ORIGINAL ARTICLE

A Randomized Trial of Peer-Delivered Self-Management Support for Hypertension

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BACKGROUND
Peer-led interventions to improve chronic disease self-management can improve health outcomes but are not widely used. Therefore, we tested a peer-led hypertension self-management intervention delivered at regular meetings of community veterans' organizations.

METHODS
We randomized 58 organizational units ("posts") of veterans' organizations in southeast Wisconsin to peer-led vs. professionally delivered self-management education. Volunteer peer leaders at peer-led posts delivered monthly presentations regarding hypertension self-management during regular post meetings. Volunteer post representatives at seminar posts encouraged post members to attend 3 didactic seminars delivered by health professionals at a time separate from the post meeting. Volunteers in both groups encouraged members to self-monitor using blood pressure cuffs, weight scales, and pedometers. Our primary outcome was change in systolic blood pressure (SBP) at 12 months.

RESULTS
We measured SBP in 404 participants at baseline and in 379 participants at 12 months. SBP decreased significantly (4.4 mm Hg; $P < 0.0001$) overall; the decrease was similar in peer-led and seminar posts (3.5 mm Hg vs. 5.4 mm Hg; $P = 0.24$). Among participants with uncontrolled BP at baseline, SBP decreased by 10.1 mm Hg from baseline to 12 months but was again similar in the 2 groups. This pattern was also seen at 6 months and with diastolic blood pressure.

CONCLUSIONS
Our peer-led educational intervention was not more effective than didactic seminars for SBP control. Although peer-led educational programs have had important impacts in a number of studies, we did not find our intervention superior to a similar intervention delivered by healthcare professionals.

CLINICAL TRIAL REGISTRATION
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Hypertension is a major cause of death and disability.[1] Despite consensus that hypertension treatment reduces morbidity and mortality,[2] many Americans continue to have suboptimal blood pressure (BP) control.[3] Even with the system resources and motivated patients inherent in clinical trials, more than one-third of patients participating in the ALLHAT study were not at their goal BP of 140/90 mm Hg after 5 years.[4]

Prior studies have suggested that interventions designed to improve self-management skills or engagement in one's own healthcare (commonly referred to as "patient activation") can lead to improved healthcare behaviors, improved chronic disease control, and/or better health outcomes.[5–7] Tested intervention approaches have included intensive peer-led educational programs,[6] brief individualized coaching before primary care clinic visits,[8] and regular coaching and feedback by nurse care managers.[9] In a meta-analysis of self-management interventions, Chodosh *et al.* found a mean systolic BP (SBP) decrease of 5 mm Hg.[5] Warsi *et al.* had similar results in a second meta-analysis, this time

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suggesting an effect on SBP that "might be compared with dietary sodium restriction."[10] However, these interventions have not been widely adopted, perhaps because of limited patient interest[11] or because they require added staff time.[8,12]

Community delivery of peer-led self-management support could improve participation rates by bringing the intervention to the patient. Successful models of community-delivered, peer-led self-management programs include Alcoholics Anonymous[13] and Weight Watchers.[14] Peer support to reduce cardiovascular risk is less studied. The evaluation of the National Heart, Lung, and Blood Institute–sponsored program "Salud Para Su Corazon (Health for Your Heart)," for example, documented a favorable reception by participants, who reported improved health behaviors; this evaluation did not compare changes in risk factors between an intervention and control group.[15]

In our study, we compared changes in BP control among veterans participating in a peer-delivered health education intervention vs. veterans exposed to similar content through professionally delivered didactic presentations. We used community-based participatory research techniques to maximize community participation and generalizability of the results.[16]

METHODS

Setting

We implemented both interventions within local units of veterans' service organizations (VSOs). We list all participating organizations in Table 1. Although VSOs have important advocacy roles, local units are also important social outlets and organize service activities such as supporting youth activities.[17,18] These units meet regularly, usually monthly, at community locations. Because most VSOs call these units

"posts," we use that term. Although many members receive Veterans Administration (VA) healthcare, most do not.

Design overview

A community advisory board composed primarily of VSO members collaborated in study design. We used a cluster randomized controlled trial design in which VSO posts were randomly assigned to one of these approaches. Our primary endpoint was change in SBP among hypertensive post members exposed to either (i) a peer-led intervention that occurred during monthly post meetings or (ii) an educational seminar intervention covering similar information in 3 90-minute professionally delivered presentations (Figure 1). The Zablocki VA Medical Center's Institutional Review Board approved the study.

