

# Evaluation of community-based care delivered by primary healthcare providers in management of hypertension in a rural area of West Bengal

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## ABSTRACT

**Background:** Lifestyle modifications and medication compliance are key strategies. **Objectives:** To evaluate the effect of community-based care delivered by trained primary healthcare providers in management of hypertension. **Materials and Methods:** A longitudinal study was conducted between two groups of newly diagnosed hypertensive patients to evaluate the impact of an educational intervention. Six blocks in a district were chosen with pairwise matching. All primary healthcare providers of one block in each pair were randomized to receive the intervention and the other was controlled. Next screening for risk factors, detection of hypertension, counseling, and follow-up care were provided. The patients within the control group received usual care as per clinician's discretion. A total of 227 patients in the "study" group and 230 patients in the "control" group were recruited from 12 subcenters selected randomly. Data analysis was done by  $\chi^2$  test, *t* test, and GLM analysis using SPSS 16. **Results:** Patients in the intervention blocks demonstrated a statistically significant mean reduction in SBP of  $16.14 \pm 0.82$  and DBP by  $11.65 \pm 0.53$  compared to  $9.83 \pm 1.02$  and  $7.68 \pm 0.66$ , respectively, in the control blocks after adjusting for age, sex, and baseline blood pressure at one-year follow-up. Regarding lifestyle-related cardiovascular risk factors, statistically significant differences were found in favor of the intervention group. **Conclusion:** The study supports and reinforces the utilization of trained primary healthcare providers under the NPCDCS program in screening and promoting blood pressure control by preventive services to hypertensive patients in the community.

**Keywords:** Comparative effectiveness research, educational early intervention, hypertension, prevention and control, treatment outcome

## Introduction

Rising levels of obesity, unhealthy dietary practices, and sedentary lifestyles have resulted in an alarming rise in non-communicable diseases (NCDs) and associated morbidity and mortality.<sup>[1,2]</sup>

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Currently, cardiovascular diseases and diabetes together comprise almost one-fourth of all leading causes of mortality in India.<sup>[3,4]</sup> Despite the high prevalence and availability of effective therapeutic measures for its control, blood pressure goals are achieved in only 25–40% of patients who take antihypertensive drugs that too at a substantial cost contributing to out-of-pocket expenditure.<sup>[5,6]</sup> Further, issues such as a lack of resources and personnel make their detection an even bigger challenge.<sup>[7-9]</sup> The role of Primary healthcare providers working at the grass root level has been envisioned under the National Programme for Prevention

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and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) to be important in the prevention and early detection of hypertension and associated comorbidities. Primary care providers can play a key role in the control of blood pressure and associated morbidities. If trained effectively, they may be utilized to help in achieving the Global NCD target, i.e. to reduce high blood pressure and thus to achieve NCD-related Sustainable Development Goal. However, evidence involving a large number of hypertensive patients and intervention effectiveness conducted in a rural community from eastern India are limited. Therefore, educational interventions were designed using the Health Belief Model theory to improve the control of hypertension.

## Objective

To evaluate the impact of training primary healthcare workers in the detection and providing community-based care in the management of hypertension.

## Specific objective

To evaluate the effect of training primary healthcare workers in decreasing the blood pressure of newly diagnosed hypertensive patients.

## Hypothesis

There is a difference in hypertension control among those who receive educational intervention or community-based care for hypertension management in comparison with those who receive usual care.

## Materials and Methods

A prospective, quasi-experimental study with a non-blinded design was conducted in six blocks of North-24 Parganas district of West Bengal, India, from April 2017–March 2019, prior to the implementation of the NPCDCS program in the district.

## Sample size

To detect a drop in means of 5 mmHg in blood pressure (clinically significant) between the intervention and the control group with pooled standard deviation estimates of 15 mmHg at a 5% significance level and 80% power and assuming an intraclass correlation coefficient (ICC) of 0.01 and cluster size 15, the minimum sample size was calculated to be 324 hypertensive patients (162 each group, assuming equal sizes) and the total number of subcenters (clusters) required to achieve the adequate statistical power was 22 (11 clusters per group). To further allow a 30% dropout rate, the final required sample size was inflated to 464 hypertensive patients (232 patients per group). Finally, from a list of all subcenters, 12 subcenters were randomly chosen in each intervention and control group with 20 hypertensive patients per subcenter.

