Circulation

ORIGINAL RESEARCH ARTICLE

Community-Based, Cluster-Randomized Pilot Trial of a Cardiovascular Mobile Health Intervention: Preliminary Findings of the FAITH! Trial

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BACKGROUND: African Americans continue to have suboptimal cardiovascular health (CVH) based on the American Heart Association Life's Simple 7 (LS7), 7 health-promoting behaviors and biological risk factors (eg, physical activity, blood pressure). Innovative, community-level interventions in partnership with trusted institutions such as African American churches are potential means to improve CVH in this population.

METHODS: Using a community-based participatory research approach, the FAITH! Trial (Fostering African American Improvement in Total Health) rigorously assessed the feasibility and preliminary efficacy of a refined, community-informed, mobile health intervention (FAITH! App) for promoting CVH among African Americans in faith communities using a cluster randomized controlled trial. Participants from 16 churches in Rochester and Minneapolis-St Paul, MN, were randomized to receive the FAITH! App (immediate intervention) or were assigned to a delayed intervention comparator group. The 10-week intervention core features included culturally relevant and LS7-focused education modules, diet/physical activity self-monitoring, and a group sharing board. Data were collected via electronic surveys and health assessments. Primary outcomes were average change in mean LS7 score (continuous measure of CVH ranging from poor to ideal [0–14 points]) from baseline to 6 months post-intervention (using generalized estimating equations) and app engagement/usability (by the Health Information Technology Usability Evaluation Scale; range, 0–5).

RESULTS: Of 85 enrolled participants (randomized to immediate [N=41] and delayed [control] intervention [N=44] groups), 76 and 68 completed surveys/health assessments at baseline and 6 months post-intervention, respectively (80% retention rate with assessments at both baseline and 6-month time points); immediate intervention [N=30] and control [N=38] groups). At baseline, the majority of participants (mean age [SD], 54.2 [12.3] years, 71% female) had <4-year college education level (39/66, 59%) and poor CVH (44% in poor category; mean LS7 score [SD], 6.8 [1.9]). The mean LS7 score of the intervention group increased by 1.9 (SD 1.9) points compared with 0.7 (SD 1.7) point in the control group (both $P<0.0001$) at 6 months. The estimated difference of this increase between the groups was 1.1 (95% CI, 0.6–1.7; $P<0.0001$). App engagement/usability was overall high (100% connection to app; >75% completed weekly diet/physical activity tracking; Health Information Technology Usability Evaluation Scale, mean [SD], 4.2 [0.7]).

CONCLUSIONS: On the basis of preliminary findings, the refined FAITH! App appears to be an efficacious mobile health tool to promote ideal CVH among African Americans.

REGISTRATION: URL: https://www.clinicaltrials.gov; Unique identifier: NCT03777709.

Key Words: African Americans ■ cardiovascular diseases ■ clinical trial ■ community-based participatory research ■ health equity ■ mobile health ■ risk factors

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Clinical Perspective

What Is New?

- In this cluster randomized controlled trial to assess the feasibility and preliminary efficacy of a refined, community-informed, mobile health intervention (FAITH! App) for promoting cardiovascular health (CVH), African Americans had improved CVH as evidenced by increased American Heart Association Life's Simple 7 composite scores.
- Substantial improvements in key CVH behaviors (diet and physical activity) were achieved after engagement with the intervention, which was sustained during a 6-month follow-up period.
- Our study demonstrates the feasibility of implementing a mobile health intervention using a community-based participatory research approach building on a partnership between researchers and African American faith communities.

What Are the Clinical Implications?

- Culturally relevant lifestyle interventions delivered by mobile health tools to comprehensively promote multiple cardiovascular risk factors through the Life's Simple 7 framework can promote ideal CVH among African Americans, thereby advancing CVH equity.

