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ORIGINAL ARTICLE

Cluster Randomized Clinical Trial of FAITH (Faith-Based Approaches in the Treatment of Hypertension) in Blacks

Main Trial Results

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BACKGROUND: Therapeutic lifestyle change (TLC) is a recommended treatment for patients with hypertension, but its effectiveness in community-based settings remains untested, particularly in black churches—an influential institution for health promotion in black communities.

METHODS AND RESULTS: The FAITH study (Faith-Based Approaches in the Treatment of Hypertension) evaluated the comparative effectiveness of a TLC intervention plus motivational interviewing (MINT) sessions versus health education (HE) alone, on blood pressure (BP) reduction among blacks with uncontrolled hypertension. Data were collected on 373 participants meeting eligibility criteria (self-identification as black, age ≥18 years, self-reported diagnosis of hypertension, and uncontrolled BP [BP ≥140/90 or ≥130/80 mm Hg with diabetes mellitus or chronic kidney disease]) from 32 New York City churches. The MINT-TLC intervention plus motivational interviewing treatment comprised 11 weekly group sessions on TLC plus 3 MINT sessions delivered monthly by lay health advisors. The HE control group received 1 TLC session plus 10 sessions on health topics delivered by local experts. The outcomes were BP reduction at 6 months (primary) and BP control and BP reduction at 9 months (secondary). The sample mean age was 63 years; 76% women, with mean BP of 153/87 mm Hg. Using linear mixed-effects regression models, the MINT-TLC intervention plus motivational interviewing group had a significantly greater systolic BP reduction of 5.79 mm Hg compared with the HE group at 6 months (P=0.029). The treatment effect on systolic BP persisted at 9 months but had reduced significance (5.21 mm Hg; P=0.068). The between-group differences in diastolic BP reduction (0.41 mm Hg) and mean arterial pressure (2.24 mm Hg) at 6 months were not significant. Although the MINT-TLC intervention plus motivational interviewing group had greater BP control than the HE group at 9 months, the difference was not statistically significant (57.0% versus 48.8%; odds ratio, 1.43; 95% CI, 0.90–2.28).

CONCLUSIONS: A community-based lifestyle intervention delivered in churches led to significantly greater reduction in systolic BP in hypertensive blacks compared with HE alone.

CLINICAL TRIAL REGISTRATION: URL: https://www.clinicaltrials.gov. Unique identifier: NCT01065831.

Key Words: African Americans ■ blood pressure ■ faith-based organizations

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WHAT IS KNOWN

- Therapeutic lifestyle change is a recommended treatment for patients with hypertension.
- Churches are an influential institution for health promotion.

WHAT THE STUDY ADDS

- A cluster-randomized intervention of motivational interviewing plus therapeutic lifestyle changes was successfully implemented in 32 black churches in New York City.
- This motivational interviewing plus therapeutic lifestyle change intervention resulted in significant reductions in systolic blood pressure during 6 months in the treatment group compared with usual health education.
- To our knowledge, this is the first community-based program to implement a lifestyle intervention for systolic blood pressure reduction, delivered by lay health workers in churches.

Recommendation of therapeutic lifestyle changes (TLC) is a recommended treatment for patients with hypertension. Despite compelling evidence of the beneficial effects of TLC on blood pressure (BP) reduction,[1,2] its effectiveness in community-based settings remains untested, particularly in black churches.[3–5] Churches are an influential institution for health promotion in black communities and often provide resources to underserved individuals who do not have access to traditional health promotion and prevention services.[4,6,7] This makes churches a valuable channel for delivery of evidence-based programs, with many advantages for undertaking behavior change programs.[8] Translation of evidence-based practice, such as TLC, to community-based settings is crucial for the successful reduction of the racial disparities in hypertension-related outcomes between blacks and whites. A number of faith-based studies have successfully trained church members as lay health advisors (LHAs) to deliver health information and counseling (eg, motivational interviewing) in black churches.[9–16] Although several studies have evaluated the effect of church-based lifestyle interventions on BP reduction,[14,17,18] their findings are hindered by serious methodologic limitations including the lack of a control group; lack of rigorous assessment of BP outcomes; and limitation of church participation to the recruitment phase of the studies, making sustainability a problem.[14,17–22]

In this article, we report the results of the FAITH trial (Faith-Based Approaches in the Treatment of Hypertension) that evaluated the comparative effectiveness of a faith-based TLC intervention plus motivational interviewing (MINT-TLC) delivered by LHAs versus a health education (HE) control, on BP reduction in hypertensive blacks.

METHODS

The data, analytic methods, and study materials will be available on request to the corresponding author for purposes of reproducing the results or replicating the procedure.

Design Overview

FAITH was a 2-arm cluster randomized controlled trial, in which we tested the hypothesis that participants in the churches randomized to the MINT-TLC group would have greater mean arterial pressure (MAP), systolic BP (SBP), and diastolic BP (DBP) reduction at 6 months (primary outcome) and greater BP control at 9 months (secondary outcome) than those in churches randomized to the HE group.

