A Clinical Trial to Improve High Blood Pressure Care in Young Urban Black Men
Recruitment, Follow-up, and Outcomes
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This randomized trial recruited and followed underserved, inner-city, hypertensive (HTN),
young black men and investigated whether a nurse-community health worker team in
combination with usual medical care (SI) increased entry into care and reduced high blood pressure
(HBP), in comparison to usual medical care (UC) alone. Emergency department records, advertising,
and BP screenings identified potential participants with HBP. Telephone calls and personal contacts
tracked enrollees. Of 1391 potential participants, 803 (58%) responded to an invitation to be
screened and scheduled a visit. Of these, 528 (66%) kept an appointment, 207 (35%) were BP eligible,
and 204 (99%) consented to enroll. At 12 months 91% of men were accounted for and 85.8%
(adjusted for death, in jail, or moved away) were seen. Mean BP changed from 153(16)/98(10) to
152(19)/94(11) mm Hg in the SI group and 151(18)/98(11) to 147(21)/92(14) mm Hg in the UC group
(\(P=NS\)). High rates of participation are attainable in this population; however, culturally acceptable
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KEY WORDS: Recruitment, follow-up, hypertension, young black men, randomized clinical trial.

Young black men < 50 years of age comprise the age-race-gender group with high blood
pressure (HBP) that remains the least well diagnosed, treated, and controlled.\(^1\)–\(^12\)
Moreover, they bear social, psychologic, economic, and educational burdens that make behavioral
changes for health improvement difficult.\(^13\)–\(^16\) Not having a primary care physician or health insurance
and receiving blood pressure medication prescriptions in an emergency room are associated with nonadher-
ence and low rates of care and control.\(^9,18\) Although young, underserved, inner-city black men were in-
cluded in studies such as the Hypertension, Detection and Follow-up Program,\(^1,7\) no studies specifically tar-
getting this high-risk group have been reported. The primary objectives of this clinical trial were to recruit
and follow a sample of underserved, inner-city, hypertensive, young black men and to investigate
whether an educational-behavioral intervention administered by a nurse-community health worker team
in combination with usual medical care lowered HBP and increased HBP control in comparison to usual
medical care alone. Secondary aims were to increase understanding of factors influencing entry into care,
remaining in care, and adherence to treatment recom-
mendations in this population, and to develop methodologies to improve HBP care and outcomes.

MATERIALS AND METHODS

Sites and Personnel Potential participants were primarily identified in the Emergency Department (ED) of the Johns Hopkins Hospital by abstracting medical records three to four times weekly to identify age, gender, race, zip code, and BP eligibility. Letters inviting men to be rescreened were followed by telephone calls. In the surrounding community, screenings at the Health Department Sexually Transmitted Disease (STD) Clinic, and advertising by widely posting and handing out colorful flyers with a figure of a young black male announcing the free BP screenings, were used. Word-of-mouth, whereby participants and community members tell others about the screening and study, was an additional strategy. Potentially eligible participants were then seen in the Hospital Outpatient General Clinical Research Center (OPD-GCRC). The recruitment was staffed by two black American women, one of whom was the community health worker who tracked and followed the enrolled men and made home visits.

Identification, Verification, and Randomization Visits Institutional Review Board approval was obtained before beginning the study. In Phase I of the three-phase recruitment process, potentially eligible individuals were identified. The following demographic information was collected: name, age, race, gender, address, telephone number, past history of HBP, and history of HBP treatment, as well as the name, address, and telephone number, if available, of one or two contact persons through whom the potential participant could receive messages and the staff could contact regarding the participant. Repeated attempts either by telephone or letter were made to schedule a visit or reschedule missed appointments.

In Phase II, men responding to the invitation and verbally agreeing to be screened were scheduled within 1 to 2 weeks for an eligibility verification visit, at which a modest financial incentive of $10 was offered.

Consenting screenees who met all of the inclusion criteria were offered enrollment. Inclusion criteria were black or African-American male resident within the Johns Hopkins Hospital catchment area; age between 18 and 49 years; BP ≥ 140 or ≥ 90 mm Hg, or BP < 140/90 mm Hg and currently taking HBP medication, on two occasions: in the ED, at a screening, or by history (Phase I), and the average of three readings measured by random zero sphygmomanometer at an OPD-GCRC HBP verification visit (Phase II)\(^{21,22}\), able to give their telephone number (if they had one) and address, and the verified name, address, and telephone number of two or three people through whom they could be reached; written informed consent to participate in the screening/eligibility verification visit, and separate written consent to participate in the subsequent clinical trial; and no acute or terminal condition precluding participation.

