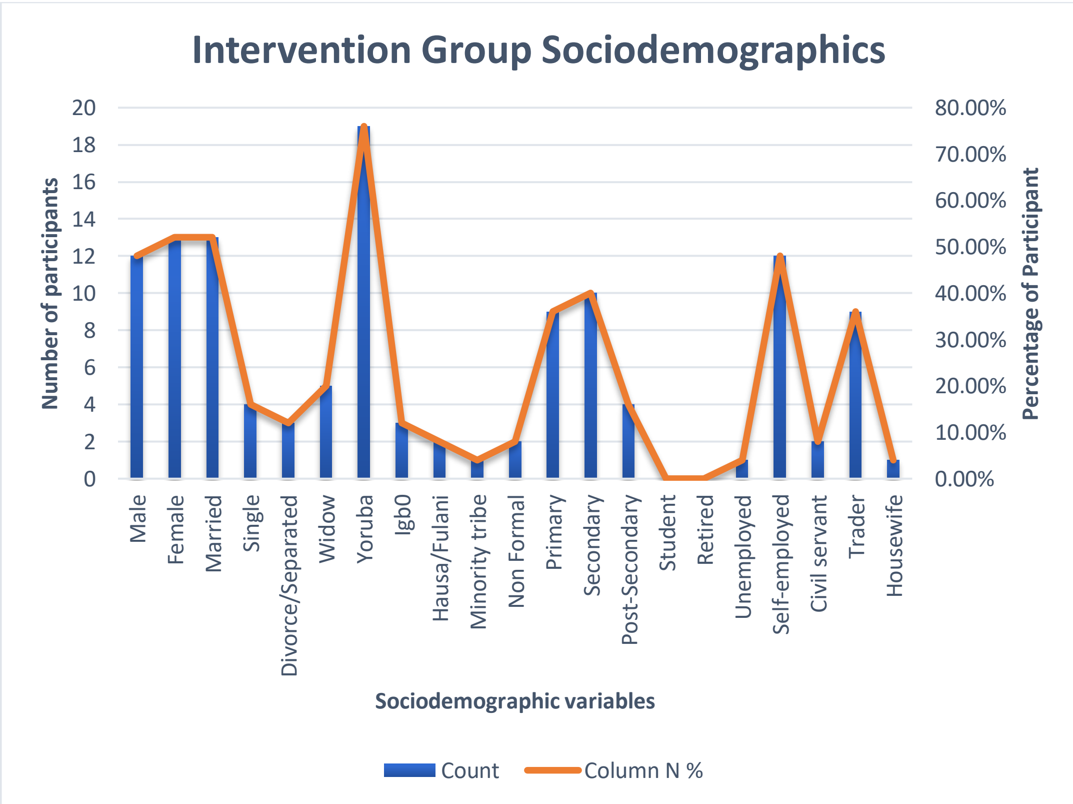

Figure 4. Experiment Group Sociodemographic Data to Show Distribution of the Social and Demographic Variables of the Study Population

Table 2. 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				
					Lower	Upper			
Pair 1	Presence of bacteria in sputum after 2 months of treatment - Presence of TB Bacteria in the sputum before treatment	0.1200	.60000	.12000	-.12767	.36767	1.000	24	.327
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 3. 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				
					Lower	Upper			
Pair 1	Sum of Behavior and Education scores 2-3 months Treatment - Sum of Behavior and Education scores before Intervention	40.68000	7.13396	1.4267 9	37.73525	43.62475	28.512	24	.000
Pair 2	Presence of TB Bacteria in the sputum 2 months after treatment - Presence of TB Bacteria in the sputum before treatment	-.80000	.40825	.08165	-.96852	-.63148	-9.798	24	.000

Discussion

The problem of negative interaction between drugs for the treatment of TB and Diabetes Mellitus, which worsened the condition of the individuals with the comorbidity led to this study to find a community-based method of treatment that is not as costly as insulin. The low resource communities in Southwest Nigeria could not afford insulin treatment in the comorbid state hence the use of Lifestyle modification intervention as an adjuvant to the treatment of this condition with the traditional sulfonylureas, metformin and first line antituberculosis drugs.

