Original Report:
Cardiovascular Disease
and Risk Factors

The FAITH Trial: Baseline Characteristics of a Church-based Trial to Improve Blood Pressure Control in Blacks

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Objective: To describe the baseline characteristics of participants in the Faith-based Approaches in the Treatment of Hypertension (FAITH) Trial.

Design: FAITH evaluates the effectiveness of a faith-based lifestyle intervention vs health education control on blood pressure (BP) reduction among hypertensive Black adults.

Setting, Participants, and Main Measures: Participants included 373 members of 32 Black churches in New York City. Baseline data collected included participant demographic characteristics, clinical measures (eg, blood pressure), behaviors (eg, diet, physical activity), and psychosocial factors (eg, self-efficacy, depressive symptoms).

Results: Participants had a mean age of 63.4 ± 11.9 years and 76% were female. About half completed at least some college (53%), 66% had an income ≥$20,000, and 42.2% were retired or on disability. Participants had a mean systolic and diastolic BP of 152.1 ± 16.8 mm Hg and 86.2 ± 12.2 mm Hg, respectively, and a mean BMI of 32 kg/m^2. Hypertension (HTN) medications were taken by 95% of participants, but most (79.1%) reported non-adherence to their regimen. Participants reported consuming 3.4 ± 2.6 servings of fruits and vegetables and received 30.9% of their energy from fat. About one-third (35.9%) reported a low activity level.

Conclusion: Participants in the FAITH trial exhibited several adverse clinical and behavioral characteristics at baseline. Future analyses will evaluate the effectiveness of the faith-based lifestyle intervention on changes in BP and lifestyle behaviors among hypertensive Black adults. *Ethn Dis*. 2015;25[3]:337-344.

Introduction

The disproportionately higher rate of hypertension (HTN) and related cardiovascular morbidity of Blacks compared with Whites is well-documented.[1] Improvements in blood pressure (BP) control can result in significant reduction in cardiovascular disease risk.[2] Adopting therapeutic lifestyle changes (TLC) such as increasing intake of fruits, vegetables, and low fat dairy foods, decreasing intake of sodium and fat, losing weight, and increasing physical activity has resulted in significant reductions in BP in trials such as PREMIER, DASH, and TONE.[3-5] Despite the proven efficacy of TLC on BP reduction,[3-5] little evidence supports their effectiveness when translated to community settings. This is particularly a concern for Blacks, given their low rate of BP control.[6] Thus, it is important to evaluate the translation and sustainability of efficacious interventions to high-risk populations in community-based settings.

The Faith-based Approaches in the Treatment of Hypertension (FAITH) trial was designed to address this gap in the literature. We conducted the intervention in churches because they have long been a center of Black life and can play a crucial role in the dissemination and translation of health programs in Black communities.[7] The primary aim of FAITH is to evaluate the effectiveness of a faith-based group-counseling TLC plus motivational interviewing (MINT-TLC) intervention delivered by lay health advisors (LHAs) vs an expert-led health education (HE) control on BP reduction at six months among hypertensive Blacks. Secondary aims include testing the effect of MINT-TLC on physical activity, weight, and fruit and vegetable intake at six months; and BP control at nine

Key Words: Hypertension, African Americans, Faith-based, Therapeutic Lifestyle Changes

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months. In this article, we describe the baseline demographic, clinical, psychosocial, and behavioral characteristics of the FAITH participants.

Methods

Participants

Details on the study design have been published elsewhere.[8] Briefly, recruitment occurred at the church and participant levels. Churches were identified through the FAITH team's informal networks, referrals from other churches, and outreach efforts. Church leadership nominated active church members to serve as LHAs. Participants recruited from within the churches were eligible for the study if they: self-identified as Black/African American; were ≥18 years old; had a diagnosis of HTN; and had uncontrolled BP at the time of enrollment (systolic BP [SBP]≥140 mm Hg *or* diastolic BP [DBP]≥90 mm Hg, or SBP≥130 mm Hg *or* DBP≥80 mm Hg for participants with self-reported diabetes or kidney disease). Exclusion criteria included non-English speaking, participation in another study, arm circumference >52 cm, cognitive impairment based on the Comprehensive Assessment and Referral Evaluation Dementia Diagnostic Scale if age ≥60,[9] unwillingness/inability to comply with the protocol, and pregnancy or plans to become pregnant within the next nine months. Figure 1 shows the flow of participants through the study.[10] All participants provided written informed consent approved by the New York University Institutional Review Board.