In Phase III, eligible consenting men were enrolled in the 12-month clinical trial. Particular emphasis was placed on explaining the rationale for and process of randomization to allay possible concerns about experimentation. The randomization materials were prepared and group assignment was revealed by trained individuals not associated with the trial, who informed the nurse and CHW of the participant’s group assignment. Participants were randomized and told of their group assignment after baseline data were collected.

Analysis The sample size was calculated so that a 5 mm Hg difference in the reduction in diastolic blood pressure (DBP) between the two groups from Week 0 to Week 52 could be detected. Estimated variances in BP change from the Trial of Mild Hypertension (TOMHS)\(^{23}\) were used in calculating sample size.\(^{24,25}\) Calculations were based on an \(\alpha\) of 0.01, a power of 0.90, and a 5 mm Hg difference in the change in DBP between the groups. To allow for a 25% loss to follow-up, we enrolled 100 rather than 77 participants in each group.

Intervention The educational intervention delivered to both groups explained HBP, goal BP, the importance of remaining in care and adhering to treatment, referral to a physician if necessary, answers to questions, and a wallet card on which to record BP. Men in the Special Intervention (SI) group also received individualized counseling, monthly telephone calls, and a home visit. All participants received an additional $25 incentive for completing the study. Telephone follow-up and home visits with contact persons were conducted to minimize missing data.

RESULTS

Recruitment and Enrollment In Phase I, 1391 potentially eligible men were identified. In Phase II, 803 (58%) responded to the invitation and made a screening/verification visit appointment. Of these, 528 (66%) kept the appointment. More than one-third, 207 (39%), met the criteria for blood pressure eligibility. Ninety-nine percent of those eligible consented (\(N = 204\)) to be randomized into the study, 103 to the SI and 101 to the Usual Care (UC) groups. Three men declined because they did not want to have their blood drawn.

A variety of sites and methods were used to identify potential participants (Table 1). The yield, defined as the number of men enrolled in the study from a site divided by the total number of men identified from
that site, varied across sites and methods. Although 48% of the men enrolled in the study were identified through the ED, the yield from the ED was only 11%. Thus, for every 100 men identified through the ED, 11 were enrolled in the study. Word-of-mouth (30%) and advertisements (33%) were three times more productive than the ED. One serendipitous finding was the intrafamilial recruitment done by enrolled participants. Through word-of-mouth, nine related men were enrolled: one set of three brothers; one father and son; one uncle and nephew; and one set of two brothers.

The number of telephone calls made to contact men and make appointments ranged from 0 to 11, and averaged 1.9 (SD 5 2). The number of letters sent ranged from 0 to 5, and averaged 0.7 (SD 5 1). The number of appointments made ranged from 0 to 6. Approximately 73% of the men kept one of the first three appointments made (Table 2). Thereafter, potential participants’ rescheduling and keeping missed appointments dropped substantially. On average, two telephone calls were made and one letter was sent to all potentially eligible participants. There was no difference in the number of screening appointments made between those who were eligible and those who did not meet eligibility criteria.

Univariate analyses revealed age, diastolic and systolic blood pressure (SBP), a reported history of taking HBP medication, and currently reporting taking HBP medication to be significantly associated with eligibility. On average, slightly older men were more likely to be eligible (39 v 35 years). Men with higher DBP (99 v 89 mm Hg) and higher SBP (155 v 148 mm Hg) at the verification visit were more likely to be eligible. Additionally, men who reported taking HBP medication in the past (58% v 28%) and those who reported they were currently taking HBP medication (35% v 15%) were more likely to be eligible.

In a logistic regression with the response being a dichotomous variable denoting eligibility status, only reported history of taking HBP medication and DBP at identification (Phase I of the recruitment process) were significantly associated with the odds of being eligible. Men who reported taking HBP medication in the past were 2.8 times more likely to be eligible than men who did not have a history of taking HBP medications. The 95% confidence interval for this estimate ranged from 1.96 to 4.02. In addition, higher DBP at Phase I of the screening process was associated with greater odds of being eligible. For example, a man whose DBP was 5 mm Hg higher than that of another at identification was 1.2 times more likely to be eligible at the verification visit (Phase II), with a 95% confidence interval of 1.10 to 1.23.

