





The IMPACT-BP Trial

A Community-Based Intervention for Sustainable Blood Pressure Control in KwaZulu-Natal, South Africa









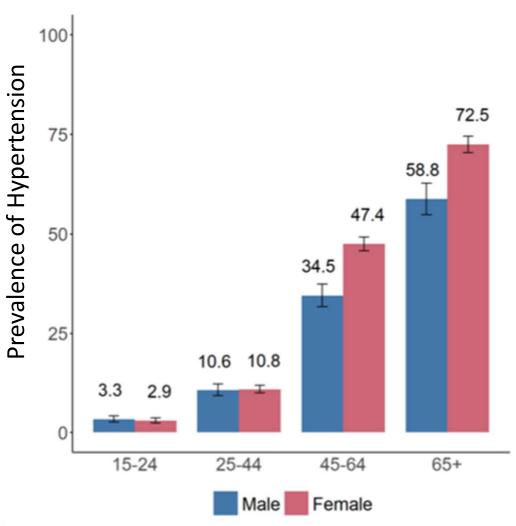
Convergence of infectious and non-communicable disease epidemics in rural South Africa: a cross-sectional, population-based multimorbidity study



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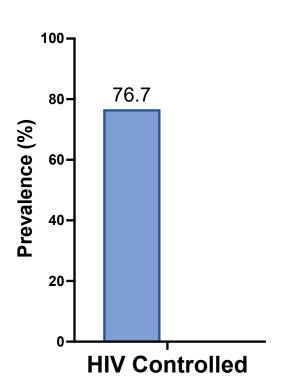
Population Prevalence of HTN in Northern KZN





Unlike HIV, HTN Control Remains Poor

Prevalence of Disease Control



Disease Control: HIV: VL<40; HTN: BP<140/90







Global report on hypertension

The race against a silent killer

The 90/90/90 Cascade: starting from scratch

Table 2. Age-standardized prevalence of hypertension among adults aged 30–79 years, and among those with hypertension, diagnosis, treatment and effective treatment coverage in 2019, by WHO region

Region	Hypertension (%)			
African	36 (38, 33)			

Hypertension matters

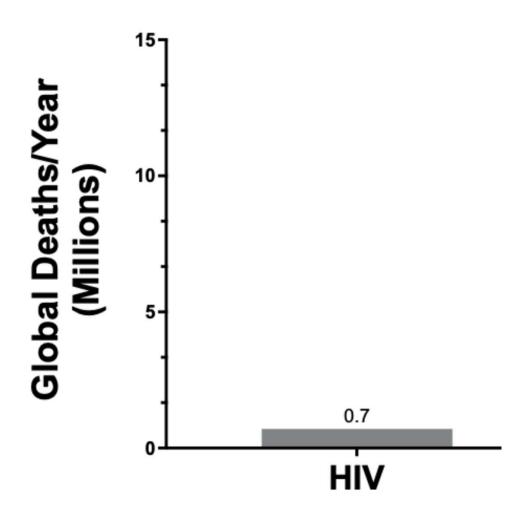


Table 4.5: The ten leading underlying natural causes of death, 2019–2021*							
Causes of death (ICD-10)	2021						
Causes of death (ICD-10)	Rank	Number	%				

IMPACT-BP

- Overarching goals:
 - Determine causes for poor hypertension control in rural South Africa
 - Co-develop an intervention with partners and end-users to address those causes
 - Implement and evaluate a novel model of care to improve blood pressure and increase disease control rates in rural South Africa

Objectives of IMPACT-BP Study

Aim 1

Design and determine the acceptability and conduct a readiness assessment for a community-based hypertension control program in rural KZN

Learning from the Health System



Learning from the Patients and HCW

Activity	Types of participants
Focus Group Discussions (32 participants)	HCWsOutreach Team LeadersHTN Patients
Key Informant Interview (9 participants)	 Clinic Supervisors/Managers Subdistrict Officials District Officials Provincial Officials Community Leaders

Learning from CHWs

"..it helps them when we have to deliver medication for them but sometimes, they have to go to the clinic to check their BP measurements, sometimes they go to the clinic and find out that the machine for testing BP is not working." -CHW

Structural Factors

Inter-generational poverty; Extreme rurality; Loss of trust in formal healthcare systems

Health System Factors

Over-burdened clinics; Poor decision support; Prioritization of acute care over primary care

Family & Community Factors

Beliefs & understandings of chronic diseases; Social support; Access to affordable, nutritious food

Individual Factors

Financial & opportunity costs of clinic visits; Low self-efficacy & perceived need; Co-morbid mental & physical health problems

Learning from SA Guidelines

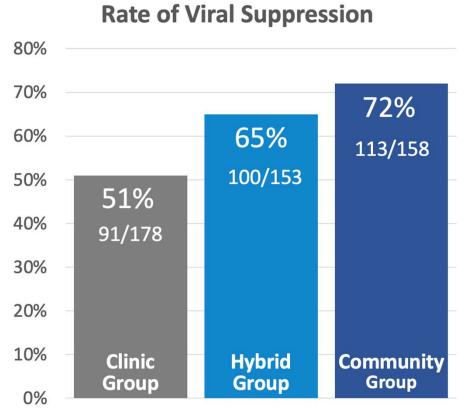
SA National DoH Strategic Framework 2019-2024:

- Reduce mortality and morbidity by accelerating implementation of a 90-90-90 strategy for NCDs
- Integration of CHWs in the public health system, strengthening clinics, and implementing a digital health strategy.

¹ National Development 2030, the Medium Term Strategic Framework 2019-2024.

