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Type 2 Diabetes Mellitus Remission in Patients with Ideal BMI in Rivers State, Nigeria

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Method: Randomization was used to divide the sixty research participants into treatment (dietary caloric restriction intervention) and control (standard of care) groups that were matched. Samples were gathered for analysis at baseline, midline, and at the conclusion of the trial throughout the participants' 24-week follow-up period.

Keywords: type 2 diabetes, diet, intervention, hba1c, glycaemic control, remission, waist circumference and BMI.

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TYPE2DIABETESMELLITUSREMISSIONINPATIENTSWITHIDEALBMIINRIVERSSTATENIGERIA

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Result: In contrast to the outcome from the intervention group, which showed a considerable weight reduction after six months, the BMI in the standard of care group experienced a gradual decline in mean values (from 26.06 to 25.0), which was not statistically significant. Mean waist size reduced from 88.82 cm to 80.0 cm (p=0.001), and BMI dropped from 26.76 kg/m2 to 22.77 kg/m (p=0.001). After six months, the patients' HbA1c decreased from the initial visit, where the mean was 7.617, to mean =6.017. Within the intervention group, the mean fasting blood sugar decreased from a group mean of 7.97 on the initial visit to a mean of 5.35 after six months. Furthermore, this study demonstrated that just three of the 17 patients with perfect BMI in the standard of care group had a decrease in HbA1c of 6.5 or less, but in the intervention group, 61% of patients with ideal BMI had HbA1c of 6.5%. The difference that was noticed was statistically significant (p=0.025), nevertheless. Thus, following 6 months of management without the use of oral hypoglycemic medications, there is a strong correlation between a decrease in BMI and a decrease in HbA1c to a normal level in individuals with T2DM.

Conclusion: In keeping with the definition of remission, fourteen of the 23 participant who has normal BMI maintained normal HBA1c for 6 months. Normalizing BMI with caloric restriction is an effective means of controlling blood glucose and type 2 diabetes mellitus.

Keywords: type 2 diabetes, diet, intervention, hba1c, glycaemic control, remission, waist circumference and BMI.

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I. Introduction

When Type 2 Diabetes patients are in resource-restrained environments with little access to sustainable care, weight increase is linked to poor glycemic control from insulin resistance. Safer, locally accessible, and scientifically supported methods of managing their health become a priority when they lack effective access to medical treatment and medicines as a result of poverty and non-medication adherence. (Sokiprim et al, 2022). Targeted lifestyle therapies have been shown to be clinically beneficial and reasonably priced for the prevention and management of diabetes today.

The rise in T2DM over the past 50 years is strongly tied to lifestyle modifications. The number of those with T2DM has risen as our lives have changed to incorporate more processed meals and less physical activity (John et al., 2018). Non-communicable illnesses are becoming a worldwide scourge, affecting both those in and above poverty. Since Nigeria has the greatest prevalence and burden of diabetes in Sub-Saharan Africa, everyone in Nigeria must prioritize getting treatment (Chinenye et al., 2014). It is impossible to overstate the importance of natural antioxidants and nutrients in avoiding illness.

Diabetes caused just under 2 million deaths yearly, ranking as the sixth most common cause of death in the world in 2016. Africa will have a 109% increase in T2DM from 2013 to 2025, closely followed by the Middle East and North Africa with 96%. The estimated worldwide rise is 55%. (John et al., 2018). 33% of male children and 39% of female children born after 2000 will acquire T2DM. (2014) Wilmot and Idris Additionally, having T2DM makes you more likely to get Alzheimer's as you age. (Barbaallo and Dominguez, 2014).

Although diet and exercise are the first steps to successfully avoid and even manage diabetes without the use of medications, the main objective of dietary usage in treating T2DM is to lower risk factors and avert complications brought on by the condition. The idea that dietary and lifestyle choices might considerably help drive type 2 diabetes into remission is currently receiving mainstream support (John, 2018).

Since the majority of the proposed dietary therapies for T2DM are Western in origin and difficult for the average Nigerian to get or observe, it may be difficult to modify them for usage locally. In order to design a menu for T2DM individuals that complies with normal operating standards, this study aims to employ regional, easily accessible whole plant-based choices.

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 in management of non communicable diseases.

