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ORIGINAL RESEARCH

Structured Lifestyle Modification Interventions Involving Frontline Health Workers for Population-Level Blood Pressure Reduction: Results of a Cluster Randomized Controlled Trial in India (DISHA Study)

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BACKGROUND: Population-wide reduction in mean blood pressure is proposed as a key strategy for primary prevention of cardiovascular disease. We evaluated the effectiveness of a task-sharing strategy involving frontline health workers in the primary prevention of elevated blood pressure.

METHODS AND RESULTS: We conducted DISHA (Diet and lifestyle Interventions for Hypertension Risk reduction through Anganwadi Workers and Accredited Social Health Activists) study, a cluster randomized controlled trial involving 12 villages each from 4 states in India. Frontline health workers delivered a custom-made and structured lifestyle modification intervention in the selected villages. A baseline survey was conducted in 23 and 24 clusters in the control (n=6663) and intervention (n=7150) groups, respectively. The baseline characteristics were similar between control and intervention clusters. In total 5616 participants from 23 clusters in the control area and 5699 participants from 24 clusters in the intervention area participated in a repeat cross-sectional survey conducted immediately after the intervention phase of 18-months. The mean (SD) systolic blood pressure increased from 125.7 (18.1) mm Hg to 126.1 (16.8) mm Hg in the control clusters, and it increased from 124.4 (17.8) mm Hg to 126.7 (17.5) mm Hg in the intervention clusters. The population average adjusted mean difference in difference in systolic blood pressure was 1.75 mm Hg (95% CI, −0.21 to 3.70).

CONCLUSIONS: Task-sharing interventions involving minimally trained nonphysician health workers are not effective in reducing population average blood pressure in India. Expanding the scope of task sharing and intensive training of health workers such as nurses, nutritionists, or health counselors in management of cardiovascular risk at the population level may be more effective in primary prevention of cardiovascular disease.

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Key Words: cardiovascular disease ■ high blood pressure ■ hypertension ■ India ■ systolic blood pressure

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CLINICAL PERSPECTIVE

What Is New?

- This study focuses on a combined strategy of community-level health promotion and health system interventions through a task-sharing strategy by involving frontline community health workers in the prevention and control of high blood pressure in multiple settings in India.

What Are the Clinical Implications?

- Minimal involvement of frontline health workers such as community health workers or accredited social health activists with nominal training may not be effective in reducing population-level blood pressure in both rural and urban settings in India.
- Expanding the scope of task sharing, intensive training, and involvement of health workers such as nurses, nutritionists, or health counselors in screening, routine measurement of blood pressure, and management may have the desirable effects in control of high blood pressure in countries like India.

Nonstandard Abbreviations and Acronyms

DISHA	Diet and Lifestyle Interventions for Hypertension Risk Reduction Through Anganwadi Workers and Accredited Social Health Activists
SLM	structured lifestyle modification

Cardiovascular disease (CVD) is an important concern of global health[1] and a prominent cause of mortality and morbidity in India.[2] High blood pressure (BP) is a leading risk factor for CVD.[3] Almost one tenth of premature deaths in India are attributable to high BP. Additionally, India contributes nearly one fifth (18%) of the estimated 212 million disability adjusted life years attributable to elevated BP.[4] Despite the global efforts to contain the burden attributable to elevated BP, both the all-age prevalence of hypertension and mean population levels of BP in India have been rising over the past 3 decades.[2,5]

It has been estimated that even a modest population-wide shift in systolic BP (SBP) of 1 mm Hg toward the left of the population distribution curve is associated with a substantial reduction in CVD incidence.[6] Achieving a 25% reduction in risk of premature mortality from CVD by 2025,[7] a target set by the United Nations as 1 of the 9 global noncommunicable disease targets of the sustainable development agenda, largely depends on the capacity of individual countries to decrease the mean BP at the population level. Novel strategies that are resource sensitive, culturally acceptable, contextually relevant, operationally scalable, and of high efficacy and effectiveness are required to minimize the disease burden attributable to high BP in low resource settings.

A task-sharing strategy of involving nonphysician health workers has been recommended as a useful means of cardiovascular risk reduction in high-risk groups.[8] Recently concluded randomized controlled trials in community settings also support the task-sharing strategy for managing individuals with established hypertension.[9,10] However, the effectiveness of the task-sharing approach in primary prevention and its impact on distribution of BP at the population level are yet to be established. We evaluated the effectiveness of the task-sharing approach of involving frontline health workers in imparting lifestyle interventions at the individual, family, and population level and their impact on the distribution of population-level BP in India. The frontline health workers acted as community agents to impart lifestyle changes for cardiovascular risk reduction at the population level (task sharing).

METHODS

The DISHA (Diet and lifestyle Interventions for Hypertension Risk reduction through Anganwadi Workers and Accredited Social Health Activists) study was designed as a cluster randomized controlled trial in 2 phases in India. The first phase of the study was carried out in centers in Shimla, Junagadh, Indore, and Pondicherry and the second phase of the study was carried out in Jodhpur, Ranchi & Patna, Dibrugarh, Bhubaneshwar, and Hyderabad. The detailed analyses of the first phase of the DISHA study are presented in this paper. The methodology of the DISHA study is published elsewhere.[11] In brief, the DISHA study (phase 1) was conducted in 4 states in India. At each site, 1 district was selected based on convenience and from each district 12 clusters were randomly selected using computer-generated random numbers. A cluster is defined as a small village (ideally including 1–3 Anganwadi centers) with 250 to 300 households. Computer-generated random numbers with 1:1 allocation were employed to assign the selected 12 clusters in each district to intervention and usual care arms (n=6 villages each in intervention and usual care arms). In order to ensure at least 10 km of distance between 2 adjacent intervention and usual care arm clusters, one of each sample cluster within a pair of adjacent intervention and usual care clusters was dropped and then replaced by another randomly identified cluster from the same district.

The data that support the findings of this study are available from the corresponding author upon reasonable request (email: dprabhakaran@ccdcindia.org). The participants were informed about the study and provided with a detailed information sheet. Written informed consent was also obtained from all study participants. The study was approved by the institutional review boards of the central coordinating center (the Centre for Chronic Disease Control, New Delhi) and all participating sites. The study protocol is registered with the Clinical Trials Registry of India (CTRI/2013/10/004049).

A baseline cross-sectional survey was conducted during 2013 to 2014 in all selected districts (ie, 12 clusters randomly selected from each site) involving both the intervention and control clusters with equal representation. The sample for the cross-sectional survey was identified from a randomly drawn 120 to 150 households in each cluster with a target to obtain a minimum of 300 participants. The cross-sectional survey included all adult family members over 18 years of age in the randomly selected households. A structured instrument, a modified version of the World Health Organization Stepwise Approach to NCD Risk Factor Surveillance instrument for chronic risk factors surveillance, was used to collect data. Detailed components of the baseline survey are published elsewhere.[11] Along with sociodemographic and behavioral variables anthropometric and BP data were also collected from all participants. All anthropometric measurements were taken with the participant wearing light clothes. The anthropometric measurements were rounded off to 1 decimal point for both weight and height. Calibrated instruments were used to collect data by following standardized techniques. Electronic BP monitors (OMRON 7080) were used to record BP and pulse rate. Three measurements were taken, 2 minutes apart and after resting each participant for at least 5 minutes before starting the measurements. Participants were restrained from consuming any beverages (coffee, tea, or soft drinks) and alcohol at least 1 hour before taking the measurements. Complete abstinence from smoking for at least 1 hour duration was also recommended before taking measurements. We took the average of the last 2 BP readings for analyses. Until the completion of the baseline survey, the intervention allocation details were completely masked from the staff involved in the data collection.

