Original Article

Effects of a Physician-Led Primary Prevention For Cardiovascular Risk Reduction Among Institutional Workers: Evidence From a Randomized Control Trial

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ABSTRACT

Cardiovascular diseases (CVDs) account for over one-third of adult deaths in Nigeria, with a rising burden among individuals under 60 years. Primary prevention remains a cost-effective approach to reduce CVD risks. To evaluate the effectiveness of a physician-led primary prevention programme in reducing cardiovascular risks among vulnerable workers. A two-arm randomized controlled trial was conducted among 223 civil servants with moderate-to-high CVD risks, selected from 1,778 screened participants across 32 government institutions. Participants were randomized into an intervention group (n=118) that received physician-led, WHO-based total cardiovascular risk management, including risk assessment, lifestyle counselling, and pharmacologic control, and a control group (n=105) that received usual care from their primary caregivers. Participants were followed up for six months. The primary outcome was change in the 10-year absolute CVD risk score (Framingham tool). Secondary outcomes included changes in systolic blood pressure (SBP), fasting blood sugar (FBS), and body mass index (BMI). Data were analyzed using paired and independent t-tests at $\alpha=0.05$. Baseline mean age was similar across groups (52±6 years). The intervention group showed a greater FBS reduction (-19.3 mg/dl; 95% CI: -36.7 to -1.9; $p<0.05$) and modest change in mean CVD risk score (-0.24%; 95% CI: -2.1 to 1.6; $p>0.05$) compared to controls. Significance within-group improvements were observed in SBP (-5.0 mmHg), FBS (-9.8 mg/dl), and BMI (-0.8 kg/m²) in the intervention arm. Although changes in overall CVD risk were not statistically significant, the physician-led intervention effectively improved major modifiable risk factors, supporting its potential for scalable workplace CVD prevention in Nigeria.

Keywords: Cardiovascular risk, Primary Prevention, Physician-led

INTRODUCTION

Cardiovascular diseases (CVDs) are the leading cause of death globally, accounting for an estimated 19.8 million deaths annually and representing nearly one-third of all global deaths[1,2]. The Global Burden of Disease Study found that the prevalence of CVD continues to rise in both high- and low-income countries, driven by unplanned urbanization, demographic transitions and lifestyle changes[3,4]. The World Health Organization (WHO) recognizes CVD prevention as a central focus of its Global Action Plan for the control of noncommunicable diseases (WHO, 2020). The plan recommends primary prevention and integrated risk management as cost-effective strategies for a more effectual outcome[5,6].

While CVD has historically been regarded as a disease of affluent nations, its burden is now disproportionately borne by low- and middle-income countries (LMICs), where more than 75% of CVD deaths occur[7]. Sub-Saharan Africa (SSA) in particular faces a double burden of disease, contending with high rates of infectious diseases, alongside the rising epidemic of noncommunicable diseases[8]. The prevalence of hypertension, the most important modifiable risk factor for CVD, is among the highest globally in SSA, affecting up to 46% of adults in some populations[9]. In Nigeria, CVD is a major contributor to morbidity and mortality, accounting for 36% of deaths among adults younger than 60 years and largely driven by poorly controlled hypertension, diabetes, obesity, and dyslipidemia[10,11].

The INTERHEART study, a case-control study among 29,972 participants across 52 countries, demonstrated that a small set of modifiable risk factors, including hypertension, diabetes, smoking, obesity, and unhealthy diet, accounted for most of the disease burden of myocardial infarction[12]. This finding highlights the importance of integrated, population-wide strategies that

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address multiple risk factors simultaneously, rather than focusing on single-risk disease management. However, evidence on the effectiveness of primary prevention interventions in LMICs, including Nigeria, remains limited and mixed[13,15]. The few interventions targeted isolated risk factors, while interventions with absolute cardiovascular risk reduction as outcome, relied more on non-physician-led models[15,].

This study, therefore, evaluated the effect of a physician-led, WHO-recommended primary prevention care model on cardiovascular risk reduction among moderate- and high-risk civil servants in Ondo State, Nigeria.

MATERIALS AND METHODS

Study Setting

The study was carried out in Akure, the capital city of Ondo State. Ondo State is in the southwest of Nigeria. It has an estimated population of 5.8 million inhabitants across its 18 local government areas. Approximately 15% of the population resides in Akure, the State capital. The state's health system consists of 928 health facilities, of which 629 (67.8%) are public, comprising primary, secondary and tertiary health facilities. However, human resource availability remains limited, with a doctor-to-population ratio of 1:7,666. The prevalence (23.9%) of CVD risk among public service workers in the State is high

Study design

This study was a parallel-group, two-arm randomized controlled trial (RCT) with an intention-to-treat framework and a follow-up period of six months. The study comprised of two parts: Screening of the civil servants to identify medium to high-risk CVD persons, and the RCT, which had three distinct phases: pre-intervention screening and recruitment, six months of the intervention, follow-up, and post-intervention evaluation.