Setting and Study Population

This study was conducted in 32 New York City churches, whose members were predominantly of African descent. The study protocol has been published elsewhere.[23] Briefly, eligibility criteria included self-identification as black, age ≥18 years, self-report of a diagnosis of hypertension, and uncontrolled BP (BP ≥140/90 or ≥130/80 mm Hg for those with diabetes mellitus or chronic kidney disease) as measured by a validated automated BP monitor. The Institutional Review Board of the New York University approved the study, and all participants provided informed consent. The trial is registered at https://www.clinicaltrials.gov: NCT01065831.

Recruitment and Randomization of Churches

As described elsewhere,[23] churches were recruited in 8 cohorts of 4 churches per cohort; and study participants were recruited from the churches after worship services and planned church events. Churches were recruited by referrals from other churches and community organizations, study staff's existing partnerships, and neighborhood outreach. Trained research assistants obtained informed consent, measured participants' BP, and scheduled them for baseline data collection once eligibility was confirmed. Randomization of the churches occurred after completion of all baseline assessments, and the study statistician randomly assigned each church to either the MINT-TLC or HE group based on a 1:1 ratio, using an online random number generator. Using a 4 church block, we assigned 2 churches to intervention and 2 churches to control in each randomization block. Study personnel were blinded to church randomization status until the end of the 3-week recruitment period. Study recruitment ran from 2010 to 2014 and was concluded after recruitment of all 32 churches. Potential participants were identified through the following methods: responses to informational presentations at churches, posting of study flyers within the church, face-to-face recruitment at the church by the study staff, pastor endorsement from the pulpit, or through church health ministries.

Description of the Intervention and Control Groups

MINT-TLC Intervention

The faith-based MINT-TLC consisted of 11 90-minute weekly group sessions (intensive phase) focused on adoption of healthy lifestyle behaviors (ie, intake of a low-fat, low-sodium diet, rich in fruit and vegetables; increasing physical activity; and weight loss), strategies for meal planning, stress management, medication adherence, structured goal setting, and tastings of healthy foods.[23] Participants were given and encouraged to keep a food and activity diary to promote self-monitoring of healthy lifestyle behaviors. The curriculum was tailored to church members by including elements of prayer, scripture, and faith-based discussion points related to health. The group sessions were followed by 3 individual motivational interviewing (Motivational Interviewing Network of Trainers [MINT]) monthly sessions (maintenance phase) that were designed to help participants focus on problem solving and maintaining lifestyle changes adopted during the intensive phase. The methodology, structure, and the content of the group sessions were adapted from PREMIER[24,25] and the Healthy Eating and Lifestyle Program trials.[26] The MINT sessions were patterned after our published practice-based trial in hypertensive black patients.[27] We recruited 3 to 4 members at each church to serve as LHAs and trained them to deliver the intervention. Briefly, LHAs from each intervention church attended a 2-day training before the start of the group sessions that included a thorough review of the curriculum, skill-building exercises for group facilitation techniques, role-plays, and interactive activities to facilitate learning. LHAs also participated in weekly debrief calls and monthly booster sessions, where they discussed their progress and any difficulties they are having with the study staff and leaders from other churches. In addition to the group session trainings, LHAs attended a 2-day training with a member of the MINT to learn basic MINT skills through role-plays and feedback. Additional details about LHA training can be found in the FAITH trial design.[23] Church leadership at the participating churches assisted the study staff in recruiting active members of the church who possessed a high school degree, were able to deliver the program, and could commit to the study requirements to serve as LHAs for the trial. The study staff partnered with LHAs to develop a recruitment strategy specific to the LHA church. Additional details of the LHA recruitment and training are reported elsewhere.[23]

HE Control

The HE group was conceived as an attention control group, designed to provide participants with the same amount of contact as the MINT-TLC group. HE group participants received 1 lifestyle session on hypertension management plus 10 informational sessions on HE topics that were led weekly by health experts. The lifestyle session on hypertension management (delivered by the authors G.O. and K.J.L.) focused on recommended lifestyle behaviors and drug management of hypertension. Participants also received the National Institute of Health booklet "Your Guide to Lowering Blood Pressure"—a well-established manual on management of hypertension specifically designed for laypeople. The remaining 10 sessions were led by health experts recruited from nonprofit health organizations, the department of health, and academic institutions. These sessions focused on health topics unrelated to hypertension, such as Alzheimer disease, fire safety, substance abuse, and environmental health. Additional information about the curriculum for both HE and MINT-TLC is outlined in Table I in the Data Supplement.

