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RESEARCH ARTICLE

Glycaemic Control and Weight Reduction in Type 2 Diabetes Mellitus Patient Using a Wholly Nigerian Diet - A Hospital Based Study

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Abstract

Background: Weight gain is linked to poor glycemic control in Type 2 Diabetes patients especially in resource restrained environment, and it is made worse by the lack of access to sustainable treatment options in these same environments. Due to poverty and limited financial resources, these individuals must prioritize safer, locally accessible, and scientifically tested methods of managing their health. Targeted lifestyle therapies have been shown to be clinically beneficial and reasonably priced for the prevention and management of diabetes today. This research seeks to assess the effectiveness of a purely Nigerian diet in helping people with type 2 diabetes mellitus lose weight and maintain excellent glycaemic control.

Method: Sixty study participants were randomized into matched control (standard of care) and Intervention (Caloric restriction dietary intervention) groups. Participants were followed for 24 weeks and samples taken 3 times a week for the duration of the study.

Results: The result revealed a significant drop in weight (Waist circumference and BMI) in the intervention group. Mean waist circumference decreased from 88.82 cm to 80.0 cm [p = 0.001] while BMI decreased from 26.67 to 22.86 kg/m^2 [p = 0.025]).

The fasting blood sugar dropped from a group mean of 7.97 mmol/l on the initial visit to a mean of 5.35 mmol/l after 24 weeks in the intervention group.

Conclusion: Caloric restriction with locally available food reduced weight and normalized fasting blood sugar in study participants with type 2 diabetes mellitus.

Keywords

Type 2 diabetes, Diet, Intervention, Glycaemic control, Remission, Waist circumference and BMI

Introduction

People who are burdened with body mass index greater than 30 and with the diagnosis of T2DM can feel like they are in the end zone of their lives, especially given that diabetes currently has no cure and on account of that fact, they are suddenly facing an intractable, progressive disease that will be with them for the rest of their lives [1]. The increase in T2DM in the last half century is directly related to changes in lifestyle. As our lifestyles have continued to change to include more processed foods and less activity, the proportion of people with T2DM has continued to rise [2].

The scourge of non-communicable diseases is increasing globally and this includes people below and on the poverty line. Nigeria has the highest number and burden of diabetes in Sub-Saharan Africa; thus, treatment of diabetes is of paramount importance to every Nigerian [3]. The role of foods and natural

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antioxidants in preventing disease cannot be over-emphasized.

The prevalence of diabetes is increasing worldwide and it is a growing health concern. The latest WHO/IDF statistics put the current global figure at 382 million and about two-thirds of these people live in developing countries [3] with high morbidity and mortality. The WHO projects that the global diabetes prevalence will hit 592 million by 2035 if nothing is done, thus making diabetes the fastest growing non-communicable disease epidemic [3].

In 2016, diabetes was the 6th leading cause of death globally, leading to just under 2 million deaths annually. Global projected increase in T2DM from 2013 to 2025 reveals that Africa will have a 109% rise, closely followed by the Middle East and North Africa with 96%. The global increase is put at 55% [2]. In the US, by 2050, it is estimated that nearly 100 million persons will have T2DM, and the cost of managing T2DM will be 2.3 times more than non-diabetics who seek hospital care [2]. For kids born after 2000, 33% of males and 39% of females will develop T2DM. Also, having T2DM increases the risk of having Alzheimer's disease with age [4].

Some Evidence has long demonstrated that remission of T2DM can occur after bariatric surgery for the treatment of obesity, evidenced by reduction in HbA1c levels, reduction in all-cause mortality and reduction in medication requirement by 8.7%-31.8%. At 18-24 months remission rates with bariatric surgery vary from 39%-93%. Long term remission outcomes are lower but still significant. Remission rates at 5 years with the STAMPEDE (Systemic Therapy in Advancing or Metastatic Prostate Cancer: Evaluation of Drug Efficacy) trial were 29%-30% at 15 years in Swedish obese subjects study follow up. However, the risks inherent in undergoing this major surgery limited its wide application [5-7].

Emerging studies in the area of Endocrinology have suggested that T2DM can actually be up turned, not through pharmaceutical agents we are used to but through strict adherence to certain dietary interventions and lifestyle modifications. Diet and exercise are the first steps to effectively prevent and even manage diabetes non-pharmacologically.

The primary goal of Medical Nutrition Therapy (MNT) in T2DM is to reduce the risk factors and forestall complications resulting from the disease. Currently, the hypothesis that dietary and lifestyle factors can contribute significantly to pushing T2DM into remission is gaining widespread acceptance [2].