Learning from Successful HIV Programs

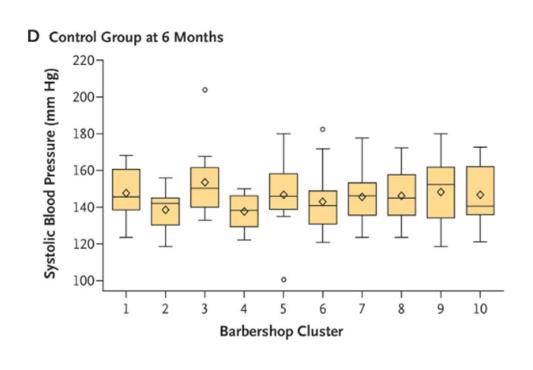


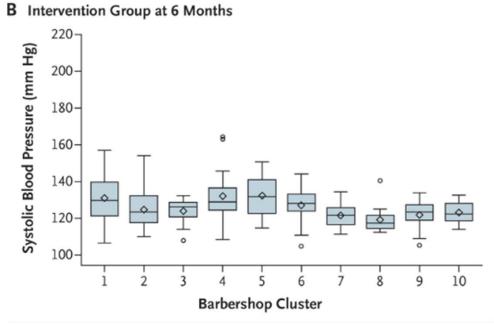


Decentralization of HIV Care

- Decongest clinics
- Reduce wait times
- Capacitate CCG/CHW workfore
- Engage patients in selfmanagement
- Reduce transportation costs

...and from innovative HTN care programs elsewhere





A community-based care model

Goals of program

- Enhance patient efficacy and selfempowerment
- Reduce transportation costs
- Decongest clinics
- Decrease wait times
- Task shift away from over-burdened nurses
- Actively support nurses to respond to respond to high blood pressure



A community-based care model

Three main program elements

- Patients to measure/monitor their own blood pressure at home
- 2. CHWs to visit patients to collect data, address challenges, and deliver medicines
- 3. Nurses to manage care remotely with mobile health tools and decision support

Objectives of IMPACT-BP Study



Design and determine the acceptability and conduct a readiness assessment for a community-based hypertension control program in rural KZN

Aim 2

Conduct a randomized trial to determine the effectiveness of a community-based hypertension control program in rural KZN

Aim 2: IMPACT-BP Trial Design

<u>Location</u>: Primary healthcare clinics in uMkhanyakude District in KZN

Design: Open-label, three-arm randomized controlled trial

<u>Eligibility</u>: age > 18, HTN (>140/90 mmHg, two readings >=6 months apart)

Exclusion criteria: (people who need physician support)

- -pregnancy
- -severe symptomatic HTN >180/110, advanced renal disease, >3 BP meds
- -planning to move within 24 months

Randomization to one of three arms:

Standard of care

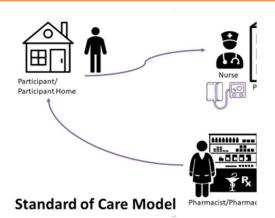
- Routine clinic-based hypertension care
- All monitoring, decision making, and prescriptions occur at clinic

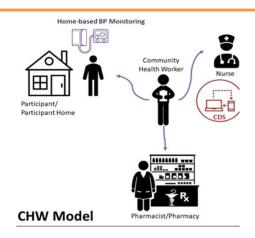
CHW

- Self-monitoring of BP
- Home visits by CHW
- Remote management of BP by nurses using app
- CHW delivery of medicines

eCHW+

- BP readings automatically sent to nurses via device
- Self-monitoring of BP
- Remote management of BP by nurses using app
- CHW delivery of medicines



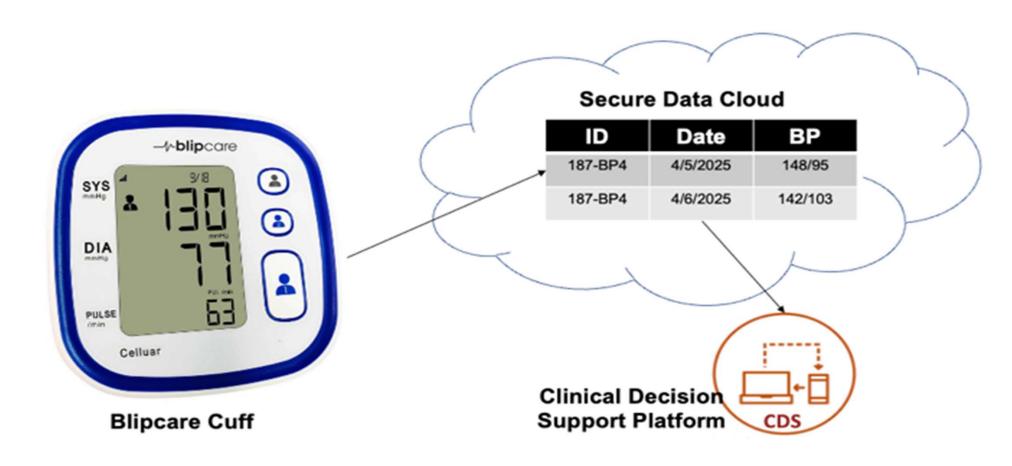




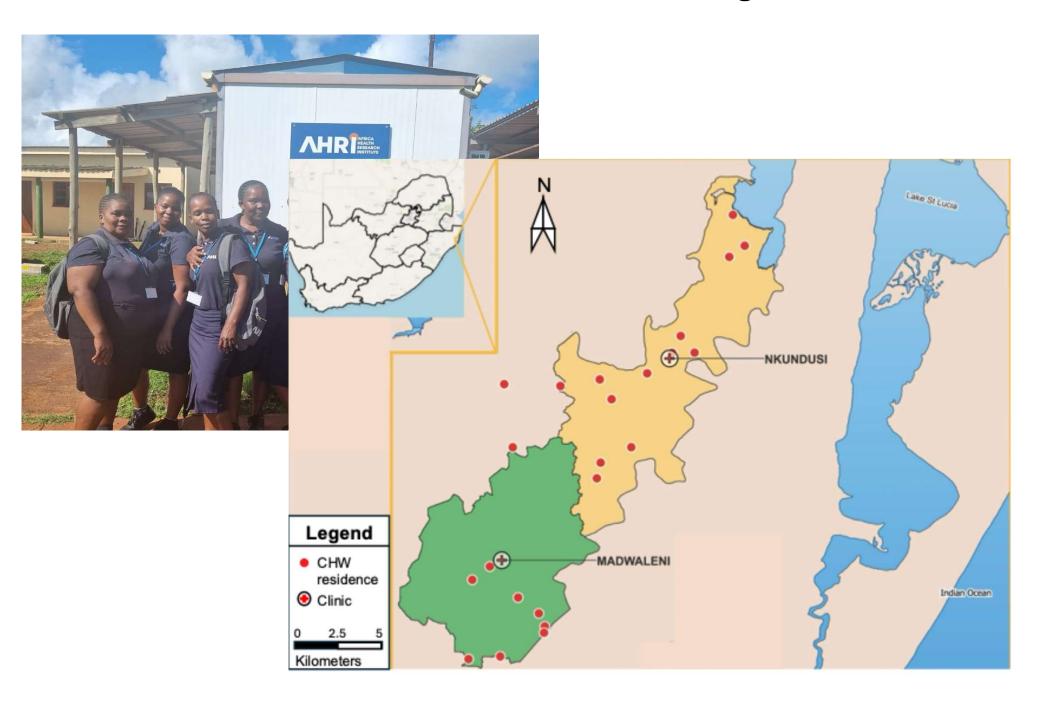
Standard Cuffs: Omron M3 Model (~1500R/\$75 each)