Post recruitment

Details of the recruitment process have been published.[19,20] Post eligibility requirements were (i) location within 60 miles of Milwaukee's Zablocki VA Medical Center; (ii) 2 members willing to serve as post representatives (PRs); (iii) willingness to devote post meeting time to project activities; and (iv) several hypertensive post members willing to participate in an evaluation study.

There were 203 eligible posts in southeast Wisconsin. Of these, 84 declined to participate based on a mailed project description; most reported they did not have enough members. An additional 61 posts decided against participation after an in-person presentation by study team members, most commonly because they could not identify members willing to serve as PRs or did not see the point of adding to their existing medical care. Thus, 58 eligible posts decided to participate.

Table 1. Participating veterans' service organizations

Veterans' service organization[a]	Posts participating/ posts contacted (%)	Study participants per organization N (% of total)
American Legion	34/106 (32.1)	258 (63.9)
Veterans of Foreign Wars	11/69 (15.9)	72 (17.8)
Vietnam Veterans of America	5/8 (62.5)	20 (5.0)
Benevolent and Protective Order of Elks[b]	2/9 (22.2)	13 (3.2)
National Association of Black Veterans	1/2 (50)	4 (1.0)
AMVETS	1/2 (50)	14 (3.5)
Disabled American Veterans	1/2 (50)	8 (2.0)
Korean War Veterans of America	1/1 (100)	7 (1.7)
Jewish War Veterans	1/1 (100)	4 (1.0)
Marine Corps League	1/1 (100)	4 (1.0)
Masons[b]	0/2 (0.0)	—
Total	58/203 (28.6)	—
Total	58	404

[a]We use "post" for each organization, but several use different terms for their units; Vietnam Veterans of America, National Association of Black Veterans, Disabled American Veterans, and Korean War Veterans of America have chapters; the Elks have lodges; and the Marine Corps League has detachments.
[b]The Elks and Masons are not veteran-specific organizations but are culturally and organizationally similar.

Participant recruitment

Study team members visited each post during a regular post meeting to provide BP screening and recruit participants. Post members were eligible for the evaluation study if they usually attended post meetings and either (i) reported doctor-diagnosed hypertension and use of at least 1 BP medication or (ii) had BP ≥140/90 mm Hg (130/80 mm Hg if diabetic). We invited potentially eligible members to provide contact information. We then contacted these individuals to arrange for private meetings at which we confirmed eligibility and obtained informed consent.

Randomization

Because the interventions required regular meetings with PRs, we grouped posts geographically for convenience and to encourage camaraderie. We used computer-generated random numbers to assign posts to the interventions, ensuring that half of the posts in each of 5 regions were assigned to each intervention. Randomization occurred after enrollment of all that region's posts and subjects.

Interventions

In consultation with our community advisory board, we elected to use an active comparator intervention. We were most interested in the added impact of a trained peer on self-management behavior because the impact of self-monitoring and education has been studied.[21] Moreover, our community advisory board believed that all participants should be engaged in health improvement activities. The interventions are summarized in Table 2.

Features common to both interventions. Both interventions were delivered in collaboration with PRs. Before randomization, we met with all PRs in groups (4–16 people) for 2 hours to review hypertension self-management,
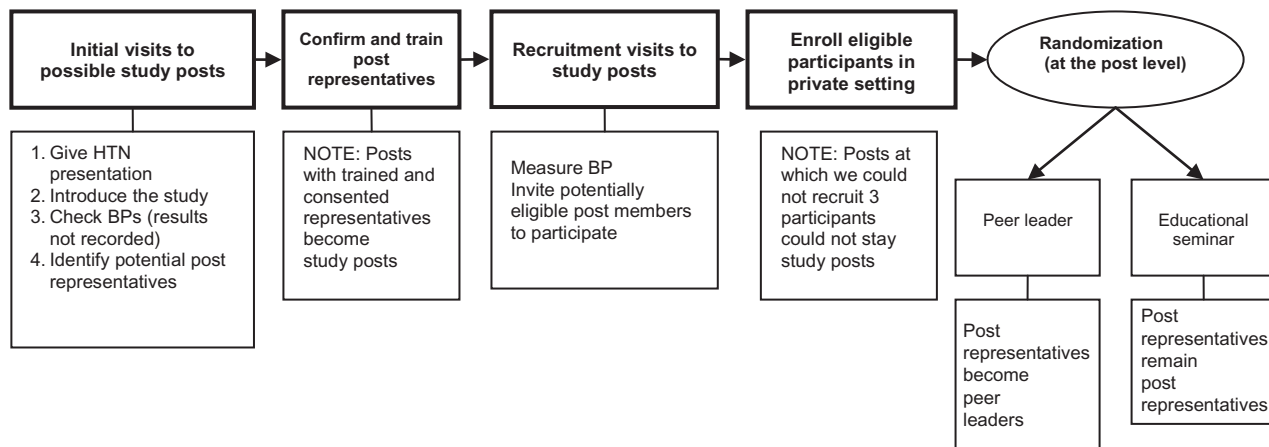