Study Population

The study participants were selected from the Ondo State civil service, a structured workforce of more than 50,000 employees across different ministries, departments, and agencies in Akure. The civil servants were selected as the study population because of their stability, sedentary work patterns, and high representation of middle-aged adults who generally are at greater risk of CVD. Participants of the CVD screening were permanent civil servants aged ≥18 years who consented to the exercise. Exclusion criteria included pregnancy, lactation, prior cardiovascular events (e.g., stroke, myocardial infarction), or very high risk (≥30%) requiring immediate specialist care

Study Variables

CVD Screening: The screening was conducted using the WHO STEP-wise approach to surveillance of NCD risk factors, which involved a combination of questionnaires, anthropometric measurements, and biochemical assessments. The questionnaire comprised sections on sociodemographic details, lifestyles and behaviours, medical histories of high blood pressure, diabetes, high total cholesterol, cardiovascular diseases and perceived life stresses. The anthropometric measurements taken were blood pressure, height, weight, waist and hip circumferences, as well as heart rates. The only biochemical measurement taken in the study was blood sugar.

Cardiovascular risk was estimated using the Framingham non-laboratory risk assessment tool, which integrates age, sex, smoking status, blood pressure, diabetes status, and body mass index (BMI). Risk scores were categorized as low (<10%), moderate (10–19.9%), high (20–29.9%), or very high (≥30%). In total, 1,778 workers were screened, and those with moderate or high CVD risk were eligible for enrollment.

Sample size calculations

The sample size was determined at two levels, firstly for the screening stage to determine the prevalence of moderate and high CD risks among the public servants and to recruit eligible participants from among them for the intervention study. Secondly, the sample size to test the effectiveness of the primary prevention model used as the intervention.

The sample size was determined using the formula for comparing two means in a superiority trial, using a prevalence of 10-year absolute moderate and high cardiovascular risk among public servants set at 50%, precision of 5%, and confidence interval of 95% and design effect of 2; a minimum sample size of 768 was calculated.

The sample size was adjusted by a factor of 2.5 to increase the chance of recruiting the appropriate number of participants with moderate to high 10-year absolute cardiovascular risk for the intervention. Therefore, the sample size of 1920 pre-intervention was obtained for the CVD screening stage.

Sample size for the intervention stage was calculated using standard formulas for continuous outcomes, assuming an expected mean effect size of 5%, statistical power of 80%, and a two-sided significance level of 0.05. A minimum of 188 participants (94 per group) was required. To account for a possible 20% attrition rate, the target sample size was increased to a total of 223 participants.

Randomization

Eligible participants were randomized into intervention and control groups in a 1:1 ratio using a computer-generated sequence of random numbers. Randomisation was stratified by sex and age group to ensure comparability between arms. Allocation concealment was maintained until the point of assignment, and participants were informed of their group only after enrollment.

Intervention arm

The intervention arm received physician-led care guided by WHO protocols for cardiovascular risk management. This comprised three main components: Cardiovascular risk assessment using the Framingham tool at baseline and endline. Lifestyle modification counselling, including individualized advice on diet, physical activity, smoking cessation, and moderation of alcohol consumption. Finally, pharmacological treatment as indicated, such as antihypertensives, antidiabetics, and statins, following WHO guidelines.

The intervention was delivered by a multidisciplinary physician team (cardiologist, endocrinologist, and a medical officer in the Department of Medicine) during structured clinic visits every four weeks over six months. Meanwhile, the control group continued with their usual care, provided by their personal healthcare provider, which

essentially comprised the traditional single risk management approach. The research team did not meet the control group again until the endline assessment.

Outcome Measures

The **primary outcome** was the change in the estimated 10-year absolute cardiovascular risk score from baseline to six months. Risk was calculated using the validated **Framingham non-laboratory prediction tool,** which incorporates age, sex, systolic blood pressure, body mass index, smoking status, and diabetes status.