Nonstandard Abbreviations and Acronyms

AHA	American Heart Association
BP	blood pressure
CBPR	community-based participatory research
CVD	cardiovascular disease
CVH	cardiovascular health
FAITH!	Fostering African-American Improvement in Total Health!
Health-ITUES	Health Information Technology Usability Evaluation Scale
LS7	Life's Simple 7
mHealth	mobile health
MSP	Minneapolis–St. Paul
PA	physical activity
PREACH	Predicting Readiness to Engage African American Churches in Health
RCT	randomized controlled trial
SDOH	social determinants of health
SOC	stage or step of change

More than half of all African Americans have some form of cardiovascular disease (CVD) including coronary heart disease, stroke, heart failure, and hypertension.[1] These disparities are even more striking among African American women compared with White women (58.8% versus 42.1%).[1] Disproportionate clustering of uncontrolled cardiovascular risk factors among African Americans compared with Whites such as obesity and diabetes are key drivers of these disparities.[2,3] Further accelerating the higher CVD risk in African Americans are multilevel psychosocial and systemic barriers or adverse social determinants of health (SDOH) such as structural racism, food insecurity, financial hardship, social isolation, and limited access to quality health care/health information, which constrain their ability to prioritize their cardiovascular health (CVH) and overall well-being.[4] Direct and indirect effects from the COVID-19 pandemic unmasked and exacerbated a plethora of pre-existing SDOH and CVH inequities overwhelmingly affecting African Americans.[5]

As a means to address CVD disparities, promote ideal CVH, and monitor progress toward CVD prevention among the US population, the American Heart Association (AHA) created the Life's Simple 7 (LS7) as a foundation of its 2020 Strategic Impact Goal.[6] The LS7 consists of 7 health-promoting behaviors and cardiometabolic risk factors (diet, physical activity [PA], smoking, body mass index, blood pressure [BP], cholesterol, and glucose). Other public and population health initiatives from Healthy People 2020, Million Hearts 2022, and the Association of Black Cardiologists, Inc, are in consensus that these 7 modifiable variables can improve CVH to prevent CVD events, particularly among African Americans.[7–10] In addition to acknowledging the importance of ideal CVH for CVD prevention, the 2019 American College of Cardiology/AHA Guideline on Primary Prevention of CVD included a Class 1 recommendation for SDOH integration into patient-centered approaches to clinical care and prevention.[11] There is growing empirical evidence demonstrating that increasing the number of ideal LS7 factors or higher LS7 scores are associated with a lower likelihood of incident CVD (coronary heart disease, stroke, heart failure, atrial fibrillation) and mortality.[12–14] However, epidemiologic evidence has revealed striking inequities in CVH, with African Americans having significantly fewer ideal LS7 components compared with their White counterparts.[2,15,16] According to Jackson Heart Study data assessing longitudinal CVD risk in African Americans, only 3.2% of the cohort met ≥5 ideal LS7 components, and none met ideal levels for all components.[17] Thus, a paradigm shift in strategies for promoting and improving LS7 profiles in African Americans is imperative to significantly impact CVD disparities within this high CVD risk population.

Given increased attention nationally on CVH equity, effective lifestyle interventions designed to improve CVH metrics among African Americans within the lens of their social, cultural, and environmental contexts are warranted.[7,18] A recent systematic review probed the evidence base for culturally tailored, community-based lifestyle interventions

promoting the AHA LS7.[19] There was a predominance of interventions targeting single cardiovascular risk factors (eg, PA, obesity) instead of the full spectrum of CVH including multiple LS7 components. Despite their potential, many of these interventions lacked sustainability and widespread dissemination within African American communities.[19] Within the review, our community-based participatory research (CBPR)–enhanced intervention in partnership with African American churches was the sole intervention integrating the AHA LS7 framework while assessing all LS7 components as a comprehensive risk-based approach to CVH promotion in African Americans.[20] Another community-based team lifestyle intervention (Black Impact) targeting all LS7 components demonstrated statistically significant improvements in CVH among African American men.[21] There is epidemiologic evidence using prediction models supporting the approach of targeting multiple risk factors, because this has greater potential to substantially reduce CVH disparities (in comparison with single risk factor interventions).[22] Furthermore, given the rapidly increasing use of mobile technologies, particularly smartphones, among minoritized racial and ethnic populations,[23] our intervention incorporated a mobile health (mHealth) component given data showing their adaptability, scalability, and effectiveness in improving cardiovascular risk profiles (eg, hypertension, diabetes).[24] As a means to foster digital health equity[25] and engender trust, we codesigned an innovative CVH and wellness digital application (FAITH! App) with African American community members that demonstrated high acceptability, satisfaction, and significant improvements in multiple LS7 components (diet, PA, BP) within a single group, pilot study of African Americans.[20,26] Participant feedback indicated a need for enhancements to provide individually tailored messaging and interpersonal features.[27]

