

Effects of a Pragmatic Type 2 Hybrid Interrupted Time Series Trial on Hypertension Treatment and Control in Nigeria

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Abstract

The burden of hypertension is large and rapidly rising in Nigeria. We sought to implement and evaluate a large-scale hypertension treatment and control program, adapted from the Kaiser Permanente Northern California and World Health Organization HEARTS models, within public primary healthcare (PHC) facilities in the Federal Capital Territory of Nigeria.

From January 2020 to December 2023, we conducted a single arm, type 2 hybrid interrupted time series trial to evaluate and implement a multilevel hypertension control program within 60 PHCs in the Federal Capital Territory of Nigeria. The co-primary effectiveness outcomes were differences in slope of monthly hypertension treatment and hypertension control rates in the pre-implementation and implementation periods. Secondary and safety outcomes were also assessed.

A total of 21,922 patients were enrolled and received care during 142,493 clinic visits. Median age was 49 (40,58) years, 68.2% were female, median body mass index was 26.6 (23.1, 30.9) kg/m².

Although the implementation treatment rate slope was 0.8% lower than the pre-implementation period (β : -0.8%, 95% CI: -1.0%, -0.5%, $p=0.002$), the baseline treatment rate increased from 86.2% (95% CI: 83.5%, 88.8%) to 96.4% (95% CI: 96.1%, 96.7%) by the end of the study period. Similarly, the overall baseline control rate increased from 21.7% (95% CI: 18.5%, 24.8%) to 55.9% even though the monthly control rate slope was 1.0% (β : -1.0%, 95% CI: -1.6%, -0.5%, $p=0.0004$) lower in the implementation period than during the pre-implementation period. Mean systolic blood pressure decreased from 152.4 (95% CI: 150.6, 154.1) mm Hg at baseline to 135.8 (95% CI: 135.4, 136.1) mm Hg at the end of the study, with similar pattern seen for mean diastolic blood pressure.

Reported serious adverse events and adverse events of special interest were not study related.

The Hypertension Treatment in Nigeria Program led to an increase in hypertension treatment from 86% to 96% and control from 22% to 56% among 21,922 patients across 60 PHCs in the Federal Capital Territory, even though the slopes in hypertension treatment and control were not higher during the implementation period.

INTRODUCTION

In 2019, the age-standardized prevalence of hypertension among adults aged 30–79 years in Nigeria was 36%, which was higher than the global average (33%).¹ Among more than 19 million Nigerian adults with hypertension, 47% are diagnosed, 27% are treated, and only 11% are controlled. These rates are far below global averages (54% diagnosed, 42% treated, 21% controlled).¹ The HEARTS technical package², developed by the World Health Organization (WHO) and informed by Kaiser Permanente Northern California hypertension control program³, guides most hypertension control programs around the world. HEARTS includes six components: Healthy-lifestyle counselling; Evidence-based treatment protocols;

Access to essential medicines and technology; Risk-based cardiovascular disease management; Team-based care; and Systems for monitoring.

Multilevel strategies such as HEARTS, including strategies to promote healthy behaviors and blood pressure lowering medications, have been shown to reduce blood pressure^{4,5}, and more recently, cardiovascular disease events.⁶ However, wide variability in implementation and effectiveness has also been reported.^{7,8}

In 2019, the Nigerian Federal Ministry of Health published its national multisectoral action plan for the prevention and control of noncommunicable diseases, including cardiovascular diseases.⁹ A priority target of this action plan was to integrate hypertension into routine primary care. To address the large and growing burden of hypertension in Nigeria and respond to this health system priority, we created the Hypertension Treatment in Nigeria Program.¹⁰ We used implementation science frameworks and methods, including a formative research period^{11,12}, to contextualize, implement, and evaluate implementation of a multilevel package based on HEARTS in 60 public, primary healthcare centers (PHCs) in the Federal Capital Territory, Nigeria. Here, we report primary effectiveness results related to systemwide hypertension treatment and control rates between the pre-implementation and implementation periods.