Figure 1. Recruitment and randomization flow diagram. Abbreviations: BP, blood pressure; HTN, hypertension.

Table 2. Comparison of peer-led and education seminar interventions

Activity	Interventions	
	Peer-led	Education seminar (ES)
Training Activities for peer leaders or post representatives	2-hour orientation to study design, use of equipment, and research principles (conducted before randomization)	
	• Peer leader training session (8 hours) • 8 mini training sessions (90 minutes each)	• Seminar planning with peer leader (90 minutes)
Educational activities[a]	Twelve 10-minute peer leader presentations at post meetings	3 professionally delivered seminars at central locations
Self-management resources provided	Blood pressure cuffs Bathroom-type scale Pedometers "Health Corner" of educational resources	Blood pressure cuffs Bathroom-type scale Pedometers
Intervention monitoring	2 staff visits to each post Peer leader submits monthly activity reports	1 staff visit to 5 randomly selected posts Study staff monitor attendance at seminars

[a]Both groups covered the topics included in these 12 sessions: self-monitoring (blood pressure, weight, steps); pedometers; medication adherence; food labels; eating out; doctor visits; sodium/Dietary Approaches to Stop Hypertension or DASH; hypertension myths; resistance exercise; fitness; social support; and stress management.

train them in BP monitor use, and answer questions. We also explained the study and basic elements of research (e.g., informed consent, privacy). We provided self-monitoring equipment (2 BP monitors, 12 pedometers, and 1 bathroom-style scale) to all posts; we asked PR to demonstrate this equipment at post meetings and encourage its use.

Peer-led intervention. The PRs of posts assigned to this intervention took on the role of peer leaders (PLs). Their activities were based on adult education principles and the chronic care model; they were adapted based on our experience with a pilot version of the intervention[22] and ongoing PL feedback. For example, because some PL were uncomfortable making presentations, we provided presentation scripts that could be used as desired. At 12 monthly post meetings, the PLs delivered brief (averaging 12 minutes) presentations on self-management topics (e.g., medication adherence, reading food labels) and distributed related educational handouts and/or equipment (e.g., pill minders). In addition, the PLs encouraged members to self-monitor using the BP monitors, pedometers, and scale. Finally, the PLs maintained a display area called a health corner, which included a variety of educational materials. Study staff visited each PL post twice during the study period to document intervention fidelity. These visits demonstrated that PL reliably made equipment available and presented the educational materials but that equipment use and attention to presentations varied among posts.[23]

PL training. The study team oriented the PLs to their role during regional 8-hour training sessions. The session addressed basic hypertension facts, the importance of self-management, and the PL role. We described and modeled teaching techniques, provided educational materials, and reviewed equipment use. We also explained how study staff would support and monitor PL activities.

Thereafter, study staff met with PLs in each region for a total of 8 90-minute sessions (4 monthly sessions, then bimonthly). At these sessions, we debriefed PLs' experiences at individual posts and planned for subsequent presentations. Study clinicians answered clinical questions that arose from PLs or their post members. Study staff and PLs worked together to address barriers and facilitators to engaging post members in self-management activities. We used feedback gathered from the PLs at these sessions to improve subsequent sessions. The attendance rate for PL training activities was 87.6% (attendance rate was calculated by dividing the actual number of attended training sessions by the possible number of attended training sessions). In total, PLs received approximately 22 hours of training. We have previously published detailed descriptions and evaluations of this training.[23,24]

Educational seminar intervention. Shortly after randomization, we met with the educational seminar (ES) group's PRs to plan the seminars. Based on PR recommendations, we scheduled 3 seminars in each region at convenient locations and times (e.g., avoiding evening presentations during winter months). The PRs guided presentation format

and topics, but we included all hypertension information included in the PLs presentations. The principal investigator and a guest speaker (e.g., a former combat medic) presented at each session. To encourage attendance, we provided heart-healthy snacks, awarded door prizes, and invited post members' friends and family. We asked PRs to advertise the seminars and provided advertising materials. Despite these efforts, attendance was scant, ranging from 2 to 18 (mean = 10.3; SD = 5.7). PRs were sometimes the only post members at the seminars, but they often collected educational materials for distribution at subsequent post meetings.