These results necessitated a more rigorous methodological assessment of the feasibility and preliminary efficacy of a refined, community-informed FAITH! App intervention among African American adults within faith communities using a pilot randomized controlled trial (RCT). We tested a 10-week app-based culturally tailored, CVH promotion intervention (immediate intervention group) versus a delayed intervention (comparator group). The primary hypothesis was that the FAITH! App intervention would be feasible and improve CVH by LS7 score among African Americans in faith communities from baseline to 6 months post-intervention.

METHODS

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Study Design Overview

Built on more than a decade of collaboration within a synergistic, CBPR academic-community partnership with African American churches in Rochester and Minneapolis–St Paul (MSP), MN, the FAITH! Trial (Fostering African-American Improvement in Total Health!) seeks to better address CVH disparities through an actionable, community-based intervention.[28] The FAITH!-specific Community Steering Committee, an advisory board composed of diverse community stakeholders, provided study oversight to ensure its community centeredness.

The overall study design, depicted in Figure S1, incorporates an exploratory sequential/participatory mixed methods design approach[29] to accomplish its 2 specific aims. Details of the trial design and recruitment process have been published.[30] Full descriptions on the FAITH! App prototype features and user-centered and participatory design processes have been previously described in detail.[25,26] To enhance the study intervention, community input through an iterative, semistructured focus group series with African American community members affiliated with partnering African American churches was conducted (Aim 1, qualitative approach).[31,31a] The app was beta-tested among 15 participants (mean age [SD], 56.9 [12.3] years; 86.7% female) with incorporation of their feedback to bolster cultural relevance for the African American faith community and encourage optimal user engagement. User satisfaction and ease of use of the refined app were high, and the app exceeded the user-rated usability score threshold of approval for subsequent testing in the RCT.[30] In Aim 2 (quantitative aim), we used a pilot cluster RCT with a delayed intervention control group, which is consistent with the overarching CBPR process to ensure intervention access to all study participants. The study was approved by the Mayo Clinic Institutional Review Board and registered (URL: https://www.clinicaltrials.gov; Unique identifier: NCT03777709). Written informed consent was obtained from all individuals before participation.

Setting and Study Population

The study was conducted among predominantly African American churches in Rochester and MSP, MN. A 2-tier approach was implemented to optimize church and participant recruitment. Recruitment of churches and study participants occurred from December 2019 through October 2020.

Church Screening and Eligibility

As described elsewhere, we recruited churches in Rochester and MSP to participate primarily through existing contacts (FAITH! Community Steering Committee) and by city-wide congregational and business listings.[32] In brief, in-person church recruitment events were initially held at health centers in Rochester and MSP, but as a result of the COVID-19 pandemic, a subsequent recruitment event was shifted to a virtual platform (Zoom) to prioritize safety and convenience. Each church was assessed for readiness to engage in health promotion program related-research by the PREACH (Predicting Readiness to Engage African American Churches in Health) model (ie, infrastructure, previous health programming)[33] by electronic and follow-up telephone screening surveys. PREACH Readiness scores ranged from 0 to 64 and were categorized into stages or levels of church infrastructure capacity to engage in research: Stage 1 (Limited, score 0 to 22), Stage 2 (Moderate, score 23 to 40), and Stage 3 (Substantial, score 41 to 64). The PREACH Readiness score was not used for church selection (eligibility criteria) to participate in the study or for randomization, but as an objective

measure to assess church characteristics and infrastructure for health promotion programming.

Defined church inclusion criteria were the following: (1) predominantly African American parishioners, (2) church pastor/senior leadership commitment to promote the study at church, and (3) willingness of church member to serve as church liaison (FAITH! Partner). Churches electronically signed a letter of mutual intent as a commitment to study participation and received a $250 incentive.