The suggested dietary interventions in T2DM are largely Western in nature (not readily seen or accessed by the common man in Nigeria); hence, they may not be readily available to adapt for local use. This study therefore, seeks to use local, readily available whole plant-based options to create a menu for T2DM subjects while obeying standard operating procedures in menu design for the purpose of this thesis.

Whole plant-based diet is also best used for T2DM to reduce pain associated with peripheral neuropathy [8]; it assists in overcoming food addiction and dependency by helping to reprogram taste buds and breaking eating patterns; it also reverses diabetic retinopathy [9,10].

NFkB pathway is activated by inflammation and free radicals which can come from radiation and toxins. NFKB can also activate telomerase, cytokines, adhesion molecules, VEGF and TNF alpha and it is associated with diabetes, etc [11]. Diet however, is a known modifier of and regulator of NFkB through phytonutrient and antioxidant formation, causing a down regulation of NFkB production and gene modulation that occurs from NFkB pathway. This down regulation has not been fully achieved with medications.

The traditional use of dietary modification can lead to the discovery of new potential treatments of several diseases. Finally, a lot of people may readily have what to eat but may not have access to funds to access health care. The use of foods they are already used to, to enable health and wellness would be extremely helpful to these individuals with T2DM. These studies on dietary modification (wholly Nigerian foods) in T2DM hasn't been studied much, as findings will help improve health outcomes in individuals with T2DM.

Lifestyle is the cause and cure of T2DM, meaning lifestyle can prevent it. T2DM improvements occur with structured intervention programs that produce significant weight loss [12,13]. Targeted lifestyle interventions are found to be clinically effective and cost effective for diabetes prevention and treatment [14-17].

While there may be pharmacological therapies out there, scholars should not be detracted from adopting new options that will mitigate T2DM prevalence noting that prevention is most cost effective, especially, in a low socioeconomic environment like ours and the very high predicted rise in the burden of T2DM in our developing world [18].

This study investigation is geared towards linking the healthful effects from *local diet* in human subjects with T2DM just treatment of T2DM with Oral Hypoglycaemic Agents, and as this will contribute to knowledge and improve the use of this diet among the Nigerian populace. Hence, conducting this kind of study to demonstrate and verify the theory that diet modification is safe enough to ameliorate/stop the misery of diabetes is gaining attention.

This study sets out to evaluate the effects of diet on diagnosed adults with T2DM compared to standard of care, in the University of Port Harcourt Teaching Hospital, Rivers State, Nigeria.

Materials and Methods

Research approach

The study had 60 study participants who were randomized and equally matched into 2 (Standard of Care-Control and Dietary Intervention- Treatment) Group. These participants were known diabetics attending diabetes clinic and were followed up for 24 complete weeks (August 2021 to February 2022) were randomized into matched control (standard of care) and treatment (dietary caloric restriction intervention) groups.

The control group and Treatment group were tested at beginning of the study, mid-way through the study and at the end of the study.

Test of significance was done using ANOVA in each of the two sets of observations (within the control and intervention group). Then, to ensure that significance in the treatment group is due to intervention, a more robust statistic with greater experimental sensitivity such as ANCOVA was carried out for totally removing the effect of covariates on the treatment group [19]. Therefore, Kpolovie [19] submits that the combination of randomization and ANCOVA provides exceptional control to the influence of covariate or extraneous variables. This is supported by Khammar, et al. [20] who stated that ANCOVA is suitable for interventional study that needs to identify, measure and control pretest or covariates before the intervention. Sixty patients (30 in each arm) satisfactorily completed the study for duration of six months without missing the treatments administered.

Recruitments

Participants were recruited from diabetic patients attending the General Outpatient and Diabetes Clinics at the University of Port Harcourt, Nigeria. To be included in the study, patients had to be known diabetics, 18 years of age or older, not on any herbal, traditional or complementary medicines in the last 2 weeks prior to commencement of the study and not any known medication that will impair Pancreatic or kidney function. Also, poorly controlled blood sugar or varying HbA1c typically HbA1c ≥ 6.5% at the last routine clinical check and Body Mass Index (BMI) > 26 kg/m^2 and < 45 kg/m^2. Patients with existing complications of diabetes or co-morbidities, severely ill patients and patients with mind altering medications were excluded.

Informed consent was obtained from each participant and then the 60 participants were randomised into open label control (Standard of care) and intervention arms of this study. The control arm consisted of diabetic patients with at least one oral hypoglycaemic agent while the intervention group received a calorie-restricted diet consisting of locally grown foods. Statistical tests were done to ensure that there was no significant difference between the control and intervention groups.