Secondary outcomes were changes in individual cardiovascular risk factors over the six-month follow-up period. These included: **Blood pressure:** systolic and diastolic blood pressure (mmHg), measured using a standardized automated sphygmomanometer after participants had rested for at least five minutes. Three readings were taken one minute apart, and the average of the last two was recorded. **Fasting blood glucose (mg/dL):** assessed after an overnight fast using a calibrated glucometer. **Body mass index (BMI, kg/m^2):** calculated as weight in kilograms divided by height in meters squared, with weight measured to the nearest 0.1 kg and height to the nearest 0.1 cm. **Waist-to-hip ratio:** measured with a non-stretch tape; waist circumference was taken midway between the lowest rib and iliac crest, and hip circumference at the widest part of the buttocks. All measurements were obtained at **baseline and six months** using standardized protocols, with trained research staff ensuring quality control and consistency.

Although not part of the outcome measure, it may be worth mentioning that two of the participants in the usual care group died from CVD, specifically hemorrhagic stroke, while another two developed diabetic complications and were consequently censored.

Statistical analysis

Data were analyzed using STATA version 18. Continuous variables were summarized as means with standard deviations, while categorical variables were presented as proportions. Baseline comparability between groups was assessed using independent t-tests and chi-square tests.

Primary and secondary outcomes were analyzed on an intention-to-treat basis. Within-group changes were examined using paired t-tests, while between-group differences were assessed with independent t-tests. Logistic regression was used to identify predictors of CVD risk reduction after adjusting for age, sex, and baseline risks. Intervention effectiveness was expressed as mean risk reduction, absolute risk reduction, and number needed to treat (NNT). Missing data were handled using the last observation carried forward (LOCF) method. A p-value <0.05 was considered statistically significant.

Ethical considerations

Ethical approval was obtained from the Ondo State Health Research Ethics Committee (Reference: OSHREC/28/06/2017004). Written informed consent was obtained from all participants prior to screening and randomization. Confidentiality of participant information was strictly maintained by de-identifying data. Participants in the control group identified with high-risk conditions requiring urgent treatment were referred appropriately for care.

RESULTS

Participant Flow and Baseline Characteristics

A total of **1778** individuals were screened for eligibility, of whom **1494 were excluded on account of not being eligible based on their low absolute cardiovascular risk score.** Sixty-one of the eligible participants did not show up for the randomization. Therefore, the remaining **223 participants** were randomized into the intervention arm **(n = 118)** and the control arm **(n = 105).** At six-month follow-up, **89%**in the intervention group and **88%** in the control group completed the study and were included in the final analysis(Figure1).

The mean age of participants at baseline in the intervention and control arms was 52.06.7 years and 52.35.0 years, respectively, and **35.2%** were male. Other baseline sociodemographic and clinical characteristics were broadly similar between the two study arms (Table 1-3).

Primary Outcome

At six months, the intervention group showed a **0.4 ± 0.6** change in the 10-year absolute cardiovascular risk score compared with **0.5 ± 0.4** in the control group. The between-group absolute cardiovascular risk reduction was **0.1%, 95% CI** -2.15 -1.67, **p = 0.96** (Table 4) Within-group analysis did not show a statistically significant reduction in cardiovascular risk score either in the intervention group (0.4%, 95% CI -0.8 – 1.7, **p = 0.4**), or the control group **(0.5%,** 95% CI -0.4 – 1.4, p=0.3) (Table 5).

Secondary Outcomes

Mean systolic blood pressure decreased by 5 **mmHg** in the intervention group versus **8.6 mmHg i**n the control group (**p0.05**). Diastolic blood pressure changes were **2.5 vs 3.5 mmHg (p 0.05)** in intervention and control arm respectively. **Fasting blood glucose levels showed a reduction of 9.8 mg/dL in the intervention group compared to an increase of 3.2 mg/dL in the control group. BMI** declined by **0.8 kg/m^2** in the intervention group versus **0.2 kg/m^2** in the control group. The mean waist-to-hip ratio did not change in either group (Table 6).

Number Needed to Treat

The number needed to treat (NNT) to achieve one case of cardiovascular risk reduction was **10** persons with either moderate to high absolute cardiovascular risk using the WHO primary prevention model.