Data collection

After obtaining informed consent, trained research assistants measured resting BP 3 times using appropriately-sized aneroid sphygmomanometers and averaged the second and third measures. They then weighed eligible participants using a calibrated bathroom-type scale and administered a baseline health survey. The survey included demographics and standardized measures of health behaviors (e.g., fruit and vegetable intake,[25] sodium intake,[26] physical activity)[27] and personal characteristics likely to affect health behaviors (e.g., active orientation to healthcare).[28,29] We re-measured BP 6 and 12 months after the intervention began. We recruited participants between August 2008 and May 2009.

Statistical analysis

Our primary outcome was change in SBP from baseline to 12 months. We compared the 2 interventions using a mixed model with a random effect for cluster and fixed effect for study group. The analysis was performed in SAS 9.2/9.3 using Proc Mixed (SAS Institute, Cary, NC). Our primary analysis used only participants who had data at both baseline and 12 months. Because we randomly assigned posts to interventions, our primary analysis did not adjust for baseline differences, but we repeated the analysis after adjusting for differences in baseline characteristic. We also repeated the analysis after performing multiple (n = 5) imputations for missing data, using SAS Proc MI to generate the imputed data and Proc MIANALYZE to combine the results. We performed similar analyses to compare SBP change in 3 preplanned subgroups: (i) individuals whose baseline BP was/was not controlled (BP <140/90 mm Hg; BP <130/80 mm Hg if diabetic); (ii) individuals who were/were not obese (body mass index ≥30 kg/meter^2) at baseline; and (iii) persons whose level of engagement in their own healthcare was in the higher or lower 2 of 4 categories of engagement, as measured by the 13-item validated Patient Activation Measure.[28]

In secondary analyses, we examined change in SBP at 6 months and changes in diastolic BP and proportion of persons with BP control at 6 and 12 months. For the binary outcome BP control, we used a generalized linear model estimated by generalized estimating equations.

Power considerations

We used methods designed for cluster randomized trials to calculate our power.[29] We used a base case assumption (intraclass correlation coefficient = 0.05; 10 members per post, 25 posts per arm) to determine that we would have power of 0.86 to detect a change of 5 mm Hg. At 12 months, our actual sample included 58 posts and 379 participants (mean = 6.5 per post; SD = 3.7); intraclass correlation coefficient was just 0.011. We calculated post hoc power to detect an SBP difference of 5 mm Hg based on the actual number and distribution of participants. We simulated multivariable normal data using a block diagonal covariance structure and a within-cluster correlation of 0.011. Based on 2,000 simulations, power was 0.834.

RESULTS

We enrolled 404 members of 58 posts; 30 posts and 219 members were assigned to the PL intervention. Compared with participants in the ES intervention, those assigned to the PL intervention were older (mean age = 68.8 vs. 67.4 years) and had lower baseline SBP (132.7 vs. 136.8 mm Hg), overall BP control, and body mass index (31.4 vs. 31.9 kg/m²). They were otherwise similar (Table 3). At 12 months, we collected data from 379 participants. Attrition was similar in the 2 groups; 13 died, 4 moved, 5 withdrew, and 3 did not come for their 12-month BP measure.

From baseline to 12 months, mean SBP decreased 3.48 mm Hg (95% confidence interval (CI) = −5.71 to −1.25;