The study questionnaires which were divided into several parts including disease and medication history, frequency of consumption of various foods, physical activity or other lifestyle practices, level of education and income, were piloted around the University of Port Harcourt Teaching Hospital and the University of Port Harcourt residents for legibility, comprehension, cultural sensitivity and relevance.

All study participants were seen on a monthly basis for clinical evaluation and assessment of adherence and morbidity. All participants were called on their mobile phones, at least once a week, to follow up and deal with any concerns as they progressed with the study. Participants with deteriorating clinical conditions were removed from the study and placed on full pharmacological therapy under the supervision of an endocrinologist, until they were stable. Each participant had a bi-weekly self-reported fasting blood glucose test. The primary end point of the study was a FBS value consistently between 3.5-5.5 mmol/l for 6 months while the secondary end-point was weight loss equivalent to 10% of body weight.

Statistical analysis

Statistical analysis was done using the computer software, Microsoft Office Excel 2017 for the graphs and Statistical Packages for Social Science (SPSS) version 22.0 for inferential statistics. The study adopted the following statistics for analysis of data-: Descriptive statistics for data cleaning, stem-and-leaf plot and box plot for detecting and removing outliers, Kolmogorov-Smirnov test and histogram for normality. Crosstab and frequency, ANOVA and ANCOVA were used answer the research questions and test the hypotheses of the study, while significant variables were subjected to post hoc or pairwise comparison tests (i.e. Bonferroni test).

In order to determine statistical significance of the differences between means, the Wilcoxon signed-rank test for dependent samples (such as: FBS) and the Mann-Whitney U test for independent samples (such as anthropometric parameters) was used. Statistical significance between the means was set at $p < 0.05$. The relationships between the indices was evaluated using Pearson's linear correlation with the level of statistical significance set at $p < 0.05$ at 95% confidence.

Ethical clearance

Ethical approval was sought and obtained from the Ethics Review Committee of the University of Port Harcourt (Annex 1) with reference number UPH/CEREMAD/REC/MM71/001.

Results and Discussion

Demographics

Demographic characteristics showed no statistically significant difference between Age ($p = 0.934$), Gender ($p = 0.605$), and the clinical group, as shown in Table 1.

Table 1: Demographics.

Variable	Group		χ^2 *(p-value)*
	Intervention **n_2 = 30**	**Control** **n_2 = 30**	
	Freq (%)	**Freq (%)**	
Age Group			
30-49	11 (36.67)	9 (30.0)	
50-69	15 (50.0)	17 (56.67)	0.934$^{\alpha}$
≥ 70	4 (13.33)	4 (13.33)	
Mean (SD)	54.73 ± 11.29	57.6 ± 9.73	1.05 (0.292)$^{\mu}$
Gender			
Male	13 (43.33)	16 (53.33)	
Female	17 (56.67)	14 (46.67)	0.27 (0.605)

*Statistically significant ($p < 0.05$); χ^2 = Chi-Square; μ = Student t-test; α = Fishers Exact p

Table 2: Descriptive statistics showing an association between clinical parameters for the standard of care (Control) group

Variables	Standard of Care (Control) group		ANOVA (F-test)	p-value
	Mean	**SD**		
FBS CONTROL				
Initial	8.570	3.3124		
3 Months	7.003	2.3839	2.298	0.107
6 Months	7.367	3.1119		
Overall	7.647	3.0059		
Waist CONTROL				
Initial	90.817	10.9359		
3 Months	89.800	10.6298	0.078	0.925
6 Months	90.000	10.1608		
Overall	90.206	10.4701		
BMI CONTROL				
Initial	26.907	4.5521		
3 Months	26.093	4.5572	0.763	0.469
6 Months	25.417	4.9173		
Overall	26.139	4.6662		
NS - Not Significant at P > 0.01; ANOVA = Analysis of variance				

Association between clinical parameters for standard of care (Control) group over 6 months

Results from Table 2 shows mean differences in the clinical parameters (FBS, waist circumference and BMI) of T2DM patients subjected to a standard of care (Control) over a 6 months period. Changes in means were noted in FBS, and waist circumference parameters in the standard of care group but for BMI that had steady drop in mean values (from 26.06 to 25.0). ANOVA results of the clinical parameters on the average presented show no significant mean differences for all the measured clinical parameters after a period of six months. As such the null hypothesis of no significant mean difference is sustained. Therefore, there are no significant mean differences on the clinical parameters (FBS, waist circumference and BMI) of T2DM patients subjected to a standard of care (Control) over a 6 months period.