METHODS

The methods for the Hypertension Treatment in Nigeria Program have been published.¹⁰ Briefly, we used a single arm, type 2 hybrid interrupted time series design to evaluate implementation and effectiveness of a multilevel hypertension control program adapted from the Kaiser Permanente Northern California program³ and WHO HEARTS technical package⁸ within PHCs in the Federal Capital Territory, Nigeria. The implementation package included a hypertension patient registry with empanelment, performance and quality reporting, simplified treatment guideline encouraging fixed-dose combination therapy, access to quality essential medicines and technology, and team-based care. The study protocol was reviewed and approved by the Health Research Ethics Committee of the Federal Capital Territory and Institutional Review Boards at the University of Abuja and Northwestern University.

Hypertension management in Nigeria

At initiation of the Hypertension Treatment in Nigeria Program, the Nigerian government created and released a national hypertension treatment protocol in April 2019.¹³ Community health extension workers had legal permission at the time of study initiation to prescribe blood pressure lowering drugs according to this protocol under physician supervision in accordance with Nigeria's national policy on task shifting and task sharing for the prevention and control of noncommunicable diseases.¹⁴

Formative period

From April 2019 to December 2019, we conducted formative research, starting with multi-stage probability sampling among the 243 PHCs in the Federal Capital Territory. To be eligible, PHCs had to have at least two full-time staff, be accessible to the study team by road and in all seasons, and be functional (i.e., defined as open at least between the hours of 8 AM and 4 PM and providing the minimum service package for primary care). All 60 PHCs that were invited agreed to participate. We used quantitative and qualitative methods to evaluate readiness, acceptability, and feasibility of the hypertension control program among PHCs.^{11,12} With these formative data, we adapted the WHO HEARTS and Kaiser Permanente Northern California models to the Nigerian context.

We then conducted initial centralized in-person health care worker training based on the US Centers for Disease Control and Prevention training program during this period with extensive follow-up on-site and online refresher training.¹⁵ Training participants included primary care physicians, pharmacists, nurses, community health officers, and community health extension workers. Training included measurement of blood pressures duplicate in seated individuals after a rest period using a standardized measurement protocol and automated, validated blood pressure monitors. Separate, specialized training was provided to pharmacists and record officers. We provided validated automated blood pressure monitors and weighing scales to PHCs that did not have functioning equipment. We provided electronic tablets to PHCs so each PHC's record officer could electronically record patient-level data using the University of Abuja's REDCap instance. We implemented quality assurance and quality control procedures for patient-level data collection in the pre-implementation period.

Pre-implementation period

From January 2020 to December 2020, PHCs sequentially enrolled and empaneled patients with hypertension. All adult (≥ 18 years) patients with persistently elevated blood pressure (systolic blood pressure ≥ 140 mm Hg or diastolic blood pressure ≥ 90 mm Hg, measured on two occasions) or a history of hypertension were eligible for inclusion. Both measures were recorded, and the average measurement was used in these analyses. Patients who were pregnant, had severely elevated blood pressure (systolic blood pressure ≥ 180 mm Hg or diastolic blood pressure ≥ 110 mm Hg), had symptomatic uncontrolled hypertension, or were uncontrolled after progressing through all steps of the treatment protocol were included and were referred to secondary and tertiary care facilities. Baseline data included: socio-demographics, medical history, anthropometry, blood pressure, heart rate, medications, and relevant laboratory studies among a subset of 20 PHCs for safety monitoring¹⁶ and when available (e.g., serum potassium, serum creatinine). Patients were treated according to the pre-existing standard of care within each primary healthcare center. Similar data were collected during monthly follow-up visits, as well as data on the incidence of serious adverse events and adverse events of special interest (e.g., angioedema, dizziness, syncope). Informed consent was not collected from patients based on the Common Rule.

To help raise awareness and create demand for hypertensive services, we began conducting community awareness events in March 2020 using local health educators. Meetings occurred one to four times per year until October 2022 and lasted 60 to 120 minutes.

Implementation period

From January 2021 to December 2023, we implemented the HEARTS multilevel package, including: 1) team-based care led by community health extension worker hypertension management (health worker-level), 2) quarterly PHC supportive supervision visits (site-level), and 3) free or reduced cost quality blood pressure lowering drugs, including fixed-dose combination therapy (system-level). Quarterly PHC supportive supervision visits were conducted in person by trained study team members and included refresher training and review of: staffing levels, patient logs, blood pressure measurement technique, availability of functioning equipment and medications, high-quality data capture, and performance and quality reports to improve care quality. Medications were purchased, distributed, and made freely available to PHCs from January 2021 to May 2022 under the supervision of four public health pharmacy experts (including co-authors GS, EU). In April 2022, after conducting interim focus group discussions, targeted community awareness events, and pilot testing, we implemented a drug revolving fund wherein patients paid a co-pay to cover procurement and administrative costs to sustain accessibility to blood pressure lowering drugs.¹⁷ Details of the drug revolving fund implementation will be published separately.

