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Effectiveness of a community-based education and peer support led by women's self-help groups in improving the control of hypertension in urban slums of Kerala, India: a cluster randomised controlled pragmatic trial

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ABSTRACT

Background With less than 20% of people with hypertension achieving their target blood pressure (BP) goals, uncontrolled hypertension remains a major public health problem in India. We conducted a study to assess the effectiveness of a community-based education and peer support programme led by women's self-help group (SHG) members in reducing the mean systolic BP among people with hypertension in urban slums of Kochi city, Kerala, India.

Methods A cluster randomised controlled pragmatic trial was conducted where 20 slums were randomised to either the intervention or the control arms. In each slum, participants who had elevated BP (>140/90) or were on antihypertensive medications were recruited. The intervention was delivered through women's SHG members (1 per 20–30 households) who provided (1) assistance in daily hypertension management, (2) social and emotional support to encourage healthy behaviours and (3) referral to the primary healthcare system. Those in the control arm received standard of care. The primary outcome was change in mean systolic BP (SBP) after 6 months.

Results A total of 1952 participants were recruited—968 in the intervention arm and 984 in the control arm. Mean SBP was reduced by 6.26 mm Hg (SE 0.69) in the intervention arm compared with 2.16 mm Hg (SE 0.70) in the control arm; the net difference being 4.09 (95% CI 2.15 to 4.09), p<0.001.

Conclusion This women's SHG members led community intervention was effective in reducing SBP among people with hypertension compared with those who received usual care, over 6 months in urban slums of Kerala, India.

Trial registration number CTRI/2019/12/022252.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Though there are many studies demonstrating the impact of peer support for better glycaemic control, limited studies are available documenting the impact of the same on reducing blood pressure (BP).

⇒ A systematic review, with all published randomised controlled trials till May 2018 to assess the effectiveness of peer-led intervention in improving the clinical outcomes of hypertension could find only three trials in this regard and none of them were conducted in a low-income and middle-income country (LMIC).

⇒ Meta-analysis of the three trials revealed a pooled mean reduction of 7.52 mm Hg in systolic BP levels among patients with hypertension.

WHAT THIS STUDY ADDS

⇒ Our study is a cluster randomised trial from an LMIC with a fairly large sample size (1952) to examine the impact of a community-based education and peer support among people with hypertension.

⇒ We demonstrated that a community-based intervention for hypertension control could be incorporated into the existing social structures and such an approach can achieve high rates of participation and such partnerships have the potential to improve community health at modest marginal cost, even in populations with good access to formal healthcare.

BACKGROUND

Elevated blood pressure (BP) is the leading risk factor for the burden of disease globally and an important preventable cause of premature mortality.[1] High BP is one of the major risk factors for ischaemic heart disease, stroke, other cardiovascular diseases (CVDs), chronic kidney disease and dementia.[2 3] Estimates shows that prevalence of hypertension (defined as systolic BP (SBP)≥140 mm Hg or diastolic BP (DBP)≥90 mm Hg and/or

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Intervention through peer groups in community is low cost and simple and can be easily scaled up to other parts of Kerala and other states in India with a substantial potential impact on uncontrolled hypertension and related cardiovascular disease (CVD).

⇒ There is also a potential to design and implement similar interventions in other LMICs where peer support groups are already active and contribute to the global agenda for hypertension control and CVD prevention.

current use of antihypertensive medication) has risen sharply in low-income and middle-income countries (LMICs).[4] Reducing population BP is critical to attain the United Nation's (UN) Sustainable Development Goal (SDG) target of reducing premature mortality from non-communicable diseases (NCDs) by one-third by 2030 compared with 2015.[5] Constituting 20% of the global population, India's progress is important for attaining these global targets. With less than 20% of people with hypertension achieving their target BP goals, uncontrolled hypertension remains a major unaddressed obstacle in India to achieve the SDG.[6–8]

Far along in the epidemiologic transition, Kerala, the southernmost Indian state, has a comparatively higher prevalence of CVDs (>5%) and hypertension (>26%) in the country.[9] Studies indicate that approximately half of the people with a diagnosis of hypertension in Kerala have received treatment and of those who receive treatment, around 30% have their BP controlled.[10 11]