Participant Screening and Eligibility

Participants were recruited by multiple methods including telephone calls, flyers by postal mail, email and social media, church pastor endorsement at church events, and direct referral from the church-designated FAITH! Partners from the enrolled churches. Joint congregation community recruitment kickoff events were also held to provide a study overview and forum for open discussion (transitioned from in-person to virtual because of the COVID-19 pandemic). In addition, a promotional video was recorded by the study principal investigator to outline study requirements and expectations for interested participants. Individuals with interest to participate in the study completed an electronic "Participant Interest/Eligibility Form" for the study team to assess their eligibility. This form was recommended by our community partners to streamline the recruitment process and for transparency to community members about the study requirements. Participant inclusion criteria by participant self-report at time of pre-enrollment screening were: Black or African American race, age ≥18 years, smartphone ownership (iOS or Android systems), basic internet skills (use navigational buttons, complete web search, access/download apps), at least weekly internet access, had an active email address, <5 fruit/vegetable servings per day, <30 minutes of PA per day, and able to engage in moderate-intensity PA. Exclusion criteria were: participation in app refinement focus group series, inability to walk up ≥2 flights of stairs or walk ≥1 city block without assistance or stopping, pregnant (because of associated hormonal and weight changes) or having plans to become pregnant in the next 2 years, or visual/hearing impairment or mental disability that would preclude independent app use. Although not a strict eligibility criterion, participants were affiliated with or members of the enrolled churches. Confirmation of church membership became irrelevant and difficult to track during the COVID-19 pandemic because of the transition from in-person to virtual worship services. However, the majority of participants tended to regularly attend services at their affiliated churches and resided in the local Rochester or MSP areas. Eligible participants completed electronic informed consent. Enrolled participants received $50 by gift card at baseline and 6 months post-intervention at health assessments. FAITH! Trial T-shirts/bags and a personal PA monitor (Fitbit Versa 2) were distributed at baseline health assessments to both the immediate and delayed intervention groups as an institutional review board requirement to maintain study integrity. Participants were encouraged to delay their use of the Fitbit until the start of their active implementation phase of the trial. *Mayo Clinic Healthy Heart for Life!* books were provided to participants in both groups at their respective study completion time points to maintain the delayed intervention group as a nonactive control group during the immediate intervention phase. Aligned with recruitment methods, participant follow-up about key study time points/events was communicated by a variety of means (eg, emailed timelines/reminders, telephone calls, etc).

Randomization and Intervention

Churches were the unit of randomization to minimize between-group contamination and to adjust for intraclass correlation as completed in other community-based studies within this demographic.[34] The study statistician randomized churches, ensuring that the number of participants in the immediate intervention (Group 1) and delayed intervention (Group 2, control group) was balanced by church size. Churches were informed of their randomization assignment after the baseline health assessments. The cluster RCT design has 2 waves of implementation with 2 groups (Figure 1). Clusters of churches were randomized to receive the intervention immediately after baseline health assessments (Time 1, Group 1) or at post-maintenance (Time 3, Group 2). Both groups completed second health assessments at post-maintenance (6 months post-intervention; Time 3) to allow for comparison of all LS7 components (LS7 scores) between Groups 1 and 2. Times 4 through 5 are data collection points after the intervention (immediate post-intervention and 6 months post-intervention) for Group 2 and are not included in this analysis. Group 2 (control group) did not receive education materials or interventions during the intervention phase for Group 1.

FAITH! App Intervention

Theoretical Framework

Sound conceptual frameworks to encourage ideal CVH behaviors were selected by the study team members to integrate into the refined FAITH! App features to align with the findings from formative evaluation studies, including feedback from past FAITH! pilot study participants and African American community members.[26,27] Within the previous pilot study post-intervention and current study Aim 1 focus group series, participants provided feedback emphasizing that the refined intervention features should foster behavior change through the recognition that individuals may be at varying stages or steps along their journey to healthy lifestyle change. Further, it was emphasized that incorporation of psychosocial factors and the SDOH is key. Thus, the Precaution Adoption Process Model and the Social Ecological Model were the underpinning frameworks of all new and refined FAITH! App features to encourage ideal CVH. The Precaution Adoption Process Model fostered behavior change based on participant self-reported stage of change (or step of change [SOC] to reflect movement or progress) to deliver predetermined decision rule-based messages according to a classification algorithm.[35]

Refined FAITH! App Features Integrating Theoretical Framework

Table S1 presents the content and theoretical basis of the refined FAITH! App features evaluated in the RCT.