Measurements and Study Outcomes

The primary outcome was change in BP (MAP, SBP, and DBP) from baseline to 6 months; the secondary outcome was BP control at 9 months. MAP is a linear combination of SBP and DBP defined by the following equation: (SBP+2×[DBP])/3. Trained research assistants measured all outcomes at baseline, 3, 6, and 9 months post-randomization. BP was assessed with a validated automated BP monitor (BpTRU, model BPM-300; VSM Medtech), following American Heart Association guidelines.[28] For this purpose, 6 BP readings were taken with the participant seated comfortably for 5 minutes before each measurement. The first reading was discarded, and an average of the remaining 5 BP readings was used as the measurement for each study visit. BP control was defined as mean BP <140/90 mm Hg (or mean BP <130/80 mm Hg for those with diabetes mellitus or kidney disease).

Statistical Analysis

Power

The church was the unit of randomization with participants nested within churches. We estimated a moderate to large (d=0.50–0.80) effect size, with 15 to 20 participants per church (cluster size) and an intraclass correlation of 0.02 and 0.05. We set the α-level at 0.05 (2 tailed) and the desired power at 0.90 to obtain the estimates of the total number of churches needed for the study. Based on these assumptions, we aimed to recruit 20 churches (10 per arm) with 20 participants per church, for a total of 400 participants. During the early phase of the trial, when recruitment did not reach the desired 20 participants per church, we revised our goals to recruit 32 churches with 10 to 11 participants per church. As a result, our statistical power increased to ≈0.99 with a final sample size of 373 participants. Power calculations were generated using sample size calculator from the University of Aberdeen.[29] Means and frequencies for participant characteristics were reported for the total sample and for treatment and control groups. Comparisons of participant characteristics between groups were calculated using linear and logistic mixed-effects regression models controlling for participant nesting within church.

Primary Analyses

For the primary hypothesis, we examined whether participants in the MINT-TLC group would have a greater BP reduction (MAP, SBP, and DBP) than those in the HE group using a linear mixed-effects regression analysis with a multilevel error structure (an autoregressive covariance matrix across the 3 measurement points for the nesting of time within persons) and variance components covariance matrix to control for the nesting of people within site (churches). A random intercept was specified for church membership, controlling for the effect of participant clustering within

church. This analysis had 1 within-person factor (time coded in months), 1 between-persons factor (MINT-TLC group versus HE group), and the interaction term between treatment group and time. Participants were nested within churches creating a 3-level analytic model (observations nested within participants nested within churches). We used multilevel modeling software (SAS, version 9; PROC MIXED)[30] to compute full-information maximum likelihood estimates of the model parameters. Using primary intent-to-treat analysis, we analyzed data from all participants who were randomized, including those lost to follow-up using maximum likelihood estimation.[31,32] Randomization of churches to the treatment arm and the absence of significant selection or attrition biases obviated the need for any covariates in the analysis.

A sensitivity analysis was also conducted to examine the primary outcome of BP reduction over time in the sample with complete data at each time point. Estimated means and CIs for treatment and control were generated at each time point using mixed-effects regressions controlling for participant nesting within church. This yielded estimates for MAP, SBP, and DBP at baseline, 3 months, and 6 months and a complete case estimate for treatment effect over time.

Secondary Analyses

For the secondary hypotheses, we examined whether participants in the MINT-TLC group would exhibit greater BP control and lower levels of MAP, SBP, and DBP at 9 months (3 months after the completion of the intervention) than those in the HE group. Treatment effects on 9-month BP control were examined using logistic regression. Missing values were estimated using multiple imputation with full conditional specification based on participants' previous BP values, as well as treatment group, age, and sex. The percentage of participants with BP control and the odds of attaining BP control are reported for both observed and intent-to-treat analyses. BP control at 9 months was defined as SBP <140 and DBP <90 mm Hg. Additional intent-to-treat analyses were run utilizing measurements of MAP, SBP, and DBP at baseline, 3, 6, and 9 months, to examine whether treatment effects for BP reduction were maintained at the 9-month follow-up. These models were also run as linear mixed-effects regressions using a multilevel error structure (diagonal or unstructured covariance matrices across the 3 measurement points for the nesting of time within persons) and variance components covariance matrix to control for the nesting of people within site (churches) with full-information maximum likelihood estimation. Treatment effects from baseline to 9 months were reported for MAP, SBP, and DBP.

RESULTS

Of the total 373 participants, 172 were assigned to the MINT-TLC group, and 201 were assigned to the HE group. The Figure shows the Consolidated Standards of Reporting Trials diagram of participant recruitment and follow-up. Baseline characteristics of the 373 participants are shown in Table 1. The majority of the participants were older (mean=63.7 years), were women (76%), had a high school education or greater (81%), were unemployed/retired (56%), and were insured (86%). Mean baseline BP was similar for both groups in terms of MAP (109.4 versus 107.6 mm Hg; *P*=0.22), SBP (153.9 versus 151.2 mm Hg; *P*=0.14), and DBP (87.2 versus 85.8 mm Hg; *P*=0.47). Other participant characteristics were also similar (Table 1). Characteristics of the participating churches can be found in Table 2. Eighteen of the churches had predominantly African American participants (56.3%), 10 were predominantly Caribbean (31.3%), and 4 were African (12.5%). There were no significant differences between churches by study condition.

