COMPARISON OF THE EFFECT OF STRUCTURED LIFESTYLE MODIFICATION VERSUS VERBAL ADVICE ONLY ON BLOOD PRESSURE CONTROL AMONG PRE-HYPERTENSIVE ADULTS IN A TERTIARY HOSPITAL IN NORTH CENTRAL NIGERIA.

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ABSTRACT:

Background: Results from several clinical trials show that comprehensive behavioural intervention programs improve lifestyle behaviors and lower blood pressure. The study compared the effect of structured lifestyle modification versus verbal advice only on blood pressure control among prehypertensive adults presenting in the GOPD of JUTH.

Study Design/Setting: The study was a randomized study involving prehypertensive adults aged 20 years and above presenting in GOPD of JUTH.

Methods: Participants were consecutively selected and randomized into two groups, a structured lifestyle modification group (Group A) and a verbal advice only group (Group B). Group A was offered a structured lifestyle modification counselling while routine verbal advice only was offered to group B. Data were collected about patients' socio-demographic, medical and lifestyle habits that included dietary and exercise history. Physical examination included blood pressure measurement. Participants were followed up monthly for twelve weeks during which blood pressure measurement was routinely carried out and changes in their lifestyle habits reported. The primary outcome was reduction in BP. The means at 95% confidence intervals of the blood pressure values of the two groups were determined using paired t-test analysis. Data were analyzed on an intention to treat basis. A p-value of <0.05 was considered significant in all analyses.

Results:

The mean systolic blood pressure reduction in group A after 12 weeks was 3.61 mmHg (1.52, 5.26; 95% CI) while the mean diastolic pressure reduction after the same duration was 0.44 (-2.25, 1.97, 95%). Paired t-test analysis revealed a statistically significant difference in the mean reduction in SBP at the end of the study,{t(31)2.23, p=0.02}. The mean reduction in diastolic blood pressure on completing the study was however not significant, {t(31)0.9, p=0.17}.

The mean systolic blood pressure reduction in group B after 12 weeks was 2.75mmHg (-1.23, 5.23, 95% CI) while the mean diastolic pressure reduction after the same period was 0.38 (-2.26, 1.98, 95% CI). Paired t-test analysis revealed no statistical difference in the mean reduction in SBP and DBP at the end of the study - {t(29)1.39, p=0.062}versus {t(29)0.92, p=0.14}

Conclusion: Findings from the study show that individuals with pre-hypertension can make and sustain, during a period of 12 weeks, structured multiple lifestyle modifications which can significantly control or reduce systolic blood pressure. There is therefore a need for improved lifestyle intervention programs, including those appropriate for delivery in the clinical setting, that enable individuals with or at risk for hypertension to adopt long-term healthier lifestyles

Keywords: Structured counselling, Verbal Advice, Lifestyle modification, Prehypertension, Blood pressure,

Introduction:

Prehypertension is defined as systolic blood pressure of (SBP) 120mmHg to 139mmHg or diastolic blood pressure (DBP) of 80mmHg to 89mmHg, based on "two or more properly measured seated blood pressure (BP) readings on each of two or more office visits".[1] If SBP and DBP fall into different categories, the category associated with the higher of the two pressures is applied.

Management of prehypertension by lowering BP into a more optimal range can be expected to lower morbidity and mortality risks. The risks associated with prehypertension are in part related to the tendency of BP to increase with age in industrialized societies. Thus, prehypertension is a precursor of clinical hypertension and consequently of the cardiovascular disease (CVD) and renal risks associated with elevated BP (ie, SBP $\geq$ 140 or DBP $\geq$ 90 mm Hg). In addition, the relationship between BP and CVD risk is continuous over the whole range of BP, and therefore, prehypertension itself is associated with BP-related morbidity and mortality. Thus, the goals of treating prehypertension are to prevent hypertension and to reduce the excess CVD risk associated with BP in this preclinical range.[3]

Current recommendations for the prevention and treatment of high BP emphasize non-pharmacological therapy, also termed "lifestyle modification". JNC-7 recommends lifestyle modification for all patients with hypertension and prehypertension.[4-6] These modificationsinclude:

1. Reducing dietary sodium to less than 2.4g per day
2. Increasing exercise to at least 30 minutes per day, four days per week
3. Limiting alcohol consumption to two drinks or less per day for men and one drink or less per day for women. One standard drink contains 10g of alcohol e.g one bottle of beer = 2.6 standard drinks
4. Following the dietary approaches to stop hypertension (DASH) eating plan (high in fruits, vegetables, potassium, calcium and magnesium, low fat and salt)
5. Achieving a weight loss goal of 4.5kg or more
6. Cessation of smoking (not recommended in JNC 7).

