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Effectiveness of community-based hypertension management on hypertension in the urban slums of Haiti: A mixed methods study

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Abstract

Hypertension is a leading contributor to mortality in low-middle income countries including Haiti, yet only 13% achieve blood pressure (BP) control. We evaluated the effectiveness of a community-based hypertension management program delivered by community health workers (CHWs) and physicians among 100 adults with uncontrolled hypertension from the Haiti Cardiovascular Disease Cohort. The 12-month intervention included: community follow-up visits with CHWs (1 month if BP uncontrolled ≥140/90, 3 months otherwise) for BP measurement, lifestyle counseling, medication delivery, and dose adjustments. Primary outcome was mean change in systolic BP from enrollment to 12 months. Secondary outcomes were mean change in diastolic BP, BP control, acceptability, feasibility, and adverse events. We compared outcomes to 100 age, sex, and baseline BP matched controls with standard of care: clinic follow-up visits with physicians every 3 months. We also conducted qualitative interviews with participants and providers. Among 200 adults, median age was 59 years, 59% were female. Baseline mean BP was 154/89 mmHg intervention versus

153/88 mmHg control. At 12 months, the difference in SBP change between groups was −12.8 mmHg (95%CI −6.9, −18.7) and for DBP −7.1 mmHg (95%CI −3.3, −11.0). BP control increased from 0% to 58.1% in intervention, and 28.4% in control group. Four participants reported mild adverse events. In mixed methods analysis, we found community-based delivery addressed multiple participant barriers to care, and task-shifting with strong teamwork enhanced medication adherence. Community-based hypertension management using task-shifting with CHWs and community-based care was acceptable, and effective in reducing SBP, DBP, and increasing BP control.

1 | BACKGROUND

Hypertension affects one out of three adults globally, leading to 10.4 million deaths and 218 million disability adjusted life years annually.[1–3] Over 80% of these deaths occur in low-middle income countries (LMICs).[4] Rates of hypertension control are dismal at ~8% in LMICs, one-third the rates seen in high-income countries, and also worse in Black patients.[5,6] Thirty nine million deaths from myocardial infarction, stroke, and heart failure could be prevented over 25 years if hypertension treatment could be scaled to 70% coverage globally.[7]

Haiti is a majority-Black LMIC where hypertension is the most common cardiovascular disease (CVD) risk factor with a prevalence of 29%, CVD is the leading cause of death, yet hypertension control is only 13% in the urban slums of Port-au-Prince.[8,9] Multiple barriers exist to hypertension control in city slum environments: weak health systems with poor access, beliefs that hypertension is due to stress and can be eliminated by stress reduction, limited physician-patient time in clinic, extreme poverty, and civil insecurity which lead to difficulty traveling to clinic and competing demands for time and money.[10–13]

Community-based models of healthcare have been widely used within LMICs to address barriers to HIV treatment and control by using task-sharing with lay health workers to increase access to care, counseling, and medication distribution.[14] However, community-based care has been less explored for non-communicable diseases like hypertension in urban slum settings, including Port-au-Prince, Haiti. To address this gap, we tested a community-based hypertension management program among Haitian adults as a sub-study within the Haiti Cardiovascular Disease Cohort to improve hypertension control.

2 | METHODS

2.1 | Study design

The community-based hypertension management program was a sub-study within the Haiti Cardiovascular Disease Cohort, with a prospective, non-randomized intervention group, and retrospectively matched control group. The Haiti Cardiovascular Disease Cohort is a longitudinal, population based cohort of 3005 adults living in Port-au-Prince, followed prospectively over time to determine prevalence and incidence of CVD, risk factors, and social determinants of health.[15] This study is conducted by Groupe Haitien d'Etude du Sarcome de Kaposi et des Infections Opportunistes Centers (GHESKIO) in Haiti, a medical non-profit organization that has operated continuously over four decades to provide clinical care and conduct research on infectious and chronic diseases.

2.2 | Participants

All participants with uncontrolled hypertension, defined as (1) one BP measurement ≥160/100 mmHg or (2) two BP measurements at different visits ≥140/90 mmHg, regardless of antihypertensive medication usage, were eligible for the intervention group. Exclusion criteria included participants planning to leave Port-au-Prince in the next 12 months, or pregnancy. Participants were recruited into the intervention group in two ways: (1) randomly calling participants to introduce the sub-study, and (2) enrolling eligible participants who were already presenting to the clinic as part of the larger Haiti Cardiovascular Disease Cohort. To minimize possible over selection of older participants with multiple chronic diseases who presented more frequently to clinic, we generated enrollment targets within age categories (<40 vs. ≥40 years) and number of comorbidities (none, one, two, or more of diabetes, chronic kidney disease, heart failure, myocardial infarction, and stroke) with percentages within each group proportional to the overall cohort. Once the intervention group reached $n = 100$, we stopped enrollment. The remaining participants not enrolled in the intervention group were eligible to be in the control group. During time of analysis, we retrospectively selected controls by matching $n = 100$ participants among those with uncontrolled hypertension not enrolled in the intervention. Additional inclusion criteria for control participants included having clinic visits with BP measurements within 3 months of intervention enrollment and 12 month visit dates to control for secular changes.