Average attendance at the MINT-TLC group sessions was 58%, whereas 46% of MINT-TLC participants completed all 3 of the monthly individual telephone-based MINT sessions, 57% completed 2 sessions, and 62% completed 1 session (mean attendance was 55%). Average attendance of the group sessions and classes for the HE group was 56%.

Of the 373 participants enrolled, 29.0% did not have complete data at 6 months (29.7% in the MINT-TLC group and 27.4% in the HE group). Comparisons of baseline characteristics between the sample with 6-month data and those without data show that they did not differ in terms of antihypertensive medication use. The sample without data at 6 months was younger, less likely to be women, more likely to have obese BMI, more likely to be employed, and had higher baseline DBP compared with individuals who had complete data at 6 months. For more information, see Table II in the Data Supplement.

Effect of MINT-TLC Versus HE on BP Reduction at 6 Months (Primary Outcome)

All churches randomized into the trial completed the study. Of the 373 participants enrolled, 71% had complete data for the primary outcome at 6 months. Table 3 provides complete results of observed and intent-to-treat BP data for both groups at baseline, 3 months, and 6 months. MAP dropped significantly during 6 months for both the MINT-TLC (–10.08 mm Hg; 95% CI, –15.64 to –4.52) and HE groups (–7.83 mm Hg; 95% CI, –10.08 to –5.59). However, the treatment by time interaction on MAP was not significant between the MINT-TLC and HE groups (–2.24 mm Hg; 95% CI, –5.57 to 1.08). Both groups had a significant reduction in systolic BP from baseline to 6 months. There was a significant treatment by time interaction with a greater SBP reduction in the MINT-TLC group (–16.53 mm Hg; 95% CI, –25.24 to –7.83) than in the HE group (–10.74 mm Hg; 95% CI, –14.25 to –7.24) and a significant between-group difference of –5.79 mm Hg (*P*=0.029; 95% CI, –10.99 to –0.59). With respect to DBP, both