A structured lifestyle modification (SLM) model for CVD risk reduction in community settings was developed as part of the intervention. Frontline health workers (mainly Anganwadi workers and accredited social health activists) were trained as change agents within each village to deliver the structured CVD risk reduction interventions in the entire intervention clusters for a minimum period of 18 months. The language spoken at each location (n=5) was different. The clusters were equally distributed in these locations. However, the frontline health workers included in the study were well versed in the local settings and they were fluent in the local language. We also adapted all study tools to local language. Similar to the baseline survey, a repeat cross-sectional survey was conducted to capture the population-level changes in risk factors and conditions in another representative sample from the same clusters immediately after the intervention phase. Therefore, the participants interviewed at the end of the study (post intervention) may not be same. The Consolidated Standards of Reporting Trials study flow chart is presented in Figure 1.

Various steps involved in the development of the SLM intervention were described previously.[11] In brief, the theoretical domain framework of Mitchie et al.[12] was followed to identify lifestyle intervention activities in different domains such as knowledge; skills; social/professional role and identity; beliefs about capabilities; beliefs about consequences; motivation and goals; memory, attention, and decision processes; environmental context and resources; social influences; emotions; behavioral regulations; and nature of the behaviors. The intervention activities were aimed to promote healthy diet, improvement in physical activity, and abstinence from tobacco and alcohol and ensure adherence to pharmacological treatment in patents with established hypertension and diabetes or other cardiovascular conditions. They were then translated into intervention aids such as information booklets, calendar, posters, and leaflets. The frontline health workers used the intervention aids to communicate the lifestyle intervention components effectively in individual, family, and community settings. In addition to the intervention aids, a calibrated salt spoon and an oil dispenser were also given to each family to measure their daily consumption of salt and oil. Individual-level (eg, individual counseling), household-level (eg, household visits by frontline health workers), and community-level (eg, display of posters, community-level activities, and competitions) interventions were planned as part of the SLM education program.

The SLM intervention was delivered to all the households in the selected clusters by trained frontline health workers. All health workers participated in a 2-day training program on common CVD risk factors, strategies to prevent the progression of risk factors, common lifestyle interventions, SLM intervention package, and on using the intervention tool for delivery of interventions. The frontline health workers were instructed to conduct 9 house visits (once in 2 months) during the intervention period. The objectives of each household visit were described in detail to all participating frontline health workers during the training program. The details of the intervention as per the Template for Intervention Description and Replication checklist are provided in Figure S1.

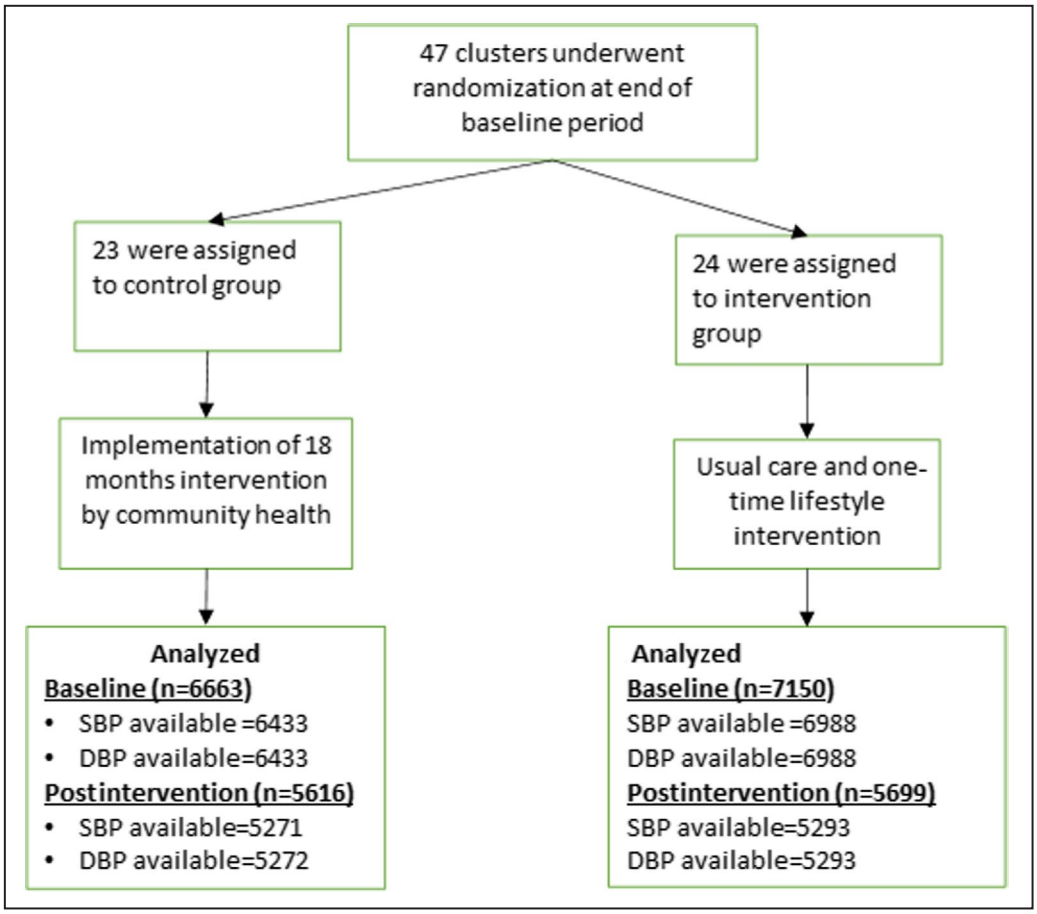

Figure 1. Randomization, intervention, and follow-up.
DBP indicates diastolic blood pressure; and SBP, systolic blood pressure.

The DISHA team at each site monitored the intervention implementation. One of 5 households in the intervention clusters was visited by the DISHA team at quarterly intervals and documented the progress of interventions in terms of number of visits made by the frontline health workers, messages delivered, and use of study tools.

Primary and Secondary Study Outcomes

The primary outcome of the study was population average difference in difference of mean change in SBP at the end of SLM interventions between intervention and control groups. Secondary outcome was population average difference in difference of mean change in diastolic BP (DBP) between intervention and control groups. Additionally, a set of process indicators were also considered, for example, the difference in proportion between intervention and control group for awareness of BP; extra salt use at table, while cooking rice, or kneading dough; tobacco use; alcohol use, and physical inactivity. Other process outcomes considered were the median change in intervention and control group for per person fruit servings per week, vegetable servings per week, free sugar consumption, and overall salt consumption in a month (Kg). A diet score was calculated using per week consumption for fruits, vegetables, salt, sugar, and oil. First, each variable was divided into 4 equal groups based on quartiles. Second, a score of 1 to 4 was assigned to each quartile for fruits and vegetables (from first to fourth quartile). Further, a score of 4 to 1 was assigned to quartile 1 to 4 of salt, sugar, and oil consumption. Finally, a diet score (range: 5–20) was calculated as sum of scores provided for fruits, vegetables, salt, sugar, and oil consumption, respectively. Some items for diet assessment were adapted from the World Health Organization Stepwise Approach to NCD Risk Factor Surveillance and some items were specifically developed for the purpose of the study. The diet score we reported is not validated in our settings. However, the same tool has been used to capture dietary practices relevant to noncommunicable diseases.