## Sampling technique

Six blocks from North-24 Parganas district were chosen after excluding the blocks in which NPCDCS was being planned to

be launched in stages in consultation with the district officials. Out of these six blocks, pairwise matching of blocks with respect to area, important health indicators, and distance from the district hospital (Barasat Sadar Hospital) was done. After that one block in each pair was randomized to receive an educational intervention delivered to all consenting primary healthcare providers selected from the three blocks to be part of the “intervention” group.

Randomization was performed at the block level with the intervention being delivered to primary healthcare providers selected from within the block. The provision of healthcare services by them was confined to their respective designated areas (subcenters and villages) within the block. There was an agreed-on policy that those primary healthcare providers in the control group would refrain from undertaking competitive measures of improvement during the project period. Training in the control group healthcare providers was provided following project completion. Further during random selection of subcenters (clusters) in each group, geographically contiguous clusters were excluded. This design served to reduce “contamination bias” between study and control group participants.

## Selection of study participants in the intervention group

Patients were selected from the community using a two-stage screening. Initially, ASHA workers made a door-to-door visit to screen all individuals above 40 years at high risk of cardiovascular diseases. A one-day orientation program of ASHAs of the selected subcenters for sensitization and household-level screening for risk factors of NCDs. Next, they referred at-risk patients to subcenters for screening for hypertension, diabetes, etc., A 20-item screening questionnaire was developed and validated.<sup>[10]</sup> Individuals above 40 years of age with a positive family history of NCDs or a risk score equal to 5 or above were sent to subcenter for measurement of physiological variables like blood pressure, blood sugar, and body mass index by the health workers. Patients with high blood pressure and blood sugar measured using standard protocol were next referred to PHCs or higher. The Medical Officer confirmed the diagnosis and prescribed treatment accordingly. WHO guidelines to define hypertension were used. The health workers maintained a record of all cases referred to the Medical Officer for confirmation and treatment, followed up the newly diagnosed hypertension cases, and provided alternate monthly home visits for delivering intervention under the project. An orientation program for Medical Officers of selected PHCs was done at the beginning to acquaint them with the objectives of the project and ensure their cooperation in maintaining continuity of care.

Intervention delivered to patients was in the form of face-to-face counseling at clinics and home visits according to an agreed protocol which was developed based on National practice guidelines for hypertension. Further culturally

appropriate information booklets with FAQs and their answers about the diseases, demonstration, and setting up of targets for achieving lifestyle changes were also provided. Counseling was done about their disease and its complications, and promotion of healthy behavior changes such as recommendations for healthy low-fat, low sodium diet, increased intake of green leafy vegetables and fresh fruits, reducing fast food intake, avoiding processed foods high in sodium and carbohydrates, regular moderate-intensity physical activity and smoking cessation with emphasis on the importance of dietary adherence and compliance to medication. Monitoring of weight and blood pressure was done during these visits and assistance with goal setting regarding physical activity, dietary recommendations, and its adherence was provided and assessed at these visits. Additionally, patients on therapeutic management were followed up to assess their compliance with therapy. The participating ASHAs and health workers were provided with a small financial incentive for their services.

### Selection of patients in the control group

As in the study group, first-stage screening by ASHA workers was done and those with a high score were referred directly to Medical Officers. The second-stage screening was not done. From the “at risk” cases referred, 20 newly diagnosed patients per sub-center were randomly selected. Those patients received usual care for hypertension and other comorbidities at individual clinicians’ discretion.

Inclusion criteria for patients were adults aged above 40 years and newly detected with hypertension confirmed following the initial screening by primary healthcare providers, who gave informed written consent to participate in the study, able to understand Bengali (local language), and were permanent residents in the study area.

Exclusion criteria were pregnant women, persons with self-reported pre-existing heart disease, stroke, seriously ill persons, and cancer patients.

### Study tools and technique

Data collection was done by interview using pretested, predesigned, and validated schedule, observation checklist, clinical examination, and record reviews. Medication adherence was assessed using an 8-item Morisky medication adherence scale. Digital BP machine, non-stretchable measuring tape, weighing machines (bathroom type), and glucometer were used following the standardization of each instrument and standard techniques. For enhancing the quality of measurement, validation of the study tool<sup>[10]</sup> was done. To reduce the interobserver measurement error, training and frequent field assistance were provided to health workers by the 1<sup>st</sup> and 2<sup>nd</sup> authors.