Lifestyle Journey

Participants selected a lifestyle journey as either a diet or PA path at baseline for which decision rule-based messages would

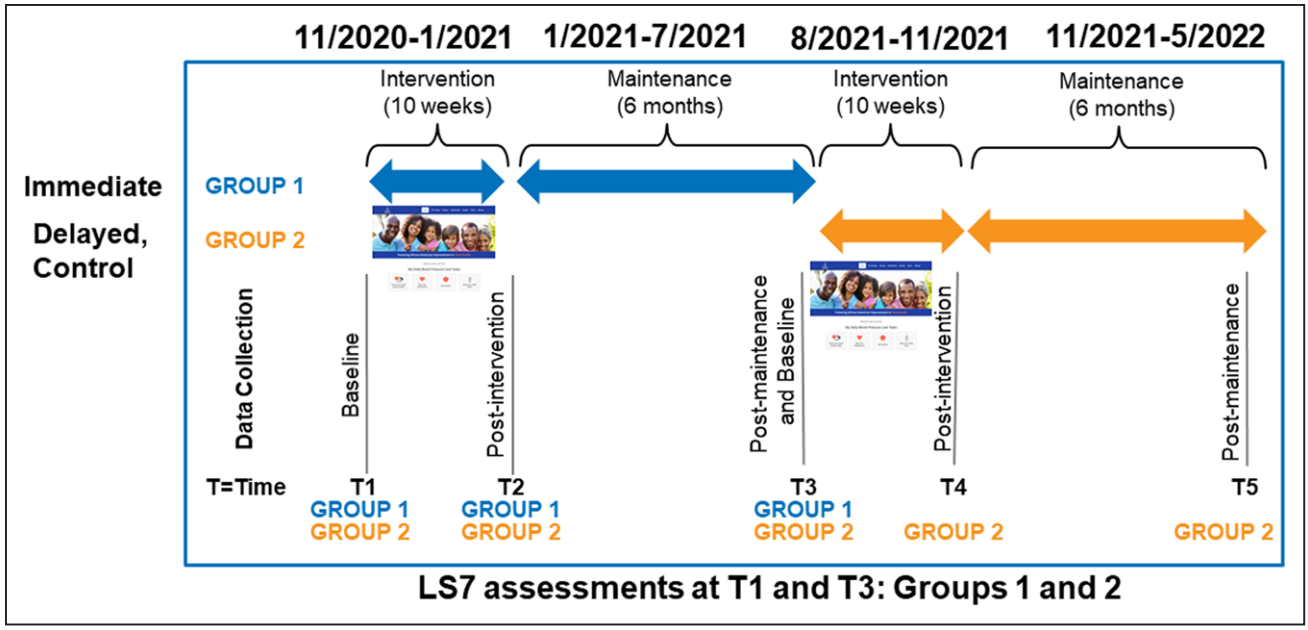

Figure 1. Randomization scheme: cluster randomized controlled trial with delayed intervention.
Group 1 (immediate intervention) is represented by the blue arrows and text. Group 2 (delayed intervention, control group) is represented by the orange arrows and text. Dates correspond with trial time points and phases (intervention, maintenance). LS7 indicates Life's Simple 7; and T, time.

have a primary focus. Participants remained on the same lifestyle journey path throughout the study intervention and maintenance phases. Harmonious with the SOC and diet/PA path, participants indicated where they were along their individual path (SOC) on a weekly basis (Steps 1 to 7: 1 [unawareness of what to do for healthy behavior] to 7 [healthy behavior maintenance]). In addition, LS7-related messages were incorporated into the message bank tailored to an individual's baseline LS7 profile (eg, weight management for suboptimal body mass index). Messages were informational, cues to action, reminders, or motivational/praise for healthy behavior change. All FAITH! App features were designed with the intention to complement one another in promoting all LS7 components (ie, multiple cardiovascular risk factors) while the participant continued along their particular lifestyle journey path throughout the intervention.