Outcomes

The co-primary effectiveness outcomes were differences in slope of monthly hypertension treatment rates (defined as a documented prescription of any blood pressure lowering drug) and monthly hypertension control rates (defined as systolic blood pressure < 140 mm Hg and diastolic blood pressure < 90 mm Hg) in the pre-implementation and implementation periods among participating primary healthcare centers. We chose this definition of control based on the 2019 Nigeria Hypertension Protocol.^{13,18} We report treatment rates both at the start (i.e., “walk-in”) and end (i.e., “walk-out”) of each visit. Secondary effectiveness outcomes included: 1) mean systolic blood pressure and diastolic blood pressure, and 2) rates of fixed-dose combination therapy use. The co-primary implementation outcomes included: reach, adoption, implementation, maintenance, acceptability, and cost, which will be reported in detail separately.

Safety outcomes included: 1) proportion of participants with adverse events of special interest, including: angioedema, acute kidney injury (defined as relative increase in serum creatinine by 50% or an absolute increase by 0.3 mg/dl [$> 0.26 \text{ umol/L}$]), electrolyte abnormalities (defined as serum potassium < 3.5 mEq/L or > 5.5 mEq/L or serum sodium < 125 mEq/L or > 145 mEq/L), syncope, or dizziness, 2) rate of relevant side effects at the participant level (i.e., count per participant), and 3) proportion of patient with any serious adverse event or unanticipated problem according to Good Clinical Practice definitions.

Sample size and power

The sample size was calculated for the primary effectiveness outcome, assuming baseline hypertension treatment (20%) and control (10%) rates reported in the literature¹⁹, as well as an effect size similar to the Kaiser Permanent Northern California program.³ We assumed attrition of 10 PHCs and estimated 1,200 patient-visits per month across 50 PHCs over 9 months of baseline (n = 10,800 visits) and 39 months of intervention (n = 46,800 visits) would provide > 80% power to detect a difference in treatment slope of 0.57% per month compared to underlying trend of 0.10% per month, resulting in hypertension treatment rate of 42.5% at the end of 48 months. This sample size also provided > 80% power to detect a difference in control slope of 0.44% per month compared to underlying trend of 0.05% per month, resulting in hypertension control rate of 27.0% at the end of 48 months. Power and sample size were estimated under a variety of conditions through Monte-Carlo simulation in SAS (v9.4, SAS Inc, Cary, North Carolina).

Statistical analyses

Summaries of continuous variables are presented as means and standard deviations or medians with interquartile ranges (IQR) based on distribution. Categorical variables are described as frequencies and percentages. Comparisons between the pre-implementation and implementation periods were made using t-tests, Mann-Whitney U tests, and Chi-square tests, respectively.

We conducted outcome analyses using the intention to treat principle. For effectiveness outcomes, we used an interrupted time series evaluation with aggregate measures of system-level monthly treatment and control rate using six-month rolling averages within each period as recommend by the WHO.² We compared differences in slope for monthly hypertension treatment and control rates change during the pre-implementation and implementation periods using a segmented linear regression with autoregressive error terms.

In subgroup analyses, we compared treatment and control rates by patient characteristics, including area council, rurality, age, sex, body mass index, education, diagnosis timing (pre-existing or new at enrollment), and months enrolled in the program, and primary healthcare center characteristics, including medication stock, staffing, patient visits, PHC readiness, and performance assessed during quarterly PHC supportive supervision visits, in unadjusted regression models using generalized estimating equations to account for multiple observations per patient. Estimates are presented as odds ratios with 95% confidence intervals.

We used a two-sided $P < 0.05$ to detect statistical significance in all analyses and did not adjust for multiple comparisons. Missing data were identified through data status quality reports and were resolved with responsible PHCs where feasible. Complete case analyses were performed. We will report home blood pressure monitoring and health coaching results separately.