Association between clinical parameters for intervention group over a 6 months period

Results from Table 3 shows mean differences on the clinical parameters (FBS, waist circumference and BMI) of T2DM patients subjected to Intervention over a 6 months period. The result showed a steady drop of parameter means from the initial visit to six months in the intervention group. The fasting blood sugar dropped from a group mean of 7.97 on the initial visit to a mean of 5.35 after six months. Similarly, the result showed substantive weight loss after six months of Intervention. This is revealed in the waist circumference mean which fell from 88.82 cm to 80.0 cm after six months, and BMI that dropped from 26.670 to 22.857 kg/m^2 after six months.

The one-way analysis of variance was conducted to investigate if there are significant mean differences on

Table 3: Statistical descriptions of the association between clinical parameters in intervention group.

Variables	Diet (Intervention) group		ANOVA (F-test)	p-value
	Mean	**SD**		
FBS CONTROL				
Initial	3.8471	0.7024		
3 Months	1.9670	0.3591	7.388	**0.001***
6 Months	1.5855	0.2895		
Overall	2.8416	0.2995		
Waist CONTROL				
Initial	88.82	9.900		
3 Months	82.93	8.777	7.572	**0.001***
6 Months	80.00	8.034		
Overall	83.92	9.574		
BMI CONTROL				
Initial	26.670	4.1194		
3 Months	24.920	4.0177	7.667	**0.001***
6 Months	22.857	3.1076		
Overall	24.816	4.0487		

*Statistically Significant at P ≤ 0.05; ANOVA = Analysis of variance

Table 4: Percentage of reduction of FBS using both standard of care (Control) and intervention after a period of six months.

Group	All participants n (%)	FBS Change n (%)			% Reduction (*No. of normal subjects after 6months – Initial no. of normal)*	Fishers exact p
		Initial	**3 Months**	**6 Months**		
Control	30 (100.0)	8/30 (26.7)	12/30 (40.0)	12/30 (40.0)	12-8 4 (13.33)	0.237µ
Intervention	30 (100.0)	11/30 (36.67)	13/30 (43.33)	20/30 (66.67)	20-11 9 (30.0)	

µFisher's exact p (recommended where cell values are < 5)

the clinical parameters (FBS, waist circumference and BMI) of T2DM patients subjected to MNT therapy over a 6 months period. ANOVA results, presented in the above table, show significant mean differences for four out of the five clinical parameters. There are significant mean differences on the clinical parameters (FBS, waist circumference and BMI) of T2DM patients subjected to MNT therapy over a 6 months period. Thus, the intervention had no significant effect on the Lipid profile of T2DM patients after six months. Though, the Lipid profile of the patients was within a normal level (below 2.60 mmol/L).

Percentage of fasting blood sugar (FBS) reduction at the individual level after six months of standard of care (Control) and intervention

Results from Table 4 show that after a period of six months, the intervention controlled the FBS level of 30% of T2DM patients, and the standard of care controlled the FBS level of 13% of T2DM patients. Therefore, the intervention has the efficacy to control the FBS in more than twice the number of T2DM patients as the standard of care. However, this observed difference was not statistically significant (p = 0.237).

Percentage of Body Mass Index (BMI) reduction at the individual level after six months of standard of care (Control) and intervention

Results from Table 5 show that after a period of six months, the intervention controlled overweight by 16.67%, unlike the standard of care controlled group with a reduction of 6.67% in overweight. Obese observed a reduction of 23.3% in the intervention group and 10% in the standard of care controlled group. Therefore, the intervention proves to be more effective than standard of care in controlling BMI of T2DM patients. However, this observed difference was not statistically significant (p = 0.681).

Percentage of normal Body Mass Index (BMI) that had remission within the standard of care (Control) and intervention

Table 5: Percentage of reduction of BMI at an individual level using standard of care (Control) after a period of six months.

Group	All participants n (%) n = 30	BMI Change n (%)			% Reduction (*No. of normal subjects after 6months – Initial no. of normal)*	Fishers exact p
		Initial	3 Months	6 Months		
Control						0.681$^{\mu}$
Normal		12/30 (40.0)	15/30 (50)	17/30 (56.7)	17-12 5 (16.7)	
Overweight		8/30 (26.7)	8/30 (26.7)	6/30 (20)	6-8 -2 (6.67)	
Obese Class 1		10/30 (33.3)	6 (20.0)	7 (23.3)	7-10 -3 (10.0)	
Obese class 2		0/30 (0)	1/30 (3.3)	0/30 (0)	0-0 0 (0.0)	
Intervention						
Normal		11/30 (36.7)	16/30 (53.3)	23/30 (76.7)	23-11 5 (16.7)	
Overweight		11/30 (26.7)	11/30 (26.7)	6/30 (20)	6-11 -5 (16.67)	
Obese class 1		8/30 (33.3)	2/30 (20)	1/30 (23.3)	1-8 -7 (23.33)	
Obese class 2		0/30 (0)	1/30 (3.3)	0/30 (0)	0-0 0 (0.0)	

$^{\mu}$Fisher's exact p (recommended where cell values are < 5)

Table 6: Percentage of Normal Body Mass Index (BMI) that had remission within the standard of care (Control) and MNT therapy (Intervention) groups after a period of six months.