### Outcome variables

The primary outcome variables were the proportion of hypertensive patients with a reduction in systolic blood

pressure (SBP) of more than five mmHg after twelve months of receiving the intervention and the difference in change in mean systolic and diastolic blood pressure (DBP) in the patients in study and control groups at 12 months of follow-up. Other outcome measures included blood sugar control at 12 months between the study and control groups.

Data analysis was done by  $\chi^2$  test, Student *t* test, and generalized linear models (GLM) analysis. All statistical procedures were performed using Statistical Package for Social Sciences version 16 (SPSS Inc., SPSS for Windows, Chicago, USA). The analysis strategy was based on the intention to treat.

### Ethical issues

The study was approved by the Institutional Ethics Committee of NRS Medical College, Kolkata, West Bengal, India.

## Results

A total of 478 newly detected hypertensive patients were approached in both study and control blocks. A total of 243 patients in the study blocks fulfilled the inclusion criteria while 16 patients were excluded (13 refused to participate and three patients died during follow-up period), thus the intervention group finally comprised 227 patients. In the control group, the number of participants after exclusion was 230 patients, with one death reported, which was excluded from the analysis [Figure 1].

The findings reveal that there was no statistically significant difference in the distribution of sociodemographic, behavior related, and clinical characteristics of patients at baseline between intervention and control groups [Table 1].

A statistically significant difference was observed in the proportion of hypertensive patients with a reduction in SBP of more than 5 mmHg at twelve months of follow-up in the intervention group compared to the control. Although a higher proportion of hypertensive patients in the study blocks showed controlled blood sugar compared to the control group; however, the difference was not statistically significant [Figure 2].

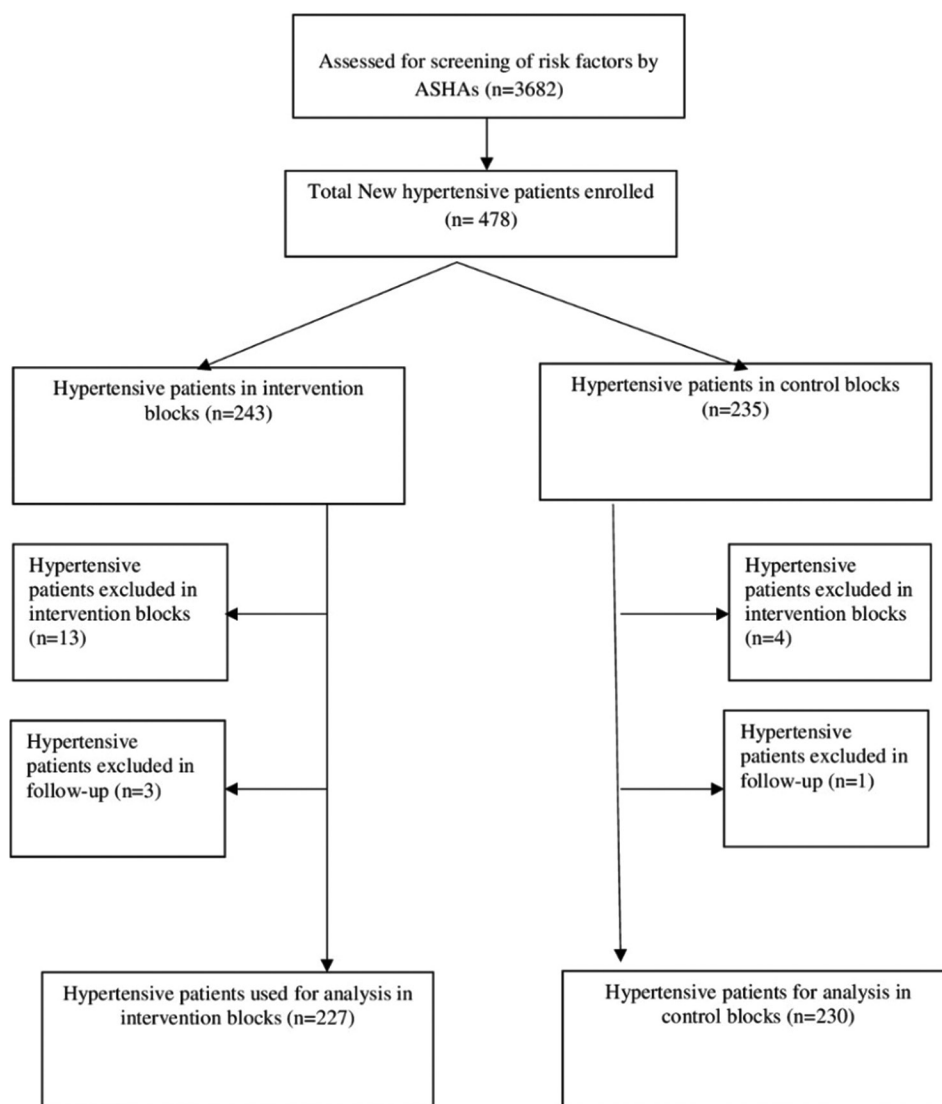
Patients in the intervention blocks demonstrated a mean reduction in SBP of 15.6 mmHg  $\pm$  8.69 compared to a mean reduction in SBP of 10.9 mmHg  $\pm$  9.1 in the control block over 1-year follow-up and the difference was statistically significant. Similarly, a statistically significant reduction in mean DBP was also found in the patients selected from the intervention blocks compared to the control. Subgroup analysis based on age, sex, and literacy was also done [Table 2].