Mixed results have been reported about the effectiveness of community health workers (CHW) in identifying and managing CVD in various states in India.[12 13] A recent systematic review with three trials on peer group support for hypertension found a beneficial effect for reducing SBP.[14] Though there are many studies demonstrating the impact of peer support among people with diabetes, few studies are available documenting the impact of peer support on reducing BP in the general community.[14]

In Kerala, 'Kudumbasree units', also known as women's self-help groups (SHGs), were created several decades ago under the leadership of local self-governments (LSG) and are one of the largest women's empowerment projects in the country.[15] Kudumbasree make efforts to alleviate poverty through an integrated approach involving effective union of resources and action. They combine different activities such as thrift and credit, microenterprises, income-generating activities and a wide range of welfare activities. Kudumbasree has chosen a family-based approach; it reaches the family through women and the community through families. The neighbourhood groups (NHGs) are the lowest tier, consisting of women from 20 to 30 households. At least one person from approximately 80% of low-income and middle-income households are registered members of Kudumbasree.[15]

Involving women's SHG members for reducing hypertension in the community by building their capacity as peer educators could be a potentially low cost, flexible means to supplement formal healthcare support and will ensure community participation for health promotion. We hypothesised that a community-based education and peer support led by local women's SHG members is feasible and will be an effective strategy to improve community hypertension control. We conducted a community-based cluster randomised pragmatic trial (cRCT) to assess the effectiveness of a community-based education and peer support programme led by women's SHG members in reducing mean SBP among people with hypertension in urban slums of Kochi Corporation, Kerala, India.

METHODS

Setting

The Corporation of Kochi is the largest municipal corporation in the Indian state of Kerala by area and population size. It is the second most important port city on the western coast of India and is the commercial capital of the state. Kochi city has 231 slums, which are highly populated urban residential areas characterised by densely packed housing units of poor-quality build and inadequate public infrastructure. The total number of households in the slums was estimated as 12949 with a population of 60 678, nearly 11% of the population of the city. The population density is 5620/km^2 and the literacy rate is 97.3%. In 2016, 16 urban primary health centres (UPHCs) staffed by medicine practitioners were established in Kochi city under the National Urban Health Mission to provide free, quality-assured primary healthcare to the slum population. Monthly per capita income of slum residents is around US$30.

Study design

A cRCT was conducted, with the slums as the clusters. The intervention was delivered through women's SHG members. Outcome assessments were conducted at the beginning and at the end of 6-month intervention. The study was conducted between June 2019 and October 2020.

Stakeholder consultation

A consultation workshop was organised to understand the perception of the stakeholders regarding the intervention. Overall, 15 people with hypertension, 5 primary caretakers of people with hypertension, 15 local women's SHG members, 5 elected local self-government representatives, 5 primary healthcare providers and 5 public health experts were invited for a full day in-person workshop. Attitudes towards the intervention were positive, and the study design and intervention were acceptable to all attendees. Many civil society representatives and SHG members suggested to include comprehensive interventions for diabetes mellitus along with the planned interventions. However, this was not possible due to budget and logistic limitations.

Recruitment

Overall, 20 urban slums were randomly selected from the list of 231 slums notified by the Municipal Corporation. A house-to-house survey was conducted by trained nurse data collectors. All those who were above the age of 18 years and were permanent residents of the household were included in the survey. Pregnant women were excluded. BP was measured at least three times using the appropriate cuff size with a digital automatic BP monitor according to the WHO STEP wise approach to NCD risk factor Surveillance (STEPS) protocol. Measurement continued until two consecutive readings differed by <10 mm Hg systolic and <6 mm Hg diastolic, with a maximum of five measurements. The mean of the last two consecutive measurements were used to define hypertensive status. All those on antihypertensive medications and/or with a BP recording of more than 140/90 mm Hg were invited to the study. Those with high BP were referred to the primary health centre after an initial one-to-one education and were provided with an education booklet on BP control.