Sharing Board

The sharing board was adjusted to include a moderator to manage weekly posts to solicit discussion on self-efficacy, self-regulation, social support, and barriers/facilitators to healthy lifestyle within the Social Ecological Model framework.[36]

Education Modules

Aligned with the Social Ecological Model, the education modules integrated content to increase awareness of health disparities affecting the African American community (eg, high hypertension prevalence in African Americans, unique stressors affecting African Americans), the importance of health equity (eg, access to quality health care providers, advocating for self and family in clinical settings) and practical strategies to overcome barriers from SDOH (eg, grocery shopping on a budget, quick heart-healthy recipes of traditional African American cuisine).

Diet/PA Tracking at the Church Level

Consistent with Social Ecological Model, a thermometer goal chart tracking diet/PA by church during the intervention delivery phase cultivated "friendly competition" and behavior economics by providing social incentives at the church level (ie, winning church of the week).[37]

Intervention Delivery Procedures

During the study intervention phase (Figure 1), participants followed a 10-week intervention with core features as (1) education modules series with an LS7 focus (eg, healthy eating, PA), (2) diet/PA self-monitoring, and (3) social networking (sharing board). The content of the education modules' curriculum included all LS7 components and major cardiovascular risk factors with learning objectives promoting ideal CVH and CVD prevention (eg, obesity, cholesterol, diabetes). The intervention was designed for participants to complete 1 education module per week (10 total), which included interactive self-quizzes. Participants were to manually enter daily fruit/vegetable servings within the tracking feature. Daily step counts (as PA tracking) were automatically synchronized with the app from the Fitbits. The moderated sharing board was updated weekly with posts from reputable sources (eg, AHA, Mayo Clinic) on each of the LS7 components, and participants were encouraged to post messages throughout the intervention. During the intervention phase, each participant received up to 2 separate personalized messages each week through the app dashboard messaging inbox. These included 1 Precaution Adoption Process Model–informed (path SOC-based) message to facilitate LS7 health behavior change (ideal diet and PA) or 1 LS7-focused message to promote the other LS7 components (smoking cessation and ideal body mass index, BP, cholesterol, glucose). Throughout the maintenance phase, participants continued to receive both message types at the same frequency. Participants were encouraged to continue to use the app features (eg, reviewing the education modules for content reinforcement, tracking daily diet/PA, and posting to the sharing board) during the maintenance phase. Participants received a detailed, step-by-step

user manual to provide guidance on independent app use. Screenshots of the app features (including the lifestyle journey SOC, tailored messaging, dashboard, etc) are included in Figures S2 and S3.

Study Measurements

Sociodemographics, relevant health history, and digital skills (electronic health literacy,[38] mobile technology/internet use skills,[39]) were collected by electronic surveys at baseline and at follow-up time points (immediate post-intervention and 6 months post-intervention). In-person health assessments for collection of clinical, laboratory, and anthropometric data were conducted at baseline (October to November 2020) and 6 months post-intervention at community venues (health centers) by a mobile clinical research unit team of trained nursing staff. Strict COVID-19 safety precaution protocols were implemented at all health assessments to prioritize participant and study team safety (eg, appointment staggering for social/physical distancing, universal mask wearing, frequent sanitizing [hand and surface]).

CVH profiles according to LS7 were assessed by measurement of PA patterns (minutes per week of moderate and vigorous intensity PA by the International Physical Activity Questionnaire),[40] self-reported cigarette smoking status (former, current, never), height (to nearest centimeter by stadiometer), weight (in kilograms with calibrated scale), BP (average of 3 sitting readings), and lipid panel (total cholesterol) and glucose (both by fingerstick measurement). Dietary quality was assessed using an electronic, self-administered, culturally sensitive food frequency questionnaire.[41] The short version of the Delta Nutrition Intervention Research Initiative food frequency questionnaire (158 items) was appropriate because it has been previously validated in a similar population of African Americans to better capture their cultural food types and patterns.[42] The instrument also affords the ability to assess macronutrients of the LS7 diet metrics according to the healthy diet score algorithm.[43–46] LS7 component criteria were adapted from AHA standards on the basis of health assessment data (Table 1).[6]