### Average effect adjusted covariates

Educational intervention for primary healthcare providers reduced SBP in patients selected from study blocks by a mean of 16.14 mmHg [CI = -17.75 to -14.52] compared to 9.83 mmHg [CI = -11.84 to -7.82] ( $P < 0.001$ ) in the control

**Table 1: Baseline sociodemographic characteristics, lifestyle, and clinical parameters of hypertensive patients in the study and control groups**

Variables	Study/intervention group n=227	Control/usual care group n=230	P
Age (year)	54.03±9.81	55.61±10.52	0.09
Gender (female) (%)	70.9%	73.9%	0.68
Religion (Hindus)	57.3%	61.3%	0.38
Education (illiteracy)	11.9%	12.2%	0.92
Family history of CVDs	16.7%	13.9%	0.40
Baseline weight (Kg)	57.25+10.03	58.73+9.07	0.09
Baseline waist circumference (cm)	91.84+7.58	93.14+7.83	0.07
Addiction to smoking or chewing tobacco (%)	25.6%	20.4%	0.19
Alcohol	9.7%	8.3%	0.59
Physical activity ≥3 times/week (%)	6.6%	7.0%	0.88
Proportion of Type 2 diabetes mellitus	30.4%	24.8%	0.18



**Figure 1: Patient enrolment flowchart**

blocks after adjusting for age, sex, and baseline blood pressure. Similarly, the reduction achieved in DBP in the study blocks was by a mean of 11.65 mmHg [CI = -12.70 to -10.59] ( $P < 0.001$ )

compared to 7.68 mmHg [CI = -8.99 to -6.37] ( $P < 0.001$ ) in the control blocks after adjusting for age, sex, and baseline blood pressure [Figure 3].

**Table 2: Changes in SBP and DBP of hypertensive patients overall and by subgroups following training of primary healthcare providers**

Variables	SBP			DBP		
	Study	Control	P	Study	Control	P
Mean (±SD) BP at baseline	155.46 (10.09)	153.73 (10.03)	0.07	89.67 (9.2)	88.95 (7.13)	0.36
Mean (±SD) BP at 12-month follow-up	139.84 (12.78)	142.77 (12.57)	0.00	77.93 (0.38)	81.87 (0.37)	0.000
Mean (±SD) change in BP	-15.6 (8.69)	-10.9 (9.1)	0.00	-11.6 (8.7)	-7.1 (8.0)	0.000
Males	-15.15 (8.8)	-11.45 (8.7)	0.00	-11.45 (8.7)	-7.02 (8.5)	0.00
Females	-16.77 (8.2)	-9.57 (10.0)	0.00	-12.12 (8.7)	-7.60 (6.4)	0.00
Age >65 years	-15.41 (8.5)	-11.21 (9.0)	0.00	-11.32 (8.7)	-6.95 (8.3)	0.00
Age ≤65 years	-16.7 (7.8)	-8.80 (9.9)	0.00	-13.30 (8.4)	-9.08 (4.6)	0.02
Illiterate	-15.50 (8.7)	-10.70 (11.7)	0.05	-11.56 (8.7)	-7.07 (8.1)	0.06
Literate	-16.40 (8.6)	-11.00 (8.7)	0.00	-12.3 (8.9)	-7.86 (7.8)	0.00