It is however unclear if these recommendations are more effective when a structured lifestyle modification is instituted rather than just verbal advice. The aim of this study therefore, is to compare the effect of structured lifestyle modification versus verbal advice on the management of prehypertension among adults.

Methodology:

The study was conducted between February to May 2012 among individuals aged 20 years and above presenting in the General Outpatients Clinic (GOPC) of Jos University Teaching Hospital (JUTH). The study was a comparative randomized study, comprising an intervention group (Group A) that received structured counseling on lifestyle modification and a control group (Group B) that was only advised verbally on lifestyle modification. Using the Power of 80% and a 95% confidence level, the sample size for means was used for the study and 62 participants were recruited, 32 in group A and 30 in group B. Patients with a systolic blood pressure of 120mmHg to 129mmHg and/or diastolic blood pressure of 80mmHg to 89mmHg were included. Information collected included the participants' socio-demographic data, history of alcohol ingestion, hypertension and smoking, current exercise activity and a 24-hour dietary recall.

Blood pressure readings were recorded to the nearest even number and the mean of three recordings computed. All patients in the group A were counseled and advised concerning diet and exercise using a structured format. They were given written diet and exercise instructions in either English or Hausa and asked to keep an exercise diary. They were asked to return for follow up at four, eight and twelve weeks. At each follow up visit, the instructions were reviewed and repeated according to the structured format in order to reinforce them. The blood pressure was recorded at each follow up visit as described above. The duration of exercise each day was also recorded. Group B did not receive any structured counseling concerning diet and exercise. They were only advised on exercise and a healthy diet. They were also followed up at four weeks, eight weeks and twelve weeks at which time their blood pressures were recorded. The pieces of advice verbally given were also reinforced at each follow up visit.

Data were analyzed using Epi Info version 3.5.3 (Centres for Disease Control and Prevention, Atlanta, Georgia, USA).[7] Background descriptive analysis was done to compare both groups. The primary outcome variable of interest was blood pressure. The means at 95% confidence intervals of the blood pressure changes were determined using

the paired t-test and the proportions of categorical variables were compared using the $\chi 2$ test or the Fisher's exact test.

Results:
Sixty two subjects fulfilled the inclusion criteria and participated in the study – 30 in the control group and 32 in the intervention group. Fifty two completed follow-up (83.9%) while 10 (16.1%) did not complete the study. Of the 10 that did not complete the study, four were in the control group while six were in the intervention group. Analysis was carried out on all participants on an Intention to treat basis.

Socio-demographic Characteristics:

	Group B N=30	Group A N=32	p value
Mean Age (years)	39.7±9.3	41.3±9.1	p=0.57
Age category(years)			
20-29	4	6	
30-39	10	12	
40-49	11	9	
50-59	4	3	
60-69	1	2	
Gender:			P=0.69
• **Male**	8	10	
• **Female**	22	22	
Educational Level:			P=0.93
• **None**	13	13	
• **Primary**	3	5	
• **Secondary**	8	8	
• **Tertiary**	6	6	
Marital Status:			P=0.20
• **Married**	27	25	
• **Single**	3	7	
Religion:			P=0.66
• **Christian**	20	23	
• **Muslim**	10	9	
Ethnicity			p=0.65
• **Indigenous People**	18	21	
• **Non-Indigenous People**	12	11	

Lifestyle Habits:

Alcohol consumption: At baseline, participants who had a current history of alcohol consumption in the form of beer, wine, whisky and local brew, of more than two standard drinks per day and a duration of at least one year, were as follows: Twelve (19.4%) in group A and 10 (17.1%) in group B. Post intervention, six (9.7%) participants in group A and eight (12.9%) participants in group B had reduced alcohol consumption, (p=0.46).

Cigarette smoking: At baseline, only one (3.3%) of the participants in group B had a current history of smoking at least two sticks of cigarette a day for at least a year. The intervention group had one (3.1%) subject who had a similar but previous history of cigarette smoking.

