South Africa

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Implementation Evaluation of a Combination Intervention for Sustainable Blood Pressure Control in Rural KwaZulu-Natal, South Africa

Study Documentation

February 6, 2026

Metadata Production

Metadata Producer(s)	Africa Health Research Institute (AHRI)
Identification	DDI.AHRI.ImpactBP

Table of Contents

Implementation Evaluation of a Combination Intervention for Sustainable Blood Pressure Control in Rural KwaZulu-Natal, South Africa

Overview

Identification	AHRI.ImpactBP
Version	V1.0.0

Abstract
IMPACT-BP was an open-label, randomised controlled trial to evaluate the effectiveness of community-based, technology-supported interventions to reduce systolic blood pressure (SBP) and improve blood pressure control among individuals with uncontrolled hypertension in rural KwaZulu-Natal.
The study aimed to determine whether home-based care improves outcomes over standard, clinic-based blood pressure management in rural South Africa.

The study compared three treatment strategies: 1) standard of care (SOC), clinic-based management of hypertension, 2) a community blood pressure monitor-based model, in which individuals received blood pressure cuffs to measure their blood pressure at home, and were monitored by nurses via community health workers (CHW) with treatment decisions made via nurses remotely via a mobile health-based clinical decision support tool, and 3) an enhanced community blood pressure monitor-based model that included home-based blood pressure cuffs that transmitted readings over cellular networks directly to clinic-based nurses (eCHW+). In both intervention groups, CHWs visited participants to record (CHW) or verify (eCHW +) blood pressure readings, dispense medications, and relay instructions from clinic nurses.

Kind of Data	Survey Data, clinical data, biomarker data, administrative records data, spatial data
Unit of Analysis	Individual-level longitudinal clinical trial data. Each record represents a single participant enrolled in the hypertension trial, with repeated measures of blood pressure, clinical assessments, medication use, and survey-based sociodemographic information collected across multiple study visits (enrolment, 6 months, and 12 months). Data are linked at the individual level using unique study identifiers.

Scope & Coverage

Keywords	Hypertension, blood pressure control, community-based intervention, digital health, eHealth, mHealth, community health workers, anti-hypertensive medication, task shifting, primary care, sub-Saharan Africa, South Africa, non-communicable diseases, health systems strengthening, randomized controlled trial, health services access, treatment outcomes
Topics	Hypertension, Blood Pressure, Blood Pressure Determination, Antihypertensive Agents, Medication Adherence, Community Health Workers, Task Shifting, Telemedicine, mHealth, Patient Care Team, Primary Health Care, Health Services Accessibility, Randomized Controlled Trial, Longitudinal Studies, Treatment Outcome, South Africa
Time Period(s)	2022-2025
Countries	South Africa

Geographic Coverage
Africa Health Research Institute (AHRI) demographic surveillance area in rural uMkhanyakude district, KwaZulu-Natal

Universe
Adults aged =18 years residing in the catchment areas of Nkundusi and Madwaleni Primary Health Care Clinics in uMkhanyakude District (KwaZulu-Natal, South Africa), with uncontrolled blood pressure. Uncontrolled blood pressure was defined as a SBP > 140 mmHg or a diastolic BP > 90mm Hg with at least one prior elevated reading 6 months or more prior. Participants were screened, enrolled, and observed between 30 November 2022 and 30 June 2025.

Producers & Sponsors

Primary Investigator(s)	Mark J. Siedner, AHRI; Massachusetts General Hospital; Harvard Medical School Nombulelo Magula, University of KwaZulu-Natal Medical School; Clairwood Hospital Thomas Gaziano, Brigham and Women's Hospital; Harvard Medical School; Harvard School of Public Health
Other Producer(s)	Africa Health Research Institute (AHRI)
Funding Agency/ies	United States National Institutes of Health (NIH) , Primary funder
Other Acknowledgment(s)	Kathy Baisley , Statistical oversight , AHRI; London School of Hygiene and Tropical Medicine Lusanda Mazibuko , Study statistical lead , Africa Health Research Institute Dickman Gareta , Head of Research Data Management , Africa Health Research Institute Siyabonga Nxumalo , Data management , Africa Health Research Institute Nsika Sithole , Project coordination , Africa Health Research Institute IMPACT-BP CHW Team , Participant engagement and data collection , Africa Health Research Institute IMPACT-BP Clinical Team , Participant clinical monitoring and data collection , Africa Health Research Institute Baptista Joao , MHealth application development , iMarketing Namibia Hosea Kambonde , MHealth application development , iMarketing Namibia Sindy Mthethwa , Program partnership , KZN Department of Health Thabang Manyaapelo , AHRI Social Science Department , Social Science Lead Shafika Abrahams-Gessel , Project Management , Harvard School of Public Health