**Table 3: Results of GLM regression for systolic and diastolic blood pressure**

Parameter	SBP			DBP		
	Estimate	Std error	P	Estimate	Std error	P
Intercept	-4.86	6.64	0.94	54.41	3.11	0.00
Interventional group	4.519	0.84	0.00	3.89	0.54	0.00
Male gender	-0.07	0.94	0.94	0.49	0.60	0.41
Age group >65 years	-0.36	1.23	0.77	0.56	0.79	0.48
Baseline SBP	0.10	0.04	0.02	-	-	-
Baseline DBP	-	-	-	0.75	0.03	0.00

The GLM analysis revealed that the educational intervention was strongly associated with a reduction in SBP ( $P < 0.001$ ), while baseline SBP was also a statistically significant predictor ( $P = 0.02$ ). The association between age group and sex was not statistically significant ( $P > 0.05$ ). There was no statistically significant interaction between the categorical predictor variables and change in SBP while controlling for the baseline SBP [Table 3].

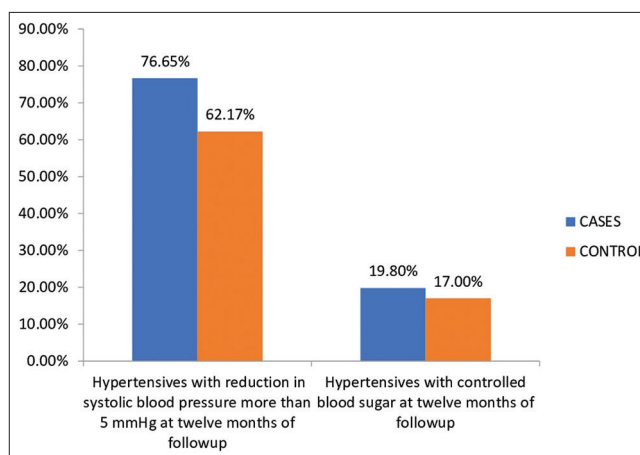
Similarly, baseline DBP and the educational intervention were found to be statistically significant ( $P < 0.001$ ) predictors, while age group and sex were not statistically related to a reduction in DBP ( $P > 0.05$ ). Again, no statistically significant interaction between the categorical predictor variables and change in DBP was found while controlling for the baseline DBP [Table 3].

Regarding lifestyle-related cardiovascular risk factors, statistically significant differences were found in favor of the intervention group with respect to weight, addiction to tobacco, regular physical activity, salt intake, and compliance with medication [Table 4].

## Discussion

Blood pressure reduction is crucial in reducing cardiovascular mortality. As low as 2 mmHg lowering of SBP can lead to a 10% reduction in myocardial infarction, stroke, etc.<sup>[11]</sup>

Previous studies have demonstrated the effectiveness of community-based care in reducing blood pressure in different countries.<sup>[12-14]</sup> Schwalm reported an absolute reduction of 11.45 mmHg (95% CI - 14.94 to - 7.97) in SBP in the



**Figure 2: The effect of the educational intervention of primary healthcare providers in reducing SBP by  $\geq 5$  mmHg and controlled blood sugar at 12-month follow-up**

intervention group (both  $P < 0.0001$ ) with 69% of patients achieving blood pressure control in the intervention group versus 30% in the control group ( $P < 0.0001$ ) similar to the present study.<sup>[15]</sup>

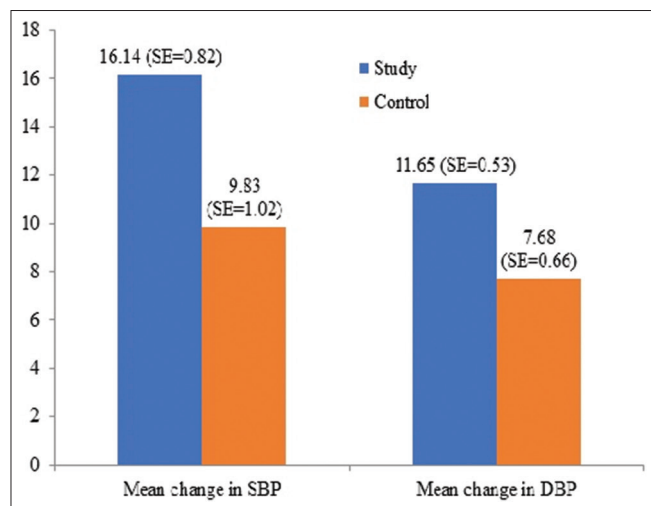
Medication adherence was found to be significantly higher in the intervention group similar to another study on community-based care delivery system to improve drug compliance.<sup>[16]</sup>

Although drug compliance was observed to be better in the intervention group, both groups showed low compliance. The reasons could be because of the non-availability of drugs and forgetfulness of patients especially as the disease is a chronic one requiring lifelong care. A regular supply of drugs is essential for sustaining long-term benefits.