2.3 | Hypertension management in the intervention versus control groups

The intervention group received community-based hypertension management with task-shifting with community health workers (CHWs) and community-based delivery of care. The intervention group received an enrollment clinic visit with a physician for BP

measurement, antihypertensive medication prescription following a treatment algorithm following national guidelines, and lifestyle counseling. Follow-up visits were conducted by a CHW in the community or participant home, including BP measurement, delivery of antihypertensive medication refills, increases of medication doses based on the algorithm when BP ≥ 140/90 mmHg (Tables S2, S3), lifestyle counseling, and clinic referral as needed. Frequency of community follow-up visits varied based on the BP: every month if BP was uncontrolled at ≥140/90 mmHg, and every 3 months if BP was controlled at <140/90 mmHg. There was an interim 6 month and a final 12 month clinic visits with a physician. In addition to prior training on BP measurement, referral to clinic, and data collection, CHWs were additionally trained on delivery of medication refills, increasing medication doses based on the algorithm, and lifestyle counseling. For participants with hypertension alone, CHWs increased medication doses with physician supervision. For participants with hypertension and other comorbidities like heart failure, CHWs only delivered medications and physicians titrated doses over the phone. Details on lifestyle counseling can be found in the Supplement.

The control group received standard of care with physician only care and clinic-based delivery of care under the parent Haiti Cardiovascular Disease Cohort. Clinic visits included the same components of BP measurement, prescription of antihypertensive medications, dosage increases based on the same treatment algorithm, and lifestyle counseling, but were conducted by physicians. Frequency of clinic follow-up visits was based on physician discretion, and usually occurred every 3 months for BP ≥140/90 mmHg, and 6 months for BP <140/90 mmHg.

Medications in both intervention and control groups were provided for free, and dispensed at follow-up visits whenever it was discovered participants did not have medications.

2.4 | Measurements

Participant socio-demographics, CVD risk factors, and disease were collected at the start of the Haiti Cardiovascular Disease Cohort for both intervention and control participants (March 2019–August 2021). Socio-demographics included age, sex, education level, income, and marital status. CVD risk factors included hypertension, body mass index (BMI), diabetes mellitus, hypercholesterolemia, chronic kidney disease, current smoking, alcohol intake, fruit/vegetable intake, and physical activity. Definitions can be found in prior publications.[16]

For the community hypertension management sub-study, the intervention group had clinic visits at enrollment (April 2022–August 2022), 6 months, and 12 months. Anthropometrics were taken including height, weight, and blood pressure (BP) measurements by a nurse following American Heart Association (AHA) and World Health Organization (WHO) guidelines using semi-automated oscillometric research-grade machines (Omron HEM 907 in clinic) and appropriately sized cuffs.[17,18] Participants sat in a quiet room for 5 min, then had three BP measurements taken separated by 1 min intervals. The average of the last two BPs was used as the sub-study BP. A physician performed a clinical exam including past medical history, medication use, and a physical exam. At 6 and 12 month clinic visits, additional measurements included medication adherence using the Hill-Bone scale,[19] adverse events modeled off of DAIDS criteria with 5 point Likert scale,[20] Acceptability of Intervention Measure, and Feasibility of Intervention Measure.[21]

For the intervention group at community follow-up visits, BP was taken by trained CHWs using the same protocol as above with a different BP machine (Omron 5 series). Additional measurements included medication adherence using the Hill-Bone scale,[19] screening for side effects, and antihypertensive medication regimens.

The control group had clinic visits as part of the cohort, including BP measurements using the same procedures as for clinic visits in the intervention group, past medical history, medication use, and a physical exam.

We also collected qualitative data using semi-structured guides. We conducted three focus groups of participants with hypertension, each with five to six participants (one group of non-intervention participants, two groups of intervention participants), recruited using purposive sampling. We also conducted single in-depth interviews with the physician and five additional intervention participants. Interviews were conducted between April and September 2023, in Haitian Creole with participants using a bilingual Haitian interviewer, and in English with the physician. Interviews were audio recorded and transcribed verbatim. Creole transcripts were translated to English for analysis by a certified transcription company.

2.5 | Outcome

The primary outcome was difference in mean SBP change from enrollment to 12 months, between sub-study groups. The secondary outcomes were difference in mean DBP from enrollment to 12 months, BP control (<140/90) at 12 months, acceptability, feasibility, and adverse events. We also examined BP outcomes at 18 months to assess sustainability/maintenance after intervention activities had completed.

2.6 | Sample size

This sub-study was powered on the primary outcome of difference in mean SBP change between groups from enrollment to 12 months. We assumed the control group would have a mean SBP of 156 mmHg (SD 15) based on preliminary data, and a −1.9 mmHg decrease based on CHW meta-analysis data in LMICs.[22] With a sample size of 100 participants, we had 80% power at a two-tailed alpha of 0.05 to detect a ≥5 mmHg additional decrease in mean SBP between intervention versus control groups at 12 months.

2.7 | Statistical analyses

At time of analysis, we selected control participants by using nearest neighbor matching with propensity scores (matchit package in

R version 4.3.3) to intervention participants based on age, sex, and SBP at time of community hypertension management sub-study enrollment, to maximize comparability between the two groups.

For descriptive statistics, given participants were not randomly assigned to intervention versus control groups, we compared demographic characteristics between groups using paired *t*-test for continuous outcomes, and Wilcoxon signed rank test and McNemar's Chi-squared test for categorical outcomes.

For continuous outcomes, we calculated the difference in mean SBP or DBP change from enrollment to 12 months between groups using a linear mixed effects model including time and intervention as fixed effects, and accounting for repeated measures and correlations within subjects by including patient as a random effect. The time*treatment interaction term serves as the primary parameter. For BP control, we calculated the percent for each group at 12 months, and used the chi-squared test to calculate the statistical significance of this difference. We included all participants who remained in the sub-study at 12 months in the primary analysis ($n = 74$). As a sensitivity analysis, we included all participants and imputed missing 12 month BP in the intervention group using last value carried forward which does not assume missingness at random. For the outcome of BP control, we did another sensitivity analysis including all participants and assumed missing 12 month BP was uncontrolled.