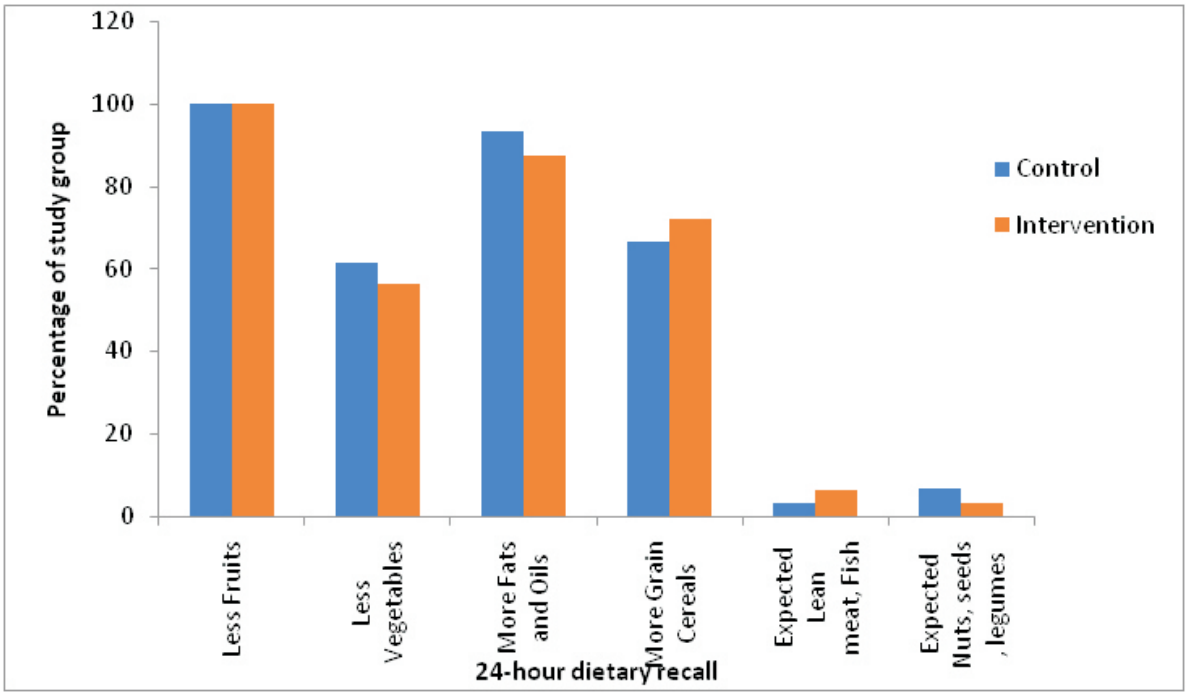
Post Intervention, the only participant who had a current history of smoking neither stopped smoking nor reduced the quantity of cigarettes smoked per day.

Exercise: At enrollment, 15 (24%) of the total participants were involved in some form of regular aerobic exercise, eight (25%) in group A and seven (23.3%) in group B. Group A exercised for an average of two days per week for an average of 39.8 minutes per day while group B exercised for an average of two days per week for an average of 36.7 minutes per day. At the end the most common exercise undertaken was brisk walking in both groups, seven (87.5%) participants in group A and five (71.4%) participants in group B.