RESULTS

From January 2020 to December 2023, 21,922 patients with hypertension met the inclusion criteria, were enrolled, and received care during 142,493 visits in 60 primary healthcare centers in the six area councils (**Supplemental Fig. 1, Supplemental Table 1**). Table 1 shows baseline sociodemographic and clinical characteristics overall and by implementation period. Sex-stratified results are reported in **Supplemental Table 2**. One-quarter (25.1%, $n = 5,506$) of patients were enrolled during the pre-implementation period, and three-quarters (74.9%, $n = 16,416$) of patients were enrolled during the implementation period. Most patients were female (68.2%). Median (IQR) age was younger during the pre-implementation period (48 [38, 57] years versus 50 [41, 58] years, $p < .0001$) with a lower proportion of patients with college/post-secondary or professional education (23.9% versus 26.1%, $p < .0001$). In the pre-implementation period, there was a higher proportion of patients with a history of diabetes (5.7% versus 4.1%, $p < .0001$), current alcohol use (4.1% versus 3.3%, $p = 0.006$), or prior history of hypertension (52.6% versus 47.4%, $p < .0001$). Among patients with a previous diagnosis of hypertension, the walk-in treatment rate was higher during the pre-implementation period (72.9% versus 62.3%, $p < .0001$), but control rates were similar between periods (19.9% versus 19.1%, $p = 0.35$). Among all enrolled patients, median (IQR) baseline blood pressures were lower in the pre-implementation period (baseline systolic blood pressure: 152 [142, 164] mm Hg versus 154 [143, 169] mm Hg, $p < .0001$; baseline diastolic blood pressure: 95 [88, 104] mm Hg versus 96 [88, 105] mm Hg, $p < .0001$). Baseline walk-out treatment rates were modestly lower during the pre-implementation period (91.4% versus 96.9%, $p < .0001$), but baseline control rates were somewhat higher (13.6% versus 12.5%, $p = 0.03$).

Table 2 shows patient engagement and hypertension status by implementation period. The median (IQR) number of visits among those enrolled during the pre-implementation period was higher compared with the implementation period (4 [1, 14] versus 3 [1, 8] visits, $p < .0001$). Two-thirds (66.7%) of patients had two or more visits with a higher proportion among patients enrolled in the pre-implementation period (71.6% versus 65.0%, $p < .0001$). Compared with the pre-implementation period, the unadjusted median blood pressures were lower in the implementation period, and the unadjusted treatment and control rates were higher.

Primary outcomes

Table 3 shows six month rolling average hypertension treatment rates, overall and stratified by sex. The overall baseline treatment rate was 86.2% (95% CI: 83.5%, 88.8%), which increased to 96.4% (95% CI: 96.1%, 96.7%) by the end of the study period with a step-up observed at the start of the implementation period. During the pre-implementation period, the treatment rate increased by 0.8% (95% CI: 0.6%, 1.0%) per month compared with 0.02% (95% CI: 0.01%, 0.03%) per month during the implementation period. The implementation treatment rate slope was 0.8% lower than the pre-implementation period (β : -0.8%, 95% CI: -1.0%, -0.5%, $p = 0.002$). Treatment rates were modestly higher for females during the pre-implementation period but somewhat lower during the implementation period.

Table 4 shows six month rolling average hypertension control rates, overall and stratified by sex. The overall baseline control rate was 21.7% (95% CI: 18.5%, 24.8%), which increased to 55.9% (55.1%, 56.7%) by the end of the study period. By the start of the implementation period, the control rate had increased to 32.5% (95% CI: 30.7%, 34.3%), despite a drop of 6.1% (β : -6.1%, 95% CI: -7.7%, -4.6%) at its onset. During the pre-implementation period, the control rate increased by 1.7% (95% CI: 1.2%, 2.1%) per month compared with 0.7% (95% CI: 0.5%, 0.9%) per month during the implementation period. The monthly control rate slope was 1.0% (β : -1.0%, 95% CI: -1.6%, -0.5%, $p = 0.0004$) lower in the implementation period than during the pre-implementation period. Unadjusted control rates were higher for females during both periods.