Randomisation

Slums were randomised using a computer-generated random number table. Randomisation was done by a statistician who was not part of the research team. Overall, 10 slums were assigned to receive the peer support intervention led by SHG members and the other 10 to continue receiving usual care.

Sample size

With an enrolment target of 10 clusters in each arm and 100 participants per cluster and an intracluster correlation (ICC) of SBP reduction of 0.02, the design yielded 90% power to detect a 5 mm Hg (SD 20) reduction in SBP in the intervention group than in the control group, with 95% CI.[16]

Control arm

The control arm received usual care through clinics, private and public hospitals and UPHCs. Clinical consultation and basic investigations are provided free of cost at UPHCs and public hospitals. The average distance from the slums to UPHCs was 1.93 km (Range 0.4–4.9 km). The public hospitals follow the hypertension treatment protocol issued by the government of Kerala.[17] The government conducts periodic training to the staff of primary healthcare on the prevention and the management of NCDs. Antihypertensive drugs are often available in public hospitals for free or through numerous private chemist shops in the city for a monthly fee of approximately US$2.

Intervention arm

Identification of women's SHG members

Local self-government counsellors, who are elected political representatives, in the intervention slums were requested to nominate one SHG member who was acceptable to all and interested in voluntary health-related activities for every NHG. Forty-three SHG members were identified and trained and of them, two dropped out due to personal reasons of ill health and migration. The mean age of the SHG members was 43.6 (SD 7.8) years and mean years of education was 10.7 (SD 1.9) years. Fourteen of them were diagnosed to have hypertension.

Training of women's SHG members

The training module included a facilitator's guide, a participant's guide, PowerPoint presentations, exercises to strengthen problem-solving skills and demonstration sessions for BP and anthropometry measurements. Chapters of the training module included an overview of CVDs, normal values of BP, blood sugar and anthropometry, complications of hypertension and diabetes mellitus, evidence-based locally adapted diet and physical activity recommendations, smoking cessation assessment and tips to encourage quitting, communication skills, basics of behaviour change, communication strategies, a practise session for using the health education materials, measurement and recording of BP and weight, conducting a patient support group meetings, initiating and supporting self-management of hypertension by the participants through goal setting and maintaining personal records. Trainings were conducted in groups of 15 members. Each training lasted for 21 hours across 3 days. After 2 months, 6-hour refresher training was conducted.

Intervention by the trained women's SHG members

The key functions of 43 trained SHG members in this study were: (1) assistance in daily hypertension management; (2) social and emotional support to encourage healthy behaviours and (3) referral to the primary healthcare system and community resources. The SHG members from the intervention areas met all participants who had elevated BP or were on antihypertensive medications in their NHG households monthly and offered them services. Each of the 43 SHG member was equipped with a digital BP monitor, a digital weighing scale, a stadiometer, a pictorial flip chart for community education, referral slips and printed training materials for reference.

A. Peer group meetings: SHG members organised monthly meetings of people with hypertension at a location decided by the community members. Next of kin or additional support persons were also encouraged to accompany the person with hypertension at each group meeting. Each meeting lasted about an hour. The first 15 min was dedicated to a presentation on a health topic by a trained SHG member using a pictorial flip chart. Topics for the six sessions were (1) introductionof normal ranges of BP, chronic nature of hypertension, complications of hypertension and need to maintain normal BP, (2) 10 ways to reduce hypertension, (3) dietary modifications desirable to reduce BP, (4) benefits of exercise and the need to be physically active, (5) need for medication adherence and tips to ensure that and (6) smoking as a risk fac-

tor for hypertension and methods to quit. Participants were then asked to discuss their views and ask questions. They were then invited to share their experiences during the month including the difficulties they faced and solutions they used to control hypertension. The last 15 min in each session was dedicated for discussing another priority health issue in the community. Local self-government leaders and members from the primary healthcare team including health workers and community health volunteers were also invited to all the meetings.

B. Monthly visits to participant: SHG members met participants in their homes and recorded their BP and weight and counselled on diet, physical activity and smoking cessation each month. They helped participants with goal setting and encouraged them to adopt healthy behaviours. They also enquired about medication adherence and referred them to primary healthcare centre when needed. They provided a summary of the proceedings of the SHG meetings to participants who could not attend.