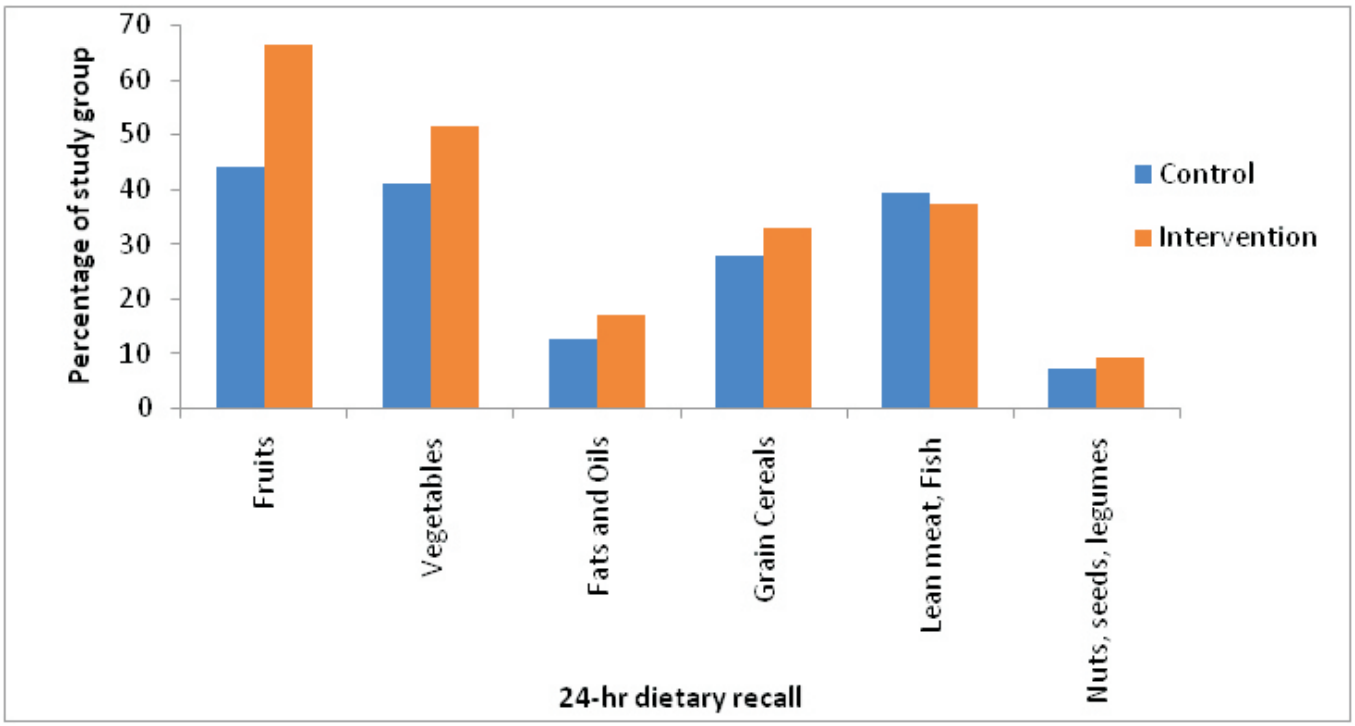
At the end of the study, 48 (77%) of the total study participants were involved in some form of regular aerobic exercise, 27 (56.25%) participants from group A and 21 (43.75%) participants from group B (p=0.18). Group A exercised for an average of four days per week for an average of 38 minutes per day while group B exercised for an average of three days per week for an average of 35 minutes per day. The most common exercise undertaken was brisk walking in both groups, 17 (53.13%) participants in group A and 15 (50%) participants in group B (p=0.81). Jogging, skipping, climbing staircases, cycling, tennis, football and other forms of aerobic exercises made up the remaining.

Dietary pattern: Based on a 24 hour dietary recall and estimated from the average equivalent of the DASH diet, the dietary pattern of participants in the study groups were compared. All patients in both groups had less than the expected daily servings of fruits with 56.4% and 61.3% of participants having less than the expected daily servings of vegetables in group A and group B respectively. Of the total study participants, 87.5% of the participants in group A had more than the expected daily servings of fats and oils versus 93.3% in group B while 71.9% of group A had more than the expected daily servings of grain and grain cereals versus 66.6% in group B. Only 6.25% of group A had the expected value for lean meat, poultry or fish against 3.33% in group B. Only 3.13% of group A had some form of nuts, seeds or legumes at enrollment versus 6.67% in group B. All participants in the study group were taking more than the expected daily servings of more than one teaspoon full of salt either in prepared meals or on the table or both.

On completing the study, 66.4% of group A had the expected daily servings of fruits against 44.2% of the control group (p=0.08). Groups A and B comprised 51.4% and 41.2% of participants who had the expected daily servings of vegetables respectively (p=0.43). In group A, 17.3% had the expected daily servings of fats and oils versus 12.7% in group B (p=0.30). Group A was made up of 32.9% who had the expected daily servings of grain and grain cereals which was comparable with 27.8% in group B (p=0.51). Only 37.3% of the control group A had the expected servings for lean meat, poultry or fish against 39.4% of group B (p=0.84). On completion of the study, 9.4% of group A had some form of nuts, seeds or legumes versus 7.3% of group B (p=0.94). All participants in both study arms had reduced their salt intake at the end of the study.