Using an explanatory sequential mixed methods approach, we conducted qualitative interviews to understand what parts of the intervention worked well, and what parts did not. For qualitative data, we used the Consolidated Framework for Implementation Research (CFIR) to inform interview guide development and data analysis. CFIR is commonly used to evaluate new interventions, guide adaptation, data collection, and analysis.[23,24] CFIR includes five main domains (Outer Setting, Inner Setting, Characteristics of Providers, Process, and Intervention Characteristics) each with multiple constructs. For this sub-study interview guide, we focused on Intervention Characteristics, Characteristics of Providers, Inner setting, and Outer setting. Within the domain Intervention Characteristics, we investigated intervention acceptability, feasibility, and fidelity. For the remaining domains, we focused on CHW self-efficacy (Characteristics of Providers), sub-study team characteristics and interaction (Inner Setting), and participant knowledge and beliefs about hypertension (Outer Setting).

Thematic content analysis was conducted in iterative steps, including initial code development with two coders, discussion of codes among study team, coding of transcripts using NVIVO, resolving coding conflicts with discussion, final code development, and re-coding of transcripts with the final codebook.

2.8 | Ethics

Ethical approval was obtained from both the Weill Cornell Medicine and GHESKIO Institutional Review Boards. Intervention participants provided written informed consent. Control participants had provided written informed consent to be part of the Haiti Cardiovascular Disease Cohort. For qualitative interviews, per protocol the physician and CHWs provided verbal consent.

3 | RESULTS

3.1 | Patient characteristics

In April 2022, a total of 516 participants were eligible for the sub-study (Figure S1). From April to August 2022, 100 participants with uncontrolled hypertension were enrolled in the intervention group. In the intervention group, the median age was 58 years (quartile 1 51 years, quartile 3 66 years), 59.0% were female, 65.0% had a primary education or lower, 67.0% made less than 1 USD/day, and over half were married or living together with their partners (Table 1). In terms of BP at enrollment, mean BP was 154.3/88.9 mmHg, 34.0% with BP ≥ 160/100 mmHg. Few participants smoked or drank alcohol, but everyone had low fruit/vegetable intake (100%). For comorbidities, a quarter were obese and 18.0% had heart failure.

For the control group, enrollment characteristics including BP were similar to intervention group, except lower values for prior antihypertensive medication prescription (35.0% vs. 93.0%) and higher rates of heart failure (33.0% vs. 18.0%).

In the intervention group, 73/100 had a 12 month clinic visit. Among the $n = 27$ lost to follow-up, compared to the demographic characteristics of the total $n = 100$ intervention group, those lost to follow-up were more likely to be male, married, with lower BP, normal weight, and fewer comorbidities (Table S1).

3.2 | Blood pressure reduction during intervention

In the main analysis for the intervention group, from enrollment to 12 months, the mean SBP change was −19.3 mmHg (95% CI −14.9, −23.7) (Figure 1), DBP change was −11.0 mmHg (95% CI −8.2, −13.9), and BP control increased from 0% to 58.1% (Table 2). For the control group, the mean SBP change was −6.5 mmHg (95% CI −2.6, −10.4), DBP change −3.9 mmHg (95% CI −1.3, −6.4), and BP control increased from 0% to 28.4%. There were greater reductions in intervention versus control groups for SBP (−12.8 mmHg; 95% CI −6.9, −18.7) and DBP (−7.1 mmHg; 95% CI −3.3, −11.0), and greater achievement of BP control (+29.7%; 95% CI 14.5, 45.0) (Figure 2).

For sustainability and maintenance, in outcomes at 18 months among participants with data, intervention versus control participants maintained greater reductions in SBP, DBP, and greater achievement of BP control (Table 2).

In a sensitivity analysis using imputed data for missing 12 month BP values, the difference in mean SBP change between intervention versus control was −12.1 (95% CI −6.7, −17.4), for DBP was −5.0 (95% CI −1.4, −8.7), and for BP control was +29.0% (95% CI 15.8, 42.2). In a sensitivity analysis, assuming missing 12 month BP values were

TABLE 1 Participant characteristics at baseline.

Characteristic	Intervention $N = 100$	Control $N = 100$	p-value
Sociodemographics			
Age[a]			
Median [Q1, Q3] (year)	58 (51, 66)	60 (51, 65)	0.4
Distribution—no. (%)			
18–29	1 (1.0%)	0 (0.0%)	0.5
30–39	7 (7.0%)	4 (4.0%)	
40–49	16 (16.0%)	16 (16.0%)	
50–59	33 (33.0%)	29 (29.0%)	
60+	43 (43.0%)	51 (51.0%)	
Female sex[a]—no. (%)	59 (59.0%)	59 (59.0%)	>0.9
Education: primary or lower—no. (%)	65 (65.0%)	74 (74.0%)	0.2
Daily income—no. (%)			0.7
<1 USD/day	67 (67.0%)	68 (68.0%)	
1–10 USD/day	16 (16.0%)	12 (12.0%)	
>10 USD/day	17 (17.0%)	20 (20.0%)	
Marital status			0.8
Single	32 (32.0%)	30 (30.0%)	
Married/living together	55 (55.0%)	59 (59.0%)	
Widowed/divorced/separated	13 (13.0%)	11 (11.0%)	
Blood pressure			
SBP[a], mean (SD) (mmHg)	154.3 (15.0)	153.3 (14.8)	0.6
DBP, mean (SD) (mmHg)	88.9 (12.1)	88.0 (9.7)	0.5
BP category—no. (%)			0.11
Hypertension stage 1 (SBP ≥140 or DBP ≥90)	66 (66.0%)	68 (68.0%)	
Hypertension stage 2 (SBP ≥160 or DBP ≥100)	34 (34.0%)	32 (32.0%)	
Previously prescribed antihypertensive medication—no. (%)	93 (93.0%)	35 (35.0%)	<0.001
Cardiovascular lifestyle behaviors			
Current smoking—no. (%)	3 (3.0%)	1 (1.0%)	0.3
Alcohol Intake > 1 drink/day—no. (%)	2 (2.0%)	1 (1.0%)	0.6
Low fruit/vegetable intake < 5 servings/day	100 (100.0%)	100 (100.0%)	–
Physical inactivity < 150 min/week—no. (%)	61 (62.2%)	62 (62.0%)	>0.9
High salt intake—no. (%)	82 (82.0%)	81 (81.0%)	0.9
Comorbidities			
BMI, median [Q1, Q3] (kg/m^2)	26.0 (22.7, 29.9)	27.1 (24.0, 30.3)	0.3
BMI category—no. (%)			0.5
Underweight (BMI < 18.5)	4 (4.0%)	2 (2.0%)	
Normal (BMI 18.5 to < 25)	39 (39.0%)	31 (31.0%)	
Overweight (BMI 25 to < 30)	32 (32.0%)	40 (40.0%)	
Obese (BMI ≥30)	25 (25.0%)	27 (27.0%)	
Diabetes mellitus—no. (%)	14 (14.0%)	18 (18.0%)	0.4
Hypercholesterolemia—no. (%)	31 (31.0%)	31 (31.0%)	>0.9
Chronic kidney disease—no. (%)	6 (6.1%)	8 (8.1%)	0.6
Heart failure—no. (%)	18 (18.0%)	33 (33.0%)	0.014