Group	All participants n (%)	BMI Change n (%)			Fishers exact p
		Initial	3 Months	6 Months	
Control	30 (100.0)				0.025$^{\mu*}$
Normal		12/30 (40.0)	15/30 (50.0)	17/30 (56.7)	
Remission		0 (0)	3/15 (20.0)	3/17 (17.6)	
Intervention	30 (100.0)				
Normal		11/30 (36.7)	16/30 (53.3)	23/30 (76.7)	
Remission		2/11 (18.18)	9/16 (56.25)	14/23 (60.87)	

*Statistically Significant at P ≤ 0.05; $^{\mu}$Fisher's exact p (recommended where cell values are < 5)

Results from Table 6 indicated the percentage of normal Body Mass Index (BMI) that had Remission within the Standard of Care (Control) and Intervention groups after a period of six months. The findings revealed that only three out of the 17 patients that had controlled BMI experienced remission (i.e. had a HBA1C < 6.5) while, the intervention group showed that 61% of patients with controlled the BMI had remission. However, this observed difference was statistically significant (p = 0.025). As such, there is overwhelming evidence to the association between reduction in BMI and remission of T2DM patients after 6 months of intervention.

Assessing the effect of individual on the FBS level of T2DM patients while controlling for the influence of standard of care

Table 7a: ANCOVA summary of the effect of intervention on FBS level of T2DM patients.

Parameter	MNT therapy on the FBS level			F	P-value	Effect Size η^2
	Initial Visit	**3 Months**	**6 Months**			
	Mean ± SD	Mean ± SD	Mean ± SD			
FBS Intervention	7.94 ± 1.97	6.42 ± 1.95	5.36 ± 1.94	6.790	**0.002***	0.136

*Statistically Significant at P ≤ 0.05

Table 7b: Post-hoc (Bonferroni) summary of the effect of intervention on FBS level of T2DM patients.

		FBS Intervention		
(I) GROUPS	**(J) GROUPS**	**Mean Difference (I-J)**	**Std. Error**	**P-value**
Initial Visit	3 Months	1.514	0.706	0.104
	6 Months	**2.568***	**0.699**	**0.001***
3 Months	Initial Visit	-1.514	0.706	0.104
	6 Months	1.054	0.690	0.391
6 Months	Initial Visit	-2.568*	0.699	**0.001***
	3 Months	-1.054	0.690	0.391