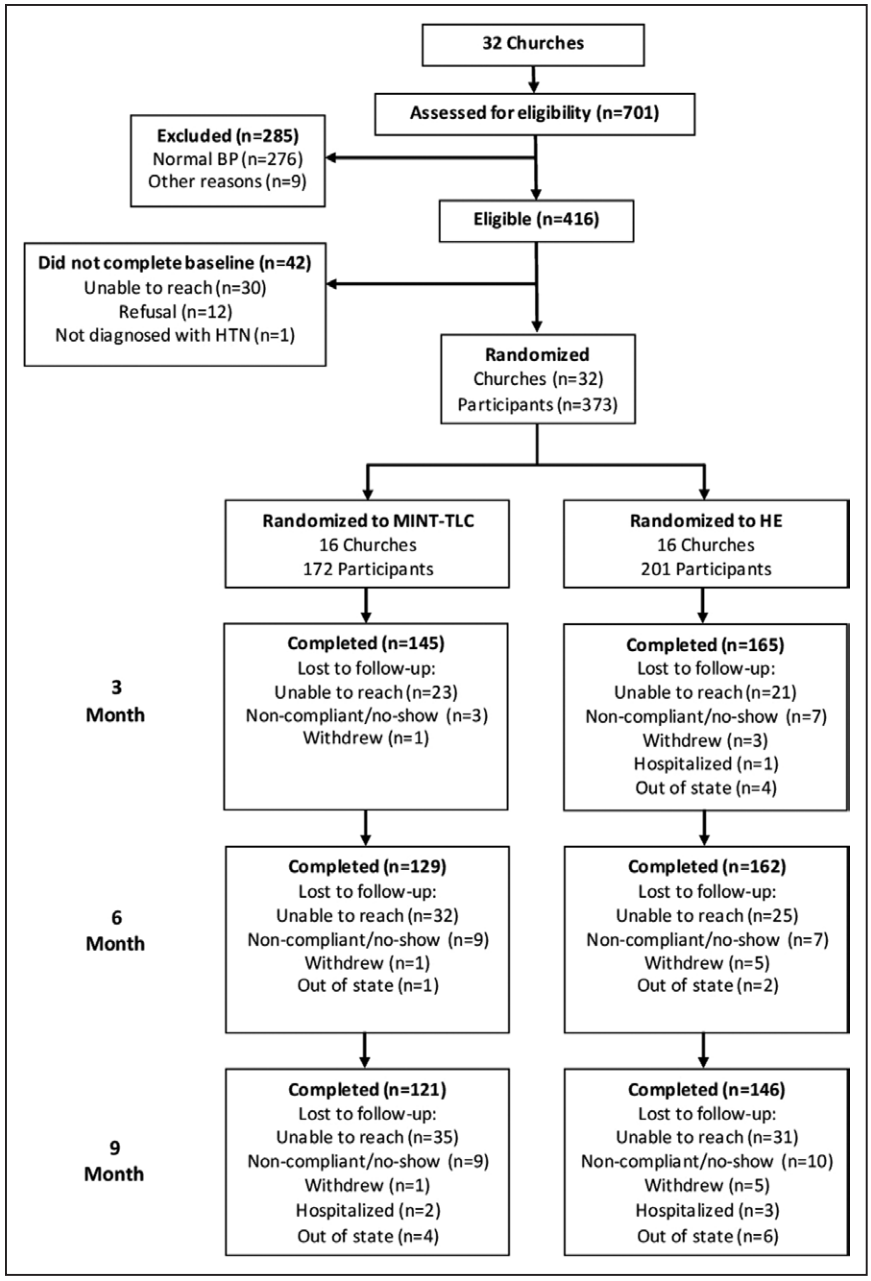

Figure. Consolidated Standards of Reporting Trials diagram for patient flow (FAITH trial [Faith-Based Approaches in the Treatment of Hypertension]).
BP indicates blood pressure; HE, health education; and MINT-TLC, therapeutic lifestyle change intervention plus motivational interviewing.

groups demonstrated significant reduction from baseline to 6 months. The between group difference in the treatment by time interaction was not significant for DBP (–0.41 mm Hg; 95% CI, –3.22 to 2.40).

To assess the impact of missing data on our results, we conducted additional analyses on only participants with complete data, and the results were essentially the same as the intent-to-treat primary analyses. In the complete case analysis of MAP, the treatment by time interaction for MINT-TLC versus HE 6 months of 2.1 mm Hg was not statistically significant (P=0.20). For the SBP analysis, the estimated between-group difference in SBP during 6 months was 5.6 mm Hg (compared with 5.8 mm Hg in the intent-to-treat analyses), and the time×treatment interaction was significant for 6 months (P=0.042). For DBP, the additional estimated drop during the 6-month period in the MINT-TLC group was negligible (0.03 mm Hg) and not statistically significant (P=0.82).

Effect of MINT-TLC Versus HE on BP Control and MAP, SBP, and DBP Levels at 9 Months (Secondary Outcome)

Of the 373 participants enrolled, 72% had complete data for the secondary outcome of BP control at 9 months. We examined BP control at 9 months using mixed-effects logistic regression controlling for nesting of participants within church. Missing values of 9-month BP control were calculated using multiple imputation. These values were used to classify all 373

Table 1. Baseline Participant Characteristics by Treatment Group

Characteristics	Total (N=373)	MINT-TLC (n=172)	HE (n=201)	*P* Value
Age, y; mean (SD)	63.7 (12.0)	63.2 (11.8)	64.1 (12.1)	0.964
Sex, n (%)				
Women	280 (75.5)	130 (75.6)	150 (75.4)	0.771
Body mass index, n (%)				0.889
Underweight (<18.5 kg/m^2)	4 (1.2)	2 (1.3)	2 (1.1)	
Normal (18.5–24.9 kg/m^2)	44 (12.8)	18 (11.5)	26 (14.0)	
Overweight (25.0–29.9 kg/m^2)	99 (28.9)	466 (29.3)	53 (28.5)	
Obese (>30 kg/m^2)	196 (57.1)	91 (58.0)	105 (56.5)	
Marital status, n (%)				0.130
Separated/ divorced/widowed	138 (38.4)	58 (34.5)	80 (41.9)	
Married/living as married	125 (34.8)	58 (34.5)	67 (35.1)	
Never married	96 (26.7)	52 (31.0)	44 (23.0)	
Education level, n (%)				0.999
No schooling	2 (0.6)	0 (0.0)	2 (1.1)	
Elementary	67 (18.8)	31 (18.5)	36 (19.0)	
High school	184 (51.5)	94 (56.0)	90 (47.6)	
College	104 (29.1)	43 (25.6)	61 (32.3)	
Employment status, n (%)				
Employed	156 (43.8)	74 (44.3)	82 (43.4)	0.994
Insurance status, n (%)				
Insured	319 (85.5)	146 (84.9)	173 (86.1)	0.835
Income, n (%)				
Household income <$20 000 per y	113 (34.2)	51 (34.0)	62 (34.4)	0.999
Smoking, n (%)				
Current cigarette smokers	79 (21.9)	36 (21.4)	43 (22.4)	0.886
Physical activity per week, n (%)				0.924
Low	130 (35.9)	59 (35.3)	71 (36.4)	
Moderate	127 (35.1)	61 (36.5)	66 (33.8)	
High	105 (29.0)	47 (28.1)	58 (29.7)	
BP, mean (SD)				
Systolic, mm Hg	152.5 (18.6)	153.9 (18.0)	151.2 (18.2)	0.143
Diastolic, mm Hg	86.5 (18.0)	87.2 (17.5)	85.8 (18.5)	0.468
MAP	108.5 (14.9)	109.4 (14.4)	107.6 (14.9)	0.223
BP medication, n (%)				0.356
0 antihypertensive medication	21 (7.3)	10 (7.2)	11 (7.3)	
1 antihypertensive medication	179 (62.2)	93 (67.4)	86 (57.3)	
2 antihypertensive medications	61 (21.2)	25 (18.1)	36 (24.0)	
≥3 antihypertensive medications	27 (9.4)	10 (7.2)	17 (11.4)	
Diabetes mellitus status, n (%)				
Self-reported diabetes mellitus	125 (34.7)	56 (33.3)	69 (35.9)	0.605