The primary outcome measure was the sputum AFB conversion after 8 weeks treatment. In the Control group, there was an increase in the Sputum AFB count after 8 weeks compared to a decrease in the Experiment group ("Figure. 5"). This means that without intervention the participants recruited with a positive chest x-ray diagnosis became AFB sputum positive after 8 weeks of treatment signifying a worsening TB. This showed a slow or poor sputum conversion, which was an early indication of failed treatment with the attendant complications. There was a rapid sputum conversion in the experiment group as seen in "Figure. 5"

The control group was exposed to the routine care in the hospitals that were treating them. These health facilities offered them nutritional advice, encouraged them to be active and avoid sedentary lifestyle and to take their medications regularly. Despite these teachings when the uptake of behavioral changes was measured, there was no difference in the uptake of the normal teachings offered in the health facilities, but a significant difference in the uptake of behavioral change in the intervention group. "Figure. 6"

This study was the first time the health promotion framework Precede-proceed was used for intervention/ experiment, which will be a future standard pathway for behavioral change experiments.

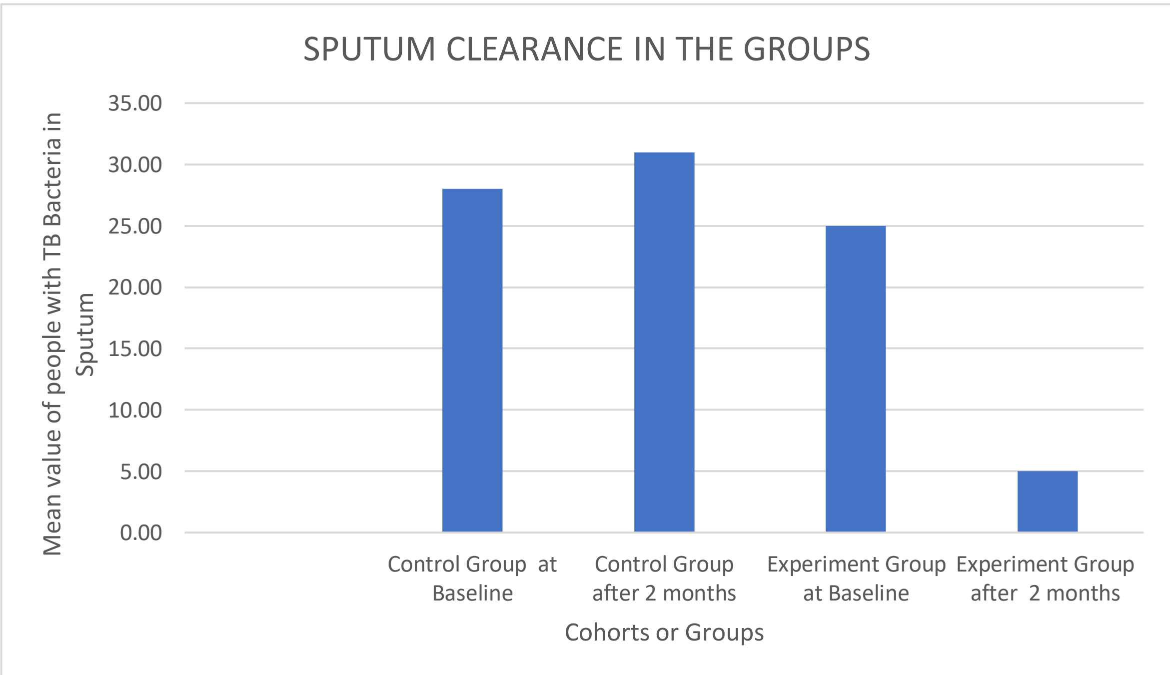

Figure. 5. Comparison of Experimental & Control Groups Mean Sputum AFB Clearance

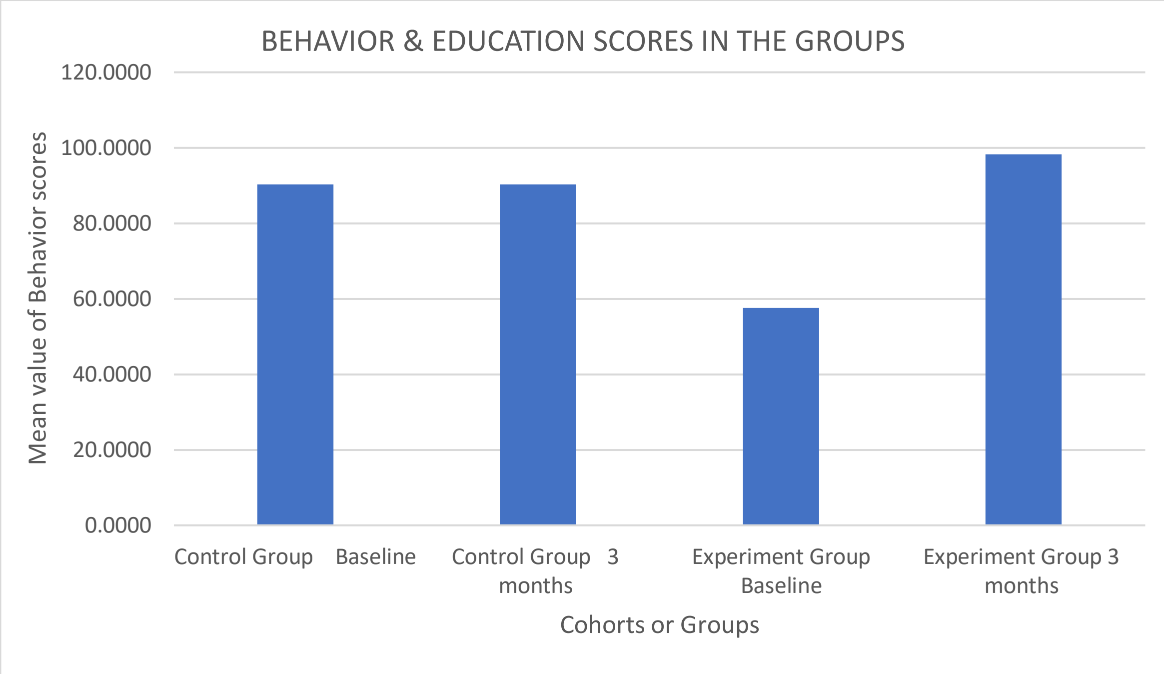

Figure. 6. Comparison of Experimental & Control Groups Mean Behavior & Education Uptake Score

This result agrees with the study by Wenzel et al, which showed that the Glycated hemoglobin level reduced among middle aged diabetic women who engaged in postural corrective exercises over 20 weeks [13]. In a study by Kirwan et al, they discovered some of the cellular and molecular mechanisms that underpin the positive effects of exercise on target organs in reducing blood glucose level in diabetes.

They opined that exercise and dietary measures reduced the blood glucose significantly which was in line with our findings in this study that gave rise to a significant sputum conversion in the intervention cohort more than the control group [14].

Another group of researchers found out that exercise enhanced the management of DM and found the newly discovered mechanism and the effect of the hormone Irisin that is secreted and activated during exercise which converts the white fat to brown fat and burns it for energy with improvement in insulin resistance and good glycemic control [15].

Another study that agreed with this study is the LOOK AHEAD ILI (Intensive lifestyle Intervention) study, which produced a reduction in HBA1c, and it was adapted to a community-based implementation known as LIFT (Lifestyle Intervention for the Treatment of Diabetes), which is a community- based weight reduction program that resulted in better glycemic control than the traditional Diabetic education administered in the clinic [16]. This study showed that HBA1c can improve with ILI more than Healthy lifestyle (HL) and all-round improvement in morbidity and mortality in older people in line with our finding in this study [17].