Statistical Analysis

The sample size was calculated with the aim to detect an epidemiologically significant difference of 2 mm Hg in SBP at the population level between the intervention and control groups of the study (8). With 3600 participants

from 12 clusters at each site, and assuming an intraclass correlation coefficient of 0.002 for BP (based on previous cluster design survey data from India), the study had 90% power to detect a mean difference of 2 mm Hg of SBP between intervention and control clusters.

Baseline characteristics were presented as mean and SD or median and interquartile range (P25, P75) or frequency and percentage as appropriate. The distribution of the variables was checked graphically by plotting histogram and using Shapiro-Wilk lambda test. For the comparison of the individual level variables, we used generalized estimating equations (GEE) to adjust for clustering with the identity link function for continuous variables and the logit link function for dichotomous variables. The intervention effect on SBP was estimated using GEE with an exchangeable correlation to account for clustering of participants within clusters. The model included group (intervention, control), time (baseline, post intervention), and time*group interaction, a term indicating differential change by group from baseline to the end of the trial. In primary analysis, the independent variables used in the model were group (intervention, control), time, time*group interaction, and baseline cluster level mean SBP. The GEE model was also reported after adjustment for age, sex, education, season of BP measurement, and duration of intervention period for each cluster.

Sensitivity analysis was also conducted in a subgroup of participants who were part of both the baseline and postintervention survey using the same GEE models. We performed additional subgroup analyses stratified by sex and participating sites.

A 2-sided *P* value of <0.05 was used to indicate statistical significance. We used STATA, version 16.0 (StataCorp.) for all analyses.

RESULTS

Figure 1 shows the number of cluster randomized and number of subjects analyzed. The baseline survey was conducted in 23 clusters in the control group (n=6663) and 24 clusters in the intervention group (n=7150). The baseline survey could not be conducted within the stipulated time in 1 control cluster owing to difficulty in accessing the site. At baseline, there were 2283 and 2437 households in the control and intervention areas, respectively (Table 1). Overall, 74% of the population belong to a rural area and 26% belong to an urban area. The population was middle aged with mean age of 39 years (SD=14.9), slightly more than 1 of 2 participants was female (54%), and 1 of 3 participants did not report any formal education (32%). Current tobacco and alcohol use were prevalent in 20% and 7% of the baseline study population, respectively. More than two thirds of the study population (73%) were either moderately or highly active. Nearly half of the participants were vegetarians (50%). Median (P25, P75) servings of fruits and vegetables per week were 3 (2–4) and 7 (6–12), respectively. Overweight was prevalent in 28% of the baseline study participants. The baseline characteristics did not differ between control and intervention clusters (Table 1).

In total 5616 participants from 23 clusters in the control area and 5699 participants from 24 clusters in the intervention area participated in the repeat cross-sectional survey at the end of the study (Table S1). Similar to the baseline survey, the population was middle aged (mean=40.3 years, SD=15.0) and the majority were women (53%). A quarter of participants (24.4%) reported no formal education. Current tobacco use was 10% each in the intervention and control clusters, and alcohol use was 5% and 6% in control and intervention clusters, respectively. One third of the participants (34.0%) in the intervention clusters were overweight, whereas this proportion was 29.0% in the control clusters. More than half of the participants (60%) were vegetarians. Overall, the median (interquartile range) servings of fruits and vegetables per week were 2 (1.0–4.0) and 7.0 (5.0–10.0), respectively.

Figure 2 shows the overall distribution of SBP and DBP at baseline and post intervention. Figure S2 shows the sitewise distribution of SBP and DBP.

Primary Outcome: Changes in BP

The mean SBP in both the control and intervention clusters increased from baseline to postintervention period (Table 2). The SBP increased from 125.7 mm Hg to 126.1 mm Hg in the control clusters, and in the intervention clusters it increased from 124.4 mm Hg to 126.7 mm Hg (Table 2). The cluster adjusted mean difference in difference was 1.91 mm Hg (95% CI, −0.02 to 3.85). The adjusted analyses show a small nonsignificant population average change in mean SBP between intervention and control clusters of 1.75 (95% CI, −0.21 to 3.70). The results were consistent in men and women and in all individual sites analyzed separately. Similar results were seen in the analyses restricted to the same individuals who were part of both the baseline and postintervention surveys (Table 3).

Similar to SBP, the mean DBP in both the control and intervention clusters increased from baseline to postintervention period (Table S2). The DBP increased from 77.1 mm Hg to 78.1 mm Hg in the control clusters, whereas in the intervention clusters it increased from 76.3 mm Hg to 78.2 mm Hg. The cluster adjusted mean difference in difference was 0.96 mm Hg (95% CI, −0.30 to 2.20). The primary multivariable GEE analyses showed a small nonsignificant population average change in mean SBP between intervention and control

Table 1. Baseline Characteristics of the Study Population

Characteristics	Control group (n=6663, k=23)	Intervention group (n=7150, k=24)	*P* value
Center, n (%)			
Indore	1857	1802	
Junagadh	1824	1765	
Pondicherry	1822	1783	
Shimla	1160	1800	
No. of Households			
Overall	2283	2437	
Indore	589	492	
Junagadh	590	627	
Pondicherry	649	672	
Shimla	455	646	
Demographics			
Age, y, mean (SD)	38.8 (14.7)	39.1 (14.9)	0.885
Women, n (%)	3601 (54)	3866 (54)	0.834
Years of schooling, mean (SD)	6.5 (5.3)	6.4 (5.2)	0.638
No formal education, n (%)	2121 (32)	2227 (31)	0.936
Primary to high school, n (%)	2672 (40)	2838 (40)	0.975
Secondary school and above, n (%)	1861 (28)	2074 (29)	0.922
Income, n (%)			
<10 000	4158 (62)	4405 (62)	0.858
10 001–20 000	1681 (25)	1773 (25)	0.801
>20 000	823 (12)	964 (13)	0.943
Don't know/refused	1	8	
Current tobacco use, n (%)	1317 (20)	1482 (21)	0.731
Current alcohol use, n (%)	482 (7)	494 (7)	0.811
Physical activity, n (%)			
Highly active	3156 (47)	3896 (54)	0.243
Moderately active	1415 (21)	1591 (22)	0.773
Low active	1522 (23)	1180 (17)	0.081
Inactive	251 (4)	186 (3)	0.453
Missing	319 (5)	297 (4)	
Diet and nutrition, n (%)			
Vegetarian	3111 (47)	3808 (53)	0.664
Ovo-vegetarian	770 (12)	726 (10)	0.818
Nonvegetarian	2782 (42)	2616 (37)	0.753
Consumption of fruits and vegetables			
<3 servings per day	6239 (94)	6702 (94)	0.918
Fruits servings per wk, median (P25, P75)	3.0 (1.0,4.0)	3.0 (2.0,4.0)	0.463
Vegetable servings per wk, median (P25, P75)	7.0 (6.0,14.0)	7.0 (6.0,9.0)	0.166
Per person free sugar consumption in a month, median (P25, P75)	1.0 (0.60,1.25)	1.0 (0.67,1.25)	0.755
Per person salt consumption in a month, median (P25, P75)	0.22 (0.17,0.33)	(0.21,0.17,0.33)	0.889
History of hypertension	367 (6)	418 (6)	0.74
History of heart disease	52 (1)	64 (1)	0.645
Hypertension, n (%)	1552 (24.1)	1564 (22.4)	0.224