Basis of designing the interventions

We designed the intervention using the transtheoretical model focussing on the decision-making of the individual, tailored to their level of knowledge and motivation.[18] Through the monthly visits by trained SGH members and the structured education by them over six sessions, we intended to increase the awareness about the healthy behaviour among the beneficiaries and help them to self-reappraise to realise that the healthy behaviour is part of who they want to be. We felt that sharing experiences in the peer group meetings and support offered by their peer would (1) arouse them emotionally to adopt healthy behaviours, (2) provide opportunities to show that society is supportive of the healthy behaviour, (3) lead to commitment to change behaviour based on the belief that achievement of the healthy behaviour is possible and (4) help them in finding supportive relationships that encourage the desired change. We felt that periodic BP monitoring could reward their positive behaviour. We believed that the presence of SHG members as peer educators in the community could also re-engineer the environment to provide them cues that support and encourage the healthy behaviour.

Records and reports

SHG members maintained a notebook which included details of meetings such as the number of enrolled participants, community members attending the meeting and major activities undertaken during the meeting. They also maintained a page for each study participant to record the details of monthly visits and their BP and weight.

Data collection

Information at baseline and at the end of the 6-month intervention were collected by trained nurses from all enrolled participants. These measures comprised (1) basic demographic information, (2) lifestyle-related factors such as tobacco use and per capita monthly consumption of salt using food frequency questionnaire, (3) awareness of hypertensive status and (4) details about the use of antihypertensive medications and medication adherence using a modified Morisky's 8-point medication adherence score.[19] SBP, DBP and body mass index (BMI) were measured for all participants at baseline and after 6 months of intervention. Out of pocket monthly expenditures related to the management of hypertension including direct and indirect costs for consultation, laboratory tests, drugs, hospitalisations, travel and wages lost were collected from patients by questionnaire at baseline and at the end of the intervention. Additional costs of the intervention, including training, BP monitors, weighing machines, stadiometer and programme management cost, were recorded.

Blinding

Blinding was not done for the participants, those administering the interventions and the data collectors.

Outcomes

The primary outcome was change in mean SBP. Secondary outcomes were the proportion of patients on antihypertensive medication and change in self-reported medication adherence scores, change in BMI, self-reported tobacco use and per capita monthly consumption of salt. The additional cost per patient per month for a unit change in BP (mm Hg) was calculated.

Data analysis

Data was analysed using IBM SPSS Statistics (V.25) using the intention-to-treat approach. We compared change in selected primary and secondary outcomes between the intervention and control arms using a generalized estimating equations (GEE) model with an exchangeable working correlation structure. Baseline characteristics of study participants in the intervention and control groups were compared using χ^2 test for the categorical variables and independent samples t-test for the continuous variables. Small imbalances in baseline covariates were adjusted for in secondary analysis using a multivariable GEE model. Subgroup analysis was performed to find the mean change in the SBP by various subgroups and the robust score test was used to obtain the p value for the significance of any observed interactions of the intervention with the subgroups.

Patient and public involvement

Opinions of people with hypertension and civil society representatives were obtained through a stakeholder consultation before the initiation of the study. Local self-government leaders, who are elected political representatives, in the intervention slums nominated the SHG members for each slum. Fourteen of the SHG members who delivered the intervention were having hypertension. Preliminary results of the intervention were disseminated in a workshop in which 4 LSG leaders, 44 SHG group

Table 1 Baseline characteristics of clusters

	Intervention arm	Control arm	Total
A. Number of slums	10	10	20
B. Number of households	1209	1342	2551
C. Total population in the slums	4578	4961	9539
D. Out of C, no. (%) more than 18 years	3521 (77%)	3831 (77%)	7352
E. Out of D, blood pressure measured at baseline	2922 (83%)	3234 (84%)	6156
F. Out of E, no. (%) of individuals with hypertension	991 (33.9%)	1083 (33.4%)	2074
G. Out of F, no (%) recruited for the study	968 (97.6%)	984 (91%)	1952
H. Average distance to nearest government health facility (mean, range)	1.62 km (0.05–4.8 km)	1.93 km (0.4–4.9 km)	

members and 12 patient representatives participated. Preliminary results were also disseminated through local media.