Abbreviations: BMI, body mass index; BP, blood pressure; DBP, diastolic blood pressure; SBP, systolic blood pressure; SD, standard deviation.
[a]Characteristics used to match controls to intervention participants.

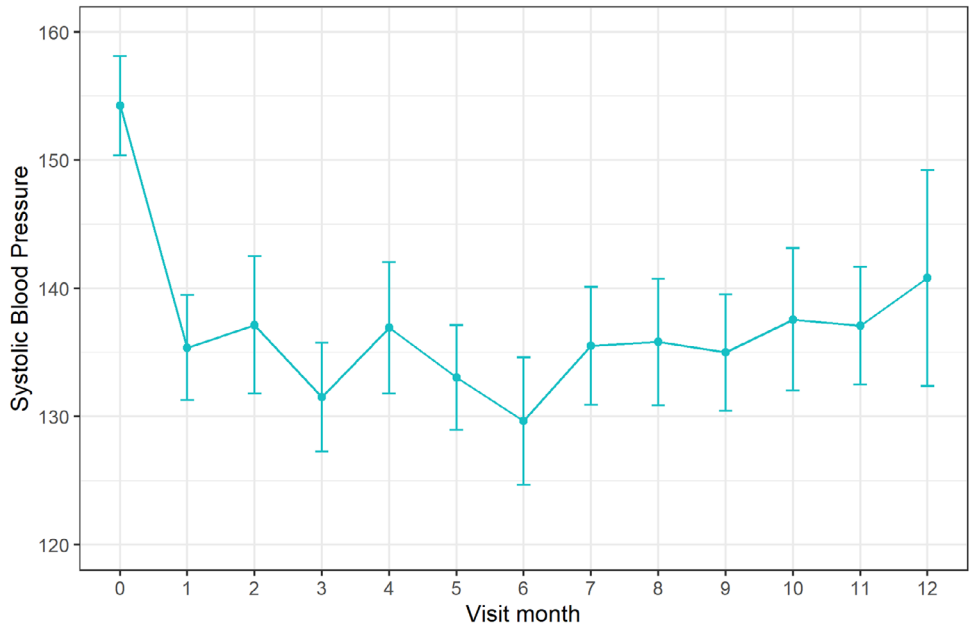

FIGURE 1 SBP change over time in intervention group.

TABLE 2 Blood pressure outcomes.

	Intervention	Control	Difference between groups (95% CI)[a]	*p*-value
BP change and BP control at 12 months	*N* = 73	*N* = 73		
SBP change, mean (95% CI)(mmHg)	−19.3 (−14.9, −23.7)	−6.5 (−2.6, −10.4)	−12.8 (−6.9, −18.7)	<0.001
DBP change, mean (95% CI) (mmHg)	−11.0 (−8.2, −13.9)	−3.9 (−1.3, −6.4)	−7.1 (−3.3, −11.0)	<0.001
BP control < 140/90—no. (%)	43 (58.1%)	21 (28.4%)	29.7 (14.5, 45.0)	<0.001
BP change and BP control at 18 months	*N* = 43	*N* = 43		
SBP change, mean (95% CI) (mmHg)	−12.5 (−8.2, −16.8)	−1.9 (−6.1, 2.4)	−10.6 (−16.6, −4.6)	<0.001
DBP change, mean (95% CI) (mmHg)	−8.5 (−5.6, −11.4)	−1.5 (−4.4, 1.4)	−7.0 (−11.0, −2.9)	<0.001
BP control < 140/90—no. (%)	21 (48.8%)	8 (18.6%)	30.2 (11.3, 49.2)	0.002

Abbreviations: BP, blood pressure; CI, confidence interval; DBP, diastolic blood pressure; SBP, systolic blood pressure.
[a]Linear mixed effect models for continuous outcomes, chi square test for categorical outcomes.

uncontrolled, the difference in BP control trended toward greater in intervention but was not statistically significant (+11%; 95% CI −2.3, 24.3).