Participant app engagement was assessed via Google Analytics.[47] Prespecified app engagement goals were achievement of ≥50% of participants completing the following during the intervention phase: initial connection and log-in to the app homepage/dashboard, ≥50% completion of education modules series, and ≥1 entry/week of diet/PA tracking. The Health Information Technology Usability Evaluation Scale (Health-ITUES), a customizable mHealth intervention usability assessment instrument, was used to assess app usability with an a priori goal of overall mean score ≥4.[48] The 20-item scale includes 4 subscales: impact (3 items), perceived usefulness (9 items), ease of use (5 items), and user control (3 items). Each item is rated on a 5-point scale from 1, strongly disagree, to 5, strongly agree, with higher scale values indicating greater perceived usability of the intervention. Impact pertains to educational content relevance and the adequacy with which the app met community needs. Perceived usefulness assessed how well the app provided participants with assistance to enact positive CVH behaviors. Perceived ease of use assessed app navigation. Last, user control evaluated internal messaging clarity for app troubleshooting. The Health-ITUES has been previously validated among community-dwelling adults using a chronic disease–focused app[48] and was used in our previous formative evaluation.[26] An overall Health-ITUES score was calculated as the mean of all 20 items, with each item equally weighted. Subscale scores were similarly calculated as the mean of the items within each subscale.

Table 1. American Heart Association Life's Simple 7: Definition of Poor, Intermediate, and Ideal Cardiovascular Health for Each Component/Metric

	Definitions		
LS7 Component/Metrics	Poor	Intermediate	Ideal
Smoking	Current	Former <1 year	Never or former >1 year
Healthy diet score (0–5 components)*	0–1	2–3	4–5
PA level†	None	1–149 min/wk moderate intensity, 1–74 min/wk vigorous intensity, or 1–149 min/wk moderate+vigorous	≥150 min/wk moderate intensity, ≥75 min/wk vigorous intensity, or ≥150 min/wk moderate+vigorous
BMI, kg/m^2	≥30.0	25.0–29.9	<25.0
BP, mm Hg	Systolic BP ≥140 or Diastolic BP ≥90	Systolic BP 120–139, Diastolic BP 80–89, or treated to goal	<120/<80 untreated
Total cholesterol, mg/dL	≥240	200–239, or treated to goal	<200
Glucose, mg/dL‡			
Fasting	≥126	100–125, or treated to goal	<100 treated
Nonfasting	≥200	140–199 without diabetes or ≤199 with diabetes	<140 without diabetes

BMI indicates body mass index; BP, blood pressure; LS7, Life's Simple 7; and PA, physical activity.

*Healthy diet score components include the following: fruits and vegetables, ≥4.5 cups/d; fish, 2 or more 3.5-oz servings/wk; fiber-rich whole grains (≥1.1 g fiber/10 g carbohydrate), 3 or more 1-oz-equivalent servings/d; sodium, ≤1500 mg/d; and sugar-sweetened beverages, ≤450 kcal/wk. Dietary recommendations are scaled according to a 2000-kcal/d diet.

†Minutes of vigorous activity are equal to 2 times the minutes of moderate activity when moderate and vigorous activities are combined.

‡Categories were developed to account for participant fasting and nonfasting status at health assessments.

Study Outcomes

LS7 Score (CVH)

The primary outcome was the average change in mean LS7 score from baseline to 6 months post-intervention, and the intervention effect was defined as the difference of this change between the immediate intervention and control groups. As a conglomerate of all LS7 components, the LS7 score maps all individual metrics for each LS7 component into a scoring system (eg, diet, PA, BP, etc). For instance, the LS7 diet metrics were categorized as poor to ideal according to the healthy diet score (range, 0 to 5, including fruits/vegetables, fish, whole grains, etc). Likewise, the PA metrics were categorized according to levels of moderate or vigorous PA from poor to ideal. As such, the LS7 score was calculated as a composite of each LS7 component by the assignment of 2 points for ideal, 1 point for intermediate, or 0 points for poor.[49] The total sum yielded a continuous measure of CVH ranging from poor to ideal (0 to 14 points). For ease of translation and understanding, the LS7 score was further categorized by metrics as 0 to 6 (poor), 7 to 8 (intermediate), and 9 to 14 (ideal) as previously conducted by our study team.[43] Secondary outcomes included change in individual LS7 component metric categories from baseline to 6 months post-intervention and were compared between the immediate intervention and control groups.