(*Continued*)

Table 1. Baseline Participant Characteristics by Treatment Group

BP indicates blood pressure; HE, health education; MAP, mean arterial pressure; and MINT-TLC, therapeutic lifestyle change intervention plus motivational interviewing.

participants as having controlled or uncontrolled BP at 6 months. Although both groups achieved significant improvement in BP control at 9 months (57.0% in the MINT-TLC group versus 48.8% in the HE group), there were no significant differences between both groups (odds ratio, 1.43; 95% CI, 0.90–2.28).

The linear regression using 9-month levels of MAP did not show a significant treatment by time interaction (2.81 mm Hg; 95% CI, −5.71 to 0.09). Examinations of 9-month SBP showed that both the MINT-TLC (−18.2 mm Hg; 95% CI, −27.6 to −8.8) and HE groups (−13.0 mm Hg; 95% CI, −16.8 to −9.2 mm Hg) continued to have significant reductions in BP from baseline to 9 months. The linear mixed-effects regression analysis including 9-month levels of SBP showed an estimated between group difference of −5.21 mm Hg (*P*=0.068; 95% CI, −10.80 to 0.39) between the MINT-TLC and HE groups. This indicates that although reductions in SBP were sustained at 9 months, the difference between groups was smaller at follow-up. The treatment by time interaction remained nonsignificant for 9-month levels of DBP (−1.13 mm Hg; 95% CI, −3.54 to 1.29).

DISCUSSION

In this study, we demonstrated that a comprehensive faith-based lifestyle intervention plus motivational interviewing, led by LHAs in churches, was associated with significantly greater reduction in SBP at 6 months, when compared with HE among blacks with uncontrolled hypertension. This effect of the lifestyle intervention on SBP persisted and remained marginally significant at the 9-month follow-up. There was no difference in the comparative effectiveness of the lifestyle intervention on diastolic BP and MAP at 6 months, as well as BP control at 9 months relative to the HE. This lack of a significant treatment effect on diastolic BP is not entirely surprising given the low baseline DBP of the sample (86.5 mm Hg) and the high prevalence of isolated systolic hypertension at baseline (n=184; 49.3%). Given this, it is possible that floor effects prevented the

Table 2. Characteristics of Participating Churches by Treatment Group

	Total (N=32)	MINT-TLC (n=16)	Control (n=16)
% Black, mean (SD)	94.8 (6.0)	95.8 (5.9)	93.8 (6.1)
Predominant ethnicity, n (%)			
African American	18 (56.3)	10 (62.5)	8 (50.0)
West Indian	10 (31.3)	5 (31.3)	5 (31.3)
African immigrant	4 (12.5)	1 (6.3)	3 (18.8)
Denomination, n (%)			
African Methodist Episcopal	2 (6.3)	1 (6.3)	1 (6.3)
Baptist	12 (37.5)	6 (37.5)	6 (37.5)
Catholic	1 (3.1)	1 (6.3)	0 (0.0)
Pentecostal	5 (15.6)	3 (18.8)	2 (12.5)
Presbyterian	1 (3.1)	0 (0.0)	1 (6.3)
Seventh-day Adventist	7 (21.9)	3 (18.8)	4 (25.0)
Other	4 (12.5)	2 (12.5)	2 (12.5)
No. of members, mean (SD)	1249 (1768)	718 (825)	1780 (2274)
Average Sabbath attendance, mean (SD)	567 (615)	445 (365)	681 (777)
Have a health ministry, n (%)	30 (93.8)	15 (93.8)	15 (93.8)

MINT-TLC indicates therapeutic lifestyle change intervention plus motivational interviewing.

MINT-TLC intervention from significantly reducing DBP during 6 months. Another possible reason for the lack of a treatment effect on DBP is that the sample without data at 6 months had higher baseline DBP than the sample with complete 6-month data (Table II in the Data Supplement). There was also no treatment effect of MINT-TLC on MAP. This is also not surprising given the nonsignificant effect of MINT-TLC on DBP because the equation used to calculate MAP places greater weight on changes in DBP than SBP.