Finally, while many individuals may have access to food, they could not have the money to pay for medical treatment. For these people with T2DM, using meals they are currently accustomed to promote health and wellness would be very beneficial. These research on dietary adjustment (exclusively Nigerian foods) in T2DM haven't received much attention, yet the results will aid T2DM patients' health outcomes.

T2DM medications are not without dangers and negative effects (Siminialayi et al., 2006). When glycaemic management was improved for 3-5 years with pharmaceuticals, ADVANCE Collaborative Group (2008) and Ling et al. (2009) found that this did not lessen macrovascular consequences because of epigenetic alterations.

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 in the University of Port Harcourt Teaching Hospital, Rivers State, Nigeria.

II. Materials and Methods

a) *Research Approach*

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.

Sixty study participants were randomly assigned and matched evenly into the two groups (Standard of Care-Control and Dietary Intervention-Treatment). These individuals were randomized into matched control (standard of care) and treatment (dietary calorie restriction intervention) groups. They were known diabetics who attended a diabetes clinic and were followed up for 24 full weeks (August 2021 to February 2022). Throughout the trial, the control group and the intervention group both reported their FBS on a biweekly basis.

ANOVA was used to conduct a test of significance for each of the two sets of observations (within the control and intervention group). Then, to completely exclude the impact of variables on the treatment group, a more robust statistic with better experimental sensitivity, such as ANCOVA, was used to guarantee that significance in the treatment group is attributable to intervention (Kpolovie, 2010).

Microsoft Office Excel 2017 was used for the graphics, and Statistical Packages for Social Science (SPSS) version 22.0 was used for the statistical analysis. For the analysis of the data, the study used the following statistics: descriptive statistics for cleaning the data, stem-and-leaf plots and box plots for spotting and eliminating outliers, Kolmogorov-Smirnov tests, and histograms for determining normality. The research issues and study hypotheses were addressed using crosstab and frequency, ANOVA and ANCOVA, and significant variables were submitted to post hoc or pairwise comparison tests (i.e. Bonferroni test). The Mann-Whitney U test was used for independent samples (such as anthropometric characteristics) and the Wilcoxon signed-rank test was used for dependent samples (such as FBS) to examine the statistical significance of the differences between means. The cutoff point for statistical significance between means was chosen at 0.05. Using Pearson's linear correlation, the associations between the indices were assessed, with the level of statistical significance set at p 0.05 at 95% confidence.

b) *Recruitments*

Participants were chosen from among the diabetes patients who visited the University of Port Harcourt, Nigeria's General Outpatient and Diabetes Clinics. Patients had to be known diabetics, 18 years of age or older, not be using any herbal, conventional, or complementary medications in the two weeks before to the study's start, and not be taking any drugs that are known to affect pancreatic or kidney function. Additionally, patients with poorly controlled blood sugar at the most recent routine clinical check, BMIs of >26 kg/m2 and 45 kg/m2, patients with pre-existing co-morbidities or complications of diabetes, patients who were critically ill, and patients who were taking drugs that affected the mind were disqualified.

Each participant gave their agreement before the study's 60 participants were randomly assigned to the open label control (Standard of care) or intervention arms. The intervention group got a calorie-restricted meal made up of items that were cultivated nearby, whereas the control arm included diabetes patients who were taking at least one oral hypoglycemic medication. To make sure there was no statistically significant difference between the control and intervention groups, statistical tests were conducted.

All trial participants underwent clinical evaluations and assessments of adherence and morbidity once per month. At least once a week, all participants were phoned on their cell phones to check in and address any issues that came up as the research went along. Participants whose clinical symptoms worsened were taken out of the trial and started receiving complete pharmacological therapy under the care of an endocrinologist until their circumstances stabilized. Every participant underwent a self-reported fasting blood glucose test every two weeks. The study's endpoints were an FBS value that remained between 3.5 and 5.5 mmol/l for six months and a weight loss of 5% of body weight.

III. Results and Discussion

a) 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*

b) 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 6months 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 6months period.

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 *c) 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 6months period.

The One-way analysis of variance was conducted to investigate if there are significant mean differences on the clinical parameters (FBS, waist circumference and BMI) of T2DM patients subjected to Intervention over a 6months period. ANOVA results, presented in the above table, show significant mean differences for all the clinical parameters. There are significant mean differences on the clinical parameters (FBS, waist circumference and BMI) of T2DM patients subjected to Intervention therapy over a 6months period. Thus, the intervention had no significant effect on the Lipid profile of T2DM patients after six months.