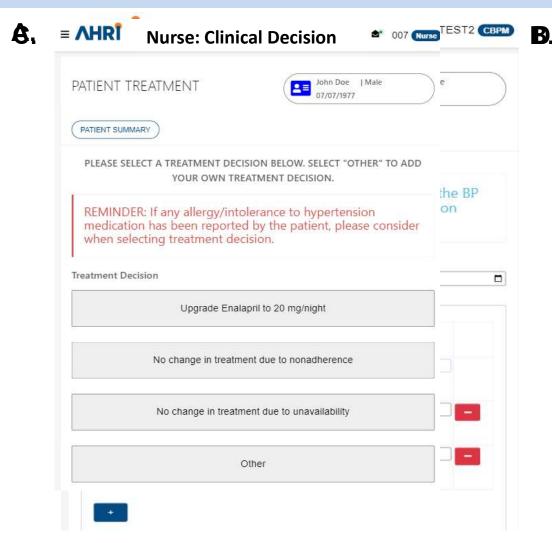
Smart Cuffs: Care Matrix Blipcare Model (~2000R/\$100 each fee includes data service)

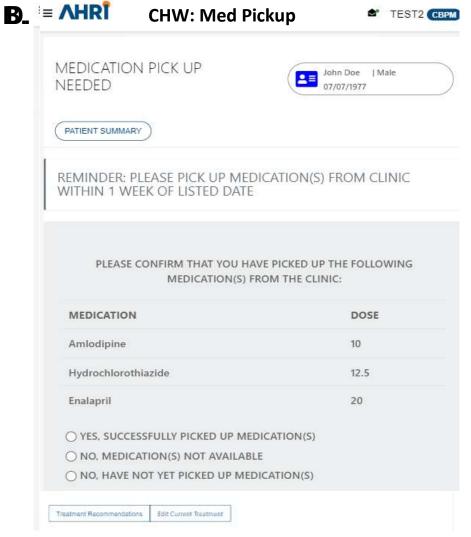


CHWs: Heart and Soul of the Program



Intervention App







Intervention App

Standard Treatment Guidelines and Essential Medicines List for South Africa

Primary Healthcare Level 2018 Edition



STEP 2: Add hydrochlorothiazide.

Entry to Step 2	Treatment	Target
» Diastolic BP 90–99 mmHg and systolic BP 140–159 mmHg without any existing disease. AND » No major risk factors. AND » Failure of lifestyle modification alone to reduce BP after 3 months. OR Mild hypertension with major risk factors or existing disease. OR Moderate hypertension at diagnosis.	Lifestyle modification AND Hydrochlorothiazide, oral, 12.5 mg daily. LoE:Pool	» BP control within 1 month to < 140/90 mmHg.

STEP3: Add a second antihypertensive medicine.

Entry to Step 3	Treatment	Target
 Failure to achieve targets in Step 2 after 1 month despite adherence to therapy. OR Severe hypertension (See table). 	 » Lifestyle modification AND • Hydrochlorothiazide, oral, 12.5 mg daily. ADD • Long-acting calcium channel blocker, e.g.: • Amlodipine, oral, 5 mg daily. 	» BP control within 1 month to <140/90 mmHg.