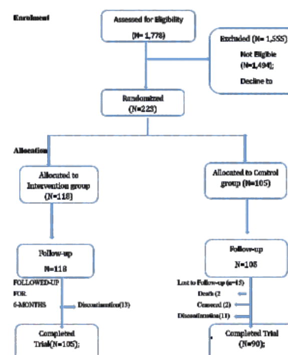

Fig 1: Study Randomization and Attrition adapted from CONSORT (Moher *et al.,* 2010; Bolarinwa, 2016)

Table 1: Group Equivalence of Socio-demographic Characteristics of Participants at Baseline Using Chi Square Test

Variable	Categories	Physician-led Care Freq. (N =118)	Physician-led Care Percent (%)	Usual Care Freq. (N =105)	Usual Care Percent (%)	Test Statistics	p-Value
Age (years)	<49	40	33.9	27	25.7	6.66	0.08
	50 - 54	36	30.5	47	44.8		
	55 -59	33	28.0	28	26.7		
	>60	9	7.6	3	2.9		
Mean Age (SD)		52.0(±6.7)		52.3(±5.0)			
Sex	Male	48	40.68	47	44.76	0.38	0.58
	Female	70	59.32	58	55.24		
Educational Status	Primary	11	9.32	5	4.76	1.90	0.39
	Secondary	15	12.71	16	15.24		
	Tertiary	92	77.97	84	80.00		
Marital Status	Married/Living with Spouse	104	88.14	96	91.43	0.65	0.42
	Not Married/ Not Living with Spouse	14	11.86	9	8.57		
Employment Grade level	Junior Staff	12	10.17	14	13.33	0.56	0.76
	Middle Level Staff	43	36.44	36	34.29		
	Senior Level Staff	63	53.39	55	52.38		
Average Monthly income in NGN	<37,950	35	29.66	25	24.03	4.98	0.29
	37,960 - 106,950	43	36.44	32	30.77		
	106,960 - 220,800	20	16.95	28	18.27		
	>220,800	20	16.95	19	20.21		

Table 2: Group Equivalence of Behavioral Characteristics of Participants at Baseline Using Chi Square Test

Variable	Categories	Physician-led Care Freq. (N=118)	Physician-led Care Percent (%)	Usual Care Freq. (N=105)	Usual Care Percent (%)	Test Statistics	P-Value
Alcohol Use	Current consumer	25	21.55	28	26.67	0.791	0.37
	Never use	91	78.45	77	73.33		
Smoking Status	Current smokers	5	5.10	5	6.10	0.084	0.77
	Never smoke	93	94.90	77	93.90		
Physical Exercise (PE) habits	Engage regularly in PE	59	50.00	51	48.57	0.045	0.83
	Does not engage in PE	59	50.00	54	51.43		

Table 3: Group Equivalence of Metabolic Characteristics of Participants at Baseline Using and Independent t-test Statistics

Variable	Physician-led Care (n=118) Mean	Physician-led Care (n=118) Standard Deviation	Usual Care (n=105) Mean	Usual Care (n=105) Standard Deviation	Test Statistics	P-Value
Fasting Blood Sugar(mg/dl)	98.8	33.5	102.2	32.4	-0.384	0.65
Systolic B.P (mmHg)	142.6	22.7	149.7	24.8	-2.25	0.99
Diastolic B.P (mmHg)	89.6	12.5	90.7	13.1	-0.618	0.73
BMI (Kg/m^2)	30.1	5.5	28.9	5.9	1.489	0.07
Waist/Hip Ratio (WHR)	0.91	0.06	0.92	0.09	-1.079	0.86

Table 4: Mean Difference of Between Group Treatment Effect of Intervention on the Primary Outcome Variable Using Independent T-test

Variable	Physician-led (n=118) Mean difference (SD)	Usual Care (n=105) Mean difference (SD)	Between Groups mean difference (95% CI) OR Absolute Risk Reduction (ARR)	t- Statistics	p-Value
10-year Absolute CVR	0.4(0.6)	0.5(0.4)	0.1	-0.05	0.96

Table 5: Within Group Effects of Intervention on the Primary Outcome Variable among Treatment and Control groups Using Paired t-test Statistics

Variable	Category	Physician led Care (n=118) Mean (SD)	Mean Diff.	Test Statistics (df)	p-Value	Usual care (n=105) Mean (SD)	Mean Diff.	Test Statistics (df)	p-Value
10-year Absolute CVR	CVR*	14.6 (6.9)	0.4	0.708	0.48	14.9 (6.7)	0.5	1.099	0.27
	EndCVR	14.2 (7.4)				14.4 (7.1)			

*Intervention Baseline

Table 6: Within Group Effects of Intervention on Secondary Outcome Variables among Treatment and Control Groups Using Paired t-test