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

Variables	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*

d) 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).

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)	0.237$^{\mu}$
Intervention	30 (100.0)	11/30 (36.67)	13/30 (43.33)	20/30 (66.67)	20-11 9 (30.0)	

μ=Fisher's exact p (recommended where cell values are <5)

Table 5: Percentage of Normal Body Mass Index (BMI) that had reduction in HbA1c to <6.5% within the Standard of Care (Control) and 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)				
Ideal (BMI)		12/30 (40.0)	15/30 (50.0)	17/30 (56.7)	
(HbA1c <6.5%)Remission		0 (0)	3/15 (20.0)	3/17 (17.6)	$0.025^{\mu *}$
Intervention	30 (100.0)				
Ideal BMI		11/30 (36.7)	16/30 (53.3)	23/30 (76.7)	
(HbA1c<6.5%)Remission		2/11 (18.18)	9/16 (56.25)	14/23 (60.87)	

**Statistically Significant at P ≤ 0.05; μ=Fisher's exact p (recommended where cell values are <5)*

e) *Assessing the effect of Individual on the FBS level of T2DM patients while controlling for the influence of standard of care*

The analysis of covariance was conducted to investigate the effect of Intervention group 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 6 show a significant difference in mean FBS level amongst treatment groups [$F(2, 86) = 6.790$, $p < .01$, partial $\eta 2 = .136$]. 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.

Table 6: ANCOVA Summary of the effect of Intervention on FBS level of T2DM patients

Parameter	Effect of Intervention 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*

f) *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 7, show a significant difference in mean FBS level amongst treatment groups [$F(2, 86) = 8.333$, $p < .01$, partial $\eta 2 = .162$]. 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.

Table 7: ANCOVA Summary of the effect of Intervention on BMI of T2DM patients

Parameter	Effect of Intervention on the BMI Control			F	P-value	Effect Size η^2
	Initial Visit	3 Months	6 Months			
	Mean ± SD	Mean ± SD	Mean ± SD			
BMI Intervention Group	26.76 ± 2.74	24.92 ± 2.73	22.77 ± 2.74	8.333	**0.001***	0.162

**Statistically Significant at P ≤ 0.05*

g) *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 8, show a significant difference in mean waist circumference (weight loss) amongst treatment groups [$F(2, 86) = 7.435$, $p < .01$, partial eta $\eta 2 = .147$]. 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.

Table 8: ANCOVA Summary of the effect of Intervention on Waist circumference of T2DM patients

Parameter	Effect of Intervention on the Waist Circumference			F	P-value	Effect Size η^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*

IV. Discussion

Even with a large number of T2DM medications being available on the market, non-adherence to therapy, side effects, cost, and poor health seeking behaviors are a major drawback for effective glycaemic control. (Jaja et al., 2016; Sokiprim et al., 2022; Siminialayi and Eme-Chioma, 2006) This occasionally makes it difficult for patients with T2DM to follow through to their treatment. An unhealthy diet like non-vegetarian with processed red meat, excess fats were even reported to have a 3.8times chance of having diabetes linked to their cause of death irrespective of age and sex. (Snowden 1985). Although this study considered age, sex and dietary patterns, it did not the health seeking behaviours and occupations of the participant. It showed a mean age of 54.74±11.29 years for intervention group with gender equally matched (see Table1).