3.3 | Adverse events, acceptability, feasibility, and final medication regimens

In the intervention group, only four participants (5.5%) reported adverse events (Table 3). Participants reported high feasibility and acceptability, with a median score on Feasibility of Intervention Measure of 5/5, and median score on Acceptability of Intervention Measure of 5/5. We also examined the number of unofficial clinic visits made in each group to evaluate potential unintended consequences (i.e., excess clinic referrals). In the intervention group, 37 participants made 50 unofficial clinic visits, for a median visit per participant of 1 (range 1–3). In the control group, 88 participants made 217 unofficial clinic visits, for a median visit per participant of 2 (range 1–6).

Participants reported high antihypertensive medication adherence, with 64 (87.7%) reporting never forgetting to take medications. For the final medication regimen, most were on amlodipine (63.0%) or hydrochlorothiazide (57.5%). The majority were on a ≥2 drug regimen (75.3%).

3.4 | Qualitative explanations for quantitative findings

Table 4 is a joint display depicting potential explanations for the quantitative findings affecting BP reduction and BP control.

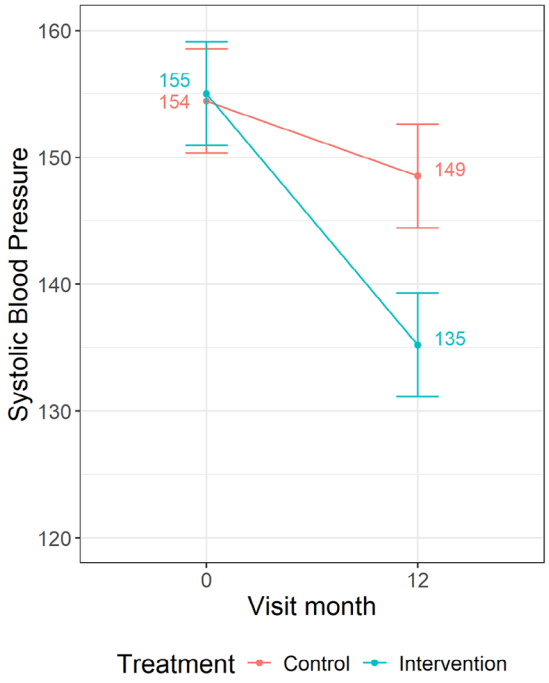

FIGURE 2 SBP change in intervention vs control groups.

3.4.1 | BP reduction during intervention

The community-based hypertension management program was effective at reducing mean SBP more in the intervention versus control group, for multiple reasons. First, major barriers to hypertension control were poverty-related barriers to clinical care (Q1) and beliefs that hypertension did not require daily medication (Q2)—not lack of diagnosis as the majority of participants had been previously prescribed antihypertensive medications. The intervention overcame these major barriers including difficulty traveling to clinic due to insecurity of lack of transport money (Q3, Q4). Participants reported community-based medication delivery improved their medication adherence by addressing difficulty traveling to obtain medications (Q5, Q6). The intervention also improved knowledge of medication adherence through counseling (Q7, Q8). Participants also accepted and enjoyed having the CHWs provide hypertension care (Q9).

From the provider level, CHWs became competent at medication titration for participants with uncomplicated hypertension (Q10, Q11), although titration for those with comorbidities with heart failure remained challenging (Q12). A key element of this success was teamwork, and a close working relationship between the CHWs and the clinician (Q13, Q14).

3.4.2 | Sustainability

For those intervention participants with follow-up around 18 months after the intervention activities were completed, SBP reduction was sustained, perhaps due to sustained improvements in attending clinic follow-up visits (Q15) and medication adherence (Q7, Q8, Q16).

TABLE 3 Secondary outcomes at 12 months.

	Intervention group $N = 73$
Adverse effects	
Dizziness	1 (1.4%)
Hypotension	1 (1.4%)
Edema	0 (0.0%)
Other	2 (2.8%)
Acceptability and feasibility	
Feasibility of Intervention Measure, median [Q1, Q3]	5 (5, 5)
Acceptability of Intervention Measure, median [Q1, Q3]	5 (5, 5)
Number community visits, mean (range)	7 (3–11)
Antihypertensive medications	
Adherence	
Ever forget to take medications	4 (5.6%)
Ever forget to take medications when feeling better	6 (8.3%)
Ever forget to take medications when feeling sick	5 (6.9%)
Never forget (no to all three questions)	64 (87.7%)
Number of medications	
0 Drug regimen	8 (11.0%)
1 Drug regimen	10 (13.7%)
2+ Drug regimen	55 (75.3%)
Regimen	
Amlodipine	46 (63.0%)
Hydrochlorothiazide	42 (57.5%)
ARB (Losartan)	22 (30.1%)
ACEi (lisinopril, enalapril, captopril)	11 (15.1%)
Beta blocker	17 (23.3%)
Furosemide	6 (8.2%)

Abbreviations: ACEi, angiotensin converting enzyme inhibitor; ARB, angiotensin receptor blocker.

3.4.3 | Acceptability, feasibility

Participants reported high acceptability of the community-based home visits and medication delivery (Q4–Q6, Q17–Q19). While there was initial hesitation with task-shifting from the physician and CHWs, with time and experience, both groups grew more comfortable (Q10). CHWs in particular reported high motivation from witnessing behavior change among their participants (Q21).

TABLE 4 Joint display of qualitative explanations for quantitative findings.

