Stroke is the fourth leading cause of mortality and a leading cause of disability in the United States.1 Over the next 2 decades, the proportion of the US population with a history of stroke is expected to rise to close to 4%, and stroke-associated healthcare costs are expected to increase by 129%.2 There are also long-standing disparities in the incidence of stroke and transient ischemic attack (TIA) in minority populations in the United States.3–7 Although stroke-related mortality has steadily declined in the United States since the 1950s, stroke death rates have remained higher in blacks than in whites.1 Minority groups are also at greater risk for recurrent stroke. Two studies, including 1 in Northern Manhattan, found a 2- to 3-fold increased risk for recurrent stroke among African Americans and Latinos relative to whites.3,8

A prior history of a stroke or TIA represents the strongest risk marker for future stroke.8,10–12 Three of the most important actions stroke and TIA survivors can take to reduce their risk of future strokes include controlling blood pressure to a goal of <140/90 mm Hg, low-density lipoprotein cholesterol <100 mg/dL, and use of antithrombotic medications at 6 months. Secondary outcomes included control of the individual stroke risk factors. All analyses were by intent-to-treat.

Results—There was no difference in the proportion of intervention and control group participants achieving the composite outcome (34% versus 34%; P=0.98). The proportion with controlled blood pressure at 6 months was greater in the intervention group than in the control group (76% versus 67%; P=0.02). This corresponded to a greater change in systolic blood pressure in the intervention versus control group (–3.63 SD, 19.81 mm Hg versus +0.34 SD, 23.76 mm Hg; P=0.04). There were no group differences in the control of cholesterol or use of antithrombotics.

Conclusions—A low-cost peer education self-management workshop modestly improved blood pressure, but not low-density lipoprotein cholesterol or antithrombotic use, among stroke and transient ischemic attack survivors from vulnerable, predominantly minority urban communities.

Clinical Trial Registration—URL: http://www.clinicaltrials.gov/show/NCT0102727. Unique identifier: NCT01027273.

Key Words: disparities ■ randomized trial ■ secondary prevention ■ self-management ■ stroke
such as Latinos and African Americans in the United States. Evidence suggests that self-management education is a promising approach to improving outcomes for individuals in these populations. Some of these programs use peer educators or community health workers who are trusted and respected members of the community, culturally and linguistically compatible with the target population, and hence, well suited to facilitating social support, education, access, adherence, and promotion of self-care. The provision of peer education in a group-based format with stroke/TIA survivors from one’s community may be conducive to a supportive environment that enhances the effectiveness of peer education. Accordingly, we used a community-based participatory research approach to develop a culturally tailored, peer-led stroke prevention group-based workshop adapted from the Chronic Disease Self Management Program. The primary goal was to determine whether participation in such a workshop could increase the proportion of stroke and TIA survivors who achieve a composite outcome of control of blood pressure (<140/90 mm Hg), lipids (LDL cholesterol <100 mg/dL), and regular use of antithrombotic medications. Secondary outcomes of interest included control of the individual stroke prevention measures, change in blood pressure and LDL cholesterol assessed as continuous variables, medication adherence, and depressive symptoms.

Methods

Study Population
Between June 2009 and January 2012, our community-academic team recruited individuals with a history of stroke or TIA through screenings at senior centers, churches, and health fairs; contacting patients with a history of a stroke on hospital registries of an academic medical center, a federally funded community health center, and a home care nursing program; and advertising the study in clinics, community organizations, and newspapers based in the Upper Manhattan and South Bronx neighborhoods of New York City. Participants were eligible if they were 240 years of age and if they reported the occurrence of a stroke or “mini-stroke” (ie, TIA) within the past 5 years. Participants were excluded if they did not have capacity to provide informed consent, if they did not have the physical or mental capacity to participate meaningfully in self-management workshops (eg, severe aphasia or cognitive impairment), if they were non-English- and non-Spanish-speaking, or if they resided in an institutionalized setting. The local institutional review board approved the study, and all participants provided written informed consent. Additional details on the Prevent Recurrence of All Inner-City Strokes Through Education (PRAISE) trial study methods have been published elsewhere.

Study Design
The study was a 2-arm randomized controlled trial with a 6-month follow-up. After in-person enrollment and baseline assessment, participants returned for an in-person interview at 6-months to determine study outcomes.