(*Continued*)

Table 1. Continued

Characteristics	Control group (n=6663, k=23)	Intervention group (n=7150, k=24)	*P* value
Body mass index, kg/m^2, n (%)	1241 (23.5)	1341 (25.3)	
<18	851 (13)	950 (13)	0.793
18–22.99	2610 (39)	3029 (42)	0.146
23–24.99	969 (15)	1005 (14)	0.572
≥25	1966 (30)	1962 (27)	0.544
Missing	267 (4)	204 (3)	
Abdominal obesity, n (%)			
>90 cm for men, >80 cm for women	2258 (34)	2392 (33)	0.791
Missing	245 (4)	172 (2)	

P values calculated adjusted for clustering effect. Hypertension defined as systolic blood pressure of ≥140 mm Hg and/or a diastolic blood pressure of ≥90 mm Hg and/or self-reported treatment for hypertension. k indicates number of clusters; P25, 25th percentile; and P75, 75th percentile.

clusters (adjusted difference, 0.84; 95% CI, −0.41 to 2.09). The results were consistent in men and women and in all individual sites analyzed separately. Similar results were seen in the analyses restricted to the same individuals who were part of both the baseline and postintervention surveys (Table 3). Figure 3 shows the adjusted mean values for SBP and DBP.

Changes in Process Indicators

The DISHA interventions did not improve population average awareness of BP, weekly per person intake of fruits and vegetables, or monthly per person free sugar consumption (Table 4). Substantial reduction in salt use was documented in both intervention and control group with steep reduction in the intervention group (93% to 49% in the intervention group, 80% to 65% in the control group). In the cluster adjusted analysis, the group receiving SLM interventions were 2.4 times more likely to reduce extra salt use than the control group (odds ratio, 2.4; 95% CI, 1.2–4.7). Further, tobacco use was reduced in both intervention and control clusters by ≈50%. Table 5 reports the median (interquartile range) for changes in process indicator for fruit servings per week, vegetable servings per week, per person free sugar and salt consumption (Kg), and diet score.

Intervention Fidelity

Overall, 87% of the household visits were completed by the frontline health workers (Table S3). There was, however, diversity in community-based activities conducted

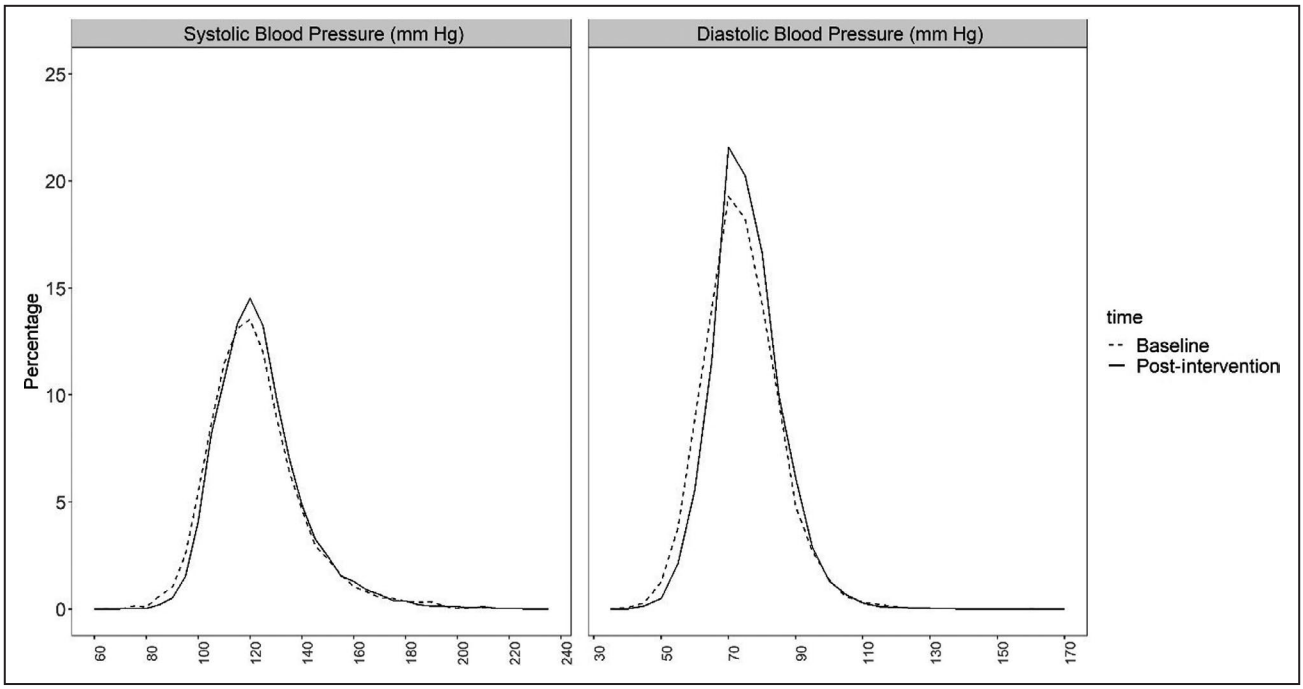

Figure 2. Distribution of systolic and diastolic blood pressure at baseline and post intervention (mm Hg).

Table 2. Systolic Blood Pressure Changes in the Study Population

	Control group		Intervention group		Cluster adjusted		Primary analysis		Secondary analysis	
	Baseline	Postintervention	Baseline	Postintervention	Adjusted difference* (95% CI)	*P* value	Adjusted difference* (95% CI)	*P* value	Adjusted difference† (95% CI)	*P* value
Systolic blood pressure, mm Hg										
Overall	125.7 (18.1)	126.1 (16.8)	124.4 (17.8)	126.7 (17.5)	1.91 (–0.02 to 3.85)	0.053	1.89 (–0.03 to 3.82)	0.054	1.75 (–0.21 to 3.70)	0.079
Men	128.1 (16.8)	128.3 (15.7)	127.4 (16.9)	129.4 (16.3)	1.58 (–0.63 to 3.79)	0.161	1.62 (–0.58 to 3.82)	0.149	1.63 (–0.61 to3.86)	0.153
Women	123.8 (18.9)	124.4 (17.4)	121.9 (18.2)	124.3 (18.2)	2.03 (–0.07 to 4.12)	0.058	1.93 (–0.18 to 4.03)	0.073	1.91 (–0.1 to 3.92)	0.063
By site										
Indore	126.7 (18.1)	122.9 (10.8)	125.5 (17.2)	123.9 (10.7)	2.75 (–1.05 to 6.55)	0.156	2.43 (–1.16 to 6.02)	0.185	2.06 (–1.13 to 5.26)	0.205
Junagadh	128.7 (18.3)	130.0 (18.4)	128.1 (17.9)	129.7 (17.7)	0.35 (–1.68 to 2.39)	0.733	0.33 (–1.72 to 2.37)	0.755	–0.25 (–2.01 to 1.51)	0.782
Puducherry	124.2 (16.9)	125.2 (17.5)	122.9 (16.4)	125.0 (17.5)	0.93 (–0.68 to 2.53)	0.257	1.00 (–0.64 to 2.64)	0.233	1.08 (–0.7 to 2.85)	0.235
Shimla	122.0 (18.8)	125.9 (18.5)	121.3 (18.9)	126.6 (19.4)	1.58 (–3.16 to 6.32)	0.513	1.47 (–3.27 to 6.21)	0.543	2.37 (–1.97 to 6.72)	0.285

Data are mean (SD) by group and time period. GEE indicates generalized estimating equation.