Description of Enrolled Participants The average age was 39 years (range, 22 to 49 years). Only 17% were employed full-time. Six percent were married, 62% never married, and 30% were separated or divorced. A third (32%) reported having three or more children, 36% reported church membership, and 58% reported ever being in jail. Mean BP was 152/98 mm Hg. Only 36% had a physician for HBP care and 39% had health insurance. The mean BP of those men currently taking BP medication (34%) was 149/95 mm Hg, compared with 153/99 mm Hg for those not taking medication.

Follow-up Follow-up visits at 12 months were conducted for 77% of the 204 men randomized (N = 157) (Table 3). Follow-up appointment rates did not differ significantly for the SI (78%) and UC groups (76%). Reasons for nonattendance were obtained for 62%

<table>
<thead>
<tr>
<th>Source</th>
<th>Identified n ( % of Total)</th>
<th>Enrolled n ( % of Total)</th>
<th>Yield* ( % Enrolled From Site)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emergency department</td>
<td>865 (62)</td>
<td>97 (48)</td>
<td>11</td>
</tr>
<tr>
<td>Word-of-mouth</td>
<td>257 (19)</td>
<td>78 (38)</td>
<td>30</td>
</tr>
<tr>
<td>Prior HBP study subjects</td>
<td>140 (10)</td>
<td>8 (4)</td>
<td>6</td>
</tr>
<tr>
<td>Advertising</td>
<td>40 (3)</td>
<td>13 (6)</td>
<td>33</td>
</tr>
<tr>
<td>STD clinic</td>
<td>39 (3)</td>
<td>4 (2)</td>
<td>10</td>
</tr>
<tr>
<td>Hospital employees</td>
<td>41 (3)</td>
<td>3 (2)</td>
<td>7</td>
</tr>
<tr>
<td>Unknown</td>
<td>9 (1)</td>
<td>1 (1)</td>
<td>11</td>
</tr>
<tr>
<td>Total</td>
<td>1391 (100)</td>
<td>204 (100)</td>
<td></td>
</tr>
</tbody>
</table>

* Yield = number of men enrolled in the study from a site divided by the total number of men identified from that site.

HBP, high blood pressure; STD, sexually transmitted diseases.

### Table 2. Number and Percentage of Screening Appointments Made and Kept

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Percent Who Showed Up</th>
<th>Per of No-Shows Who Rescheduled</th>
</tr>
</thead>
<tbody>
<tr>
<td>Made 1st</td>
<td>803</td>
<td>52%</td>
<td></td>
</tr>
<tr>
<td>Kept 1st</td>
<td>421</td>
<td>74%</td>
<td></td>
</tr>
<tr>
<td>Made 2nd</td>
<td>252</td>
<td>50%</td>
<td>66%</td>
</tr>
<tr>
<td>Kept 2nd</td>
<td>127</td>
<td>62%</td>
<td>50%</td>
</tr>
<tr>
<td>Made 3rd</td>
<td>76</td>
<td>61%</td>
<td>50%</td>
</tr>
<tr>
<td>Kept 3rd</td>
<td>35</td>
<td>63%</td>
<td>50%</td>
</tr>
<tr>
<td>Made 4th</td>
<td>21</td>
<td>66%</td>
<td>50%</td>
</tr>
<tr>
<td>Kept 4th</td>
<td>3</td>
<td>67%</td>
<td>50%</td>
</tr>
<tr>
<td>Made 5th</td>
<td>5</td>
<td>28%</td>
<td>50%</td>
</tr>
<tr>
<td>Kept 5th</td>
<td>1</td>
<td>25%</td>
<td>50%</td>
</tr>
<tr>
<td>Made 6th</td>
<td>1</td>
<td>20%</td>
<td>50%</td>
</tr>
<tr>
<td>Kept 6th</td>
<td>1</td>
<td>100%</td>
<td>50%</td>
</tr>
</tbody>
</table>
(N = 29) of the 47 men not keeping the appointments. The most common reasons included being in jail (N = 7), moving out of state (N = 7), and having died (N = 6). Eighteen men, 9% of the 204 randomized men, could not be located despite persistent efforts. The follow-up attendance rates adjusted for death, being in jail, and moved out of state were 86% and 85% for the SI and UC groups, respectively. In univariate analyses, there was no difference between those men who came to the 12-month follow-up visit and those who did not with respect to the following variables: baseline DBP and SBP, treatment group assignment, taking HBP medication at baseline, being employed full- or part-time, having insurance, or graduating from high school.