Baseline Assessments
At baseline, research assistants confirmed each participant’s eligibility, assessed their demographic status, reviewed medication lists, surveyed medical problems to obtain a Charlson Comorbidity Index and assessed stroke-related disability using the Modified Rankin Scale. Trained study personnel also administered validated self-report measures of depressive symptoms and medication adherence, measured blood pressure, and collected blood to measure LDL cholesterol. Participants brought medication bottles to provide prescription information.

Randomization
After completion of baseline assessments, research assistants allocated participants to a randomly selected group. Randomization was generated by a computerized random-number sequence in blocks of 2, 4, or 6 people. Participant assignments were placed in sealed, opaque envelopes by a third party who had no contact with participants. Randomization was stratified by recruitment approach; those recruited from community-based, academic medical center, community health center, and the homecare nursing agency were randomized separately.

Treatment Groups
Peer Education Intervention Group
Participants randomized to the peer education intervention group were scheduled to attend a weekly peer-led workshop for 6 weeks, with each session scheduled for 90 minutes. The workshop was modeled on the Chronic Disease Self-Management Program, in which participants learn and practice self-management skills in a supportive group environment.

The workshop comprised didactic components that (1) explained the biology of stroke and stroke treatments in terms lay people could understand; (2) stressed the importance of adherence to preventive medications to reduce stroke recurrence; and (3) provided suggestions for optimizing medication adherence and working with a healthcare team. Sessions took place in groups of 8 to 10 participants in either English or Spanish and were led by 2 peer leaders with similar socioeconomic backgrounds and health problems as the participants. Participants could bring a family member, friend, or home attendant if they chose. At the end of each session, participants were asked to make an “action plan” that specified a concrete step they could take to help prevent a recurrent stroke. They were encouraged to choose something relevant to what they had learned during that week’s session. Subsequent sessions would begin with participants reporting back to the group on the results of their efforts to implement this action plan. Hence, key ingredients of the peer education intervention workshop included modeling of self-management and problem-solving techniques, guidance for self-management, weekly action planning for specific behaviors, feedback on progress, and social persuasion through group support. At the randomization visit, participants in the intervention group additionally received a small packet of culturally sensitive stroke education materials and a list of local health providers, including those that accepted patients without health insurance. Participants also received their baseline results pertaining to their blood pressure and LDL cholesterol in writing and were encouraged to discuss these results with their healthcare provider.

Wait-List Control Group
Participants in the wait-list control group were told they would receive access to the peer education workshops at no cost after a 1-year waiting period. At the randomization visit, they received the same small packet of stroke education materials, list of local health providers, and advice to discuss blood pressure and cholesterol results with their healthcare providers as participants in the intervention group.

Follow-Up Assessments
Six months after randomization, participants in both groups returned for in-person follow-up assessments. Data collection at the 6-month study visit was similar to the baseline visit. Research assistants who performed follow-up assessments were blinded to group assignment.

Outcomes and Measurements
The primary outcome was the proportion of participants who achieved goals for all 3 key stroke prevention measures: blood pressure
method, eliminating the need for fasting. Use of antithrombotic medication with a pharmacy refill measure of medication adherence. The adherent (6–8 points) groups, and these categorizations are concordant on the scale can classify individuals into nonadherent (<6 points) and adherent (6–8 points) groups, and these categorizations are concordant on the scale can classify individuals into nonadherent (<6 points) and adherent (6–8 points) groups, and these categorizations are concordant on the scale can classify individuals into nonadherent (<6 points) and adherent (6–8 points) groups, and these categorizations are concordant on the scale can classify individuals into nonadherent (<6 points) and adherent (6–8 points) groups, and these categorizations are concordant on the scale can classify individuals into nonadherent (<6 points) and adherent (6–8 points) groups, and these categorizations are concordant on the scale can classify individuals into nonadherent (<6 points) and adherent (6–8 points) groups, and these categorizations are concordant on the scale can classify individuals into nonadherent (<6 points) and adherent (6–8 points) groups, and these categorizations are concordant on the scale can classify individuals into nonadherent (<6 points) and adherent (6–8 points) groups.