Secondary outcomes

Supplemental Tables 3 and 4 show six month rolling average systolic and diastolic blood pressures, respectively, overall and stratified by sex. Results followed the expected pattern based on the hypertension control rates. Mean systolic blood pressure was 152.4 (95% CI: 150.6, 154.1) mm Hg at baseline, which decreased to 135.8 (95% CI: 135.4, 136.1) mm Hg by the end of the study period with a step-up observed at the start of HEARTS implementation. The decrease in systolic blood pressure was 0.7 (95% CI: 0.4, 0.9, $p < .0001$) mm Hg lower per month in the implementation period than in the pre-implementation period. Mean diastolic blood pressure was 93.5 (95% CI: 92.3, 94.6) mm Hg at baseline, which decreased to 84.2 (95% CI: 84.0, 84.4) mm Hg by the end of the study period despite a step-up observed at the start of HEARTS implementation. The decrease in diastolic blood pressure was 0.3 (95% CI: 0.1, 0.4, $p = 0.004$) mm Hg lower per month in the implementation period.

Supplemental Table 5 shows six month rolling average rates of fixed-dose combination therapy use during the pre-implementation and implementation periods. The overall baseline fixed-dose combination therapy rate was 16.3% (95% CI: 4.8%, 27.8%), which increased to 65.2% (95% CI: 64.0%, 66.3%) at the study end, with a 32.1% (95% CI: 30.7%, 33.5%) step-up observed at the start of HEARTS implementation. Monthly increases in fixed dose combination therapy was 0.4% (95% CI: 0.04%, 0.8%, $p = 0.03$) higher during the implementation period.

Safety outcomes

Adverse events, including serious adverse events, are reported in **Supplemental Table 6**. There were 13 deaths (0.2% of patients seen) during the pre-implementation period, and 79 deaths (0.4% of patients seen) during the implementation period. Adverse events of special interest were infrequently reported ($< 0.1\%$), including dizziness (17 occurrences in 16 patients). None of these events were deemed study related.

Subgroup analyses

The results of the subgroup analyses for hypertension treatment and control across the entire study duration are shown in Figs. 1a and 1b, respectively. The odds of hypertension treatment were higher among patients from rural areas, age group 50–55 years compared with 18–41 years, college or

professional education compared with secondary education, and who received care from primary healthcare centers with higher visits per permanent healthcare staff levels. Compared to patients from Abuja Municipal Area Council, patients from Abaji, Bwari, Gwagwalada, and those who were female, underweight, had a pre-existing diagnosis of hypertension, enrolled 11 or more months, and who received care from primary healthcare centers with 4–8 permanent healthcare staff compared with 1–3 staff had lower odds of receiving treatment. Treatment did not differ by primary healthcare center readiness or performance.

The odds of hypertension control were higher in all area councils outside of Abuja Municipal Area Council, patients older than 41 years, females, individuals who were underweight, had a pre-existing hypertension diagnosis, were enrolled more than 1 month and who received care at primary healthcare centers with higher medication stocks, higher visits per permanent healthcare staff, and demonstrated readiness and high performance during quarterly PHC supportive supervision visits. Patients who were from rural areas, were overweight or obese, or were on medications other than amlodipine 5 mg (Step 1) had lower odds of having controlled hypertension.

Discussion

Summary and explanation of results

The Hypertension Treatment in Nigeria Program enrolled 21,922 patients with hypertension from 60 primary healthcare centers in the Federal Capital Territory over four years. Implementation of the multilevel package was led by community health extension workers as outlined by Nigeria's national policy on task shifting and task sharing for the prevention and control of non-communicable diseases.¹⁴ While the study did not demonstrate differences in treatment and control rate slopes between the pre-implementation and implementation periods, there were substantial increases in the rates of hypertension treatment and control observed between baseline and study end, with an overall 10% increase in treatment rates and a 34% increase in control rates. By the study end, treatment rate reached 96% and the control rate reached 56%, with corresponding decreases in systolic and diastolic blood pressure. Additionally, the program showed a significant increase in fixed-dose combination therapy use which contributed to the high hypertension control rate²⁰, and there were few adverse events.