Despite the proven efficacy of TLC on BP reduction,[3-5] little evidence supports their effectiveness when translated to community settings.

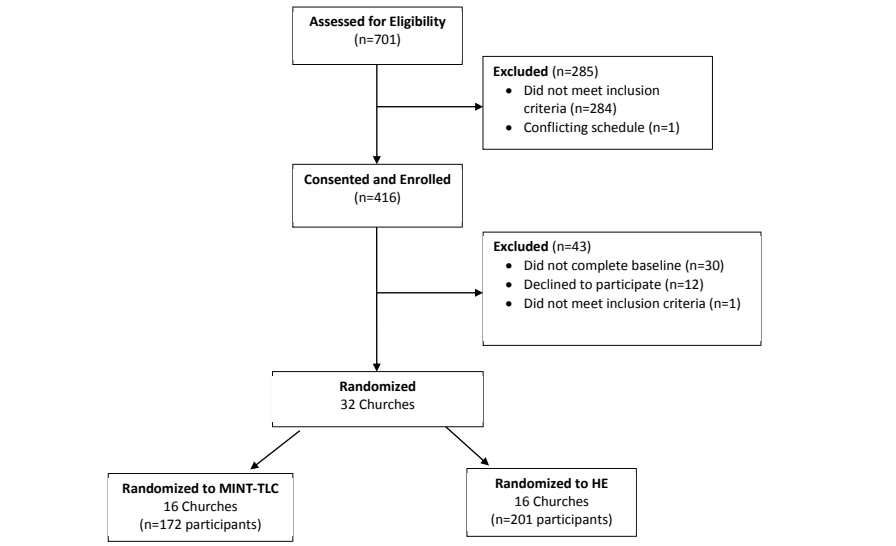

Figure 1. Flow of participants through study

Description of the MINT-TLC Intervention and HE Control Groups

Randomization occurred at the church level; all participants at a given church received the same intervention: MINT-TLC or HE. Churches randomized to the MINT-TLC group received weekly LHA-led group TLC sessions for three months followed by three monthly individual MINT sessions. The HE churches received weekly expert-led group sessions for 11 weeks. The first HE session focused on lifestyle management of HTN and the remaining sessions covered health topics unrelated to HTN. Participants also received the NHLBI booklet *"Your Guide to Lowering Blood Pressure."* In both groups, recruitment was limited to 20 participants per church in order to facilitate interactivity in the group sessions. Additional details on the intervention are described elsewhere.[8]

Measures

At the church level, we collected data on general characteristics including church size, denomination, and existence of a health ministry upon being recruited into the trial. Participants' baseline data collection occurred before church randomization to MINT-TLC or HE. Data collection procedures were standardized across all churches. Trained study staff administered the questionnaires and collected

Table 1. Characteristics of participating churches

	Total *N*=32		Control *n*=16		Intervention *n*=16	
% Black, mean, SD	94.8	6.0	93.8	6.1	95.8	5.9
Predominant ethnicity, *n*, %						
African American	18	56.3	8	50.0	10	62.5
West Indian	10	31.3	5	31.3	5	31.3
African immigrant	4	12.5	3	18.8	1	6.3
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	0	0.0	1	6.3
Pentecostal	5	15.6	2	12.5	3	18.8
Presbyterian	1	3.1	1	6.3	0	0.0
Seventh Day Adventist	7	21.9	4	25.0	3	18.8
Other	4	12.5	2	12.5	2	12.5
Number of members, mean, SD	1249	1768	1780	2274	718	825
Average Sabbath attendance, mean, SD	567	615	681	777	445	365
Have a health ministry, *n*, %	30	93.8	15	93.8	15	93.8