Author reflexivity statement: see online supplemental material 2.

RESULTS

A total of 1952 participants were recruited, 968 in the intervention arm and 984 in the control arm (table 1, figure 1).

Baseline characteristics of participants were fairly balanced between intervention and control groups (table 2). Although, the control arm included more patients receiving antihypertensive drugs (55.5%) compared with the intervention arm (49.5%) and the mean SBP at baseline was slightly lower in control arm than intervention (145.4 (SD 21.5) vs 147.7 (21.3)).

Number of people with hypertension with each trained SHG member varied from 18 to 29. Trained SHG members conducted 93% of the planned monthly visits to study participants. In the intervention arm, 2.5% opted out at various stages of intervention. Out of the 258 planned peer group meetings, 73% were held with an average attendance per meeting of 13 (SD 2.5). Proportion of male out of total participants was less than 33% in 12% of the peer group meeting. During the 6 months' period, 14.3% of the study participants in the intervention arm never attended a peer group meeting.

The mean reduction of the SBP among the participants in the intervention arm was 6.3 mm Hg (SD 21.1) compared with 2.2 (SD 21.3) in the control arm, with a net difference of 4.1 (95% CI 2.2 to 4.1), p<0.001. For DBP, the mean reduction in the intervention arms was 2.5 (SD 11.9) compared with 1.1 (SD 11.8) in the control arm with a net difference of 1.5 (95% CI 0.4 to 2.6), p 0.007. ICC for SBP reduction was 0.01. After adjusting for age, the net difference in the reduction of SBP between the intervention and control arm was 4.1 mm Hg (2.2, 6.1), p<0.001 and the same for DBP was 1.6 (0.5, 2.6), p<0.001.

The net reduction in mean change in SBP among the overweight and obese was greater than that observed among the normal and underweight participants (6.2 vs 1.7 mm Hg, respectively, p=0.03) (table 3). There was no other significant heterogeneity in the intervention effect observed by subgroups.

The net difference between change in the intervention arm when compared with the control arm showed significant increase in medication adherence scores by 0.9 (0.6, 1.1), a reduction in per-capita salt consumption by 1.1 g/day (0.7, 1.6) and an increase in coverage of treatment with antihypertensive drugs by 5.4% (2.5%–8.3%). We did not observe a significant change in BMI (table 4).

The mean monthly out-of-pocket expenditures for the management of hypertension among participants in the intervention arms did not change substantially (baseline: mean US$9.0 (median 8.1, IQR 16.2) vs end line: mean US$9.3 (median 8.1, IQR 14.0), p 0.752), (US$1=74 rupees)). Total additional cost for the current programme interventions excluding the research cost, medicines and investigations was US$36 680. Additional cost per patient per month for an overall mean reduction of 1 mm Hg in SBP was estimated as US$1.54.

DISCUSSION

Our results indicated that a community-based intervention led by women's SHG members was effective in reducing BP and improving hypertension control among people living in urban sums of Kerala, India. The reduction in BP was more evident among those with higher BMI. The intervention also significantly increased patients' adherence to antihypertensive medication and reduced per capita salt consumption.

A recent systematic review with three trials on peer group support for hypertension found a beneficial effect on SBP reduction with a pooled mean reduction of 7.52 mm Hg (95% CI: −14.39 to −0.66).[14] Our study findings are consistent with the findings from this systematic review. A recent CHW-led group-based education and monitoring intervention in India reported that there was a 5 mm Hg decline in SBP in the intervention than the control group within 3 months of intervention.[20] A multicomponent intervention including a CHW-led home-based intervention, physician education and weekly text messaging in