Intervention App

line_no he	eart_attack	join_1	diabetes_history	join_2	avg_sys_min	avg_sys_max	join_3	avg_dias_min	avg_dias_max jo	in_4	dose_4	rec_1	rec_2	rec_3
G1 no	0	and	no	and	140	15	9 and	90	99 a	nd r	null	Add Hydrochlorothiazide 12.5 mg/d	Add Amlodipine 5 mg/night	Add Enalapril 10 mg/night
G2 no	0	and	no	and	160	INF	and/o	r 100	INF a	nd r	null	Add Hydrochlorothiazide 12.5 mg/d + Amlodipine 5 mg/night	Add Hydrochlorothiazide 12.5 mg/d + Enalapril 10 mg/night	Add Hydrochlorothiazide 12.5 mg/d
G3 no	0	and	no	and	0	13	9 and		89 a	nd r	null	Congratulations for reaching blood pressure goals, continue on current treatment for hypertension.		
G4 no	0	and	no	and	140	INF	and/o	r 90	INF a	nd r	null	Add Amlodipine 5 mg/night	Add Enalapril 10 mg/night	No change in treatment due to nonadhere
G5 no	0	and	no	and	140	INF	and/o	r 90	INF a	nd r	null	Add Amlodipine 5 mg/night	Add Enalapril 10 mg/night	No change in treatment due to nonadhere
G6 no	0	and	no	and	140	INF	and/o	r 90	INF a	nd r	null	Add Hydrochlorothiazide 12.5 mg/d	Rotate Amlodipine to Hydrochlorothiazide 12.5 mg/d	Upgrade Amlodipine to 5 mg/night
G7 no	0	and	no	and	140	INF	and/o	r 90	INF a	nd r	null	Add Hydrochlorothiazide 12.5 mg/d	Rotate Amlodipine to Hydrochlorothiazide 12.5 mg/d	Upgrade Amlodipine to 10 mg/night
G8 no	0	and	no	and	140	INF	and/o	r 90	INF a	nd r	null	Add Hydrochlorothiazide 12.5 mg/d	Rotate Amlodipine to Hydrochlorothiazide 12.5 mg/d	Add Enalapril 10 mg/night
G9 no	0	and	no	and	140	INF	and/o	r 90	INF a	nd r	null	Add Hydrochlorothiazide 12.5 mg/d	Upgrade Enalapril to 10 mg/night	Rotate Enalapril to Hydrochlorothiazide 12
G10 no	0	and	no	and	140	INF	and/o	r 90	INF a	nd r	null	Add Hydrochlorothiazide 12.5 mg/d	Rotate Enalapril to Hydrochlorothiazide 12.5 mg/d	Upgrade Enalapril to 20 mg/night
G11 no	0	and	no	and	140	INF	and/o	r 90	INF a	nd r	null	Add Hydrochlorothiazide 12.5 mg/d	Rotate Enalapril to Hydrochlorothiazide 12.5 mg/d	Upgrade Enalapril to 20 mg/night
G12 no	0	and	no	and	140	INF	and/o	r 90	INF a	nd r	null	Add Hydrochlorothiazide 12.5 mg/d	Rotate Enalapril to Hydrochlorothiazide 12.5 mg/d	Add Amlodipine 5 mg/night
G32 no	0	and	no	and	140	INF	and/o	r 90	INF a	nd r	null	Upgrade Amlodipine to 5 mg/night	Upgrade Enalapril to 10 mg/night	No change in treatment due to nonadhere
G33 no	0	and	no	and	140	INF	and/o	r 90	INF a	nd r	null	Upgrade Amlodipine to 5 mg/night	Upgrade Enalapril to 20 mg/night	No change in treatment due to nonadhere
G34 no	0	and	no	and	140	INF	and/o	r 90	INF a	nd r	null	Upgrade Amlodipine to 5 mg/night	Upgrade Enalapril to 20 mg/night	No change in treatment due to nonadhere
G35 no	0	and	no	and	140	INF	and/o	r 90	INF a	nd r	null	Upgrade Amlodipine to 5 mg/night	No change in treatment due to nonadherence	No change in treatment due to unavailabili
G36 no	0	and	no	and	140	INF	and/o	r 90	INF a	nd r	null	Upgrade Enalapril to 10 mg/night	Upgrade Amlodipine to 10 mg/night	No change in treatment due to nonadhere
G37 no	0	and	no	and	140	INF	and/o	r 90	INF a	nd r	null	Upgrade Amlodipine to 10 mg/night	Upgrade Enalapril to 20 mg/night	No change in treatment due to nonadhere
G38 no	0	and	no	and	140	INF	and/o	r 90	INF a	nd r	null	Upgrade Amlodipine to 10 mg/night	Upgrade Enalapril to 20 mg/night	No change in treatment due to nonadhere
G39 no	0	and	no	and	140	INF	and/o	r 90	INF a	nd r	null	Upgrade Amlodipine to 10 mg/night	No change in treatment due to nonadherence	No change in treatment due to unavailabili
G40 no	0	and	no	and	140	INF	and/o	r 90	INF a	nd r	null	Upgrade Enalapril to 10 mg/night	No change in treatment due to nonadherence	No change in treatment due to unavailabil
G41 N	^	and	00	and	140	INE	and/n	, 01	INE a	nd /	null.	Lingrada Eppianril to 20 ma/piaht	No change in treatment due to populherance	No change in treatment due to unavailabil



Table 1. Summary of Study Visit Procedures

	Enrollment Visit	6-Month Visit	12-month Visit
Screening and eligibility form	✓		
Consent form	✓		
Point of care creatinine	✓		
Sociodemographic questionnaire	✓		
Tracking form	✓		
Hypertension KAP	✓	✓	✓
Medication adherence	✓	✓	✓
Hypertension treatment history	✓	✓	✓
Resource use form	✓	✓	✓
Health related quality of life	✓	✓	✓
Blood pressure measurements	✓	✓	✓
Chart review for medication and laboratory history	✓	✓	✓

Study Outcomes

Outcome measurements:

- 6 months/12 months
- Home visits by study staff, not involved in CHW program, blinded to study arm



Primary Outcome:

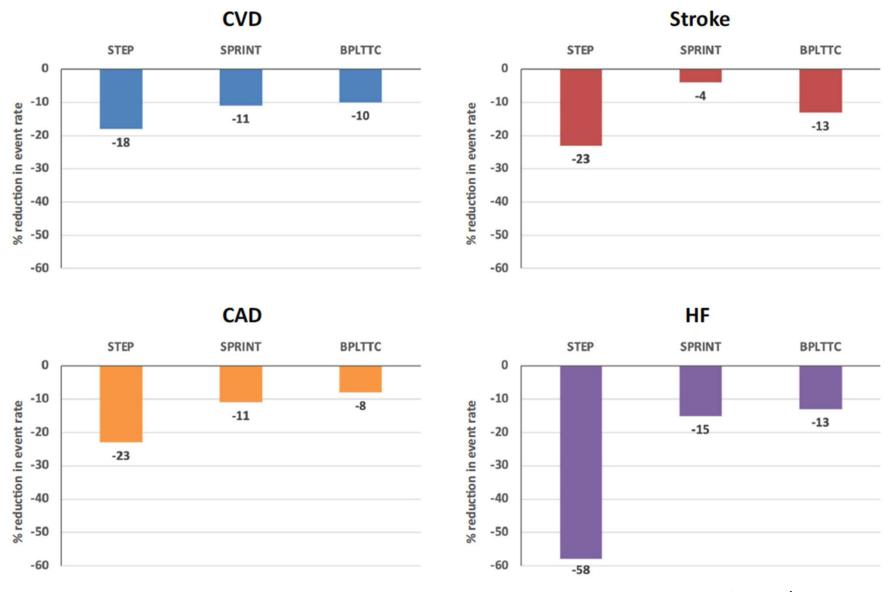
Change in systolic blood pressure from enrollment to 6 months