the physiological measurements. The primary outcome (BP) was measured as six BP readings using a validated, automated BP monitor (BpTRU) with the participant seated comfortably for five minutes before measurement, following American Heart Association guidelines.[11] The average of the last five readings served as the BP reading. Mean arterial pressure (MAP) was calculated using the formula: 1/3 x SBP + 2/3 x DBP. Height and weight were measured using standardized procedures and used to calculate body mass index (BMI). Data on participants' prescribed antihypertensive medications were collected via self-report. We used validated instruments to assess self-reported socio-demographic characteristics, dietary intake (NCI fat and fruit/vegetable screeners),[12] self-efficacy and intrinsic motivation for physical activity and fruits/vegetables,[13, 14] medical comorbidity, depressive symptoms (Patient Health Questionnaire (PHQ)-8),[15] health-related quality of life (SF-12),[16] and medication adherence (Morisky Adherence Scale).[17]

Analysis

Summary data on baseline characteristics are expressed as mean ± standard deviation (SD) for continuous variables and percentage for categorical variables. Data are presented for the total population and by treatment group. We used independent samples t-tests, analysis of variance, and crosstabs with a c^2 statistic to compare the MINT-TLC and HE groups. As a clustered trial, we increased the error terms using a Variance Inflation Factor that reflected the degree of dependence in the data for any results that were significant in the conventional analyses. Statistical analyses were conducted using SPSS, version 20.[18] A 2-sided $P<.05$ was considered statistically significant.

Results

Church Characteristics

Thirty-two churches with predominantly Black memberships participated in the trial. The membership of the churches ranged from 105 to 8300 members, with an average of 1249 members (Table 1). The HE control group had more large churches (>500 members; $P=.043$).[19] People of African descent comprised at least 80% of all churches, with an average of 95%. Eighteen of the churches had predominantly African American/Black members, 10 were predominantly West Indian, and four were African. All churches were Christian and all but one was Protestant; the largest number of churches were Baptist ($n=12$). Most churches reported having a health ministry. There were no significant differences between the churches by study condition.

Demographic Characteristics

The mean age of the total sample was 63.4 ± 11.9 years (Table 2). Fifty-nine percent of participants identified as African American and one-third as West Indian (30.9%). The majority of participants were female (76.4%), had some college education (53%), and reported an annual income ≥$20,000 (65.7%). Almost half (42.1%) were retired or on disability and one-third (34.7%) had private insurance. There were no significant between-group differences on demographic characteristics.

Clinical Characteristics

The mean baseline SBP and DBP were 152.1 ± 16.8 and 86.2 ± 12.2 mm Hg, respectively and the MAP was 108 ± 11.6 mmHg (Table 3). Participants had a mean BMI of 32.1 ± 7.1 kg/m^2. One-quarter (26%) of participants were overweight, and an additional 52.5% were obese. While diabetes was the most common co-

Table 2. Baseline demographic characteristics for the overall population and by treatment group

	Total N=373		Control n=201		Intervention n=172		P
Female, *n*, %	272	76.4	146	74.1	126	75.0	.846
Age, mean, SD	63.39	11.9	64.12	12.1	63.21	11.7	.473
Ethnicity, *n*,%							.311
African American	210	59.1	113	58.5	97	59.8	
African	21	5.9	15	7.7	6	3.7	
West Indian	110	30.9	56	29.0	54	33.3	
Other	14	3.9	9	4.6	5	3.1	
Marital status, *n*,%							.091
Single	96	26.7	44	23.0	52	30.9	
Married	125	34.8	67	35.0	58	34.5	
Separated	19	5.2	7	3.6	12	7.1	
Divorced	64	17.8	37	19.3	27	16.0	
Widowed	55	15.3	36	18.8	19	11.3	
Level of education, *n*,%							.696
<High school	69	20.2	38	21.5	31	18.7	
High school diploma/GED	91	26.6	44	25.0	47	28.4	
Some college and above	181	53.0	94	53.4	87	52.7	
Employment status, *n*,%							.362
Employed/self-employed	156	43.5	82	43.1	74	44.0	
Retiree	127	35.4	74	38.9	53	31.5	
On disability	24	6.7	11	5.7	13	7.7	
Unemployed/not working	51	14.2	23	12.1	28	16.6	
Yearly family income, *n*,%							.932
<$20,000	113	34.2	62	34.4	51	34.0	
≥$20,000	217	65.7	118	65.6	99	66.0	
Insurance, *n*,%							.377
Private insurance	111	34.7	65	34.2	46	35.7	
Medicare	83	26.0	52	27.3	31	24.0	
Medicaid	58	18.1	31	16.3	27	20.9	
Military/VA	7	2.1	6	3.1	1	.8	
Other	60	18.8	36	18.9	24	18.6	
None	54	14.5	28	14	26	15	