The failure to observe increased slopes during the implementation period compared to the pre-implementation period may be explained by the higher than anticipated hypertension treatment and control rates at baseline and increases during the pre-implementation period. Additionally, training, data collection, and supportive supervision visits initiated by the study team at the beginning of the pre-implementation period likely had a larger effect than was previously anticipated. The slopes during the implementation period may have also been attenuated by ceiling effects. Treatment and control rates were > 90% and > 30%, respectively, at the beginning of the implementation period. In an analysis of 12.2 million patients with hypertension in 32 low- and middle-income countries where HEARTS had been

implemented, median hypertension control was 48%.⁸ Further, the hypertension control rate in the Nigeria Hypertension Control Initiative, which conducted concurrently with this study, reached only 32%.⁸

Results in context

There have been an increasing number of reports evaluating hypertension program implementation and effectiveness in primary care settings in low- and middle-income countries.^{6,8,21,22} Like the current study, most used a quasi-experimental study design, but few reported temporal trends in outcomes.

Hypertension control rates reported from these programs range from 4.9% in one program in China to 85.5% in the Philippines.⁸ The India Hypertension Control Initiative²³, the largest program of its kind with > 4 million participants, had a control rate of 43% starting from a baseline control rate of < 5%. The Nigeria Hypertension Control Initiative includes 36,345 patients recruited from Kano and Ogun states with an estimated 916,000 adults with hypertension in the catchment area. The hypertension control rate was lower (23%) in the Nigeria Hypertension Control Initiative than the current study, which may be due to differences in the patient characteristics, frequency of training and supportive supervision visits, and implementation of a drug revolving fund to reduce out-of-pocket costs associated with blood pressure lowering medications. These latter two strategies—supportive supervision and drug revolving fund implementation—have not been widely implemented as part of HEARTS yet address important barriers to fidelity and sustainability.

Community health worker-led hypertension control programs have been shown not only to reduce blood pressure but also to improve cardiovascular outcomes. For example, the China Rural Hypertension Control Project showed a 33% lower risk of major cardiovascular events (1.62% versus 2.40% per year) over 36 month follow-up in a cluster randomized trial of 33,995 participants from 326 villages.⁶ Similarly, the Control of Blood Pressure and Risk Attenuation–Bangladesh, Pakistan, and Sri Lanka [COBRA-BPS]) cluster randomized trial including 2,645 participants from 30 communities showed a 1.4% lower absolute rate of all-cause mortality at 24 months in the intervention arm (2.9% versus 4.3%), which received community health extension worker treatment of hypertension, compared with usual care.⁴ This multicomponent intervention has also been demonstrated to be cost effective.²⁴ Cost and budget impact results of the Hypertension Treatment in Nigeria Program will also be useful to inform decision-making related to incorporation of hypertension services into health insurance coverage packages as outlined by the *Lancet* Nigeria Commission.²⁵ The next step for our research team is to expand the Hypertension Treatment in Nigeria Program to Nigeria's five other geopolitical zones with the long-term goal of improving clinical outcomes.

Strengths and limitations

Our study has several strengths, including use of formative research to adapt the multilevel implementation package, including supportive supervision and a drug revolving fund, a pragmatic study design, a large number of primary healthcare centers with low staff attrition, and large number of patients enrolled and followed longitudinally.

On the other hand, there were some limitations. First, while we sought to ensure high quality blood pressure measurement and data collection through training at the beginning of the pre-implementation period, PHCs may have been susceptible to the Hawthorne effect.²⁶ Additionally, the release of the national treatment protocol in 2019 may have increased awareness about hypertension treatment throughout the pre-implementation period. Despite these factors, we observed substantial increases in hypertension treatment and control rates through this program.

Second, we used an interrupted time series design, which, although pragmatic, has limitations related to causal inference compared with other study designs and may have been susceptible to contextual factors beyond our control. However, we balanced rigor with pragmatism and the large effect size observed in the Kaiser Permanente Northern California experience²⁷, which allowed us to make adaptations required during the COVID-19 pandemic and other study-related adaptations to support fidelity (e.g., supportive supervision) and sustainability (e.g., drug revolving fund implementation). This study design was also more acceptable among our stakeholders and has been successfully used in other settings.⁸