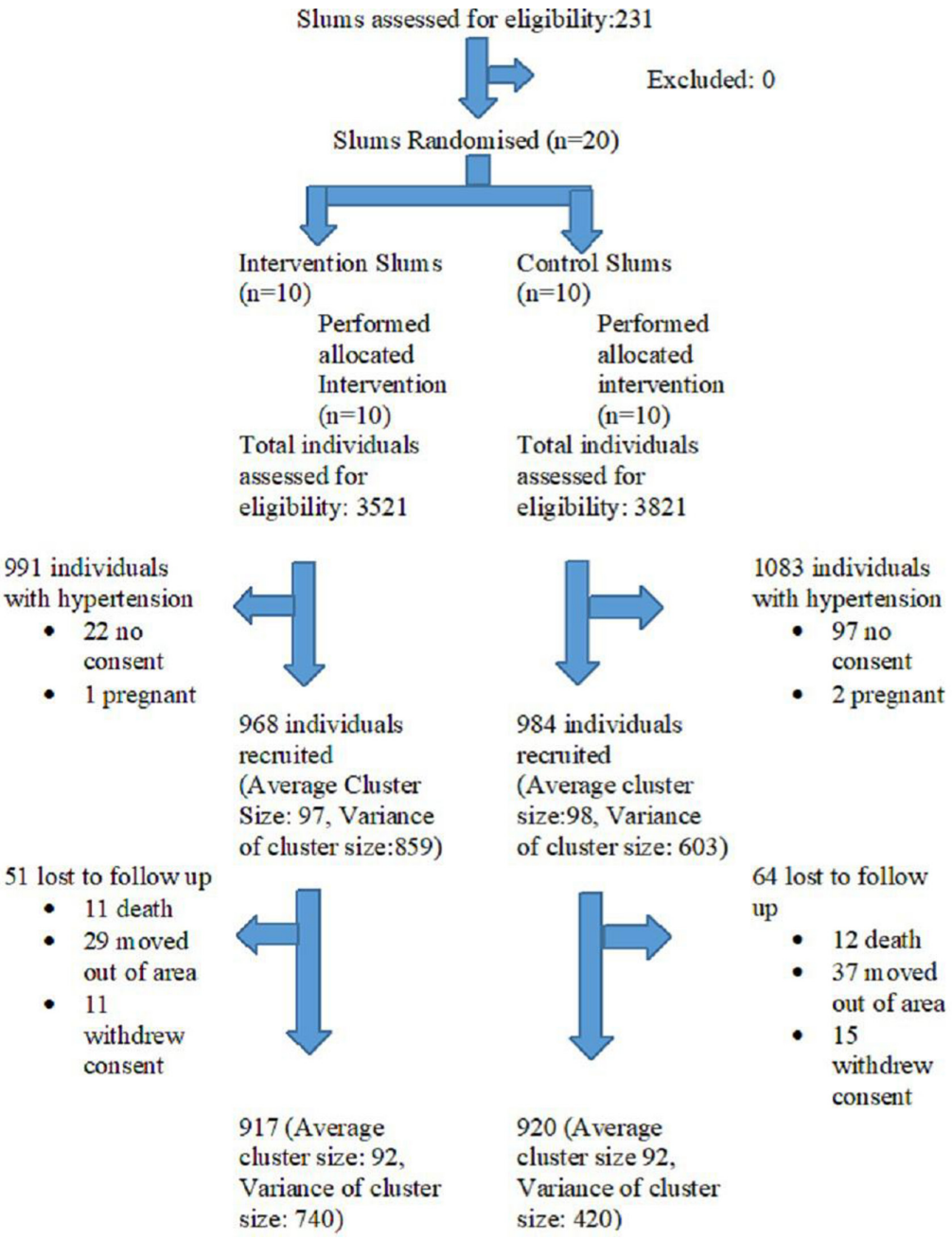

Figure 1 Flow diagram of study participants.

a low-income setting in Argentina also showed a similar reduction in SBP over a 6-month period.[16] In our study, we did not engage or train the practitioners, rather the SHG members generated the demand for better BP control and motivated the patients to seek healthcare in a setting where practitioners generally follow standards of care.[21]