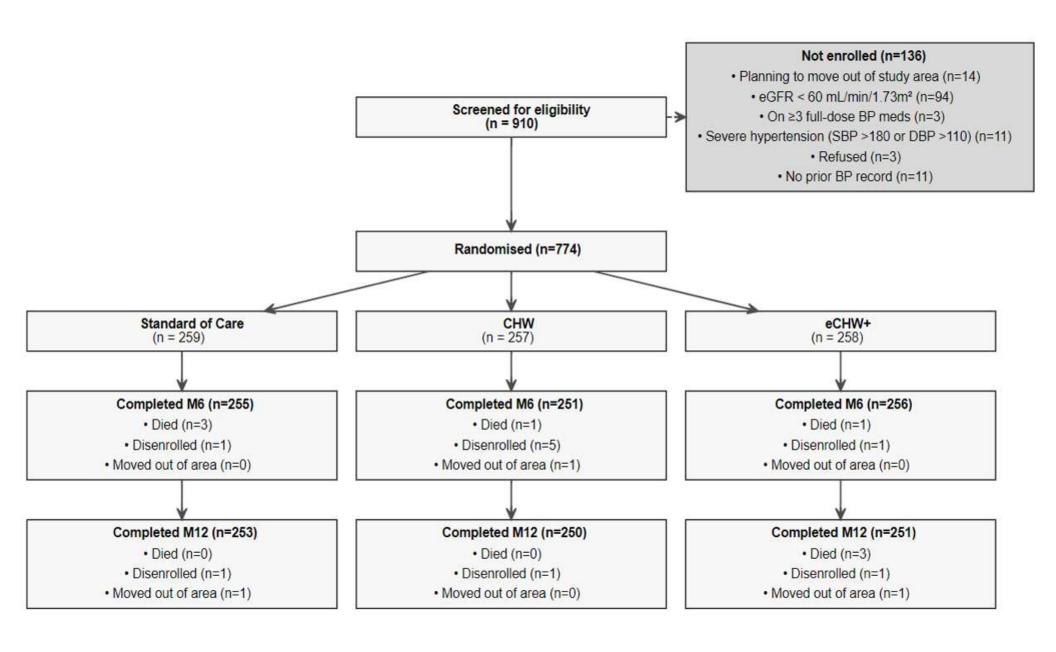
Secondary Outcomes:

- Systolic blood pressure change at 12 months
- Proportion of participants with blood pressure control (<140/<90) at 6 and 12 months

Powered for 5mm Hg change

Clinical benefit of 5mm Hg reduction in systolic blood pressure

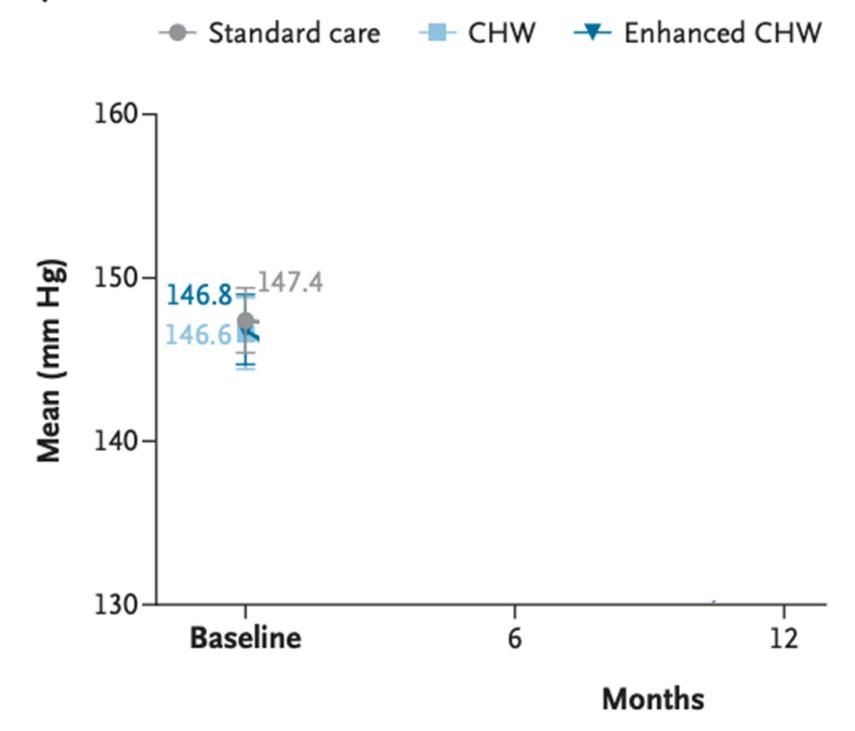




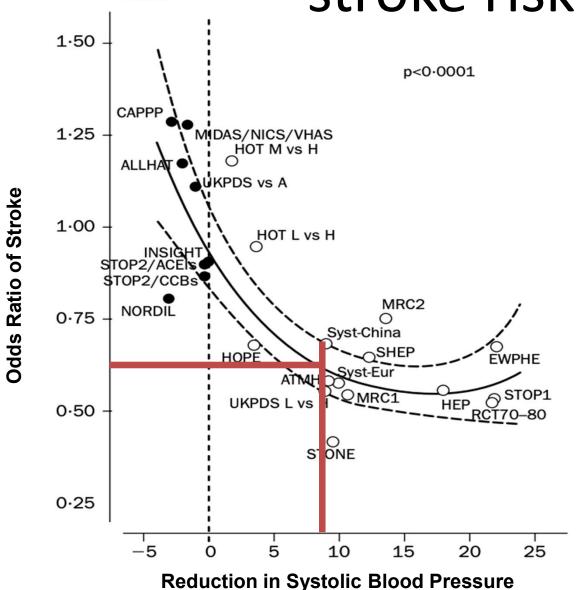
Clinical characteristics at randomization

	SOC	CHW	eCHW+	Total
	(n=259)	(n=257)	(n=258)	(n=774)
Age (years), mean (SD)	62 (12)	63 (12)	62 (11)	62 (12)
Female, n (%)	194 (74.9%)	202 (78.6%)	192 (74.4%)	588 (76.0%)
SBP at baseline (mmHg), mean (SD)	147.4 (16.4)	146.6 (18.0)	146.8 (17.2)	147.0 (17.2)
SBP≥160 mmHg at enrolment, n (%)	50 (19.3%)	53 (20.6%)	53 (20.5%)	156 (20.2%)