Table 3. Baseline comparison of intervention groups

Characteristic	Peer leader (n = 219)	Seminar (n = 185)	P value[a]
Male, no. (%)	185 (84.5)	168 (90.8)	0.07
Age, y, mean (SD)	68.8 (10.0)	67.4 (10.3)	0.02
White race, no. (%)	214 (97.7)	175 (94.6%	0.12
Education, no. (%)			
≤High school graduate	70 (32.1)	69 (37.3%	0.08
Some post high school	88 (36.7)	80 (43.2%	
College graduates	60 (27.5)	36 (19.5%	
Retired, no. (%)	151 (69.0)	127 (68.7)	0.73
Household income, no. (%)			
<$20K	11 (5.0)	11 (6.5)	0.2
$20K to <$25K	15 (6.9)	20 (10.8)	
$25K to <$35K	35 (16.0)	29 (15.7)	
$35K to <$50K	42 (19.2)	33 (17.8)	
$50K to <$75K	36 (16.4)	34 (18.4)	
≥$75K	37 (16.9)	27 (14.6)	
Refused/no answer	43 (19.6)	31 (16.8)	
Health insurance coverage, no. (%)	213 (97.3)	172 (93.0)	0.09
Patient Activation Measure, mean (SD)	59.1 (14.6)	56.2 (12.0)	0.10
Related comorbidity,[b] no. (%)			
Diabetes mellitus	61 (27.9)	47 (25.4)	0.86
Coronary disease	67 (30.6)	53 (28.7)	0.74
Heart attack/myocardial infarction	38 (17.4)	27 (14.6)	0.54
Stroke	15 (6.9)	18 (9.7)	0.23
Renal disease	11 (5.0)	13 (7.0)	0.41
Baseline SBP, mean (SD)	132.5 (14.1)	136.9 (16.9)	0.02
Baseline DBP, mean (SD)	71.3 (10.5)	73.8 (12.1)	0.08
Controlled blood pressure,[c] no. (%)	131 (59.8)	89 (48.1)	0.02
Antihypertensive drugs, mean (SD)	1.64 (1.1)	1.52 (1.0)	0.29
BMI, kg/m², mean (SD)	30.8 (5.9)	31.5 (6.0)	0.01
Weight, lb, mean (SD)	207.2 (44.4)	213.8 (43.5)	0.28

Abbreviations: BMI, body mass index; BP, blood pressure; DBP, diastolic blood pressure; SBP, systolic blood pressure.
[a]P values from χ², t tests or Wilcoxon rank-sum tests as appropriate.
[b]Comorbidity reported by patient on baseline survey.
[c]Controlled = BP <140/90 mm Hg, unless with diabetes, then controlled = BP <130/80 mm Hg.

$P = 0.002$) in PL posts and 5.45 mm Hg (95% CI = −7.89 to −3.00; $P < 0.0001$) in ES posts. This difference was not significant (1.97 mm Hg; 95% CI = −1.34 to 5.28; $P = 0.24$). After adjustment for baseline age, weight, and SBP, the changes in mean SBP were −4.66 (95% CI = −6.62 to −2.70), and −4.08 (95% CI = −6.23 to −1.93) in the PL and ES groups, respectively (difference = 0.58; 95% CI = −2.34 to 3.51; $P = 0.70$). In our preplanned subgroup analyses (Table 4), SBP dropped 10.1 mm Hg overall from baseline to 12 months among persons who were above goal at baseline but did not change in those at goal. SBP decreases were similar in subgroups defined by weight and Patient Activation Measure category. Within each subgroup, there was no significant intervention effect. The imputed analysis gave similar results (overall drop in SBP = 3.68; 95% CI = −6.03 to −1.32; $P = 0.02$, with no significant difference between PL and ES).

The decrease in SBP at 6 months was smaller and not statistically significant (−1.73 mm Hg; $P = 0.08$); there was no intervention effect. The pattern was similar for DBP. Overall, mean DBP dropped from 72.8 mm Hg at baseline to 70.6 mm Hg at 12 months; 6-month results were intermediate; again, there was no intervention effect. The proportion of persons with poorly controlled BP decreased from 45.5% at baseline to 39.8% at 6 months, then to 32.5% at 12 months ($P < 0.001$); the improvement was similar in the 2 groups.

DISCUSSION

In a large, randomized controlled trial comparing 2 approaches to supporting hypertension self-management, we found no significant differences in BP improvement between the two groups; indeed the small, non-significant difference we did observe favored the control intervention. This lack of effect is significantly different from the benefit seen in uncontrolled or usual care controlled trials of community-led peer support interventions addressing other chronic diseases, which generally showed positive effects.

It is unclear why the peer-led intervention did not have a greater impact than our control intervention when other self-management interventions have been effective. We hypothesize that the control intervention may itself have

generated significant peer support. In qualitative assessments, we found that many of the PRs in the ES group very actively encouraged self-monitoring and discussions with one's physician.[30] Although we had more frequent meetings with the PLs and made greater efforts to ensure intervention fidelity in their posts, variable enthusiasm among volunteers that had become "activated" may have been more important than our efforts to guide their activities. Indeed, because a nonsignificant trend favored the control intervention, it may be that the less intrusive approach was more effective; perhaps empowering the control post by providing BP cuffs, scales, and general advice was all that was needed, and our attempts to provide added support to the intervention posts were counterproductive.