Sampling

Sampling Procedure

Participants were recruited from the Nkundusi and Madwaleni primary health care clinics within the AHRI Health and Demographic Surveillance Site (HDSS). All adults presenting at the clinics for primary care during weekdays were screened for eligibility. Eligible participants were aged =18 years, resided in the clinic catchment area, had elevated blood pressure at screening (systolic >140 mmHg or diastolic >90 mmHg), and had at least one previous elevated blood pressure reading documented =6 months prior. Exclusion criteria included pregnancy, breastfeeding, symptomatic elevated blood pressure (>180/110 mmHg), advanced chronic kidney disease (glomerular filtration rate <60 ml/min/1.73m²), and use of =3 full-dose anti-hypertensive medications. Enrolled participants were randomized to one of three study arms (SOC, CHW, eCHW+) in blocks of 9, stratified by clinic and current use of anti-hypertensive therapy.

Data Collection

Data Collection Dates	start 2022-11-01 end 2025-06-30

Data Processing & Appraisal

Data Editing

Study data were entered into REDCap and underwent verification and cleaning prior to analysis. Blood pressure outcomes were averaged as specified, and missing values were identified for potential imputation. Randomisation and intervention adherence data were linked with outcome and covariate data. Data were de-identified prior to analysis. Quality control procedures included duplicate entry checks, automated range checks for blood pressure, and consistency checks across visits.

Accessibility

Access Conditions

The representative of the Receiving Organization agrees to comply with the following conditions:

1. Access to the restricted data will be limited to the Lead Researcher and other members of the research team listed in this request.
2. Copies of the restricted data or any data created on the basis of the original data will not be copied or made available to anyone other than those mentioned in this Data Access Agreement, unless formally authorized by the Data Archive.
3. The data will only be processed for the stated statistical and research purpose. They will be used for solely for reporting of aggregated information, and not for investigation of specific individuals or organizations. Data will not in any way be used for any administrative, proprietary or law enforcement purposes.
4. The Lead Researcher must state if it is their intention to match the restricted microdata with any other micro-dataset. If any matching is to take place, details must be provided of the datasets to be matched and of the reasons for the matching. Any datasets created as a result of matching will be considered to be restricted and must comply with the terms of this Data Access Agreement.
5. The Lead Researcher undertakes that no attempt will be made to identify any individual person, family, business, enterprise or organization. If such a unique disclosure is made inadvertently, no use will be made of the identity of any person or establishment discovered and full details will be reported to the Data Archive. The identification will not be revealed to any other person not included in the Data Access Agreement.
6. The Lead Researcher will implement security measures to prevent unauthorized access to licensed microdata acquired from the Data Archive. The microdata must be destroyed upon the completion of this research, unless the Data Archive obtains satisfactory guarantee that the data can be secured and provides written authorization to the Receiving Organization to retain them. Destruction of the microdata will be confirmed in writing by the Lead Researcher to the Data Archive.
7. Any books, articles, conference papers, theses, dissertations, reports, or other publications that employ data obtained from the Data Archive will cite the source of data in accordance with the citation requirement provided with the dataset.
8. An electronic copy of all reports and publications based on the requested data will be sent to the Data Archive.
9. The original collector of the data, the Data Archive, and the relevant funding agencies bear no responsibility for use of the data or for interpretations or inferences based upon such uses.
10. This agreement will come into force on the date that approval is given for access to the restricted dataset and remain in force until the completion date of the project or an earlier date if the project is completed ahead of time.
11. If there are any changes to the project specification, security arrangements, personnel or organization detailed in this application form, it is the responsibility of the Lead Researcher to seek the agreement of the Data Archive to these changes. Where there is a change to the employer organization of the Lead Researcher this will involve a new application being made and termination of the original project.
12. Breaches of the agreement will be taken seriously and the Data Archive will take action against those responsible for the lapse if willful or accidental. Failure to comply with the directions of the Data Archive will be deemed to be a major breach of the agreement and may involve recourse to legal proceedings. The Data Archive will maintain and share with partner data archives a register of those individuals and organizations which are responsible for breaching the terms of the Data Access Agreement and will impose sanctions on release of future data to these parties.