Variable	PHYSICIAN-LED CARE (n=118) Mean (SD)	Mean diff	Test Stat. (df)	p-Value	USUAL CARE (n=105) Mean (SD)	Mean diff	Test Stat. (df)	p-Value
Blood Pressure								
SBP*	142.6 (22.7)	5.0	2.929	0.002	149.7 (24.9)	8.6	5.118	0.00
EndSBP	137.6 (19.5)				141.1 (17.2)			
DBP*	89.6 (12.6)	2.5	2.783	0.003	90.6 (13.2)	3.5	3.243	0.00
EndDBP	87.1 (11.7)				87.1 (13.7)			
Blood Sugar								
BS*	96.0 (25.7)	9.8	4.657	0.000	102.4 (13.3)	-3.2	1.505	0.93
EndBS	86.2 (19.9)				105.6 (12.2)			
BMI								
BMI*	30.1 (5.5)	0.8	4.331	0.000	28.9 (5.8)	0.2	1.258	0.106
EndBMI	29.3 (5.2)				28.7 (5.9)			
WHR								
WHR*	0.9 (0.1)	0.0	-1.706	0.955	0.9 (0.1)	0.0	-0.753	0.80
EndWHR	0.9 (0.1)				0.9 (0.1)			

DISCUSSION

This randomized controlled trial evaluated the effectiveness of a physician-led, WHO-recommended primary prevention model for cardiovascular disease (CVD) among civil servants in Ondo State, Nigeria. The intervention did not produce a statistically significant reduction in the mean 10-year Framingham risk score compared with usual care, but significant improvements were observed in fasting blood glucose and body mass index, with modest reductions in blood pressure. Waist-to-hip ratio remained unchanged. The calculated number needed to treat suggested that one in ten participants directly benefited, a clinically meaningful effect for preventive interventions.

These findings align with international evidence showing

that while primary prevention interventions often improve intermediate risk factors, their impact on global CVD risk scores is modest[13,14,15]. In Nigeria, workplace or hospital-based interventions have similarly demonstrated improvements in blood pressure and metabolic parameters without consistently shifting absolute risk[16]. The limited change in overall risk may reflect the strong weighting of non-modifiable factors, particularly age, within risk algorithms such as Framingham[20]. Indeed, of the 25 commonest cardiovascular risk assessment models or algorithms, age stands out as the most influential cardiovascular risk factor[21,22], emphasizing age as the most important risk factor for CVD.

Nonetheless, evidence from population-level interventions, including the WHO MONICA and Seven Countries studies, demonstrates that even modest individual improvements can translate into substantial reductions in CVD morbidity and mortality at scale[23,24]. This underscores the potential of physician-led primary prevention models when integrated into broader public health strategies.
The clinical relevance of primary prevention with particular reference to the WHO model used in the study is considered acceptable, although other studies evaluating the model are scarce; but, given the substantial morbidity and mortality outcomes associated with cardiovascular disease, the prevention of harm in one individual for every 10 treated constitutes a meaningful and justifiable clinical benefit for domestication at scale.

Finally, in considering the implications for practice and policy, the findings suggest that physician-led primary prevention is feasible and beneficial in addressing intermediate CVD risk factors in workplace settings[17]. Although changes in absolute 10-year risk were modest, the intervention improved blood glucose, BMI, and blood pressure, which are key drivers of CVD morbidity. Policymakers should consider embedding structured primary prevention in occupational health schemes and subsidising essential medications[25]. Workplace wellness policies could amplify individual benefits and support adherence to lifestyle advice[25,26].

Future research should assess long-term outcomes, develop and validate indigenous risk prediction models, and evaluate combined individual- and system-level strategies, including workplace and policy interventions.

STRENGTHS AND LIMITATIONS

Strengths of this study include its randomized design, pragmatic workplace setting, use of a validated non-laboratory Framingham tool, and a relatively high follow-up rate. The development of a simplified physician algorithm represents a practical innovation that could support wider clinical uptake.

Limitations include the short six-month follow-up, and reliance on self-reported adherence to lifestyle advice. The trial was limited to civil servants, restricting generalizability, and the risk tool applied may not fully reflect risk dynamics in African populations. Contamination between groups cannot be fully excluded.

CONCLUSION

A physician-led primary prevention model did not significantly reduce mean 10-year cardiovascular risk among Nigerian civil servants compared with usual care, but it yielded important benefits in fasting blood glucose, BMI, and blood pressure. At a population level, such gains may contribute meaningfully to reducing the burden of cardiovascular disease.

RECOMMENDATIONS

Health authorities should integrate structured primary prevention into clinical guidelines and workplace health policies. Subsidized access to risk-reducing medications and workplace-based wellness programmes should be prioritized. Research efforts should focus on longer-term follow-up, enhancing adherence, and developing risk assessment tools tailored to African populations.

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Competing interests
The authors declare no competing interests.

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