The observed reduction in SBP may be due to a combination of several different mechanisms: lower salt intake, higher adherence to antihypertensive medications among those newly and already initiated on treatment and treatment initiated among previously untreated hypertensive participants. A recent meta-analysis of RCTs, which determined the effects of longer-term modest salt reduction on BP, has shown that there will be around a 3 mm Hg reduction in SBP for 5 g/day reduction of salt consumption among people with hypertension.[22] Therefore, our observed 1 g/day reduction in salt consumption may have contributed to approximately 0.6 mm Hg reduction in SBP. Studies have demonstrated that even mild improvements in medication adherence will reduce BP and a full dose of antihypertensive medications with high adherence reduces SBP by about 9 mm Hg, so 0.86-unit higher medication adherence score (out of maximum 8) observed in the current study might have contributed to approximately 1 mm Hg reduction in SBP. Also, it must be noted that an additional 14% of people with hypertension in the intervention area initiated antihypertensive medications, which likely contributed to further reduction in overall BP.

Table 2 Baseline characteristics of participants (N (%) or mean (SD))

	Intervention arm (N=968)	Control arm (N=984)	P value
Age (years)	56.8 (12.4)	55.7 (12.5)	0.05
Female gender	584 (60%)	603 (61%)	0.35
Years of education	7.1 (3.7)	7.3 (3.4)	0.08
Widow/r/separated	157 (16%)	126 (13%)	0.02
History of diabetes mellitus	258 (27%)	232 (24%)	0.06
History of major cardiovascular disease	143 (15%)	125 (13%)	0.10
Body mass index (Kg/m^2)	25.5 (4.8)	25.8 (4.6)	0.15
Systolic blood pressure (BP) (mm Hg)	147.7 (21.3)	145.46 (21.5)	0.02
Diastolic BP (mm Hg)	89.1 (12.2)	88.2 (11.6)	0.13
Prescribed an antihypertensive drug by a medical practitioner	479 (50%)	546 (56%)	0.01
Medication adherence score (out of 8)	4.5 (1.7)	4.6 (1.4)	0.39
Current tobacco smoking	94 (10%)	91 (9%)	0.73

In the current study, a significant BP reduction in patients in the control arm was also observed. Same pattern has been observed in many previous trials also.[16 20] Patients at control arm received BP measurements at baseline and those with high BP were referred to the primary health centres after an initial one-to-one education. They were also provided with an education booklet on BP control. There was an improvement documented in the proportion of people initiated on antihypertensive medications and their medication adherence

Table 3 Mean difference in the systolic blood pressure by subgroups

		Intervention arm		Control arm			
Characteristics	Category	Number	Blood pressure change (SEM)	Number	Blood pressure change (SEM)	Net difference (95% CI)	P value
Age	≥60 years	395	−6.53 (1.12)	364	−0.42 (1.17)	−6.10 (−9.29 to −2.92)	0.46
	<60 years	522	−6.05 (0.88)	556	−3.30 (0.87)	−2.75 (−5.19 to −0.32)	
Gender	Male	369	−5.45 (1.03)	358	−2.42 (0.99)	−3.02 (−5.84 to −0.20)	0.35
	Female	549	−6.80 (0.93)	562	−1.99 (0.95)	−4.81 (−7.44 to −2.17)	
Baseline body mass index	≥25	471	−6.99 (0.98)	504	−0.81 (1.01)	−6.17 (−9.95 to -3.39)	0.03
	<25	446	−5.49 (0.98)	416	−3.79 (0.94)	−1.69 (−4.38 to 0.99)	
H/o major CVD	Yes	134	−5.62 (1.80)	111	−2.48 (1.96)	−3.14 (−8.40 to 2.12)	0.71
	No	783	−6.37 (0.75)	809	−2.11 (0.75)	−4.25 (−6.34 to −2.15)	
Educational status	<8th grade	454	−6.52 (1.01)	418	−1.44 (1.12)	−5.08 (−8.04 to −2.12)	0.76
	≥8th grade	463	−6.05 (0.96)	502	−2.79 (0.88)	−3.25 (−5.82 to -0.69)	
Marital status	Living with spouse	766	−6.02 (0.75)	805	−2.34 (0.76)	−3.68 (−5.79 to −1.57)	0.30
	Widow/r/ separated	151	−7.61 (1.85)	115	−1.04 (1.69)	−6.57 (−11.67 to −1.47)	