A Systolic Blood Pressure

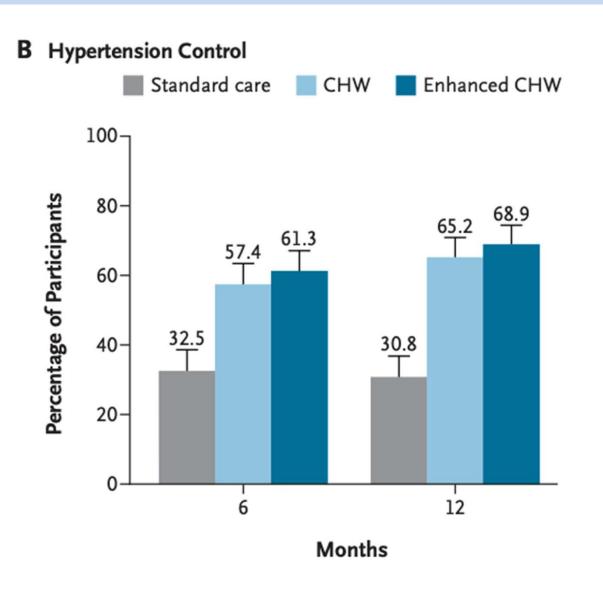


Reductions in blood pressure and stroke risk



The 8-10% reduction in BP seen would be predicted to correspond to an approximate 40% reduced odds of stroke

Blood pressure control rates



Subgroup	No. of Participants	Difference in Mean Sys vs. Standard Care at	
Age		1	
<60 yr		1	
CHW	95	├	-8.4 (-12.6 to -4.2)
Enhanced CHW	101	├	-7.2 (-11.4 to -3.1)
≥60 yr		1	· · · · · · · · · · · · · · · · · · ·
CHW	156	├	-7.8 (-11.3 to -4.3)
Enhanced CHW	155	⊢ •−	-10.4 (-13.9 to -6.9)
Sex		į	,
Female		1	
CHW	197	├	-6.9 (-10.0 to -3.8)
Enhanced CHW	190	├	-8.5 (-11.6 to -5.4)
Male		1	
CHW	54	-	−11.0 (−16.6 to −5.4)
Enhanced CHW	66		-10.7 (-16.0 to -5.4)
Systolic blood pressure		!	
<160 mm Hg		1	
CHW	200	├	-7.2 (-9.7 to -4.7)
Enhanced CHW	203	├	-7.0 (-9.5 to -4.5)
≥160 mm Hg		1	
CHW	51	──	−11.7 (−16.7 to −6.7)
Enhanced CHW	53	◄●	-17.7 (-22.7 to -12.8)
HIV status		1	
Negative			
CHW	132		-7.3 (-11.4 to -3.1)
Enhanced CHW	147	├	-9.1 (-13.1 to -5.0)
Positive		İ	
CHW	119	H	−9.1 (−13.0 to −5.3)
Enhanced CHW	109	├	−9.7 (−13.7 to −5.7)

Safety: Severe adverse events

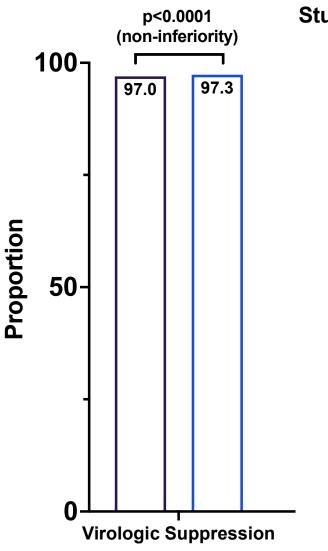
Outcome	CHW (N = 257)	Enhanced CHW (N = 258)	Standard Care (N = 259)
Adverse events during observation period — no. (%)			
Total adverse events	7 (2.7)	10 (3.9)	4 (1.6)
Severe adverse events	7 (2.7)	10 (3.9)	4 (1.6)
Adverse events related to trial procedures	0	0	0
Deaths	1 (0.4)	4 (1.6)	3 (1.2)

Results in Context

Other health system HTN trials in LMICs

- Meta-analysis of 9 RCTS of remote or telehealth
 - < 1mm Hg reduction in systolic blood pressure (not significant)
- COBRA BPS trial
 - 5 mmHg reduction in systolic blood pressure
 - Required physician management in the clinic
- SimCard Trial in rural India and China
 - 2.7 mm Hg reduction in systolic blood pressure (secondary outcome)

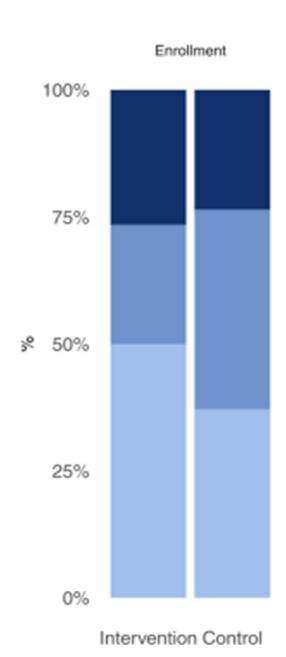
Cluster RCT of HIV/NCD Integration

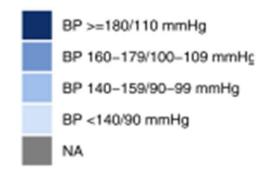


Study Outcomes

- ☐ Standard of Care☐ Care Integration
 - Integrating care did not diminish HIV control.
 - But had modest effects on NCD disease control







Structural Factors

Inter-generational poverty; Extreme rurality; Loss of trust in formal healthcare systems

Health System Factors

Over-burdened clinics; Poor decision support; Prioritization of acute care over primary care

Family & Community Factors

Beliefs & understandings of chronic diseases; Social support; Access to affordable, nutritious food

Individual Factors

Financial & opportunity costs of clinic visits; Low self-efficacy & perceived need; Co-morbid mental & physical health problems

Multidimensional intervention to address multiple barriers to care:

- 1. Empower individuals to measure their own blood pressure (self-empowerment)
- 2. Eliminate transportation costs/time for patients
- 3. Decongest clinics, decrease wait times and patient loads
- 4. Provide nurses with automated clinical decision support to minimize activation energy for medication titration