Citation Requirements

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DOI: https://doi.org/10.23664/AHRI.IMPACTBP

Files Description

Dataset contains 1 file(s)

AHRI.ImpactBP.Aim 2 Clinical Trial.2025	
# Cases	774
# Variable(s)	32

Variables List

Dataset contains 32 variable(s)

File AHRI.ImpactBP.Aim 2 Clinical Trial.2025

#	Name	Label	Type	Format	Valid	Invalid	Question
1	study_id	Trial Unique Identifier	discrete	character-6	774	0	-
2	se_sex	Sex	discrete	numeric-8.0	774	0	-
3	se_scree ..	Screening Site	discrete	numeric-9.0	774	0	-
4	se_age_c ..	Age at screening (years)	discrete	numeric-8.0	774	0	-
5	se_take_ ..	Are you taking any medications for your blood pressure?	discrete	numeric-8.0	774	0	-
6	sbp1	SBP at baseline	continuous	numeric-9.0	774	0	-
7	dbp1	1 dbp	continuous	numeric-9.0	774	0	-
8	sbp2	SBP at 6 months	continuous	numeric-9.0	762	12	-
9	dbp2	2 dbp	continuous	numeric-9.0	762	12	-
10	sbp3	SBP at 12 months	continuous	numeric-9.0	754	20	-
11	dbp3	3 dbp	continuous	numeric-9.0	754	20	-
12	se_systo ..	First (out of 3) BP measurement at baseline	continuous	numeric-8.0	774	0	-
13	se_bmi	Body mass index (kg/m^2)	continuous	numeric-9.0	774	0	-
14	se_resul ..	eGFR (ml/min/1.73m^2)	continuous	numeric-8.0	774	0	-
15	ra_study ..	Randomised study arm	discrete	numeric-8.0	774	0	-
16	sd_runwa ..	Have internal running water in the household?	discrete	numeric-8.0	772	2	-
17	sd_time2 ..	Time to clinic	continuous	numeric-8.0	772	2	-
18	sd_trans ..	Main mode of transport to clinic	discrete	numeric-8.0	772	2	-
19	sd_cost2 ..	Cost to clinic (category/code)	discrete	numeric-10.0	434	340	-
20	sd_rand2 ..	Money spent to get to clinic (in Rands)	continuous	numeric-8.0	413	361	-
21	hm_ever_ ..	Diabetic	discrete	numeric-8.0	772	2	-
22	mh_hivre ..	HIV co-infection	discrete	numeric-10.0	773	1	-
23	ageband	Age category	discrete	numeric-11.0	774	0	-
24	bmi_cat	BMI category	discrete	numeric-11.0	774	0	-
25	hiv_status	HIV co-infection	discrete	numeric-10.0	773	1	-
26	educatio ..	Education level	discrete	numeric-27.0	773	1	-
27	employme ..	Employment status	discrete	numeric-12.0	765	9	-
28	AssetInd ..	Asset Index Quintile (Deprivation)	discrete	numeric-14.0	765	9	-
29	sbp_group	SBPâ‰¥160 mmHg at enrolment	discrete	numeric-9.0	774	0	-
30	age60	Ageâ‰¥60	discrete	numeric-9.0	774	0	-
31	change_m6	Change at 6 months	continuous	numeric-9.0	762	12	-

File AHRI.ImpactBP.Aim 2 Clinical Trial.2025

#	Name	Label	Type	Format	Valid	Invalid	Question
32	change_m12	Change at 12 months	continuous	numeric-9.0	754	20	-

Variables Description

Dataset contains 32 variable(s)