morbid condition reported by participants (34.7%), half reported having no comorbid conditions (56%). Almost all (94.4%) of the participants reported taking at least one anti-hypertensive medication. There were no significant between-group differences on the clinical characteristics.

Behavioral and Psychosocial Characteristics

Participants reported eating an average of 3.4 ± 2.6 servings of fruits/vegetables per day, and 30.9% of their energy from fat (Table 4). Only 18% of participants consumed ≥5 servings of fruits/vegetables per day. Despite low levels of intake, mean self-efficacy and intrinsic motivation for eating fruits/vegetables was high (mean: 3.17±0.66 [range: 1-4, higher scores=higher self-efficacy] and 5.86±1.07 [range: 1-6, higher scores=higher motivation]), respectively. One-third of participants (35.9%) reported low physical activity levels. Although, on average, participants reported high levels of intrinsic motivation to be physically active (mean: 5.61±1.25), they had lower mean self-efficacy (2.75±0.74). One-third (33.5%) of participants reported the presence of some depressive symptomatology (PHQ score>4). The mean score on the Mental Component Summary of the SF-12 was 46.3±5.7 while the mean score on the Physical Component Summary was 50.0±4.9. Finally, most (79.1%) participants reported non-adherence to their anti-hypertensive medication regimen. Although a few of these characteristics exhibited a trend toward a significant between-group difference, none reached our a priori criteria for statistical significance. Moreover, these trends are reduced if we adjust for clustering in the data and disappear entirely after adjusting for the large number of statistical comparisons reported.

Approximately 80% of participants reported non-adherence to prescribed antihypertensive medications … suggesting that barriers to medication-taking are largely going unaddressed in this community-based setting.

Table 3. Baseline clinical data for the overall population and by treatment group[a]

	Total[a]		Control[a]		Intervention[a]		*P*
Systolic blood pressure	152.1	16.8	150.6	16.7	153.9	16.8	.058
Diastolic blood pressure	86.2	12.2	85.5	11.3	87.1	13.2	.211
Mean arterial pressure	108.1	11.56	106.93	10.79	109.14	12.23	.469
Heart rate	74	13.0	74.4	12.7	73.6	13.4	.337
Weight classification, *n,%*							.638
Under/normal weight	46	12.4	27	13.4	19	11.1	
Overweight	97	26.0	52	25.9	45	26.2	
Obese	196	52.5	105	52.2	91	52.9	
Comorbidity, *n,%*							
Heart attack	10	2.8	5	2.6	5	3.0	.851
Stroke	34	9.4	21	11.0	13	7.7	.285
Diabetes	125	34.7	69	35.9	56	33.3	.822
Kidney disease	12	3.3	6	3.1	6	3.6	.395
Number of conditions, *n,%*							
0 conditions	202	56.0	100	52.1	102	60.4	.128
1-2 conditions	140	38.8	83	43.2	57	43.7	
≥3 conditions	19	5.3	9	4.7	10	5.9	
Smoking status, *n,%*							.395
Never smoked	254	70.6	138	71.9	116	69.1	
Previously smoked	79	21.9	43	22.4	36	21.4	
Currently smokes	27	7.5	11	5.7	16	9.5	
Drinking status, *n,%*							.389
Never drank	140	39.0	79	41.1	61	36.3	
Previously drank	100	27.9	53	27.7	47	30.0	
Currently drinks	119	33.1	59	30.9	60	35.7	
Number of hypertension medications, *n,%*							
0	21	5.6	11	5.5	10	5.8	.16
1	179	48.0	86	42.8	93	54.1	
2	61	16.4	36	17.9	25	14.5	
3	19	5.1	13	6.5	6	3.5	
≥4	8	2.2	4	2.0	4	2.3	