Although there is evidence that leveraging the influence of cultural institutions, such as the black church, can increase the salience of health messages for cardiovascular risk reduction among blacks[33] to our knowledge, few studies have evaluated the comparative effectiveness of this strategy versus HE in improving hypertension control in black churches. For example, in a recent systematic review of 27 obesity-related lifestyle interventions conducted in black churches,[34] 12 studies utilized LHAs to deliver the entire intervention. Only 2 of these studies measured the impact of the lifestyle intervention on BP reduction.[20,35] Both studies had significant methodologic flaws, including use of a pre-post design, short duration of intervention, small sample sizes, primary focus on outcomes other than BP, and most importantly, none of these studies used a randomized controlled trial design, making it difficult to evaluate the true effect of lifestyle interventions on BP reduction in these settings.[20,35] To our knowledge, FAITH is the first and largest community-based cluster randomized trial of lifestyle intervention to rigorously evaluate the effectiveness of a comprehensive lifestyle intervention on BP reduction among blacks with uncontrolled hypertension in black churches. Although we are aware that other RCTs of lifestyle intervention among blacks with hypertension are currently ongoing,[36] the primary results of these studies have not been published yet and as such, we cannot comment on their relative effect on BP reduction.

The magnitude of the systolic BP reduction reported in previous studies[14,17,18] were relatively smaller than the effect we observed in FAITH, where we demonstrated a net reduction of 5.8 mm Hg in SBP reduction in the MINT-TLC group. At 9-month follow-up (3 months after the completion of the intervention), this treatment effect was reduced to 5.2 mm Hg. Such net reduction in SBP, if sustained for 1 year, has been associated with significant reduction in cardiovascular events. For example, using data from the Atherosclerosis Risk in Communities study, investigators found that a 1-mm Hg reduction in SBP is associated with 20 and 13 fewer heart failure events per 100 000 person years in blacks and whites, respectively.[37] A recent systematic review of 123 large-scale BP-lowering trials among 613 815 participants showed that every 10 mm Hg reduction in SBP significantly reduced the risk of major cardiovascular disease events by 20%, coronary heart disease by 17%, stroke by 27%, and heart failure by 28%.[38] The comparatively larger effect we noted in our study was probably because of several reasons in addition to the internal validity of the FAITH trial. First, in contrast to previous church-based lifestyle interventions, which were based only on group classes,[14,17–20,39–42] FAITH combined delivery of group sessions with individual motivational interviewing counseling sessions that reinforced maintenance of lifestyle behavior change. Second, the interventions in FAITH were delivered by trained LHAs from the same churches, who also served as recruitment portals for the trial; thus assuring feasibility and implementation of the intervention. Other strengths of the FAITH trial include rigorous measurement of the primary outcome in addition to the RCT design we used. Finally, the FAITH intervention had comparable rates of session attendance to other community-based lifestyle trials.[26,43]

The policy implications of our findings are important because, increasingly, the use of community health workers or LHAs have been proposed as an effective vehicle for implementation of evidence-based public health practices in community-based settings given their relatively low cost and potential for sustainability.[44] According to the Centers for Disease Control, evidence-based interventions led by community health workers are associated with effective communication of health messages in culturally salient ways.[45] A recent analysis by Dodani et al[36] showed that lay health educators are dependable partners in implementation of community-

Table 3. Intent-to-Treat and Complete Case Mean SBP and DBP and MAP in the HE and MINT-TLC Groups