Baseline dietary pattern of the control and intervention groups based on a 24 hour dietary recall



Post-intervention dietary pattern of the control and intervention groups based on a 24 hour dietary recall.

Baseline Blood Pressure: The mean systolic blood pressure of the group A was 128.84±6.83mmHg and 130.25±6.39mmHg for group B (p=0.42). The mean diastolic blood pressure of groups A and B were 82.41±5.83mmHg and 82.79±5.11mmHg (p=0.94) respectively.

Blood Pressure Changes in Groups A and B:

Blood pressure changes within Group A: For group A, 23.3% of participants had at least a 5% reduction of systolic blood pressure, while 11.25 % had at least a 5% reduction in diastolic blood pressure. The mean systolic blood pressure reduction in the intervention group after 12 weeks was 3.61 mmHg (1.52, 5.26; 95% CI) while the mean diastolic pressure reduction after the same duration was 0.44 (-2.25, 1.97, 95%). Paired t-test analysis revealed a statistically significant difference in the mean reduction in SBP at the end of the study, {t(31)2.23,

p=0.02}. The mean reduction in diastolic blood pressure on completing the study was however not significant, {t(31)0.9, p=0.17}. Six participants attained normal blood pressure values.

Blood pressure changes within group B: In group B, 14.25% of the participants had at least a 5% reduction in systolic blood pressure while 9.5% had at least a 5% reduction of diastolic blood pressure. The mean systolic blood pressure reduction of the control group after 12 weeks was 2.83 mmHg (-1.23, 5.23, 95% CI) while the mean diastolic pressure reduction after the same period was 0.38 (-2.26, 1.98, 95% CI). Paired t-test analysis revealed no statistical difference in the mean reduction in SBP and DBP at the end of the study - {t(30)1.39, p=0.062} versus {t(30)0.92, p=0.14}. Two participants had normal blood pressure values at the end of the study.

Discussion:

Data from seminal studies have demonstrated the effectiveness of diet and other lifestyle changes in lowering BP.[8,9] The Hypertension Prevention Trial,phases I and II of the Trials of Hypertension Prevention (TOHP),PREMIER trial,and TOHP long-term follow-up datashow that in participants with prehypertension and hypertension, lifestyle intervention can help control BP and reduce the worsening of high blood pressure levels.[10,11]Prehypertension status was the principal blood pressure–related outcome of this study at 12 weeks and the present findings, like these other studies confirm that structured therapeutic lifestyle changes can be an effective tool to help control prehypertension. There was a statistically significant difference in the systolic blood pressure changes at the beginning and the end of the study within the structured lifestyle modification group (group A). Although a change in systolic blood pressure was statistically significant in group A, greater reductions in blood pressures were noted in group A than in group B suggesting that a structured approach in changes in lifestyle habits may be more beneficial and of higher clinical relevance. The prevalence of systolic prehypertension at 12 weeks in group A and group B were 81.25% and 93.33% respectively, corresponding to control rates of 18.75% and 6.67% respectively. These control rates do not compare favourably with the PREMIER studies where the best rates of blood pressure control (lowest prevalence of elevated blood pressure) and the greatest reductions in blood pressure were observed at six months.[12,13] A longer duration of study of at least six months may have been comparable with the PREMIER studies.

A few studies have observed that the cumulative effect on blood pressure when several intervention components are implemented simultaneously is less than what would be predicted based on their separate effects implemented alone.For example, weight loss, that involves exercise, is known to be highly effective in reducing blood pressure, and the added effect of the DASH diet may be lessened under conditions of weight loss; similar results were seen when the DASH diet was consumed in the context of a reduced salt (low-sodium) diet.[14,15] Nevertheless, recommendations for blood pressure control should include all lifestyle changes that are known to improve blood pressure status when implemented alone, because some degree of additivity is probable as was observed in this study.

Conclusion: The lifestyle habits that included dietary and exercise pattern, observed among participants showed that, compared to the group B, participants in group A demonstrated better results with more positive outcomes in terms of improved systolic and diastolic blood pressures. Overall, findings from this study show that individuals with prehypertension can make and sustain, during a period of 12 weeks, multiple lifestyle modifications which can control systolic blood pressure and reduce the risk for cardiovascular and other chronic diseases.

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