The principles of prevention and management in T2DM include frequent blood glucose monitoring, reduction in calories etc. Blood glucose monitoring before and after meal will enable early recognition of glucose abnormalities and allow prompt action to prevent several diabetic complications. Particpants in this study had blood sugar monitored daily on self-assessment of daily glycaemic control. Tonstadetal. (2013) showed that appropriate diet was associated with weight reduction in patients at risk for T2DM when BMI was adjusted. The intervention group were on 1,200kcal per day in this present study. A UK study demonstrates that a weight loss program can result in type 2 diabetes remission even in those with a normal body mass index (BMI) by reducing body fat, notably in the liver and pancreas. Twenty participants with type 2 diabetes with a BMI of 27 kg/m2 or less participated in the ReTUNE (Reversal of Type 2 Diabetes Upon Normalisation of Energy Intake in Non-obese People) experiment. Participants had shed 9% of their body weight after a year. They observed reductions in liver fat, total triglycerides, and pancreatic fat, and their body fat considerably dropped, reaching the same level as individuals without type 2 diabetes. This was also shown to be associated by increases in insulin production and decreases in A1c and fasting plasma glucose levels, Furthermore, the study showed that T2DM has the same etiology and pathogenesis whether BMI is normal or elevated. This knowledge ought to have a significant impact on the recommendations doctors give to their patients. Encourage patients to lose weight is not very pleasant to a patient with T2DM however, this is one of the dramatic aspects about dealing with people in this group. The improvements in T2DM are seen with systematic intervention programs that result in considerable weight reduction (Katula et al., 2013; Mohammed et al., 2012). For the prevention and treatment of diabetes, targeted lifestyle interventions have been demonstrated to be both clinically and financially successful (Shurney 2012; Herman, 2015). The study 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 with and effect size of 0.13. (see Table 6). Furthermore, the study showed that twice the number of study participants in the intervention group had a drop in Fasting blood glucose (well controlled) throughout the study period compared to the control group in a ratio of almost 2:1. It is safe to document that the intervention had more efficacy at glycaemic control (see Table 4). Lim et al 2011 found normalized in the diabetic group (from 9.2±0.4mmol/L to 5.9±0.4 mmol/l, p=0.003). This finding were similar to finding in Pories et al. (1987), affirmed in 2017 by Schauer et al.; reaffirmed by the Diabetes Remission Clinical Trial (DiRECT) study and currently by Sokiprim et al (2022) using wholly Nigerian diet to achieve remission in T2DM patients. Similarly, the result showed substantive weight loss after six months of Intervention. This is revealed in the waist circumference mean which fell from 88.82cm to 80.0cm after six months, and BMI that dropped from 26.670 to 22.857kg/m^2 after six months (Table 3). The very small effect size of 0.16 for BMI shows no interference with the control (Table 7).

This study has provided proof that a healthy diet may help maintain good glycaemic control and restore patients' health to normal. A calorie reduction over a period of weeks or months may cause weight loss with a decline in leptin synthesis, a reduction in fatty acid infiltration into liver and muscle cells, and the potential for a legacy effect. This may be the cause of the outcome seen with the decrease in HbA1c after weight loss (see table 5). All of them cause weight reduction, a decrease in inflammatory mediators, and an increase in insulin sensitivity. Dysbiosis is brought on by the disturbance of the microbiome caused by the Western diet, antibiotics, and other factors, as well as a decrease in the synthesis of the short-chain fatty acid butyrate, which helps control blood sugar. Studies shows 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. (Trapp et al. 2010; Oputa and Chineye, 2015).

The study's observations of changes occurred quickly. The participant receiving one call and two texts each week as follow-up for rewards and long-term health education might be the cause of this. They were reminded to take daily blood sugar readings, keep a chart, and follow the research protocol during the calls, which served as the psychological support and interactions they needed to deal with worries during the study time (Akoko et al, 2022). Additionally, it assisted in keeping an eye on potential problems both inside and across groups. If long-term lifestyle interventions are not supported, sustainable improvements may be phased out due to a lack of an adequate support structure and unfavorable environmental factors, such as no immediate financial advantage to the hospital where the study was conducted. According to Van Ommen et al. (2017), the theory and practice are different, and we are facing a multifaceted dilemma that calls for removing obstacles on the basis of the economy, society, psychology, and biology.

The study provides some evidence that weight loss can improve glycaemic control and insulin sensitivity, returning to normal blood sugar levels in patients with T2DM and caloric restrictions to 1,200 kcal per day. As a result, doctors are encouraged to emphasize the need for selfcare in these patients once again. The limited sample size and persistence of the glycaemic control after achieving blood sugar control for six months are the study's shortcomings. When standard of care variables were taken into consideration, the study demonstrated the viability of diet in weight loss and glycemic management (control group). Evidence may be seen in the analysis of covariance for the FBS (Tables 6), BMI (Tables 7) and waist circumference (Tables 8). It is advised to conduct more research to determine the longevity of the Nigerian diet's ability to maintain remission and ameliorate organ effects of poorly controlled T2DM

V. Conclusion

In keeping with the definition of remission, fourteen of the 23 participant who has normal BMI maintained normal HBA1c for 6 months. Normalizing BMI with caloric restriction is an effective means of controlling blood glucose and type 2 diabetes mellitus.

The Authors of this study declares *no conflict of interest.*

The authors also acknowledge the limitations with the study as some results were self-reported by study Participants.

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