Trained research assistants measured blood pressure using a BP Tru automatic sphygomanometer according to the American Heart Association guidelines. The average of the last 2 of 3 readings was used for analyses. LDL cholesterol was measured using the direct method, eliminating the need for fasting. Use of antithrombotic medication was assessed by a review of medication bottles during the baseline visit or by asking patients to read the names of all their pill bottles at home by telephone. Consistent with the recent recommendations of the American Heart Association/ American Stroke Association guidelines, participants were considered to be using an appropriate antithrombotic medication if they took aspirin (>50 mg per day ≥3 days per week), clopidogrel, or the combination of aspirin and dipyridamole as antiplatelet therapy, or anticoagulation with warfarin or equivalent medication for patients with atrial fibrillation and had no contraindication to antiplatelet and anticoagulant medication. We measured medication adherence using the Morisky Medication Adherence Scale, which includes 8 items that assess pill-taking behaviors. Summary scores on the scale can classify individuals into nonadherent (<6 points) and adherent (6–8 points) groups, and these categorizations are concordant with a pharmacy refill measure of medication adherence. The team measured depressive symptoms using the 8-item version of the Patient Health Questionnaire, a well-validated measure of depressive symptoms in racially and ethnically diverse patients, which has been validated in stroke survivors. A score of 10 or higher has a sensitivity of 91% and specificity of 89% for diagnosing depression in stroke survivors. The 8-item version is identical to the 9-item version except it omits 1 item asking about suicidal ideations.

Statistical Analysis
We evaluated differences between participants randomized to the intervention and control groups using t-tests for continuous variables and χ² analysis for categorical variables. We used intent-to-treat analyses to compare participants on all key outcomes. As a sensitivity analysis, we used generalized estimating equations to compare the likelihood of achieving the composite outcome and the individual stroke prevention measures at 6 months in the intervention group as compared with the control group after accounting for control status at baseline. We used mixed models to compare the change in blood pressure and change in lipids between baseline and 6 months between patients in the intervention and control groups. Missing values were imputed using multiple imputation under the assumption that values were missing at random. As our findings were similar when we performed analyses with and without imputing missing values, we only present data pertaining to our imputed data. We additionally performed exploratory (ie, not prespecified) subgroup analyses for the effect of the intervention on blood pressure by sex and race/ethnicity and tested for significance using a treatment × subgroup interaction test.

Sample size was calculated for the composite outcome of combined control of blood pressure, LDL cholesterol, and antithrombotic use. Based on prior literature, we used a conservative estimate of baseline use of stroke prevention measures (40%) for our sample size estimate. With 80% power, 5% significance level, and a 2-tailed test, we estimated that we would need 270 participants per group to detect a 20% relative difference in the proportion of participants in the intervention group who achieved the composite outcome as compared with the proportion achieving the composite outcome in the control group (ie, 70% in intervention arm versus 56% in control arm). To account for loss to follow-up, we increased the sample size to 600.

All analyses were conducted based on the intention-to-treat principle. PASS (version 08.0.13, NCSS, LLC, Keysville, UT) was used for sample size calculation, and SAS 9.2 software (SAS Institute Inc., Cary, NC) was used for all other analyses.

Results
Of 2665 individuals who were screened for study participation, 52% were ineligible, 24% declined, and 600 enrolled and were randomized (301 intervention and 299 control; Figure). We retained 85% at 6-month follow-up. There were no significant differences in key sociodemographic or clinical characteristics between participants who did and did not complete follow-up.
Participants randomized to the intervention and control groups were similar in demographic and clinical variables at baseline (Table 1). The mean (SD) age of participants was 63 (11) years, 59% were women, 86% were nonwhite, 57% had an annual household income of <$15,000, and nearly one-third had a less than high school education. Approximately one-third had blood pressure above goal, 42% had LDL cholesterol above goal, 18% were not taking an antithrombotic medication, and only 35% were at goal for all 3 stroke prevention measures. Forty percent reported nonadherence to medications. Among participants randomized to the intervention, the mean number of workshop sessions attended was 4. Seventy-one percent attended ≥50% of the scheduled sessions and 16% did not attend any sessions.