*Cluster adjusted-GEE analysis with an exchangeable covariance matrix, to account for clustering of participants within clusters/villages.

†Adjusted-GEE analysis with an exchangeable covariance matrix, to account for clustering of participants within clusters/villages and model is adjusted for baseline cluster mean systolic blood pressure.

‡Adjusted-GEE analysis with an exchangeable covariance matrix, to account for clustering of participants within clusters/villages and model is adjusted for baseline cluster mean systolic blood pressure, age, sex, education, and season and duration of intervention. Note: Men and Women is adjusted for baseline cluster mean systolic blood pressure, age, education, and season and duration of intervention.

Table 3. Blood Pressure Changes in the Study Population (Analyses in Same Individuals)

	Control group		Intervention group		Cluster adjusted		Primary analysis		Secondary analysis	
	Baseline	Postintervention	Baseline	Postintervention	Adjusted difference‡ (95% CI)	*P* value	Adjusted difference‡ (95% CI)	*P* value	Adjusted difference* (95% CI)	*P* value
Systolic blood pressure, mm Hg										
Overall	126.4 (18.6)	127.2 (17.0)	124.0 (17.6)	127.8 (17.3)	2.81 (0.24 to 5.37)	0.032	2.76 (0.22 to 5.3)	0.033	2.05 (–0.38 to 4.49)	0.099
Men	128.7 (17.5)	128.7 (15.6)	127.3 (16.6)	130.3 (16.1)	2.91 (0.01 to 5.8)	0.049	2.88 (–0.02 to 5.77)	0.052	2.33 (–0.73 to 5.4)	0.136
Women	124.6 (19.2)	126.1 (17.9)	121.5 (17.9)	125.8 (18.0)	2.75 (–0.03 to 5.52)	0.052	2.67 (–0.08 to 5.41)	0.057	1.79 (–0.5 to 4.08)	0.126
Diastolic blood pressure, mm Hg										
Overall	77.3 (11.4)	78.6 (9.8)	76.1 (11.2)	78.3 (10.1)	0.85 (–0.64 to 2.33)	0.264	0.80 (–0.67 to 2.27)	0.284	0.53 (–0.99 to 2.05)	0.496
Men	78.3 (11.8)	79.4 (9.7)	77.6 (11.5)	79.8 (10.2)	1.22 (–0.64 to 3.08)	0.200	1.16 (–0.7 to 3.02)	0.222	0.98 (–1.05 to 3.01)	0.345
Women	76.5 (11.1)	78.0 (9.8)	75.0 (10.8)	77.1 (9.8)	0.57 (–0.89 to 2.03)	0.447	0.52 (–0.92 to 1.97)	0.479	0.13 (–1.19 to 1.46)	0.842

Data are mean (SD) by group and time period. GEE indicates Generalized estimating equation.

*Cluster adjusted-GEE analysis with an exchangeable covariance matrix, to account for clustering of participants within clusters/villages.

†Adjusted-GEE analysis with an exchangeable covariance matrix, to account for clustering of participants within clusters/villages and model is adjusted for baseline cluster mean systolic/diastolic blood pressure.

‡Adjusted-GEE analysis with an exchangeable covariance matrix, to account for clustering of participants within clusters/villages and model is adjusted for baseline cluster mean systolic/diastolic blood pressure, age, sex, education, and season and duration of Intervention Note: Men andWomen is adjusted for baseline cluster mean diastolic blood pressure, age, education, and season and duration of Intervention.