*Statistically Significant at P ≤ 0.05

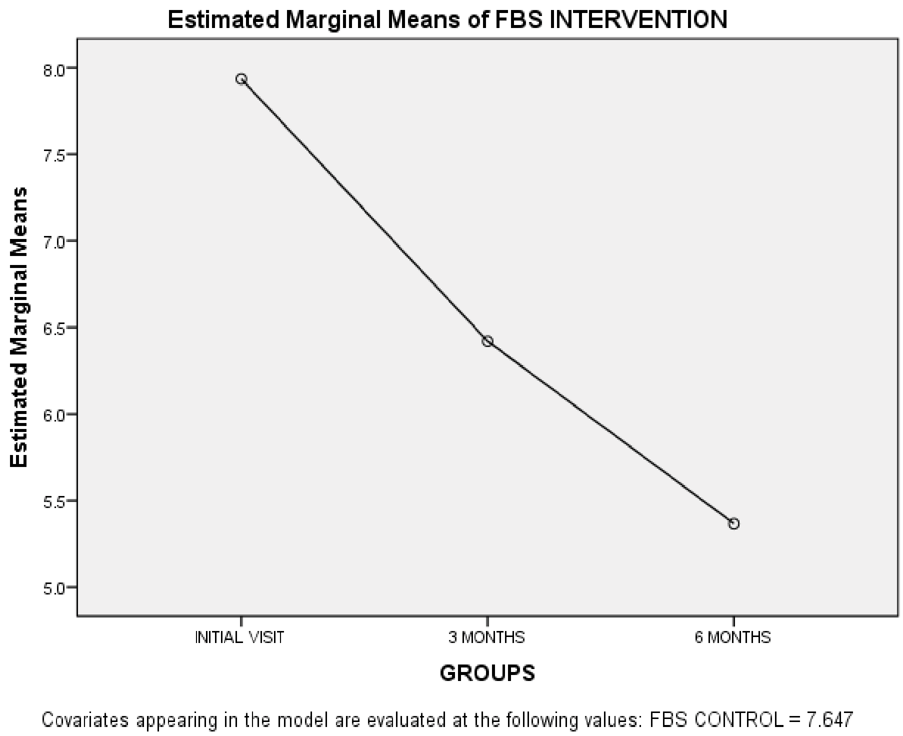

Figure 1: Estimated marginal means of FBS intervention.

The analysis of covariance was conducted to investigate the effect of MNT therapy on the fasting blood sugar (FBS) level of T2DM patients over a period of six months while controlling for the influence of standard of care. ANCOVA results, presented in Table 7a, show a significant difference in mean FBS level amongst treatment groups [$F(2, 86) = 6.790$, $p < 0.01$, partial $\eta^2 = 0.136$]. However, the calculated effect size indicates a small proportion of variance accounted for about 13.6% change in the FBS level of the treatment group.

Bonferroni Post hoc tests (Table 7b) showed there was a significant difference between group 1 (Initial visit) and group 3 (6 months) ($p < 0.01$) only. Comparing the estimated marginal means showed that the lowest FBS level was in group 3 (mean = 5.36 mmol/L) compared to groups 2 and 1. The graph below highlights the mean differences amongst the groups (Figure 1).

Table 8a: ANCOVA summary of the effect of intervention on BMI of T2DM patients.

Parameter	MNT therapy on the BMI Control			F	P-value	Effect Size ▯^{2}
	Initial Visit	**3 Months**	**6 Months**			
	Mean ± SD	Mean ± SD	Mean ± SD			
BMI Intervention	26.76 ± 2.74	24.92 ± 2.73	22.77 ± 2.74	8.333	**0.001***	0.162

*Statistically Significant at P ≤ 0.05

Table 8b: Post-hoc (Bonferroni) summary of the effect of intervention on BMI level of T2DM patients.

		BMI Intervention		
(I) GROUPS	**(J) GROUPS**	**Mean Difference (I-J)**	**Std. Error**	**P-value**
Initial Visit	3 Months	1.846	0.972	0.183
	6 Months	**3.990***	**0.978**	**0.001***
3 Months	Initial Visit	-1.846	0.972	0.183
	6 Months	2.144	0.972	0.090
6 Months	Initial Visit	-3.990*	0.978	**0.001***
	3 Months	-2.144	0.972	0.090

*Statistically Significant at P ≤ 0.05

Assessing the effect of intervention on the BMI level of T2DM patients while controlling for the influence of standard of care

The analysis of covariance was conducted to investigate the effect of MNT therapy on the Body Mass Index (BMI) of T2DM patients over a period of six months while controlling for the influence of standard of care. ANCOVA results, presented in Table 8a, show a significant difference in mean FBS level amongst treatment groups [$F(2, 86) = 8.333$, $p < 0.01$, partial ▯^{2} = 0.162]. However, the calculated effect size indicates a small proportion of variance which accounted for about 16.2% change in the BMI of the treatment group.

Bonferroni Post hoc tests (Table 8b) showed there was a significant difference between group 1 (Initial visit) and group 3 (6 months) (p < 0.01) only. Comparing the estimated marginal means showed that the lowest BMI level was in group 3 (mean = 22.77 kg/m^2) compared to groups 2 and 1 respectively (mean = 24.915 kg/m^2, mean = 26.76 kg/m^2). The graph below highlights the mean differences amongst the groups (Figure 2).

Assessing the effect of intervention on the waist circumference of T2DM patients while controlling for the influence of standard of care

The analysis of covariance was conducted to investigate the effect of intervention on the waist circumference of T2DM patients over a period of six months while controlling for the influence of standard of care. ANCOVA results, presented in Table 9a, show a significant difference in mean waist circumference (weight loss) amongst treatment groups [$F(2, 86) = 7.435$, $p < 0.01$, partial eta ▯^{2} = 0.147]. However, the calculated effect size indicates a small proportion of variance, accounting for about 14.7% change in the waist circumference of patients in the treatment group.