BP reduction during intervention
Quantitative result: During the first year, blood pressure improved in both sub-study groups, but more in the (58% vs. 35%) in intervention group.
Qualitative explanations: Given the majority of intervention participants had been previously prescribed antihypertensive medications, lack of diagnosis was not a major barrier to hypertension control. Instead, major barriers included: poverty-related barriers to clinical care, and beliefs that hypertension is an asymptomatic condition that does not require daily medication. Q1: "There's no money for transportation [to clinic]." ~ Participant 2, FGD 1 Q2: "[Patients] think hypertension, it's like an acute disease. I got hypertension and take my meds for two weeks and I'm okay. It's difficult for them to understand that you have to continue to take it." ~ MD IDI
Qualitative explanation: Intervention successfully addressed gap of patient difficulty coming to GHESKIO, due to insecurity or no money for transport due to poverty. Q3: "Yes, when in the clinic visit, when we tell the participant, a lot of participants prefer the field worker bring medication at home. Because most of the time they don't have money. Also they have fear to get on the street and go to GHESKIO to have medication." ~ MD IDI Q4: "Previously, I struggled to afford transportation costs, especially to acquire medications. When the agent started delivering the medications, it brought me joy." ~ Participant 1, FGD 1
Qualitative explanation: Medication delivery facilitated medication adherence for participants. Q5: "I started taking my medications regularly, and I've seen significant improvements…The program has been a real lifeline. I used to buy medicines elsewhere, but GHESKIO provides efficient medication. My blood pressure used to be high, but now it's normalized. I really appreciate the program." ~ Participant 3, FGD 2 Q6: "Having medications delivered to our homes is more convenient, especially considering the country's challenging situation and my age, which sometimes makes it difficult for me to travel." ~ Participant 4, FGD 2
Qualitative explanation: Counseling in the program taught participants how to take their medications which improved medication adherence, and how to change lifestyle behaviors like diet. Q7: "I knew about my hypertension, but I wasn't aware of the correct way to take my medications. Since I joined the GHESKIO program, I've learned more about the schedule and how to take them. Other clinics never provided this level of information. Since the medications were delivered, my health has improved considerably. It's been eye-opening." ~ Participant 3, FGD 2 Q8: "I had problems with my blood pressure, but I didn't realize it was hypertension. I had medications at home but didn't take them regularly. The GHESKIO program has helped me stick to a regular routine, educating me on what I can and cannot eat." ~ Participant 4, FGD 2
Qualitative explanation: Strong, interpersonal relationships between CHWs and participants. Q9: "Everything was fine. The agent who used to visit me was like a friend. He would even call me to remind me to take my medicine." ~ Participant 1, FGD 2
Quantitative result: 75% participants required a two drug regimen to achieve BP control.
Qualitative explanation: CHWs became competent at medication titration for uncomplicated patients. Titration for those with comorbidities like heart failure remained challenging. Q10: "When we continue the sub-study, the field worker gets more experience to adjust the medication and just confirm with the doctor… For the patient without comorbidities, the field worker, the experience was good and the field worker give them the appropriate adjustment and coordination with the other staff." ~ MD IDI Q11: "Things I didn't know before that I learned, thanks to this job I have more knowledge about blood pressure." ~ CHW 2 FGD Q12: "The sub-study is easy for the field worker and when the field worker, when we have a participant who take an uncomplicated regimen. And if also the participant don't have a lot of disease. But it's a little bit complicated for the field worker when we have participants with a lot of comorbidities, to follow the management of the medication." ~ MD IDI
Qualitative explanation: CHW competency was achieved as the result of training, great working relationship with the doctor, and experience. While task shifting was challenging at first, team efficacy increased and improved over time. Q13: "There's no negative experience, we only have positive experience with the knowledge we have according to the training we receive. Sometimes we analyze the patient's case, we check their blood pressure, we ask them question and we make a diagnosis about the patient's blood pressure, sometimes I have an idea [about medication increase] and I call the doctor to confirm and it turned out that he had the same idea. That made me understand that I learned, and I can manage that case. As my colleague mentioned if we have a case that's beyond our knowledge we call the doctor, depending on the case we may set an appointment with the patient and doctor so he can check to see what's wrong and then he tries to fix it." ~ CHW 4, FGD Q14: "We're working together, the nurse, because I think this sub-study could not be possible without all the teamwork. I would not be able for me only to make the sub-study done. We have to also congratulate our nurse. She does a good job. And also the field worker who works every day, and on the weekend also, and on Sunday. Sometimes they call me on the phone and some patients have no time because they are sellers, and they only have Sunday. And maybe after the church and late, they go to the field to the participant home. They are close to the patient. Some patients really appreciate it. They do a good job." ~ MD IDI
Sustainability
Quantitative result: SBP reduction and BP control was sustained for some intervention arm participants after 18 months.
Qualitative explanation: Intervention improved participant medication adherence and clinic attendance, even beyond the 12-month sub-study period. Q15: "One participant had irregular follow-up before the program. But after the program, he is regular in his follow-up, he cares a lot about taking his medications, cares about his blood pressure, and even brings his wife to clinic" ~ MD IDI Q16: "Before [this program], I knew I had hypertension but didn't take my medications regularly. Now, I've started taking them as prescribed through GHESKIO." ~ Participant 2, FGD 2

(Continues)

TABLE 4 (Continued)