File : AHRI.ImpactBP.Aim 2 Clinical Trial.2025

study_id: Trial Unique Identifier

Information	[Type= discrete] [Format=character] [Missing=*]
Statistics [NW/ W]	[Valid=774 /-] [Invalid=0 /-]

se_sex: Sex

Information	[Type= discrete] [Format=numeric] [Range= 1-2] [Missing=*]
Statistics [NW/ W]	[Valid=774 /-] [Invalid=0 /-]

Value	Label	Cases	Percentage
1	Male	186	24.0%
2	Female	588	76.0%

Warning: these figures indicate the number of cases found in the data file. They cannot be interpreted as summary statistics of the population of interest.

se_screening_site: Screening Site

Information	[Type= discrete] [Format=numeric] [Range= 1-2] [Missing=*]
Statistics [NW/ W]	[Valid=774 /-] [Invalid=0 /-]

Value	Label	Cases	Percentage
1	Nkundusi	451	58.3%
2	Madwaleni	323	41.7%

Warning: these figures indicate the number of cases found in the data file. They cannot be interpreted as summary statistics of the population of interest.

se_age_calc: Age at screening (years)

Information	[Type= discrete] [Format=numeric] [Range= 26-90] [Missing=*]
Statistics [NW/ W]	[Valid=774 /-] [Invalid=0 /-]

Value	Label	Cases	Percentage
90	90+		

Warning: these figures indicate the number of cases found in the data file. They cannot be interpreted as summary statistics of the population of interest.

se_take_bp_med: Are you taking any medications for your blood pressure?

Information	[Type= discrete] [Format=numeric] [Range= 0-1] [Missing=*]
Statistics [NW/ W]	[Valid=774 /-] [Invalid=0 /-]

Value	Label	Cases	Percentage
0	No	23	3.0%
1	Yes	751	97.0%

Warning: these figures indicate the number of cases found in the data file. They cannot be interpreted as summary statistics of the population of interest.

sbp1: SBP at baseline

Information	[Type= continuous] [Format=numeric] [Range= 94-219.5] [Missing=*]
Statistics [NW/ W]	[Valid=774 /-] [Invalid=0 /-] [Mean=146.95 /-] [StdDev=17.2 /-]

dbp1: 1 dbp

Information	[Type= continuous] [Format=numeric] [Range= 64-131.5] [Missing=*]
Statistics [NW/ W]	[Valid=774 /-] [Invalid=0 /-] [Mean=90.918 /-] [StdDev=10.458 /-]

sbp2: SBP at 6 months

Information	[Type= continuous] [Format=numeric] [Range= 95-213.5] [Missing=*]
Statistics [NW/ W]	[Valid=762 /-] [Invalid=12 /-] [Mean=139.909 /-] [StdDev=16.746 /-]

File : AHRI.ImpactBP.Aim 2 Clinical Trial.2025

dbp2: 2 dbp

Information	[Type= continuous] [Format=numeric] [Range= 60.5-131] [Missing=*]
Statistics [NW/ W]	[Valid=762 /-] [Invalid=12 /-] [Mean=87.674 /-] [StdDev=9.611 /-]

sbp3: SBP at 12 months

Information	[Type= continuous] [Format=numeric] [Range= 84.5-203] [Missing=*]
Statistics [NW/ W]	[Valid=754 /-] [Invalid=20 /-] [Mean=137.68 /-] [StdDev=15.125 /-]

dbp3: 3 dbp

Information	[Type= continuous] [Format=numeric] [Range= 49.5-117.5] [Missing=*]
Statistics [NW/ W]	[Valid=754 /-] [Invalid=20 /-] [Mean=86.64 /-] [StdDev=9.459 /-]

se_systolic1: First (out of 3) BP measurement at baseline

Information	[Type= continuous] [Format=numeric] [Range= 107-227] [Missing=*]
Statistics [NW/ W]	[Valid=774 /-] [Invalid=0 /-] [Mean=156.796 /-] [StdDev=17.13 /-]

se_bmi: Body mass index (kg/m^2)

Information	[Type= continuous] [Format=numeric] [Range= 10.1999998092651-64.0999984741211] [Missing=*]
Statistics [NW/ W]	[Valid=774 /-] [Invalid=0 /-] [Mean=29.704 /-] [StdDev=7.236 /-]

se_result_scr_test_egfr: eGFR (ml/min/1.73m^2)