Bonferroni Post hoc tests (Table 9b) showed there was a significant difference between group 1 (Initial visit) and group 2 (3 months) (p < 0.05) and groups 1 and 3 (p < 0.01). Comparing the estimated marginal means showed that the most weight loss in waist circumference was in group 3 (mean = 80.024 cm) compared to groups 2 and 1 (mean = 82.98 cm and 88.747 cm respectively). The graph below highlights the mean differences amongst the groups.

Discussion

In recent past, T2DM was diagnosed and typically prevalent in older age groups but with poor lifestyle it is now seen in all ages. The Centres for Disease Control report on diabetic statistics [21] clearly showed ages 45 and older had the highest number of new cases of diabetes in 2015. This remission study done in Nigeria by Nigerians using locally available everyday food items is one of a few recent studies investigating the population with T2DM that included a small number of subjects with outcome for possible translation into further studies and implantation in main stream endocrine clinics. Although the study looked at demographic factors, it did not show that sex and age affected FBS, or weight reduction. This study had a mean age of 54.74 ± 11.29 years for intervention group with gender equally matched (see Table 1). Tonstad, et al. [22] after adjusting for BMI and socio demographic and lifestyle factors demonstrated that the right diets were associated with a substantial reduction in risk of diabetes compared to non-vegetarian diets who were even reported to have a 3.8 times chance of having diabetes linked to their cause of death [23].

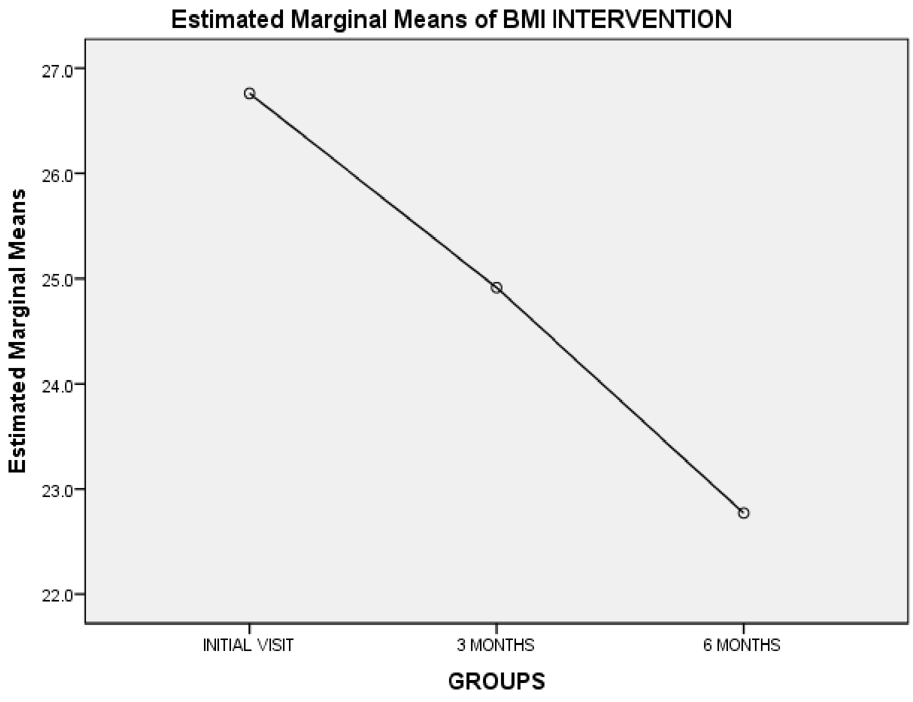

Figure 2: Estimated marginal means of BMI intervention.

There is a tremendous number of medications available for T2DM which aren't devoid of side effects, cost and health seeking behaviours [24,25] which sometimes hinders patient with T2DM from being compliant with therapy, Siminialayi and Eme-Chioma [18] averred that there are obviously an enormous number of therapies available for the treatment of type 2 diabetes mellitus, though some of these may not be readily available in our environment while others are still at developmental stages. This however, should not detract us from putting in place or adopting measures that will possibly reduce the prevalence of type 2 diabetes mellitus in our population. The evidence that the right diet can contribute to remission and normalization of patients health has been demonstrated by this study and was also affirmed by Pories, et al. [26], reaffirmed in 2017 by Schauer, et al. [6] and later by the Diabetes Remission Clinical Trial (DiRECT) study.

The principles of prevention and management in T2DM include frequent blood glucose monitoring, reduction in carbohydrate and Therapy adjustment. Blood glucose monitoring before and after meal will enable early recognition of glucose abnormalities and allow prompt action to prevent several diabetic complications.