It was found in a study in an Indian tertiary hospital that poor glycemic control was associated with a slow sputum conversion after two months [11]. This agreed with the finding in this study. In their paper Middelbeek, et al, opined that Medical Nutrition Therapy (MNT), which is the nutrition education and application on a day-to-day basis for the care of a disease, was found to be an effective and cost-effective way of diabetic care [18]. This was the approach that was used in this study and was found to be effective and affordable to very rural and poor communities in Oyo state, Nigeria. Sami, W., et al in their review stated that dietary habits and sedentary lifestyle were the major risk factors in the increasing incidence of Type 2 diabetes in developing countries. They found out that when people were conversant with Diabetes complications and take in knowledge, change their attitude, and practice a better dietary habit, there was a better diabetic control and reduction in complications [19]. This was in line with this study's conceptual and theoretical framework and in agreement with the findings. In another study it was found that diet has same effect on glycemic control as Bariatric bypass surgery [20]. It was shown in this study that the severity of TB evidenced by number of lung lesions, concentration of AFB in the sputum affected the clearance rate. If the disease was severe, there was delay in sputum clearance after the intensive phase of treatment which lasted for 2 months but in this study, the participants were newly diagnosed cases with 20% of participants with lung lesions in the control group compared with 16% in intervention group [25].

The effect of Covid-19 pandemic on TB surveillance in Nigeria followed the trend in other countries like Afghanistan where the detection of TB cases was on the decline due to diversion of resources to contain this emerging pandemic, which will indirectly worsen the effect on TBDM comorbidity than the situation in the pre-covid -19 era [26, 27]. The TB burden in the population showed that male prevalence was higher than the female and what was found out in this study was the reverse with the female having a higher prevalence [28]. This showed that the TBDM followed the diabetic sex prevalence distribution pattern of higher female prevalence than male [29].

There was some levels of under coverage due to some low resource people would go to traditional healers and religious worship centers for miraculous healing. Only those interested enrolled in the program. There was survivorship by excluding certain categories of patients to eliminate confounders like those on chronic disease medications. There were non-responders who were replaced in the experiment and there may be recall bias in filling out the questionnaires during the experiment. All these may limit generalization of results.

This study must be carried out with a larger population and other TB patients in other non-governmental centers like private health facilities, Herbal homes and religious places. This study should be done in other regions of Nigeria with more Local government areas involved, which makes the findings to be extrapolated and used as a national data. The experiment should be done up to 6 months to determine all other indices of poor outcome especially Drug resistance, relapse and death.

The result of this experiment when integrated into the treatment protocol of the people with TBDM comorbidity will increase the cure rate by improving glycemic control as an adjuvant to the regular oral affordable diabetic drugs, because it counters the hyperglycemic action of the TB drugs. As a public health intervention, it can be integrated as standard management protocol for the care of those with TBDM comorbidity. The lifestyle modification that was used in this study can be adopted by government agencies saddled with the responsibility of managing TB patients. This intervention can be part of the care plan for those with TBDM in the rural or urban areas especially in low resource communities, which will help to achieve TB eradication.

This study has also shown the importance of screening TB patients for DM and managing them with the adjuvant of lifestyle modification used in this study. The result of this study will help the government to adopt this lifestyle modification strategy as a policy in the management of TBDM patients and achieving the goal of TB eradication set by WHO in the world by 2050 since poor treatment outcome will lead to drug resistance, relapse or death [21].

Conclusion

This study answered the questions raised in the introduction, research questions and objectives. An effective lifestyle modification was designed for the local community, which was accepted by the participants in this study.

This study adapted the PRECEDE framework originally designed for health promotion to an experimental tool integrating other behavior theories. It has been shown in the foregoing that the treatment outcome of TB patients who also have Diabetes with anti-TB drugs was poor, as seen in the control group where the clearance of TB bacteria from the sputum of participants after eight weeks of treatment with anti-Tuberculosis drugs was poor 95%CI: 0.12(-0.12 – 0.36; $p>0.05$). After intervention with the lifestyle modification program the level of TB bacteria infection of the sputum reduced significantly 95%CI; -0.8(-0.9 - -0.6; $p<0.05$), which was an indication of a good treatment outcome.

This intervention improved the treatment outcome of the TB in participants with TBDM comorbidity.

Conflict of Interest

There is no conflict of interest in this study.

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