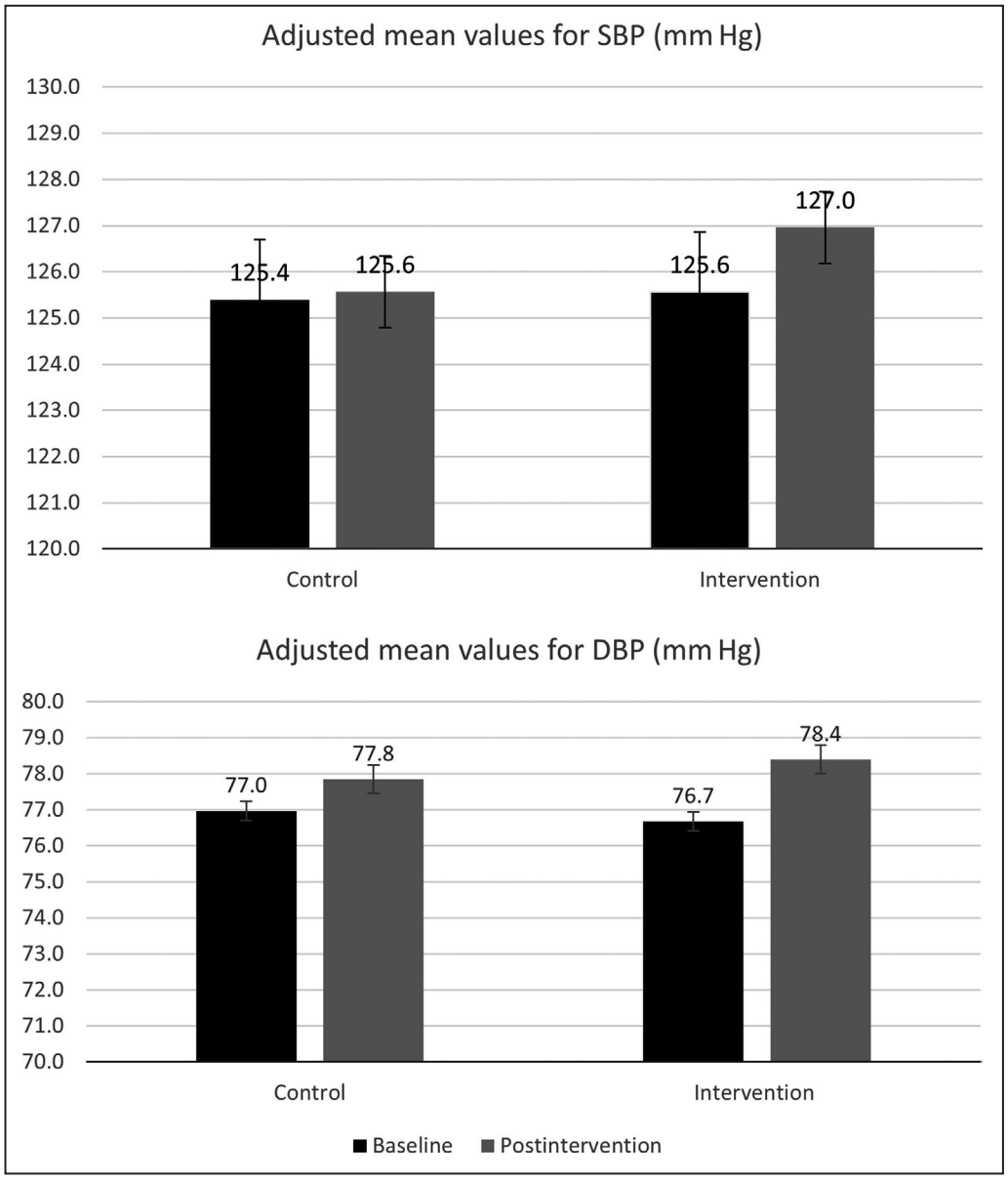

Figure 3. Adjusted mean values (95% CI) by control and intervention group at baseline and post intervention for systolic blood pressure (mm Hg) and diastolic blood pressure (mm Hg).
Adjusted-GEE analysis with an exchangeable covariance matrix, to account for clustering of participants within clusters/villages and model is adjusted for baseline cluster mean systolic/diastolic blood pressure, age, sex, education, and season and duration of intervention. DBP indicates diastolic blood pressure; GEE, generalized estimating equation; and SBP, systolic blood pressure.

at each site, for example, demonstration, video presentation, health lifestyle etc. Overall, 105 group activities were performed over a period of 18 months of intervention at the community level in the selected intervention areas (Table S4). The sitewise household visit details are provided in Table S5.

DISCUSSION

The DISHA study, a large community-based cluster randomized trial in India, could not demonstrate the effectiveness of SLM interventions in reducing the population average mean BP in rural India. The study findings do not support the role of task-sharing strategies involving minimally trained and lower-level cadres of nonphysician health workers in providing SLM interventions for the primary prevention of hypertension in community settings in India. The DISHA study interventions could not make an impact at the population level even in terms of improving the overall awareness of hypertension and inculcating the best behavioral practices related to maintenance of BP within the optimal range.

Table 4. Changes in process indicator related to primary outcome variable

Variables	Control group		Intervention group		Cluster adjusted		Primary analysis		Secondary analysis	
	Baseline n=6663	Post-intervention n=5616	Baseline n=7150	Post-intervention n=5696	OR* (95% CI)	*P* value	OR (95% CI)†	*P* value	OR (95% CI)‡	*P* value
Aware of blood pressure, n (%)	367 (5.5%)	266 (4.7%)	418 (5.8%)	283 (5.0%)	0.88 (0.59–1.31)	0.531	0.87 (0.59–1.29)	0.49	0.95 (0.68–1.33)	0.781
Blood pressure measured by a doctor or other health worker, n (%)	2275 (34.1%)	4076 (72.6%)	2546 (35.6%)	4347 (76.3%)	1.14 (0.48–2.7)	0.765	0.99 (0.4–2.46)	0.976	1.04 (0.41–2.62)	0.936
Add extra salt (at table, cooking rice, or kneading dough), n (%)	6209 (93.2%)	2735 (48.7%)	5692 (79.6%)	3694 (64.9%)	6.79 (2.33–19.82)	<0.001	5.34 (1.61–17.73)	0.006	5.84 (1.84–18.55)	0.003
Tobacco use, n (%)	1317 (19.8%)	562 (10.0%)	1482 (20.7%)	598 (10.5%)	0.97 (0.69–1.37)	0.862	0.91 (0.61–1.37)	0.665	0.83 (0.51–1.35)	0.458
Alcohol use, n (%)	482 (7.2%)	281 (5.0%)	494 (6.9%)	357 (6.3%)	1.25 (0.85–1.84)	0.254	1.27 (0.86–1.88)	0.226	1.31 (0.85–2.03)	0.223
Physical inactivity, n (%)	251 (3.8%)	588 (10.5%)	186 (2.6%)	629 (11.0%)	1.55 (0.49–4.84)	0.455	1.43 (0.47–4.4)	0.528	1.47 (0.47–4.59)	0.506

Data are number (%) by group and time period. Note: Logistic model adjusted for cluster variable used where GEE model did not converge. GEE indicates generalized estimating equation; and OR, odds ratio.
*Cluster adjusted-GEE analysis with an exchangeable covariance matrix, to account for clustering of participants within clusters/villages.
†Adjusted-GEE logistic regression analysis with an exchangeable covariance matrix, to account for clustering of participants within clusters/villages and model is adjusted for baseline proportions.
‡Adjusted-GEE logistic regression analysis with an exchangeable covariance matrix, to account for clustering of participants within clusters/villages and model is adjusted for baseline cluster mean proportion, age, sex, education, and duration of intervention.

The DISHA study results were consistent across all individual sites and in both men and women. The consistent results indicate that the strategy adopted as part of the DISHA intervention is inadequate to influence BP-related behavioral patterns at the population level. The villages selected as part of the DISHA study are mostly rural communities in the transition stage or with a special population such as predominantly tribal communities. The secular trend at the population level was strong enough to take over the influence of the interventions on BP at the population level. The magnitude of the population average difference in BP after the intervention was minimal in our study and indicates that more intensive intervention may be required to achieve a desirable effect at the population level.

The DISHA study was designed to detect moderate but meaningful differences in BP at the population level. So far, studies have assessed the impact of lifestyle interventions on cardiovascular risk factors at the individual level.[13–15] However, these studies are not appropriate to evaluate the potential impact of the interventions in real-life settings at the population level. In other words, the DISHA study was a scale-up evaluation of the SLM intervention strategy aimed at primary prevention at the population level. The study area was large and the non-physician health workers had to travel to several hundreds of households within the assigned area for the delivery of interventions. Therefore, the "dose" of the DISHA study interventions may not have been adequate to influence behavior at the population level. The lack of effect on BP and on other process indicators such as awareness and practices may be partially attributable to the relatively small "dose of interventions" in the DISHA study.