a. Data are mean / SD unless specified otherwise.

Discussion

Therapeutic lifestyle changes are a standard treatment recommendation for hypertensive patients. While the efficacy of TLC on BP control is well-documented, there is little data on their impact on BP reduction in community-based settings, especially in Blacks. The FAITH trial was designed to test the effect of a church-based lifestyle intervention delivered by LHAs on BP reduction in hypertensive Blacks in New York City. Similar to other faith-based trials in hypertensive adults,[20-23] our sample comprised mostly well-educated, retired, and female participants. However, a strength of FAITH was its focus on Black adults with uncontrolled HTN, a population that has a disproportionately greater burden of HTN-related outcomes including heart failure, stroke, and end-stage renal disease.[24] Indeed, baseline clinical data indicated that the majority of participants in the FAITH trial exhibited several adverse risk factors that are precursors for future cardiovascular diseases. Similar to national estimates in Blacks, more than three-quarters of FAITH participants were obese or overweight.[25] Approximately 80% of participants reported non-adherence to prescribed antihypertensive medications, which is considerably higher than the estimate 50% of US adults with HTN who are non-adherent to their medications,[26] suggesting that barriers to medication-taking are largely going unaddressed in this community-based setting.

The behavioral data support our clinical findings. Despite reporting high levels of intrinsic motivation and

Table 4. Baseline psychosocial factors and lifestyle behaviors for the overall population and by treatment group[a]

	Total[a]		Control[a]		Intervention[a]		*P*
N of FV Servings/day	3.4	2.60	3.59	2.6	3.19	2.59	.142
% Energy from fat	30.94	4.36	30.53	3.74	31.42	4.95	.055
Physical activity level, *n*,%							.864
Low	130	35.9	71	36.4	59	35.3	
Moderate	127	35.1	66	33.8	61	36.5	
High	105	29.0	58	29.7	47	28.1	
Intrinsic motivation score[b]							
FV autonomous	5.86	1.07	5.95	0.98	5.74	1.15	.065
FV controlled	2.8	1.90	2.9	1.92	2.69	1.86	.292
PA autonomous	5.61	1.25	5.65	1.27	5.56	1.22	.485
PA controlled	2.87	1.76	2.95	1.82	2.77	1.69	.343
Self-efficacy score[c]							
FV	3.17	0.66	3.2	0.64	3.13	0.69	.278
PA	2.75	0.74	2.76	0.72	2.73	0.77	.704
Depressive symptoms, %[d]							
Score >4	33.5		29.4		38.40		.193
Functional health[e]							
Physical component score	49.95	4.87	49.87	4.67	50.04	5.14	.222
Mental component score	46.27	5.69	45.81	5.61	46.81	5.75	.336
Medication adherence, %[f]							
Perfect adherence	20.9		21.2		20.5		.655

FV, fruit and vegetable intake; PA, physical activity.
a. Data are mean / SD unless specified otherwise.
b. Range: 1-7 (Higher scores=more autonomy).
c. Range: 1-4 (Higher scores=greater self-efficacy).
d. Range 0-24 (Higher scores=more depressive symptoms).
e. Range: 0-100 (Higher scores=better physical/mental functioning).
f. Range: 0-11 (Lower scores=better adherence).