This was not easy

(it was real life, aka "implementation science")



Community health worker labor dispute

- 3 months before study launch
- DoH informs us that we are not permitted to work with current cadre of staff

- Partner with DoH to rapidly hire 30 "community blood pressure monitors"
 - Residents of same catchment areas to permit service to community
 - Same HR guidelines (high school diploma, able to walk miles/day)
- Develop and implement training curriculum (to both sets of workers)

Nationwide power outages

- Persistent through much of study period
- Impacted power at clinics and cell phone towers

- Redesign architecture of mobile health platform
 - Allow offline access for CBPMs
- Provide all clinic nurses with multiple SIM cards to "tower hop" and access BP control interface





Destructive weather Oct 23

- Destroyed one of the recruitment clinics
- Unpassable roads

- Paused recruitment activities
- Partnered with DoH on clinic repairs
- Provided staff and CBPMs with "storm gear"

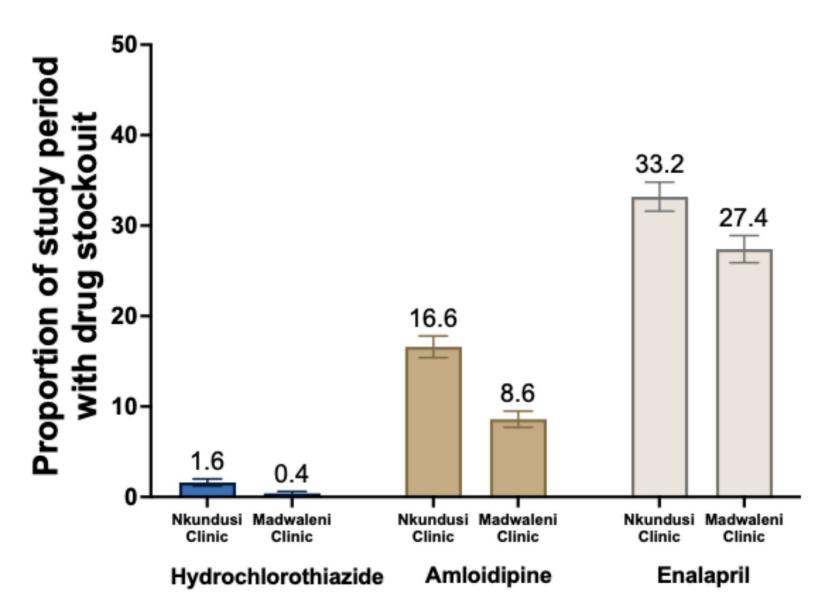


Armed carjacking spree

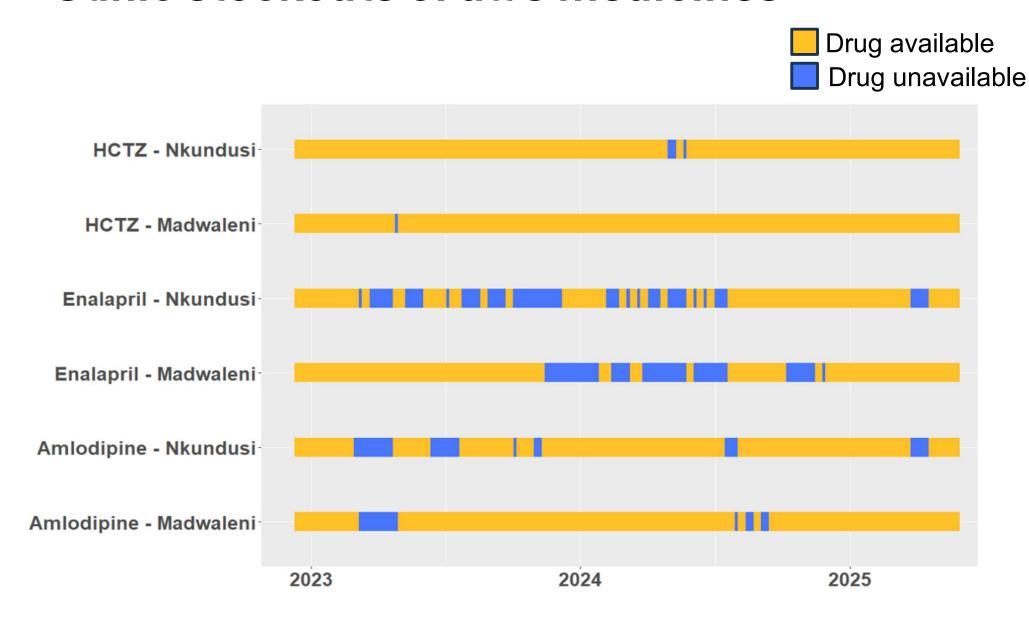
Three research vehicles at AHRI were victims

- Paused all study activities
- AHRI hired a security company and instituted updated policy:
 - Limit field work to sedans (when roads passable)
 - All field vehicles work in pairs
 - 24-hour patrols
 - Staff panic buttons
- Trainings for all staff on safety best practices

Stockouts of all 3 medicines



Clinic stockouts of all 3 medicines

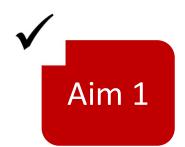


Conclusions

 In a rural area of South Africa, we observed 8-10mm Hg reductions in systolic blood pressure and 30% improvements in blood pressure control with a community-based chronic disease care model

What's Next?