Third, enrollment, evaluation, management, and retention largely reflected routine clinical conditions, which may affect the generalizability of the observed treatment and control rates, which were limited to patients who attended clinic visits. The study focused on PHC-based measures, and not all patients followed up. However, we have previously reported increases in retention with HEARTS implementation in this program²⁸ and included empanelment to minimize losses to follow-up. Nonetheless, patients who did not follow-up likely had lower treatment and control rates, so our real-world estimates may be higher than the true population rates. We also enrolled a lower proportion of males compared with females and consequently, our overall treatment estimate may be understated, and overall control rate overstated, compared to the broader population. This difference in enrollment may be influenced by differences in health seeking behavior as observed in other studies^{4,6} as well as awareness about hypertension services. However, from January 2020 to January 2023, we conducted 307 community awareness meetings affiliated with 58 of the 60 primary healthcare centers to raise awareness of and drive demand for this program, and of the 6,477 adults who participated in these meetings, 47% were males (unpublished). As such, the enrollment and overall estimates may reflect the population that is aware of and receptive to hypertension care.

Conclusions

The Hypertension Treatment in Nigeria Program showed an increase in hypertension treatment from 86–96% and control from 22–56% among 21,922 patients across 60 PHCs in the Federal Capital Territory. However, the slopes in hypertension treatment and control were not higher during the implementation period. Strategies to widen and sustain the reach of hypertension screening, diagnosis, treatment, and control across Nigeria through HEARTS, including supportive supervision and drug revolving fund implementation, are important areas for future investigation.

Abbreviations

FCT: Federal Capital Territory

HEARTS: Healthy-lifestyle counselling; Evidence-based treatment protocols; Access to essential medicines and technology; Risk-based cardiovascular disease management; Team-based care; and Systems for monitoring

IQR: Interquartile ranges

PHCs: Primary healthcare centers

REDCap: Research Electronic Data Capture

WHO: World Health Organization

Declarations

Ethics approval and consent to participate

Informed consent was waived per the Common Rule. Ethical oversight was provided by the University of Abuja Teaching Hospital Health Research Ethics Committee. The study was also reviewed by the Federal Capital Territory Ethics Committee and Northwestern University Institutional Review Board. The trial is registered at www.clinicaltrials.gov under NCT04158154.

Consent for publication

Not applicable

Availability of data and materials

The datasets generated and/or analyzed during the current study will be available in the NHLBI BioData Catalyst (biodatacatalyst.nhlbi.nih.gov).

Competing interests

MDH has received travel support from the American Heart Association and World Heart Federation and consulting fees from PwC Switzerland. MDH has an appointment at The George Institute for Global Health, which has a patent, license, and has received investment funding with intent to commercialize fixed-dose combination therapy through its social enterprise business, George Medicines. MDH has pending patents for heart failure polypills.

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Authors' contributions

DBO and MDH conceptualized and obtained funding for the study. DBO, MDH, LRH, GI, NRK, and ASB oversaw project administration. AAO, GLS, TMO, NR, HE, GS, ENU, RCBO, and DBO conducted the investigation, supervised community health extension workers, and provided resources. ASB, ELJ, SO, JY, and BMA oversaw data curation and conducted formal analyses. MDH wrote the original draft. All authors read and approved the final manuscript.

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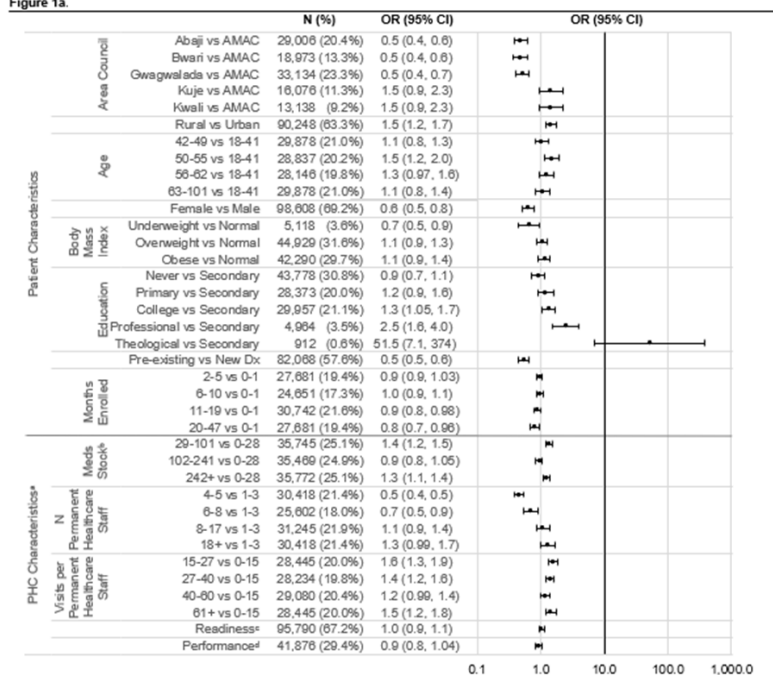
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Tables