Other community-friendly study features may have also obscured an intervention effect. Because all hypertensive post members could participate, many participants had no room to improve. However, in a subgroup analysis (Table 4), there was no evidence of an advantage of the PL over the ES intervention in participants whose SBP was uncontrolled at baseline. This feature provides some evidence that both interventions may have favorably impacted BP control because regression to the mean is less of an issue when the entire population is sampled but the limits of uncontrolled studies are well known. Finally, although all posts (and PLs) volunteered for this project, we noted that the persistence of engagement varied among posts.[23,30] Thus, the intervention may have been more effective if it had been delivered by paid community health workers to more highly screened posts.[31] Unfortunately, we do not have robust measures of post and PL engagement, so we cannot reliably test the importance of this effect.

Although numerous studies have examined self-management education, we believe that ours is the first US study to examine this with a peer-delivered intervention targeting an entire community group. Thus, although studies of educational approaches delivered by telephone, the Internet, or group visits have demonstrated improved BP control,[5,10,21,32,33] most have involved individual communication within clinical populations. Iso et al. did demonstrate improvement in BP in a Japanese population after 8 community educational presentations, but their evaluation included only 111 volunteers from a population of

Table 4. Change in systolic blood pressure among preplanned subgroups

| | 12-month change in SBP, Mm Hg, mean (SEM) | | Difference in change PL − ES |
Characteristic	PL	ES	(95% CI)
Uncontrolled HTN	−8.0 (1.6)	−12.0 (1.6)	4.0 (−0.5 to 8.4)
Controlled HTN	−0.5 (1.3)	1.6 (1.6)	−2.1 (−6.2 to 2.0)
Body mass index <30 kg/m²	−2.7 (1.5)	−6.1 (1.8)	3.4 (−1.3 to 8.0)
Body mass index ≥30 kg/m²	−4.3 (1.6)	−5.2 (1.6)	0.9 (−3.6 to 5.4)
PAM <53 (levels 1 or 2)[a]	−2.6 (1.5)	−5.8 (1.7)	0.4 (−4.3 to 5.2)
PAM ≥53 (levels 3 or 4)[a]	−4.6 (1.7)	−5.0 (1.8)	3.3 (−1.2 to 7.7)

Abbreviations: CI, confidence interval; ES, educational seminar group; HTN, hypertension; PAM, Patient Activation Measure; PL, peer leader group; SBP, systolic blood pressure.

[a]Level 1: PAM ≤ 45.2; Level 2: 47.4 ≤ PAM ≤ 52.9; Level 3: 56.4 ≤ PAM ≤ 66.0; Level 4: PAM ≥ 68.5.

17,000 individuals.[34] In contrast, our intervention sought BP reduction across a broad community population, and we achieved a relatively high participation rate in our evaluation study. Based on observations at post visits, we estimated that 1,307 members regularly attend meetings. Assuming a 60% hypertension prevalence, we estimated that 784 post members were hypertensive. Although a crude estimate, this suggests that the 404 study participants make up 51.5% of the members of participating posts who could have enrolled.

Several factors beyond the lack of a true control group complicate interpretation of our results. First, the academic and veteran partners invested several years in partnership development before this study.[22] These issues could limit broader implementation of our approach. Second, because most of our participants were older, white, and male, these results may not apply to other populations. However, other groups have demonstrated improvement of various endpoints in interventions targeting more diverse populations, although few have used such a rigorous design.[35] Finally, we note that several studies in veteran populations have demonstrated a positive impact of peer support on chronic disease control. Although these interventions were significantly different from our study of hypertensive veteran members of VSOs,[36–38] they suggest that peer support may have been significant in all participating posts.[39]

Despite these caveats, we believe our results provide important information regarding community-based approaches to improving chronic disease self-management. First, this approach demonstrates that such activities can achieve high rates of participation when delivered within the existing structure of community organizations. Second, we demonstrated that a community-based intervention could be incorporated into the regular proceedings of participating organizations, contributing to long-term sustainability. We continue to collaborate with most participating posts on health promotion activities. Such partnerships have the potential to improve community health at modest marginal cost, even in populations with good access to formal healthcare. Finally, our results emphasize the importance and challenges of rigorously evaluating community interventions.

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DISCLOSURE

The authors declared no conflict of interest.

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