Objectives of IMPACT-BP Study



Design and determine the acceptability and conduct a readiness assessment for a community-based hypertension control program in rural KZN



Conduct a randomized trial to determine the effectiveness of a community-based hypertension control program in rural KZN

Aim 3

Estimate the <u>fidelity, sustainability,</u> <u>acceptability, and cost-effectiveness</u> of community-based hypertension control program in rural KZN

Acceptability and Improvements

Type of interviews	Type of participant	Number of interviews
Focus Group Discussion	CHWs, study participants, HCWs	9
Key Informant Interviews	DOH province, district, clinic staff, study participants, study nurses	14

Patient Interviews

"The way my CHW treats me is like she is my daughter, as you were calling me yesterday, I was with her, she came to deliver medication, and she is very open, we talk a lot" —Intervention Arm Participant

CHW Interviews

"...we end up becoming social workers ...you end up helping a person with a lot of things. One of my participants would even call me she is having problems with her kids and say she had a problem now I have to listen and advise her..." -CHW

HCW Interviews

"Because of AHRI and IMPACT-BP, my clinic used to be full all the time, but now it is better because they are helping me with my patients. None of my patients have had complications; they are well-managed, so I would love the study to continue. I have even seen on my graph statistics that I analyse every month, and I do not have CVA patients" –Clinic Manager

Fidelity

Fidelity measure	Target	Study Data	Policy relevance
Home BP monitoring			Verifies
	30	30.5	participant
frequency/month		(SD 26.9)	engagement
(mean/month)			and feasibility

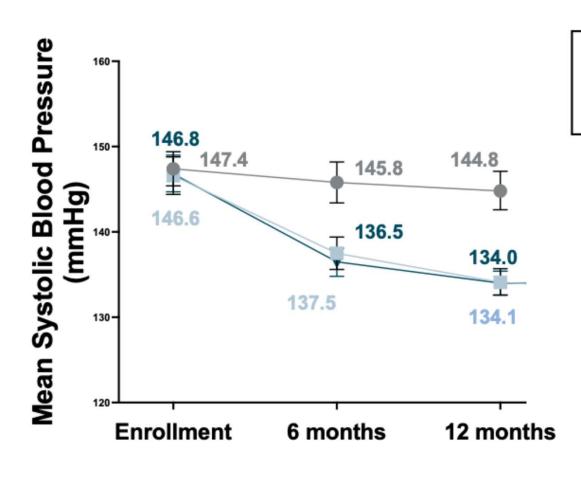
Fidelity

Fidelity measure	Target	Study Data	Policy relevance
Home BP monitoring			Verifies
frequency/month	30	30.5	participant
(mean/month)	30	(SD 26.9)	engagement
(mean/month)			and feasibility
Medication delivery	/7 days	2.2 days	Efficient care
Time (mean days)	≤7 days	(SD 2.9)	coordination

Fidelity

Fidelity measure	Target	Study Data	Policy relevance
Home BP monitoring			Verifies
frequency/month	30	30.5	participant
(mean/month)	30	(SD 26.9)	engagement
(mean/month)			and feasibility
Medication delivery	≤7 days	2.2 days	Efficient care
Time (mean days)	≥/ uays	(SD 2.9)	coordination
Response to critical		2 days	Effective
BP (>180/110)	≤2 days	(SD 1.8)	emergency
DL (>100/110)			response

Sustainability



- Standard of Care
- CHW
- ▼ eCHW+

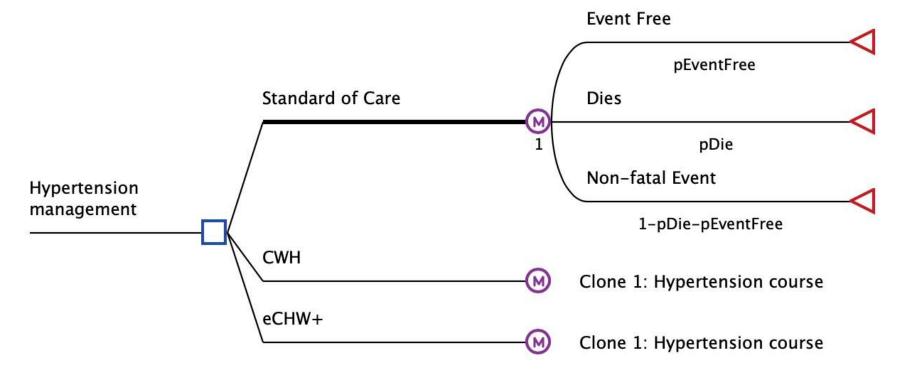
Cost and Cost Effectiveness

1. Estimating program cost and tradeoffs

Costs	Standard of Care	Intervention
Clinic staff time	\$\$\$ (health system)	\$
CHW time		\$ (health system)
BP cuffs		\$ (health system)
Transportation costs	\$\$\$ (patient)	\$ (patient)

Cost and Cost Effectiveness

2. Estimating lifetime cost-effectiveness



An example:

-if each 5 blood pressure cuffs costs around (\$400) and prevents one stroke (\$2,500 and 4 DALY lost)

Future Directions

- Expansion to multimorbidity care
 - HIV and DM
- Expansion of model to urban settings
 - Fully automated BP monitoring system
 - Pharmacy pick-up/drop-off
- Transportability (Rosebud, South Dakota)



Thembile Khambule IMPACT-BP CBPM

Acknowledments



Acknowledgments

Funders



CBPMs

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Full text of published manuscript & appendices



RESEARCH SUMMARY f X in ⊠ ₩

Home-Based Care for Hypertension in Rural South **Africa**

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Home-Based Care for Hypertension in Rural South Africa

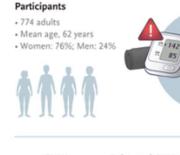
A Research Summary based on Siedner MJ et al. | 10.1056/NEJMoa2509958 | Published on September 1, 2025

WHY WAS THE TRIAL DONE?

Elevated blood pressure results in approximately 10 million deaths per year. Numerous low-cost, effective therapies are available, but poorly controlled hypertension is common particularly in populations with structural barriers to health care, such as overcrowded clinics and transportation costs. Whether home-based blood-pressure management can improve outcomes in places with such barriers is unknown.

HOW WAS THE TRIAL CONDUCTED?

Adults in rural South Africa with uncontrolled hypertension were assigned to receive home-based care, enhanced homebased care, or standard, clinic-based care. Home-based care comprised patient monitoring of blood pressure, home visits from a community health worker (CHW) for data collection and medication delivery, and remote nurse-led decision making supported by a mobile application (CHW group). Enhanced home-based care was similar but used blood-pressure machines that transmitted readings directly to the nurses' mobile app (enhanced CHW group). The primary outcome was the systolic blood pressure at 6 months. Safety was also assessed.





TRIAL DESIGN

Questions?

Thank you for your time and attention!

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