Acceptability, Feasibility
Quantitative result: Participants reported high acceptability and feasibility on AIM and FIM scales.
Qualitative explanation: Participants liked the community-based visits and community-based medication delivery. Participants felt taken care of by the CHWs, and believed their blood pressure decreased. Q17: "Since coming here, I've been saved, my blood pressure used to be 180/122. Despite visiting the hospital, nothing changed. When the agents interacted with me, I decided to participate. It was a struggle for me, but now, with the check-ups and medications, I feel better." ~ Participant 4, FGD 1 Q18: "I think the current program is working well. I've had a positive experience and am happy with how it's being carried out." ~ Participant 4, FGD 2 Q19: "I'm grateful to be a part of the program, especially considering the security challenges in the country. The agents risk their lives to bring us medicines, and they guide us on how to use them and control our diet." ~ Participant 5, FGD 2
Qualitative explanation: Both physician and CHWs grew comfortable with task-shifting, and CHWs taking on more roles such as medication delivery and titration. CHWs motivated by the behavior change they saw in participants, and liked contributing to that positive change. Q20: "Some people understand what we do, they understand its importance and they appreciate it, they respect when you have an appointment with them and they also take their medicines, you see how their blood pressure improves and for some of them the blood pressure even gets controlled. It is satisfying for us as we see we did not work in vain…it is satisfying for me knowing they do, and also it helps me knowing that I help others, although the job is very hard." ~ CHW 4 FGD
Remaining challenges in BP control
Quantitative result: In intervention group, 42% did not achieve BP control.
Qualitative explanation: Participants had other priorities such as need for food and income leading to lack of involvement with sub-study procedures. Q21: "Some of the patients are not really interested in taking the medications…Some patients simply don't want you to visit them, even if you call them to let them know you are coming, when you get to their houses or at the meeting point, you don't see them. So you have to be going back and forth. These are the ones who are not really interested, the ones who think they should get something extra in addition to the cardiovascular care they are getting… They would like, I mean, is not their priority, they would like to receive something else, like money or food. That's their priority. For that reason, they don't want to meet you even if you have an appointment with them they don't want to. You struggle with them for several months to see if they could take their medications. Despite your counseling, they never get to accept your help." ~ CHW 4 FGD
Qualitative explanation: Poverty and lack of access of affordable healthy foods limited feasibility of following counseling on increasing fruit and vegetable intake. Q22: "The most challenging part was when we recommended them [participants] to eat fruits, when we told them there is a certain amount of fruit they should eat weekly, when you visit them they say to look at where they live and see if they can do what you're asking. Then we have to stay silent because if we talk they will start asking us for help and we cannot give them what they need." ~ CHW 3 FGD
Qualitative explanation: Some participants preferred to go to clinic for medications rather than receive them through the CHW. Q23: "When the medications are delivered to me, I miss out on the medical consultation" ~ Participant 4, FGD 1
New findings
Quantitative result: During follow-up visit pill counts, some participants would routinely have 2–4 weeks of fewer pills than they should based on last visit and number of dispensed pills.
Qualitative explanation: Participants were sharing medications with their friends and families. Q24: "Sometimes, I even share my own medicines with those who cannot afford them." ~ Participant 5, FGD 2 Q25: "My sister and I are similar in age, and we both have diabetes and hypertension. We share medications, and I don't see anything wrong with it. It can be a lifesaver for them." ~ Participant 3, FGD 2
Quantitative result: During sub-study visits, participant family members often wanted their BP measured, even though they were not formally enrolled in the sub-study.
Qualitative explanation: Participants interested in expanding the community hypertension management program to include their household members, beyond the current scope. Q26: "I believe it [the community hypertension management program] would be beneficial for both our households and the community. People might pay more attention if they receive guidance from an agent." ~ Participant 2, FGD 2

Abbreviations: BP, blood pressure; CHW, community health worker; GHESKIO, Groupe Haitien d'Etude du Sarcome de Kaposi et des Infections Opportunistes Centers.

3.4.4 | Remaining challenges to BP control

Despite these successes, 42% of participants in the intervention group did not achieve BP control by the end of the sub-study. Persistent barriers included severe poverty, which led to competing priorities (Q21) and inability to purchase more expensive healthy foods (Q22). Lastly, one participant reported preferring to go to the clinic for medications rather than receive them in the community with a CHW (Q23).

3.4.5 | New findings

There were two unanticipated findings in this sub-study. Participants were interested in expanding the community-based hypertension program to include their household members, and shared medications with family and friends (Q24–25). This indicated an interest to expand the program to family and the wider community (Q26).

4 | DISCUSSION

We found the intervention of community-based hypertension management resulted in greater BP reduction than matched controls over 12 months. Mixed methods analysis found CHWs were able to successfully titrate antihypertensive medications under physician supervision, and both participants and staff found the program to be acceptable and feasible. However, challenges around extreme poverty and difficulty changing lifestyle behaviors like increasing fruit/vegetable intake persisted. Unexpected findings included participants expressing interest in expanding the program to family and friends, with medication sharing.

Our finding that task-shifting with CHWs led to a −12.8 mmHg greater SBP reduction in intervention versus control groups is larger than previous task-shifting studies. In a systematic review and meta-analysis of 43 trials examining SBP reduction in task-shifting interventions with mostly 6 and 12 month follow-up with nurses ($n = 30$), pharmacists ($n = 10$), or CHWs ($n = 19$), the greatest SBP reduction was achieved by pharmacists (−8.12 mmHg, 95% CI: −10.23 to −6.01), and smallest for CHWs (−3.67 mmHg, 95% CI: −4.58 to −2.77).[22] The difference between our findings and this meta-analysis may be due to the fact that while our CHW intervention included algorithm-based treatment escalation under physician supervision, most of the prior studies only included BP measurement, counseling on lifestyle modification, and linkage to care.[25–28] Only one study in Tibet and India among participants with pre-existing CVD or at high CVD risk involved CHWs titrating medications, which increased the percentage on medications, but did not measure BP outcomes.[29]

We had relatively high loss to follow-up, with 27% of the intervention group not completing a 12 month clinic visit. One reason may be that barriers to clinic-based care were insurmountable in some cases, resulting in some participants unable to complete this last visit. Notably, those lost to follow-up were more likely to be male with lower BP and fewer comorbidities. Men have been found to access healthcare less frequently than women, possibly related to male norms of risk-taking and ideas of masculinity precluding regular medical care.[30] Men also have been found to have worse health outcomes than women across multiple health outcomes, likely related to less frequent healthcare access.[30] Future research on BP control should include implementation strategies specifically targeting men with hypertension without comorbidities who are less likely to seek care.