Tables 1 to 4 are available in the Supplementary Files section.

Figures

Figure 1a.



* Assessed at quarterly PHC supportive supervision visits

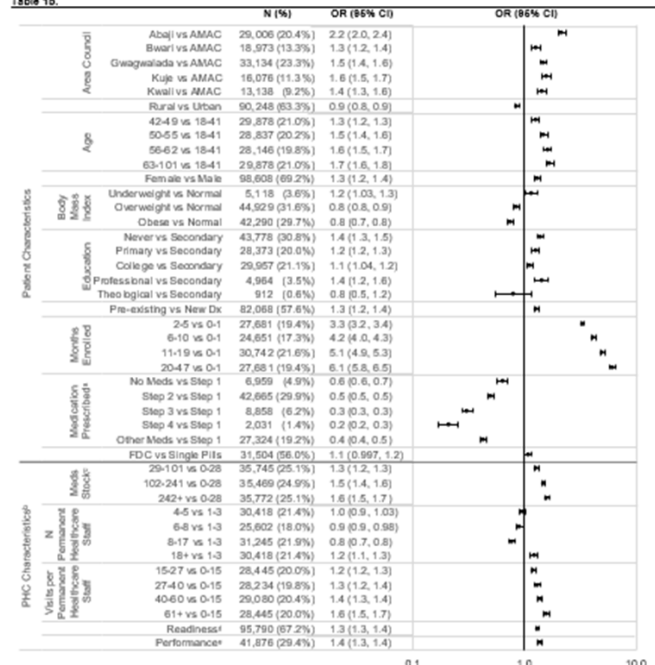
* 30-day doses of amlodipine, losartan, and hydrochlorothiazide

* PHCs with complete vs incomplete readiness as defined by: 1) availability of blood pressure lowering medications, 2) 2 or more community health extension workers, junior community health extension worker, or chief health officer, and 3) functional BP apparatus

* PHCs with complete vs incomplete adherence to protocols as assessed by: 1) screening of all patients seen in the last 3 working days (coverage), 2) blood pressure measurement (fidelity), and 3) the presence or absence of error(s) in treatment cards (data quality)

Abbreviations: AMAC, Abuja Municipal Area Council; BP, blood pressure; Dx, diagnosis; Meds, medication; PHC, primary healthcare center

Table 1b.



* Step 1: Amlodipine 5 mg, Step 2: Amlodipine 5 mg + Losartan 50 mg, Step 3: Amlodipine 10 mg + Losartan 100 mg, Step 4: Amlodipine 10 mg + Losartan 100 mg + Hydrochlorothiazide 25 mg, Moduretic (Amlodipine + Hydrochlorothiazide) is categorized as 'other' per the medication protocol. Results are consistent when including Moduretic as a substitute for the Step 2 and 3 categories.

* PHCs with complete vs incomplete readiness as defined by: 1) availability of blood pressure lowering medications, 2) 2 or more community health extension workers, junior community health extension worker, or chief health officer, and 3) functional BP apparatus

* PHCs with complete vs incomplete adherence to protocols as assessed by: 1) screening of all patients seen in the last 3 working days (coverage), 2) blood pressure measurement (fidelity), and 3) the presence or absence of error(s) in treatment cards (data quality)

Abbreviations: AMAC, Abuja Municipal Area Council; BP, blood pressure; Dx, diagnosis; FDC, fixed dose combination; Meds, medication; PHC, primary healthcare center

Figure 1

a. Odds (95% CI) of Treatment by Patient and Primary Healthcare Center Characteristics.

b. Odds (95% CI) of Control by Patient and Primary Healthcare Center Characteristics.

Supplementary Files

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