Information	[Type= continuous] [Format=numeric] [Range= 50-132] [Missing=*]
Statistics [NW/ W]	[Valid=774 /-] [Invalid=0 /-] [Mean=76.052 /-] [StdDev=14.974 /-]

ra_study_arm: Randomised study arm

Information	[Type= discrete] [Format=numeric] [Range= 1-3] [Missing=*]
Statistics [NW/ W]	[Valid=774 /-] [Invalid=0 /-]

Value	Label	Cases	Percentage
1	SOC	259	33.5%
2	CBPM	257	33.2%
3	eCBPM+	258	33.3%

Warning: these figures indicate the number of cases found in the data file. They cannot be interpreted as summary statistics of the population of interest.

sd_runwater: Have internal running water in the household?

Information	[Type= discrete] [Format=numeric] [Range= 0-1] [Missing=*]
Statistics [NW/ W]	[Valid=772 /-] [Invalid=2 /-]

Value	Label	Cases	Percentage
0	No	660	85.5%
1	Yes	112	14.5%
Sysmiss		2	

Warning: these figures indicate the number of cases found in the data file. They cannot be interpreted as summary statistics of the population of interest.

sd_time2clinic: Time to clinic

Information	[Type= continuous] [Format=numeric] [Range= 2-3000] [Missing=*]
Statistics [NW/ W]	[Valid=772 /-] [Invalid=2 /-] [Mean=46.595 /-] [StdDev=111.877 /-]

sd_transport: Main mode of transport to clinic

Information	[Type= discrete] [Format=numeric] [Range= 0-96] [Missing=*]
Statistics [NW/ W]	[Valid=772 /-] [Invalid=2 /-]

File : AHRI.ImpactBP.Aim 2 Clinical Trial.2025

sd_transport: Main mode of transport to clinic

Value	Label	Cases	Percentage
0	Walk	338	43.8%
1	Bus/taxi	401	51.9%
2	Car	28	3.6%
96	Other	5	0.6%
Sysmiss		2	

Warning: these figures indicate the number of cases found in the data file. They cannot be interpreted as summary statistics of the population of interest.

sd_cost2clinic: Cost to clinic (category/code)

Information	[Type= discrete] [Format=numeric] [Range= 0-2] [Missing=*]
Statistics [NW/ W]	[Valid=434 /-] [Invalid=340 /-]

Value	Label	Cases	Percentage
0	No	21	4.8%
1	Yes	413	95.2%
2	Don't Know	0	
Sysmiss		340	

Warning: these figures indicate the number of cases found in the data file. They cannot be interpreted as summary statistics of the population of interest.

sd_rand2clinic: Money spent to get to clinic (in Rands)

Information	[Type= continuous] [Format=numeric] [Range= 10-200] [Missing=*]
Statistics [NW/ W]	[Valid=413 /-] [Invalid=361 /-] [Mean=28.68 /-] [StdDev=23.372 /-]

hm_ever_diabetes: Diabetic

Information	[Type= discrete] [Format=numeric] [Range= 0-1] [Missing=*]
Statistics [NW/ W]	[Valid=772 /-] [Invalid=2 /-]

Value	Label	Cases	Percentage
0	No	667	86.4%
1	Yes	105	13.6%
Sysmiss		2	

Warning: these figures indicate the number of cases found in the data file. They cannot be interpreted as summary statistics of the population of interest.

mh_hivresult: HIV co-infection

Information	[Type= discrete] [Format=numeric] [Range= 0-2] [Missing=*]
Statistics [NW/ W]	[Valid=773 /-] [Invalid=1 /-]

Value	Label	Cases	Percentage
0	Negative	346	44.8%
1	Positive	360	46.6%
2	Not tested	67	8.7%
Sysmiss		1	

Warning: these figures indicate the number of cases found in the data file. They cannot be interpreted as summary statistics of the population of interest.

ageband: Age category

Information	[Type= discrete] [Format=numeric] [Range= 1-3] [Missing=*]
Statistics [NW/ W]	[Valid=774 /-] [Invalid=0 /-]

Value	Label	Cases	Percentage
1	Under 45	57	7.4%

File : AHRI.ImpactBP.Aim 2 Clinical Trial.2025

ageband: Age category

Value	Label	Cases	Percentage
2	45 - 59	256	33.1%
3	60 or older	461	59.6%

Warning: these figures indicate the number of cases found in the data file. They cannot be interpreted as summary statistics of the population of interest.