There was no difference in the proportion of intervention and control participants who at 6 months had attained all 3 stroke prevention measures (34% versus 34%; P=0.98). Furthermore, there were no differences in the proportion of intervention and control participants who at 6 months had controlled LDL cholesterol (54% versus 58%; P=0.46) or who took an antithrombotic medication (82% versus 84%; P=0.61). A higher proportion of participants randomized to the intervention had controlled blood pressure at 6 months as compared with control participants (76% versus 67%; P=0.02; Table 2). This corresponded to 1.13× (95% CI, 1.02–1.25) increased likelihood of having controlled blood pressure at 6 months if assigned to the intervention compared with the control group. In the sensitivity analysis that controlled for baseline blood pressure control status, the difference in blood pressure control status at 6 months attributable to the intervention was nearly statistically significant (P=0.07). Participants in the intervention group had a greater change in systolic blood pressure at 6 months than control participants (−3.63 SD, 19.81 mm Hg versus +0.34 SD, 23.76 mm Hg; P=0.04), but no significant difference in diastolic blood pressure (−1.95 SD, 10.26 mm Hg versus −0.63 SD, 11.88 mm Hg; P=0.18). The proportion of participants who were adherent increased by 7.4% in the intervention group compared with 10.5% in the intervention group compared with 5.7% in the control group (P=0.16). There were no significant interactions between the effect of the intervention and either sex or race/ethnicity.

Table 1. Baseline Patient Characteristics

<table>
<thead>
<tr>
<th>Patient Characteristics</th>
<th>Peer Education Intervention Group (N=301)</th>
<th>Wait-List Control Group (N=299)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographic</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age, mean (SD), y</td>
<td>63 (11)</td>
<td>64 (11)</td>
<td>0.59</td>
</tr>
<tr>
<td>Women, %</td>
<td>60</td>
<td>59</td>
<td>0.82</td>
</tr>
<tr>
<td>Race or ethnicity, %</td>
<td></td>
<td></td>
<td>0.39</td>
</tr>
<tr>
<td>Black</td>
<td>40</td>
<td>43</td>
<td></td>
</tr>
<tr>
<td>Latino</td>
<td>42</td>
<td>37</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>13</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>4</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Annual income ≤$15,000, %</td>
<td>56</td>
<td>58</td>
<td>0.62</td>
</tr>
<tr>
<td>Less than high school education, %</td>
<td>31</td>
<td>30</td>
<td>0.98</td>
</tr>
<tr>
<td>Insurance</td>
<td></td>
<td></td>
<td>0.97</td>
</tr>
<tr>
<td>Medicaid, %</td>
<td>29</td>
<td>30</td>
<td></td>
</tr>
<tr>
<td>Medicare, %</td>
<td>39</td>
<td>40</td>
<td></td>
</tr>
<tr>
<td>Commercial, %</td>
<td>26</td>
<td>24</td>
<td></td>
</tr>
<tr>
<td>Uninsured, %</td>
<td>6</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Clinical</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Years since last stroke or TIA, mean (SD)</td>
<td>1.8 (1.4)</td>
<td>1.8 (1.5)</td>
<td>0.79</td>
</tr>
<tr>
<td>Systolic BP, mean (SD), mm Hg</td>
<td>131 (22)</td>
<td>132 (22)</td>
<td>0.59</td>
</tr>
<tr>
<td>Diastolic BP, mean (SD), mm Hg</td>
<td>78 (12)</td>
<td>78 (12)</td>
<td>0.46</td>
</tr>
<tr>
<td>Use antihypertensive medication, %</td>
<td>78</td>
<td>83</td>
<td>0.11</td>
</tr>
<tr>
<td>LDL cholesterol, mean (SD)</td>
<td>97 (38)</td>
<td>97 (35)</td>
<td>0.80</td>
</tr>
<tr>
<td>Use of antilipid medication, %</td>
<td>65</td>
<td>63</td>
<td>0.63</td>
</tr>
<tr>
<td>Charlson Comorbidity Index, mean±SD</td>
<td>3.7 (2.1)</td>
<td>3.6 (2.1)</td>
<td>0.44</td>
</tr>
<tr>
<td>Modified Rankin Score 3 or 4, %</td>
<td>48</td>
<td>46</td>
<td>0.59</td>
</tr>
<tr>
<td>Depressed (PHQ score ≥10), %</td>
<td>31</td>
<td>28</td>
<td>0.39</td>
</tr>
<tr>
<td>Nonadherent to medications, %</td>
<td>42</td>
<td>38</td>
<td>0.41</td>
</tr>
</tbody>
</table>

BP indicates blood pressure; LDL, low-density lipoprotein; PHQ, Patient Health Questionnaire-8 item version; and TIA, transient ischemic attack.
In this study, participants randomized to a peer-led community-based stroke education workshop as compared with a wait-list control group did not achieve greater combined control of 3 key stroke prevention measures, nor did they improve their control of LDL cholesterol or antithrombotic use when these stroke prevention measures were examined individually. A greater proportion of stroke and TIA survivors randomized to the intervention did, however, achieve controlled blood pressure, and this was associated with a group difference in systolic blood pressure of \( \approx 4 \) mm Hg. The intervention was also associated with a trend toward an improvement in medication adherence and depression.