In addition to antihypertensive medication, lifestyle interventions based on the detection of risk factors, effective counseling, and demonstration delivered by primary healthcare workers were observed to have positive effects in the control of hypertension. Primary health workers are the first contact of patients in rural areas. Consequently, any interventions directly delivered by them are better understood, well accepted, and lead to positive behavior change

**Table 4: Lifestyle-related risk factors and medication compliance at 12 months of follow-up between study and control groups**

Outcome measures at 12 months of follow-up	Hypertensive patients in intervention (study) block	Hypertensive patients in control block	P
Mean weight (kg)	56.39±9.90 (SD)	58.75±9.13(SD)	0.008
Mean waist circumference (cm)	82.75±5.14	83.06±4.81	0.50
Current addiction to tobacco	11%	17.8%	0.03
Alcohol use	4.4%	6.5%	0.32
Low fruits/vegetable intake (<5 servings/day)	86.5%	90.7%	0.12
High salt intake (>1 tsp or 5g/day)	33.5%	65.2%	0.000
Irregular physical activity (<150 min/week)	23.8%	44.8%	0.000
Compliance to medication (perfect adherence on 8-item Morisky, MMAS score=8)	11.7%	4%	0.002

**Figure 3: The effect of the educational intervention of primary healthcare providers in reducing BP of hypertensive patients after adjusting for covariates**

in the community.<sup>[17]</sup> At 12-month follow-up, findings revealed significant changes in both mean SBP (16.14 vs 9.83 mmHg) and mean DBP (11.65 vs 7.68 mmHg) compared to the control group. This suggests that primary healthcare providers can deliver effective hypertension control interventions after proper training. Further, intensive supervision at follow-up by health workers, the active finding of newly detected cases with lesser chances of complications than long-standing patients, and short-term follow-up of patients possibly aided the results. However, long-term follow-up is required to assess sustainable gains. The findings suggest both baseline SBP and DBP to be significant predictors of blood pressure control similar to other studies.<sup>[18,19]</sup> This necessitates the need for detecting new cases early so that management can be initiated early and subsequent complications may be prevented or delayed; hence, community-based care can provide a feasible and cost-effective solution.

Regarding lifestyle factors, positive changes were reported at 12 months in mean weight, current addiction to tobacco, lowered salt intake, physical activity, and medication compliance in the intervention group. This indicated that even short-term projects can effectively reduce BP and lead to the adoption of healthy lifestyle behavior. The CORFIS study in Malaysia also showed similar results.<sup>[20]</sup>

This study emphasizes that primary care providers can be utilized in providing community-based care that can help in the early detection of hypertension and associated risk factors. The study also demonstrated that effective educational intervention and imparting training programs to the primary care providers can bring about a demonstrable benefit in terms of reduction of SBP and DBP and also improvement in lifestyle and medication compliance. Primary care providers being closest to the community can help in bringing about behavioral and lifestyle changes through face-to-face counseling, health promotion, providing assistance, and early referral if needed and thus help in achieving health-related targets.

## Conclusion

The study demonstrated the benefits of reduction of blood pressure in the community by primary care providers through effective community-based care. The strength of the study is providing evidence on the effectiveness of employing community health workers in the detection and control of hypertension even over a short follow-up period. This may ultimately prove beneficial in reducing long-term complications and reducing burden both financially and on the caseload in secondary and tertiary healthcare systems. The study was done before the implementation of the NCD program in the district. The study thus invoked the new message of involving the trained grass root workers in early detection and better control of hypertension.

However, the study had some limitations. Mortality was initially included for outcome analysis; however, as all the cases were newly diagnosed hypertensives with a follow-up period of 12 months only, the reported mortality was very low although the exclusion of such few cases was unlikely to influence the study results. A relatively short follow-up (12 months) time for outcomes assessment of chronic non-communicable diseases like hypertension was another limitation. More evidence is needed on sustainability and long-term outcomes.

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### Ethical policy and institutional review board statement

The study was approved by the Institutional Ethics Committee of NRS Medical College, Kolkata, West Bengal.

### Patient declaration of consent statement

Written informed consent was taken from the study participants. Anonymity and confidentiality of the participants were maintained.

### Financial support and sponsorship

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### Conflicts of interest

There are no conflicts of interest.

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