BP Change and Control  Although the mean changes in DBP were significantly different from zero for both the treatment and control groups, they were not statistically different from one another (Table 4). The mean changes in SBP were not statistically different from zero for either group. In separate regression analyses for changes in DBP and SBP from baseline to follow-up, none of the following variables were significantly associated with the change: having a doctor for HBP, taking medication for HBP, having health insurance, being employed, graduating from high school, or being in the SI treatment group. The mean BP levels at baseline and 12-month follow-up are higher than the national recommended levels for control, ie, BP < 140/90 mm Hg (Table 4).26 Logistic regressions were done to assess if any explanatory variables were associated with the probability of having controlled BP at 12 months. As with the change in BP levels, we found no variables significantly associated with controlled BP.

A critical finding of the study is that entry into care and remaining in care remained at low rates. Although more men (N = 38) entered care than dropped out of care (N = 10) during the 12-month study period, there were no differences between the SI and UC groups (39% and 35% at baseline and 19% and 17% at follow-up, respectively).

DISCUSSION

This clinical trial demonstrated the feasibility of identifying, recruiting, and following-up a sample of young, underserved, inner-city, hypertensive, black American men. To our knowledge, this is the first and only study focusing exclusively on improving HBP care for this high-risk group. High rates of recruitment, randomization, tracking, and follow-up were demonstrated. Additionally, this study evaluated the effects of an educational-behavioral intervention for an underserved population within the context of the traditional health care system. Although significant changes in DBP reduction were found, there was no difference between groups. A greater proportion (39% and 35% of SI and UC, respectively) of men reported entering care at the end of the 12-month follow-up visit than dropping out of care (19% and 17% of SI and UC, respectively).

The labor-intensive recruitment effort called for a committed staff with creativity, persuasiveness, and great familiarity with the target population and com-

| TABLE 3. 12-MONTH FOLLOW-UP DATA RATE AND REASONS FOR NONATTENDANCE (N[%]) |
|---------------------------------|-----------------|-----------------|
|                                | Special Intervention Group (N = 103) | Usual Care Group (N = 101) | Total (N = 204) |
| 12-Month Visit                 |                               |                  |                  |
| Due                            | 103                           | 101              | 204              |
| Seen                           |                                |                  |                  |
| Unadjusted                     | 80 (78%)                      | 77 (76%)         | 157 (77%)        |
| Adjusted for deceased, in jail, or moved out of state | 80 (86%) | 77 (85%) | 157 (85%) |
| Reasons for nonattendance      |                                |                  |                  |
| Cannot locate                  | 10                            | 9                | 19 (9%)          |
| Jail                           | 2                              | 5                | 7 (3%)           |
| Moved out of state             | 3                              | 4                | 7 (3%)           |
| Deceased                       | 5                              | 1                | 6 (3%)           |
| Working                        | 1                              | 1                | 2 (1%)           |
| Refusal                        | 1                              | 1                | 2 (1%)           |
| Hospitalized                   | 0                              | 2                | 2 (1%)           |
| Stroke (severe memory loss)    | 1                              | 1                | 2 (1%)           |
| Total                          | 23                            | 24              | 47 (23%)         |

* Random zero blood pressures not available for one man at baseline and two men at follow-up.
munity. The value of the ED as a site for identifying potential participants indicates the continuing importance of the ED in underserved urban areas. The value of word-of-mouth as a method of identifying potential participants reflects the interest enrolled and potential participants as well as others in the community had in health care for these men. It may be that encouragement to join a study from one’s peers is more influential than information received from other sources.