	Mean BP, mm Hg			Mean Difference From Baseline		Effect Size, mm Hg	
	Baseline	3 mo	6 mo	3 mo	6 mo	Baseline to 3 mo	Baseline to 6 mo
MAP (intent-to-treat)							
MINT-TLC	109.6 (104.2 to 114.9)	104.5 (96.4 to 112.7)	99.5 (88.6 to 110.4)	−5.0 (−7.8 to −2.3)	−10.1 (−15.6 to −4.5)	−1.1 (−2.8 to 0.5)	−2.2 (−5.6 to 1.1)
HE	107.8 (105.6 to 109.9)	103.8 (100.5 to 107.2)	99.9 (95.5 to 104.5)	−3.9 (−5.0 to −2.8)	−7.8 (−10.1 to −5.6)	…	…
MAP (complete case)*							
MINT-TLC	109.4 (104.3 to 114.5)	100.9 (94.5 to 107.4)	100.0 (92.9 to 107.2)	−8.5 (−9.9 to −7.1)	−9.4 (−11.4 to −7.4)	−1.3 (−4.5 to 1.8)	−2.1 (−5.1 to 1.0)
HE	107.6 (105.5 to 109.6)	100.4 (97.7 to 103.1)	100.2 (97.3 to 103.1)	−7.2 (−7.8 to −6.6)	−7.3 (−8.2 to −6.5)	…	…
SBP (intent-to-treat)							
MINT-TLC	153.8 (147.5 to 160.0)	145.5 (134.9 to 156.1)	137.2 (122.3 to 152.2)	−8.3 (−12.6 to −3.9)	−16.5 (−25.2 to −7.8)	−2.9 (−5.5 to −0.3)	−5.8 (−11.0 to −0.6)
HE	151.0 (148.5 to 153.6)	145.6 (141.4 to 149.9)	140.3 (134.2 to 146.3)	−5.4 (−7.1 to −3.6)	−10.7 (−14.3 to −7.2)	…	…
SBP (complete case)*							
MINT-TLC	153.9 (147.7 to 160.2)	140.7 (133.1 to 148.4)	139.3 (128.5 to 150.1)	−13.2 (−14.6 to −11.8)	−14.6 (−19.1 to −10.1)	−3.1 (−8.3 to 2.2)	−5.6 (−11.0 to −0.2)
HE	151.2 (148.6 to 153.7)	141.0 (137.9 to 144.2)	142.1 (137.7 to 146.5)	−10.1 (−10.7 to −9.5)	−9.1 (−10.9 to −7.2)	…	…
DBP (intent-to-treat)							
MINT-TLC	87.3 (80.9 to 93.7)	84.0 (75.3 to 92.8)	80.7 (69.6 to 91.8)	−3.3 (−5.7 to −1.0)	−6.6 (−11.3 to −1.9)	−0.2 (−1.6 to 1.2)	−0.4 (−3.2 to 2.4)
HE	86.0 (83.4 to 88.7)	82.9 (79.3 to 86.5)	79.8 (75.3 to 84.3)	−3.1 (−4.1 to −2.2)	−6.2 (−8.1 to −4.3)	…	…
DBP (complete case)*							
MINT-TLC	87.2 (80.9 to 93.5)	81.1 (74.2 to 87.9)	80.4 (73.5 to 87.4)	−6.1 (−6.7 to −5.6)	−6.8 (−7.4 to −6.1)	−0.5 (−3.0 to 2.0)	−0.3 (−2.8 to 2.2)
HE	85.8 (83.2 to 88.4)	80.1 (77.2 to 82.9)	79.4 (76.5 to 82.2)	−5.7 (−6.0 to −5.5)	−6.4 (−6.7 to −6.2)	…	…
MINT-TLC sample size*	n=172	n=142	n=118				
HE sample size*	n=201	n=152	n=147				

Intent-to-treat means, differences, effect sizes, and CIs were generated using linear mixed-effects repeated-measures regression with a random intercept for clustering within church and full information maximum likelihood estimation. DBP indicates diastolic blood pressure; HE, health education; MAP, mean arterial pressure; MINT-TLC, therapeutic lifestyle change intervention plus motivational interviewing; and SBP, systolic blood pressure.

*Observed means, differences, effect sizes, and CIs for MAP, SBP, and DBP were calculated using complete data at baseline, 3 mo, and 6 mo. Sample sizes with complete data for MINT-TLC and HE groups are shown for each time point. Participant nesting was controlled for by specifying a random intercept for clustering within church.

based hypertension control programs, such as FAITH. Thus, if our LHA-led approach in the FAITH trial is widely adopted, it will have significant public health impact on the reduction of the racial disparities in uncontrolled hypertension between blacks and whites.

We should note the following limitations of our study. First, the duration of the trial was only 6 months, making it difficult to evaluate its long-term impact. The reduced treatment effect of MINT-TLC on SBP at 9 months relative to the HE control is a major issue for many lifestyle interventions.[46] In our study, a lack of relapse prevention strategies (eg, effective coping strategies for relapse triggers) in our MINT-TLC curriculum to support participants' newly adopted lifestyle changes may partially explain the reduced treatment effects once the intervention ended.[46] Future studies should propose much stronger maintenance sessions to sustain the gains made during the intensive phase of the lifestyle intervention. In our study, we provided only individual monthly sessions. Second, the LHAs were paid for their time, which makes program sustainability difficult to evaluate beyond the end of the trial. Third, we experienced a 30% attrition rate during the course of the trial. This may be related to the intensity of the group sessions and their duration (90 minutes each). Future research should make efforts to prevent attrition in younger participants, men, individuals with obese BMI, and individuals

who are employed. This could be accomplished by oversampling of participants with these characteristics or targeted retention techniques aimed at reducing attrition. Fourth, although our study was able to enroll a greater percentage of male participants than previous faith-based studies,[14,19,21,35] the 3:1 ratio of women to men participating in FAITH reflects the challenges of recruiting black men for hypertension trials and may suggest that these methods may not be particularly engaging for black men. Future studies would benefit from targeted recruitment strategies to engage black men. Fifth, we were unable to collect ongoing data about antihypertensive medication changes in our sample. Although both treatment and control groups had comparable levels of antihypertensive treatment at baseline, we cannot guarantee that differential changes in antihypertensive medication regimens in the MINT-TLC group during the 9 months of measurement may have contributed to our results. However, given the pragmatic nature of this study and its community-based focus, we were unable to systemically collect data on changes in antihypertensive medication use. Finally, our findings may only be generalizable to black churches with similar demographic characteristics (largely low income) as in the FAITH trial. Future implementation of the intervention would require revising the materials for the general population to disseminate it more broadly.

ARTICLE INFORMATION

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