bmi_cat: BMI category

Information	[Type= discrete] [Format=numeric] [Range= 1-4] [Missing=*]
Statistics [NW/ W]	[Valid=774 /-] [Invalid=0 /-]

Value	Label	Cases	Percentage
1	Underweight	17	2.2%
2	Normal	208	26.9%
3	Overweight	198	25.6%
4	Obese	351	45.3%

Warning: these figures indicate the number of cases found in the data file. They cannot be interpreted as summary statistics of the population of interest.

hiv_status: HIV co-infection

Information	[Type= discrete] [Format=numeric] [Range= 0-2] [Missing=*]
Statistics [NW/ W]	[Valid=773 /-] [Invalid=1 /-]

Value	Label	Cases	Percentage
0	Negative	413	53.4%
1	Positive	360	46.6%
2	Not tested	0	
Sysmiss		1	

Warning: these figures indicate the number of cases found in the data file. They cannot be interpreted as summary statistics of the population of interest.

education_level: Education level

Information	[Type= discrete] [Format=numeric] [Range= 0-2] [Missing=*]
Statistics [NW/ W]	[Valid=773 /-] [Invalid=1 /-]

Value	Label	Cases	Percentage
0	None	303	39.2%
1	Less or primary education	183	23.7%
2	More than primary education	287	37.1%
Sysmiss		1	

Warning: these figures indicate the number of cases found in the data file. They cannot be interpreted as summary statistics of the population of interest.

employment_status: Employment status

Information	[Type= discrete] [Format=numeric] [Range= 0-1] [Missing=*]
Statistics [NW/ W]	[Valid=765 /-] [Invalid=9 /-]

Value	Label	Cases	Percentage
0	Not employed	678	88.6%
1	Employed	87	11.4%
Sysmiss		9	

Warning: these figures indicate the number of cases found in the data file. They cannot be interpreted as summary statistics of the population of interest.

AssetIndexQuintile: Asset Index Quintile (Deprivation)

Information	[Type= discrete] [Format=numeric] [Range= 1-5] [Missing=*]

File : AHRI.ImpactBP.Aim 2 Clinical Trial.2025

AssetIndexQuintile: Asset Index Quintile (Deprivation)

Statistics [NW/ W]	[Valid=765 /-] [Invalid=9 /-]

Value	Label	Cases	Percentage
1	Most Deprived	162	21.2%
2	Deprived	147	19.2%
3	Moderate	151	19.7%
4	Less Deprived	153	20.0%
5	Least Deprived	152	19.9%
Sysmiss		9	

Warning: these figures indicate the number of cases found in the data file. They cannot be interpreted as summary statistics of the population of interest.

sbp_group: SBPâ‰¥160 mmHg at enrolment

Information	[Type= discrete] [Format=numeric] [Range= 0-1] [Missing=*]
Statistics [NW/ W]	[Valid=774 /-] [Invalid=0 /-]

Value	Label	Cases	Percentage
0	No	618	79.8%
1	Yes	156	20.2%

Warning: these figures indicate the number of cases found in the data file. They cannot be interpreted as summary statistics of the population of interest.

age60: Ageâ‰¥60

Information	[Type= discrete] [Format=numeric] [Range= 0-1] [Missing=*]
Statistics [NW/ W]	[Valid=774 /-] [Invalid=0 /-]

Value	Label	Cases	Percentage
0	No	313	40.4%
1	Yes	461	59.6%

Warning: these figures indicate the number of cases found in the data file. They cannot be interpreted as summary statistics of the population of interest.

change_m6: Change at 6 months

Information	[Type= continuous] [Format=numeric] [Range= -75.5-55] [Missing=*]
Statistics [NW/ W]	[Valid=762 /-] [Invalid=12 /-] [Mean=-7.15 /-] [StdDev=18.934 /-]

change_m12: Change at 12 months

Information	[Type= continuous] [Format=numeric] [Range= -85-45] [Missing=*]
Statistics [NW/ W]	[Valid=754 /-] [Invalid=20 /-] [Mean=-9.385 /-] [StdDev=18.47 /-]