Table 4 Effect of the intervention on medication adherence, body mass index, salt consumption, hypertension awareness, medications and tobacco use

Characteristics	Intervention arm		Control arm			
	N	Mean or % change (baseline - post intervention) (SEM/SD)	N	Mean or % change (baseline - post intervention) (SEM/SD)	Net difference (95% CI)	P value
Change in medication adherence score from baseline	389*	+1.44 (0.11)	452*	+0.58 (0.06)	+0.86 (0.61 to 1.11)	<0.001
Change in body mass index (kg/m^2)	917	−0.40 (0.11)	920	−0.38 (0.12)	−0.02 (−0.30 to 0.35)	0.89
Change in average daily per capita salt consumption (g)	917	−0.83 (0.13)	920	+0.26 (0.16)	−1.10 (−1.6 to −0.66)	<0.001
% of participants who interpreted their blood pressure correctly	917	+13.6% (1.1)	920	−0.2% (0.15)	+13.8 (11.2 to 15.7)	<0.001
% of participants on antihypertensive medicines	917	+14.2% (1.1)	920	+8.8% (0.9)	+5.4% (2.48 to 8.32)	<0.001
% of current tobacco smokers	917	−1.5	920	−0.3	−1.2% (−0.33 to −2.33)	<0.001

*Assessed for those who were taking antihypertensive drugs at the baseline.

in the control arm. This would have resulted in the reduction in BP.

We have demonstrated that a community-based intervention for hypertension control could be incorporated into the existing social structures and such an approach can achieve high rates of participation. Such partnerships have the potential to improve community health at a modest marginal cost, even in populations with good access to formal healthcare. Given that a 5 mm Hg reduction of SBP could reduce the risk of major cardiovascular events by about 10%, these findings have great public health significances.[23]

A systematic review found that community-based interventions aiming at positive behaviour change and medication adherence for reducing BP were considered cost-effective and in trials in LMICs, cost of such educational interventions ranged from US$0.62 (China) to US$29 (Pakistan) for a 1 mm Hg reduction in SBP.[24] In the current study, additional cost per patient per month for an overall mean reduction of 1 mm Hg in SBP was estimated as US$1.54. The lower cost of the interventions makes this strategy a likely good option for Indian settings and potentially other LMICs.

Our study had several major strengths. Clusters were randomised, and the recruitment of the participants was systematic. We accounted for the slight imbalance in baseline characteristics through multivariate analysis and findings were unchanged. Outcomes were collected by trained data collectors who were not involved in the intervention, thereby reducing systematic bias and measurement error. Possibility of intervention contamination was less as the slums selected were far apart. Finally, as a pragmatic randomised trial, we had only a few eligibility criteria, increasing the generalisability of our results to the population of hypertensive patients in slums of Kerala or even India and similar LMICs.

Our results should be interpreted in the light of several limitations. Changes in self-reported measures, such as salt intake, may be less reliable compared with objective measures. Reporting bias may occur if people in the intervention group are biased toward their own perceptions regarding the intervention efficacy. Additional costs incurred by primary healthcare system due to increased access by beneficiaries in terms of drugs, investigations and other healthcare services were not included while estimating the cost of the intervention. Incremental cost-effectiveness ratio for quality adjusted life years saved was not calculated because extensive assumptions were necessary for modelling, which was outside the scope of this report.

To summarise, a community-based intervention led by women's SHG members was effective in reducing BP among people with hypertension over 6 months in urban slums of Kerala, India. This intervention is low cost and simple and can be scaled up to other parts of Kerala or other states in India with a substantial potential impact on uncontrolled hypertension and related CVD. Currently, India has over 6.6 million SHGs with 72 million members.[25] Further research is needed to understand how this intervention might be adapted for other areas

where the health system and the SHGs are weak. Working with wider community groups other than SHGs could further expand access to this intervention. There is also a potential to design and implement similar interventions in other LMICs where peer support groups are already active and contribute to the global agenda for hypertension control and CVD prevention.[4 5]

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