Controlling blood pressure remains the cornerstone of the prevention of recurrent stroke.\(^{17,42}\) A meta-analysis of the effects of antihypertensive medications showed that a reduction in systolic blood pressure of 5 mm Hg was associated with a 20% reduction in stroke.\(^{43}\) Although the optimal target blood pressure for stroke survivors is still being explored, reductions in blood pressure have been associated with lower rates of stroke even among stroke survivors with controlled blood pressure.\(^{43,44}\) To put our intervention in perspective, a recent Cochrane meta-analysis of interventions to improve modifiable risk factors in stroke survivors found that there were no significant benefits of organizational, educational, or behavioral interventions on risk factor control.\(^{45}\) Accordingly, this peer-led approach to improving stroke outcomes may be welcomed as a means of improving stroke outcomes, particularly in vulnerable communities with a high proportion of low-income minorities.

In contrast, with blood pressure control, achieving LDL cholesterol goals <100 mg/dL was a class B recommendation according to the American Stroke Association guidelines at the time the study was conducted,\(^{17}\) and the newest guidelines for managing cholesterol suggest that use of statins might be a more important target for stroke prevention than LDL number in future studies.\(^{46}\) As LDL cholesterol is largely dependent on prescribing practices of clinicians, clinical uncertainty about the importance of LDL cholesterol goals may have limited the effect of this patient intervention on this goal. With respect to antithrombotic use, over 80% of participants in both groups were taking antithrombotics at baseline. As participants were, in part, enrolled from nonmedical settings, we did not have access to medical records and could not ascertain the type of stroke (hemorrhagic versus ischemic) or the proportion with an indication for antithrombotic medication for stroke prophylaxis. In population-based samples, \( \approx 10\% \) of stroke survivors have contraindications to antithrombotics. Hence, we may have been unable to demonstrate an effect of our intervention on this stroke prevention measure because of ceiling effects.

There were several notable strengths of this study. In partnership with our community action board, we successfully recruited a group of stroke and TIA survivors who are often excluded from clinical trials.\(^{47}\) Many of our participants were nonwhite, had incomes below the poverty level, lacked health insurance, and had significant levels of disability and distress as measured by the modified Rankin score and the PHQ, respectively. Despite these vulnerabilities, the majority of participants attended more than half of the workshop sessions, confirming that such an approach is feasible, even among low-income, minority stroke survivors. This community-based, peer-led intervention has the potential to be more easily sustained in the low-income, nonwhite communities at highest risk for stroke as opposed to other more resource-intensive strategies, such as individualized case-management or tailored health education that involve significant time and effort by healthcare professionals.\(^{45}\)
The study also had several limitations. The generalizability of our findings to other stroke and TIA survivor populations remains unknown. Recruitment required substantial effort and led to the inclusion of many participants already reaching study goals for stroke prevention. The optimal approach to identifying participants for such an intervention would benefit from careful consideration. For example, limiting recruitment to stroke centers or TIA clinics may facilitate a more targeted approach but may exclude the large number of stroke/TIA survivors who do not follow at such centers. We did not use an attention control group, and thus, it is difficult to determine which aspects of the intervention were most important for achieving the improvement in blood pressure control. Future studies could assess the extent to which the use of peer educators is a key component of chronic disease self-management interventions, particularly in minority populations. The provision of an educational packet to participants in the wait-list control group may have contributed to a contamination bias that would have biased our results to the null. We did not assess the extent to which blinding was maintained among research assistants performing outcomes assessments. Our measure of medication adherence was based on self-report and was not specific to stroke medications. Future studies could examine the effect of the intervention on objective measures of adherence to stroke prevention medications to determine the extent to which such approaches lead to better risk factor control through increased medication or lifestyle adherence or through empowering patients to be proactive when visiting their clinicians.

In summary, a peer education workshop can be successfully delivered to stroke and TIA survivors in vulnerable communities and can produce modest improvements in blood pressure control. Given the strong association between blood pressure and stroke risk, this peer-led approach may be helpful for reducing disparities in stroke outcomes. Future studies should assess the effect of targeting this type of intervention to stroke/TIA survivors who are not reaching goals for stroke prevention.

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Disclosures
None.

References


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