We found CHWs can successfully and accurately titrate antihypertensive medications, which may be an important approach to achieve BP control in resource limited settings. This is consistent with a systematic review which found team-based care with non-physicians titrating medications had the largest impact on SBP reduction (−6.6 mmHg, 95% CI: −9.0 to −4.2) out of all implementation strategies examined (health coaching, home BP monitoring, team-based care with physicians titrating medications).[31] Task-shifting with CHWs is essential for countries like Haiti which have very limited physicians (0.2 per 1000 population) and nurses (0.4 per 1000 population).[32] Furthermore, using CHWs in our intervention group was not associated with an unintended consequence of more unexpected clinic visits—in fact, it was associated with fewer compared to control. This suggests the community visits by the CHW were successful at replacing follow-up clinic visits by the physician for BP management, without an unintended increase in unexpected clinic visits. In LMICs, where there is a shortage of even nurses and pharmacists, utilizing CHWs will be an important avenue forward to achieving BP control.

While our intervention of task-shifting and community-based delivery of care did reduce SBP greater than control, mixed methods analysis showed challenges remained around extreme poverty. Poverty is commonly cited in studies on barriers to hypertension control due to challenges purchasing medications,[13,33,34] foregoing work to attend clinic, and the high cost of healthier food options.[35] While community-based care in our intervention did address barriers like difficulty accessing clinic due to civil unrest or lack of money for transportation, participants still reported it was challenging to purchase more fruits and vegetables due to the higher cost. Continued financial burdens of achieving BP control need to be addressed in future versions of the intervention.

Participants expressed interest in expanding the community-based hypertension management program to family and friends, and freely shared medications with others who either had or thought they had hypertension. Family-based approaches to healthcare delivery are common in pediatric care,[36] but not in chronic disease management for adults, and may be a promising avenue for future research in BP control and CVD health promotion.[37] Findings on impact of family-based approaches are mixed. In a randomized controlled trial in India targeting families of individuals with coronary heart disease, task-shifting with CHWs and community-based care on screening for CVD risk factors, structured lifestyle interventions, and linkage to care improved the odds of achieving a composite primary outcome of controlled BP, glucose, cholesterol, and abstinence from tobacco (OR 2.2).[38] However, another behavioral intervention in rural Kerala using neighborhood groups to promote healthy fruit/vegetable intake showed only modest increases in fruit intake, but did show reduction in consumption of salt, sugar, and oil.[39]

Limitations of this sub-study include possible selection bias due to lost to follow-up and non-randomized selection of control participants. We mitigated lost to follow-up by using last measured BP carried forward in a sensitivity analysis, which showed similar results to the main analysis. Control participants were less likely to be prescribed antihypertensive medications at enrollment, suggesting they may have been less aware of their hypertension diagnosis compared to intervention participants. However, we mitigated this potential selection bias by matching controls based on age, sex, and baseline SBP.

In conclusion, we found a community-based hypertension management intervention that combined task-shifting with CHWs and community delivery of care resulted in a −12.8 mmHg greater BP reduction compared to a control group. CHWs were able to successfully titrate antihypertensive medications under physician supervision, and participants expressed interest in expanding the program to friends and family members.

AUTHOR CONTRIBUTIONS

Concept and design: Lily D. Yan, Margaret L. McNairy, and Vanessa Rouzier; Acquisition, analysis, or interpretation of data: Reichling St Sauveur, Radhika Sundararajan, Marie Christine Jean Pierre, Vanessa Rouzier, Fabiola Preval, Serfine Exantus, Mirline Jean, Josette Jean, Guyrlaine Pierre-Louise Forestal, Obed Fleurijean, Jean W. Pape, Radhika Sundararajan, Margaret L. McNairy, and Lily D. Yan; Drafting of manuscript: Reichling St Sauveur, Radhika Sundararajan, Margaret L. McNairy, and Lily D. Yan; Critical review of manuscript for important intellectual content: Reichling St Sauveur, Radhika Sundararajan, Marie Christine Jean Pierre, Vanessa Rouzier, Fabiola Preval, Serfine Exantus, Mirline Jean, Josette Jean, Guyrlaine Pierre-Louise Forestal, Obed Fleurijean, Nour Mourra, Anju Ogyu, Rodolphe Malebranche, Jean Pierre Brisma, Marie M. Deschamps, Jean W. Pape, Radhika Sundararajan, Margaret L. McNairy, and Lily D. Yan; Statistical analysis: Anju Ogyu and Lily D. Yan; Obtained funding: Lily D. Yan, Margaret L. McNairy, and Jean W. Pape; Administrative, technical, or material support: Vanessa Rouzier, Josette Jean, Guyrlaine Pierre-Louise Forestal, Marie M. Deschamps, Jean W. Pape, Rodolphe Malebranche, and Jean Pierre Brisma; Supervision: Jean W. Pape and Lily D. Yan.

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CONFLICT OF INTEREST STATEMENT

The coauthors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

Researchers who provide a methodologically sound proposal may have access to a subset of deidentified participant data, with specific variables based on the proposal. Proposals should be directed to the principal investigator at liy9032@med.cornell.edu. To gain access, data requestors will need to sign a data access agreement. Data are available following publications through 3 years after publication and will be provided directly from the PI.

PATIENT CONSENT STATEMENT

None.

PERMISSION TO REPRODUCE MATERIAL FROM OTHER SOURCES

None.

CLINICAL TRIAL REGISTRATION

Clinicaltrials.gov NCT03892265

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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