A thirty percent drop in Fasting blood glucose was observed in the intervention group in this study (Table 5 and Table 9a). Lim, et al. found normalized in the diabetic group (from 92 ± 0.4 mmol/L to 5.9 ± 0.4 mmol/l, p = 0.003).

A reduction in calorie over several weeks to months may result in weight loss with a decrease in leptin production, decreased fatty acid infiltration into liver and muscles cells. All of these leads to weight loss and a fall in the mediators of inflammation. Western diet, antibiotics and other factors causes dysbiosis from disruption of the microbiome and a reduction in the production of short-chain fatty acid- butyrate that assists in blood sugar management [27]. Parker [28] averred that a high protein, low carbohydrate diet in patients with T2DM can achieve weight loss, reduced insulin requirements and reduced HbA1c level. Trapp, et al. [29] demonstrated that a high fibre-based diet helped to reverse diabetes despite no weight loss occurring implying the type of food consumed impacted blood sugar regulation. The BMI is also known as the Quetelet's index. The normal range is 18.5-24.9 kg/m^2, BMI values below 18.5 suggest underweight and/or malnutrition. From 25.0-29.9 is overweight, 30-39.9 is obese, while 40.0 and above is severe obesity. BMI, however, as a measure of excess weight does not differentiate lean body mass from fat [30]. Of the twenty-three participants (77%) in the dietary intervention group had a normal BMI at the end of 6 months of which 14 (61%) (p = 0.025) had remission of T2DM. This was associated with remission with weight loss of 5-10% (Table 6, Table 8a and Table 8b). Similar study by Lean, et al. [31] showed 25 (41%) remission in participants with 0-10 kg weight loss.

The limitations in this study are the small sample

Table 9a: ANCOVA Summary of the effect of MNT therapy on Waist circumference of T2DM patients.

Parameter	**MNT therapy on the Waist Circumference**			**F**	**P-value**	**Effect Size** □^{2}
	Initial Visit	**3 Months**	**6 Months**			
	Mean ± SD	Mean ± SD	Mean ± SD			
Waist Circumference	88.75 ± 6.47	82.98 ± 5.73	80.02 ± 6.74	7.435	**0 .001***	0.147

*Statistically Significant at P ≤ 0.05

Table 9b: Post-hoc (Bonferroni) summary of the effect of Intervention on Waist circumference of T2DM patients.

		BMI Intervention		
(I) GROUPS	**(J) GROUPS**	**Mean Difference (I-J)**	**Std. Error**	**P-value**
Initial Visit	3 Months	**5.767**	**2.301**	**0.042***
	6 Months	**8.723**	**2.300**	**0.001***
3 Months	Initial Visit	-5.767	2.301	**0.042***
	6 Months	2.956	2.299	0.606
6 Months	Initial Visit	-8.723	2.300	**0.001***
	3 Months	-2.956	2.299	0.606

*Statistically Significant at P ≤ 0.05

size and sustainability of the remission after 6 months of achieved remission. The study showed the feasibility and confirmed the durability over the study period by successfully linking the change observed in the intervention group to be responsible for remission when controlling for influences of standard of care (control group). Analysis of covariance for HbA1c (Table 8a and Table 8b); FBS (Table 7a and Table 7b); and BMI (Table 8a, Table 8b, Table 9a and Table 9b) all show evidence.

To sustain change is relatively difficult on a long term as daily life changes can phase away due to lack of proper support and negative environmental pressure. However, on the short-term lifestyle changes as with dietary intervention can be sustained if they are rigidly imposed or as with this study, participant got one call and 2 text messages per week follow up and remind them of the need do daily blood sugar test and chart and to adhere to study protocol. It also helped to monitor possibilities of complications in the groups. Another reason the study observed as a barrier to implantation of a dietary intervention program for T2DM was that it appeared to have no immediate economic benefit within the context of the teaching hospital where this study was done. Van Ommen, et al. [32] had similar finding in their study and thus concluded that the theory and practice differ and we face a multifactorial challenge that requires removing economic, social, psychological and biological barriers.

There is an urgent need for our health decision-makers at all levels to implement adopted policies and plans of action to halt the escalating trend and burden of Diabetes through effective primary care [33]. As this study clearly suggests for the remission of T2DM.

Conclusion

It is safe to say that the everyday food of a typical Nigerian can be managed significantly as medicine through reduction in calories for possible remission of T2DM as Poor Adherence from high cost of medication, medication fatigue and side effects are barriers to successful management of T2DM. This is a renewed call for the altruistic public, relevant stakeholders to ensure making feasible option as dietary and lifestyle interventions more known and available patients in this part of the world with T2DM to hope in the possibilities of remission of a once life-long disease.

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