Despite following a behavioral change model targeting multiple CVD risk factors and adopting a theoretical framework for intervention mapping, the effect was almost null on BP reduction. Additionally, the DISHA study also emphasized self-regulation and self-monitoring with introduction of measurement tools for both oil and salt in all households within the study area. The desirable changes observed in salt use may be directly attributable to the self-regulation and self-monitoring of salt use with the help of a measurement device. Although a systematic review of multiple risk factors intervention for primary prevention of CVD in low and middle income country settings indicates a moderate effect with low quality of evidence on the pooled effect on BP,[16] recent community-based studies in high-risk individuals with hypertension show clinically meaningful reduction in BP.[9,10] Further, tobacco and alcohol use in general are relatively high in the rural male population. However, it is very low in women. This is a major factor in the lower overall prevalence of tobacco and alcohol use. In addition, we speculate that there could be a reporting bias. Generally, and particularly among women and in areas where there is alcohol prohibition (1 of our sites had

Table 5. Median (Interquartile Range) for Changes in Process Indicator

Variables	Control group		Intervention group	
	Baseline	Post-intervention	Baseline	Post-intervention
	n=6663	n=5616	n=7150	n=5696
Fruit servings per wk, median (P25, P75)	3.0 (1.0, 4.0)	3.0 (2.0, 4.0)	3.0 (2.0, 4.0)	2.0 (1.0, 4.0)
Vegetable servings per wk, median (P25, P75)	7.0 (6.0, 14.0)	7.0 (5.0, 10.0)	7.0 (6.0, 9.0)	7.0 (5.0, 10.0)
Per person free sugar consumption in a month (kg), median (P25, P75)	1.0 (0.6, 1.3)	1.0 (0.6, 1.3)	1.0 (0.7, 1.3)	0.8 (0.5, 1.0)
Per person salt consumption in a month (kg), median (P25, P75)	0.2 (0.2, 0.3)	0.2 (0.2, 0.4)	0.2 (0.2, 0.3)	0.2 (0.1, 0.3)
Diet score, median (P25, P75)	13 (11,15)	11 (7,13)	13 (10,15)	12 (9,14)

Data are median (interquartile range) by group and time period. P25 indicates 25th percentile; and P75, 75th percentile.

prohibition in their location) participants are reluctant to report these habits to health workers. However, there was no difference in the prevalence of both tobacco and alcohol use across the intervention and control clusters and even after the exclusion of Junagadh where there was government-mandated prohibition.

Similar studies conducted in other parts of India also indicate that minimally trained nonphysician health care workers' involvement in health promotion is inadequate to influence knowledge and behaviors of several lifestyle factors affecting cardiovascular risk.[17] The moderate impact is documented in a meta-analysis of task-sharing interventions involving community health workers in low and middle income country settings.[18,19] Additionally, a recent meta-analysis also did not find a clinically meaningful impact on glycemic outcomes in task-sharing interventions with minimally trained community health workers.[20] Unlike the DISHA study, most of these studies were conducted in relatively high-risk groups and not at the population level. The absence of clear effects of the health promotion interventions delivered by nonphysician health workers in DISHA on BP raise uncertainty about the effectiveness of this strategy in primary prevention at the population level. However, intensive training, adequate supervision, and involvement of higher cadres of nonphysician health workers may help in achieving BP desirable outcomes at the population level.[21,22]

The lack of impact of the intervention on BP reduction in our study is expected as the process indicators in the intervention group closely mirrored the control group. The subjective responses in the process indicators, social desirability among participants in the study area to provide positive responses to the process indicators, and contamination or spillover bias, despite maintaining a safe distance between intervention and control clusters, may have influenced the results.

Strengths and Limitations

The randomized comparison groups, the large size of the study with adequate power to detect the primary outcome difference, involvement of multiple sites, and efforts to evaluate the impact at the population level are the strengths of the DISHA study. However, there was no blinding of the interventions because of the nature of the interventions under investigation. Efforts were also made to perform outcome evaluations in a completely standardized way across all participating villages. Although the DISHA study was adequately powered to detect the primary outcome difference of 2 mm Hg, the difference observed was relatively small.

CONCLUSIONS

Task-sharing interventions involving minimally trained nonphysician health workers are not effective in bringing down population average BP in multiple settings in India. Evidence from the DISHA study is insufficient to recommend task-sharing interventions involving minimally trained nonphysician health workers for primary prevention of cardiovascular risk factors in rural and urban settings in India. Expanding the scope of task sharing, intensive training of nonphysician health workers, and involvement of health workers such as nurses, nutritionists, or health counselors in the management of cardiovascular risk at the population level may be more effective in low and middle income country settings.

APPENDIX

DISHA Study Investigators and Study Team

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Supplemental Material

Tables S1–S5
Figures S1–S2

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Supplemental Material

Table S1. Post-Intervention characteristics of the study population.

Characteristics	Control group (n=5616, k=23)	Intervention group (n=5699, k=24)	p value
Centre, n (%)			
Indore	1,354	671	
Junagadh	1,592	1,652	
Pondicherry	1,447	1,909	
Shimla	1,223	1,467	
No. of Households			
Overall	1781	1788	
Indore	455	207	
Junagadh	475	499	
Pondicherry	483	630	
Shimla	368	452	
Demographics			
Age in years, mean (SD)	40.2(14.9)	40.3(15.1)	0.554
Women, n (%)	2986(53)	3022(53)	0.72
Years of schooling, mean (SD)	8.9(4.5)	9.4(3.8)	0.701
No formal education, n (%)	1410(25)	1347(24)	0.79
Primary to high school, n (%)	2234(40)	2318(41)	0.577
Secondary school and above, n (%)	1972(35)	2034(36)	0.605
Income, n (%)			
<10,000	1793(32)	1588(28)	0.823
10,001-20,000	1615(29)	1918(34)	0.317
>20,000	1253(22)	1351(24)	0.848
missing	955(17)	842(15)	
Current tobacco use, n (%)	562(10)	598(10)	0.983
Current Alcohol use, n (%)	281(5)	357(6)	0.908
Physical activity, n (%)			
Highly active	1164 (21)	1276 (22)	0.788
Moderately active	1000 (18)	897 (16)	0.864
low active	2134 (38)	2218 (39)	0.541
Inactive	588 (11)	629 (11)	0.606
missing	730 (13)	679 (12)	
Diet and nutrition, n (%)			
Vegetarian	3556(63)	3246(57)	0.853
Ovo-vegetarian	208(4)	319(6)	0.509
Non-vegetarian	1852(33)	2134(38)	0.761
Consumption of fruits & Vegetables			
<3 servings per day	4924(88)	4815(85)	0.783
Fruits servings per week, median (IQR)	3.0 (2.0, 4.0)	2.0 (1.0, 4.0)	0.495
Vegetable servings per week, median (IQR)	7.0 (5.0, 10.0)	7.0 (5.0, 10.0)	0.68
Per person free sugar consumption in a month, median (IQR)	1.0 (0.6, 1.3)	0.8 (0.5, 1.0)	<0.0001

Per person salt consumption in a month, median (IQR)	0.2 (0.2, 0.4)	0.2 (0.1, 0.3)	0.184
h/o Hypertension	266(5)	283(5)	0.801
h/o heart disease	30(1)	41(1)	0.457
Hypertension	1241(23.5)	1341(25.3)	0.212
Body mass index in Kg/m^2, n (%)			
<18	600(11)	497(9)	0.152
18-22.99	1809(32)	1764(31)	0.564
23-24.99	780(14)	787(14)	0.865
≥25	1655(29)	1926(34)	0.277
missing	772 (14)	723 (13)	
Abdominal obesity, n (%)			
>90cm for men & >80cm for women	2165(39)	2692(41)	0.427
missing	735(13)	699(12)	

K, Number of Clusters; P values calculated adjusted for clustering effect; Hypertension was defined as systolic blood pressure (SBP) of ≥140 mmHg and/or a diastolic blood pressure (DBP) of ≥90 mmHg and/or self-reported treatment for hypertension.

Table S2. Diastolic blood pressure changes in the study population.