self-efficacy (for fruit/vegetable intake), participants fell well below the daily recommended levels for fruit/vegetable intake and physical activity for American adults.[27,28] According to a 2013 CDC report,[29] US adults eat an average of 2.7 servings of fruit/vegetables per day. This intake is slightly below the average 3.4 fruit/vegetable servings per day reported by FAITH participants. However, these consumption rates are still considerably lower than the AHA recommendation of 8-10 servings per day to help lower BP.[30] Moreover, only 18% of participants met the national guidelines to consume at least five servings of fruits and vegetables daily.[29] These data are in line with previous research, which has shown that while TLC are challenging for most people, levels of adverse lifestyle behaviors are much higher in minorities.[31]

Another noteworthy aspect of FAITH was the inclusion of important psychosocial factors to characterize the potential barriers that could hinder the adoption of healthy lifestyle behaviors for BP control in this high-risk population. One-third of FAITH participants reported experiencing depressive symptomatology within the past two weeks, which has been implicated as a major barrier to behavior change in underserved populations.[31,32] Furthermore, participants reported levels of general mental health functioning that were below the national average for U.S. adults ≥50 years of age.[33]

In contrast to other church-based interventions in Blacks,[20-23,34-36] FAITH recruited an ethnically diverse sample of participants of African descent. Although most studies look at Blacks in the United States as a whole, they are not a monolithic group. Previous studies suggest that Blacks living in the United States but born outside of the United States have lower rates of cardiovascular disease risk and HTN.[37] These groups also have different dietary patterns[37] and may have different challenges and attitudes toward managing their BP. Although little examination of the health status and behaviors of these subpopulations of African descent have been done in

the United States, studies of other immigrant groups have found that these factors deteriorate with acculturation and length of stay in the United States.

Although previous church-based interventions have resulted in significant BP reductions,[20-23,35,38,39] to our knowledge, FAITH is the first trial to rigorously evaluate the effect of a peer-led lifestyle intervention on BP reduction in a cohort of hypertensive Blacks. For example, some of the studies used a pre-post quasi-experimental design, and did not report baseline BP, making it difficult to determine their true impact of the intervention on BP reduction. Similarly, previous trials lacked rigorous assessment of outcomes and treatment fidelity procedures, making replication in other community-based settings difficult. Moreover, the interventions in these studies lacked elements of sustainability, such that the educational components were developed and administered by research staff, and partnership with the churches was limited to the recruitment phase. In contrast, the session content for FAITH was informed by qualitative research with church members, which was then delivered by church members who were trained as LHAs. Moreover, our success in recruiting 32 Black churches and 373 participants was due to our ability to create a *faith-based* program that engaged both the church leadership and members, who in turn, provided the resources needed to implement the intervention. Finally, few studies were theory-based or measured the psychosocial factors that may influence change in BP, hindering an assessment of the mechanisms of the effects of the interventions. However, our findings may only be generalizable to Black churches with similar demographic characteristics. Future implementation of the intervention would require revising the materials for the general population in order to disseminate it more broadly.

Conclusion

Baseline data of participants in the FAITH trial indicate that we were able to recruit a high-risk population with a variety of risk factors associated with future cardiovascular morbidity and mortality. Future analyses of the FAITH trial will determine whether a comprehensive lifestyle intervention, delivered by trained LHAs can effectively reduce BP and adverse lifestyle behaviors among hypertensive Black adults.

Acknowledgements

This study is registered at www.clinicaltrials.gov no. NCT01065831.

The authors would like to thank the FAITH staff Sheldon Watts, PhD, MPH; Jessica Forsyth, PhD; Amanda Hoyte, BS; Lindsey Smith, MPH; Adetutu Adekoya, BA; Yendelela Cuffee, PhD; Rhoena Desir BA; Kourtney Bennett PhD; and Sheyla Richards MD for their work on the project. We also acknowledge Mark Butler and William Chaplin at Saint John's University for their biostatistical support of this project.

This work was supported by grant R01HL092860 from the NIH (PIs: Ogedegbe and Lancaster). The funding organization played no role in the study conception, design, writing of the manuscript, or decision to submit the manuscript for publication. The authors have no conflicts of interest to disclose.

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