Several modifications in strategy were made to improve recruitment. Three rather than two verified contact persons were identified whenever possible to increase the likelihood of reaching the men, getting messages to them, or learning about their health status and reasons for not keeping appointments. Several sites where young men gather were considered as possible screening sites. Neighborhood recreation centers, valuable recruitment sites previously, were unavailable due to city budget cutbacks. Unemployment centers, the City Detention Center, and homeless shelters were rejected because staff at these sites reported difficulty following-up and tracking men. The Sexually Transmitted Disease Clinic of the City Department of Health agreed to become a screening site. Several strategies—for example, screening at church-based health fairs and neighborhood prevention centers, were discontinued given their labor intensive and time-consuming, and thus can be labor intensive and time-consuming, and thus can be expensive. The persistent seeking of the men who missed scheduled appointments, as reflected in Table 2, supports the strategy of intensively pursuing those who did not attend. The benefit of scheduling more than one appointment might be questioned, as 70% of those who were recruited kept their first scheduled appointment. On the other hand, the argument can be made for scheduling more than one appointment, as the remaining 30% were already identified, had been contacted, and constituted a pool of available potential participants. Pursuing them avoided the need to continue to initially identify and assemble a group to be scheduled for a first appointment. Placing a priority on contacting men with the highest blood pressures at initial identification was useful. The higher the blood pressure at first identification, especially the diastolic pressure, the more likely the BP elevation will be sustained at the verification visit and that the man will be eligible. In addition, men who had been or were in HBP care were more likely to participate in the three-stage recruitment process than those who were not in care or had not been previously diagnosed with HBP, suggesting that those who had demonstrated some concern with respect to their blood pressure were more likely to enroll in the study.

Numerous men who were asked to make verification visits stated this was the first time they had been contacted by the health care system and offered preventive services. The men were very surprised that anyone was interested in them. However, for many participants, the provision of transportation, minimal financial assistance with medical visit fees, and medication were not sufficient incentives to overcome their negative prior experiences and the perceived absence of benefit. One man, when asked why he had not seen the doctor he identified as his usual source of HBP care, replied, “I don’t do doctors. They make you wait. They talk down to you and they really don’t like to take care of people like me.” This suggests that satisfaction with care and provider-patient relationship are important factors in successful HBP care and control in this population. Additionally, the readiness of this population to make changes and maintain action by entering and remaining in care, as well as adhering to treatment strategies, will need to be addressed in the future to increase involvement from precontemplation to action.36,37

Several problems adversely affected our ability to significantly increase entry into care, remaining in care, adherence to treatment, and BP reduction. The elimination or reduction of health care benefits for young men covered by the Maryland Medical Assistance Program resulted in increased use of the ED for primary care services and a reduction in the numbers of men seeking care in primary care sites. The strong aversion to usual medical care felt by the participants resulted in no significant increase in the use of HBP care services. Internal organizational factors such as no flexibility in clinic hours to accommodate working men or unavailable equipment also contributed to the problem.

A study focusing on young black men with HBP has not been reported before. This may be because of the perception that young black American men aren’t interested in their health and are impossible to follow-up and track. As shown in this study, once a man is seen and determined by a multistage process to be eligible, almost all will consent to participate. Once their interest was established, the men were quite responsive to the community health worker and nurse. Modest financial and tangible incentives such as sunglasses and squeeze bottles with the study logo were helpful. Drop-in BP checks, call-in availability, and referrals to job training and substance abuse rehabilitative programs were identified as additional strategies to meet the expressed needs of the SI men. Based upon prior work in the community, we believe that the men participating in this study are representative of a population most damaged by high blood pressure. The inconsistent, episodic health-care-seeking behaviors, and the rates of incarceration and mor-
tality, are not unusual for the community. They are, however, of sufficient concern that the mayor has recently appointed a task force to examine issues related to black men, including health insurance, employment, and job readiness and training.

An enthusiastic, energetic, committed, and persistent minority staff was the essential ingredient for success. Their nonjudgmental concern about the health of the study population, their ability to establish rapport with the men and the contact persons, and their knowledge and experience contributed greatly to the design of relevant and acceptable recruitment and retention strategies. In addition to the staff and experienced investigators committed to making a difference for a needy population, our success is due in part to increasing partnership between the community and the academic health center. Interdisciplinary efforts to meet the needs of underserved populations require sensitivity, particularly when conducting research in black American communities where attitudes may have been affected by past experiences or perceptions. The three men who qualified for eligibility but did not enroll declined because they did not want to have blood drawn, not because of concerns about participating in an experiment. In focus groups before recruitment men unanimously stated that the race and gender of the investigators and nurse did not matter, but their “personalities” did. Further elaboration brought forth terms such as “interested,” “cares,” “doesn’t judge,” and “will be there for me.” It was important to the men that the community outreach workers share their black ethnic background and that they were comfortable in the community, but it was not necessary that they live in the neighborhood.

The low rates of entry, remaining in traditional medical care, and blood pressure control indicate that innovative, more culturally acceptable ways of delivering care to this population must be examined. We encourage other investigators to more fully integrate social, behavioral, and communication sciences with the biomedical sciences in multidisciplinary, clinic/community investigations to demonstrate improved health outcomes for this high-risk population.

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