	Control group		Intervention group		Cluster adjusted		Primary analysis			
Diastolic Blood pressure	**Baseline**	**Post-Intervention**	**Baseline**	**Post-Intervention**	**adjusted difference* (95% CI)**	**p value**	**adjusted difference^ (95% CI)**	**p value**	**adjusted difference # (95% CI)**	**p value**
Overall	77.1 (11.3)	78.1 (9.9)	76.3 (11.2)	78.2 (10.6)	0.96 (-0.30,2.22)	0.136	0.88 (-0.38,2.15)	0.17	0.84 (-0.41,2.09)	0.187
Men	78.3 (11.6)	79.3 (10.0)	77.5 (11.4)	79.9 (10.8)	1.27 (-0.31,2.85)	0.114	1.32 (-0.26,2.91)	0.102	1.30 (-0.31,2.90)	0.113
Women	76.1 (11.0)	77.1 (9.7)	75.3 (10.9)	76.6 (10.2)	0.58 (-0.7,1.86)	0.374	0.53 (-0.76,1.82)	0.421	0.46 (-0.73,1.65)	0.448
Site wise										
Indore	77.8 (12.2)	79.0 (7.6)	77.6 (11.4)	82.3 (9.0)	3.70(1.78,5.62)	<0.001	3.55 (1.87,5.23)	<0.001	3.21 (1.97,4.45)	<0.001
Junagadh	77.6 (11.0)	78.2 (10.7)	76.8 (11.2)	78.0 (10.2)	0.64(-0.78,2.06)	0.379	0.58 (-0.87,2.03)	0.43	0.50 (-0.95,1.96)	0.499
Puducherry	77.1 (10.7)	77.6 (10.3)	76.6 (10.9)	77.3 (11.2)	0.13(-1.57,1.83)	0.881	0.17 (-1.57,1.9)	0.852	0.42 (-1.40,2.23)	0.654
Shimla	75.3 (11.3)	77.7 (10.6)	74.4 (10.9)	77.6 (10.6)	0.78(-2.9,4.46)	0.678	0.72 (-2.95,4.39)	0.699	0.85 (-2.38,4.09)	0.605

Data are mean (SD) by group and time period

*Cluster adjusted-GEE analysis with an exchangeable covariance matrix, to account for clustering of participants within clusters/villages.

^Adjusted- GEE analysis with an exchangeable covariance matrix, to account for clustering of participants within clusters/villages and model is adjusted for baseline cluster mean diastolic blood pressure

#Adjusted- GEE analysis with an exchangeable covariance matrix, to account for clustering of participants within clusters/villages and model is adjusted for baseline cluster mean systolic blood pressure, age, sex, education, season and duration of Intervention [note: ~~Overall(~~Men~~)~~ and ~~Overall (~~women~~)~~ is adjusted for baseline cluster mean systolic blood pressure, age, education, season and duration of Intervention]

Table S3. Overall and sitewise expected and completed household visits.

Site name	Start Date of Intervention	Number of months in intervention	Number of Visits done	Number of HH expected to be visited	Number of HH visits completed	% visits completed
Indore	18th Feb. 2014	18+ months	9	11115	9490	85%
Junagadh	19th April 2014	17 months	8-9	13277	10953	82%
Pondicherry	1st March 2014	18+ months	9	12798	10946	86%
Shimla	1st March 2014	18+ months	9	8946	8946	100%
Overall				**46136**	**40335**	**87%**

Table S4: Overall and sitewise group activities performed

	Demonstration	Video presentation	Healthy lifestyle	Physical activity	Traditional methods	Competition	Peer Led session	Total
Indore	4	2	13	3	8	2		32
Junagadh	7	4	7	5	3	5		31
Pondicherry	2	3	3	2	3	5		18
Shimla	1	2	7	1	7	4	2	24
Overall	**14**	**11**	**30**	**11**	**21**	**16**	**2**	**105**

Table S5. Number of household visits conducted (sitewise).

Indore	Number of HH expected to be visited	Number of visits completed	% Visits completed
Tanda Kheda	1854	1724	93%
Bodiya	2763	1546	56%
Shinduriya	1656	1583	96%
Baslaii	1836	1721	94%
Kotda Kala	1296	1233	95%
Kapasthal	1710	1583	93%
Junagadh			
Sabalpur – 1	1403	1197	85%
Bhavnath - 1	1318	1042	79%
Bhavnath - 2	1556	1531	98%
Saragavada - 1	1760	1149	65%
Saragavada - 2	2465		0%
Rayaka - 1	4777	3952	83%
Pondicherry			
Solainagar	2367	1840	78%
Dharmapuri	2250	2036	90%
Veerampattinam	1935	1668	86%
Arasur	2025	1691	84%
Thiruvandarkoil	2160	1925	89%
Kuruvinatham	2061	1786	87%
Shimla			
Chikkar, Satlai, Jhandi	1134	1134	100%
Jamog, Ganchidi, Halog	1719	1719	100%
Sharoti, Chorri	2205	2205	100%
Shakoli, Bhawana	1224	1224	100%

Baloh, Charund, Ghanahatti	1512	1512	100%
Rampur Kaunthal,Dhanayatu	1152	1152	100%

Figure S1. Intervention description using TIDieR (Template for Intervention Description and Replication) Checklist.

WHAT
Materials: It includes individual level (for example, individual counselling), household level (for example, household visits by frontline health workers) and community level interventions (for example, display of posters, community level activities and competitions)
Procedures: Delivered in the form of Booklet,18- month calendar, hypertension-specific leaflets, healthy lifestyle-specific leaflets, salt spoon to quantify use of salt, oil dispenser to quantify use of oil. At group level, recipe demonstrations, video screenings, street theatre, peer led discussions and competitions were conducted. At mass level, display of posters, banners and leaflets
WHO PROVIDED
Frontline community health workers identified from the local villages.
HOW
Delivered face to face at household, group and community level
WHERE
Household visits. The frontline health workers organised public meeting each month in community settings.
WHEN and HOW MUCH
Intervention for 18-month period. *Individual Level*: Household visits and one to one counselling of household members. Once every two months (9 visits). Booklet,18- month calendar, hypertension-specific leaflets, healthy lifestyle-specific leaflets, salt spoon to quantify use of salt, oil dispenser to quantify use of oil. *Group level:* Group meetings with specific target groups such as men, women, youth, persons with hypertension. Once a month (18 meetings). Recipe demonstrations, video screenings, street theatre, peer led discussions, competitions. *Mass:* Display of posters or banners with key messages in public places or at gatherings. Distribution of leaflets. 1 poster changed every 3 months.
HOW WELL
Every three months the intervention process was evaluated in terms of campaign components and the delivery mechanisms. A formal reporting system was established to communicate the details of community level interventions at each cluster to the coordinating centre. Although the interventions were exclusively implemented by frontline health workers, the DISHA project staff at each site monitored the intervention implementation. They visited at least 20 % of households in the intervention clusters at quarterly intervals and documented the progress of interventions in terms of number of visits made by the frontline health workers, messages delivered, and utilization of study tools. Additionally, a team from the coordinating centre conducted monitoring visits to the sites once in six months to verify the implementation process. Details of Household visits, group activities and monitoring visits are provided in Tables S3, S4 and S5.

Figure S2. Sitewise distribution of systolic and diastolic blood pressure at baseline and post-intervention.