Intervention Feasibility

Feasibility primary outcomes were prespecified app engagement goals and app usability. Prespecified app engagement goals were assessed at intervention phase completion. App usability was assessed by the overall Health-ITUES and subscale scores at post-intervention.

Statistical Methods

Power

For the primary outcome of LS7 score, an effect size of 1-unit difference in mean LS7 score was used on the basis of evidence from a meta-analysis indicating that each unit increase in LS7 metrics is associated with an estimated 19% and 11% reduction in CVD and all-cause mortality, respectively.[50] Initial power calculations to estimate adequate sample size included an aim to recruit 10 participants per church (cluster size) on the basis of an assumption of 0.01 intracluster correlation and 0.5 coefficient of variation of church sizes to provide 85% power (SD, 2; 5% type I error rate). These estimates were based on calculations generated in previous FAITH! studies.[51,52] On the basis of these calculations, we initially aimed to recruit 16 churches and 200 participants to ensure 160 completers (80 participants per arm, assuming a 20% attrition rate). The recruitment goal was revised to adapt to COVID-19 pandemic-related challenges. The church recruitment goal of 16 churches (8 per arm), with a mean of 5 participants per church (40 participants per group) would provide 80% power to detect a difference of 1.45 in average LS7 score change between groups (effect size 0.73 [mean difference divided by SD]; 5% type I error rate, assuming SD of 2, 0.01 intracluster correlation, and 0.5 coefficient of variation of church sizes). Assuming a 20% attrition rate, recruitment of at least 80 participants to ensure at least 60 completers would provide adequate power based on these calculations.

Main Analyses

Participant characteristics were summarized with frequencies and percentages or means and SDs, as appropriate. Baseline comparisons between the intervention and control groups were assessed with χ^2 tests, 2-sample t-tests, or Wilcoxon rank-sum tests, as appropriate. The within-group and between-group differences from baseline to 6 months post-intervention for the primary outcome (LS7 score) were assessed for statistical significance with linear regression models (Y=difference) incorporating generalized estimating equations to account for correlation within church. Because of low correlation, the independence structure was used in the generalized estimating equation models (for the primary outcome [change in LS7 score], the intracluster correlation coefficient was −0.09). Differences in the continuous LS7 components were analyzed similarly. The "intervention effect" was defined as the difference in average change from baseline to 6 months between the intervention and control groups. For the individual categorical LS7 components (poor/intermediate/ideal), the differences from baseline to 6 months post-intervention were assessed within group with McNemar's tests, and between group with generalized estimating equation logistic regression models (modeling the odds of intermediate/ideal versus poor and including a time by group interaction). Within the intervention group, the pre/post change in mean LS7 score between those selecting a diet or PA path was assessed using the same generalized estimating equation methods described. Sensitivity analyses were also performed using the last observation carried forward approach for the LS7 score, an imputation method that assumes no change from baseline among participants with incomplete follow-up data (ie, last observed nonmissing LS7 score used). Intervention feasibility analyses were restricted to the immediate intervention group (Group 1) only because Group 2 is currently active in the trial maintenance phase. All analyses were performed using SAS version 9.4 (SAS Institute Inc, Cary, NC). *P* values <0.05 were considered statistically significant.

RESULTS

Study Sites and Participants

Among 18 churches assessed for eligibility, 140 individuals expressed interest in study participation by attending a kickoff event or completing a program interest form (see Figure 2 for modified CONSORT [Consolidated Standards of Reporting Trials] flow diagram). A total of 16 churches (N=4 Rochester, N=12 MSP) enrolled into the RCT and were cluster-randomized to Groups 1 and 2. From enrolled churches, 85 participants (60% of approached individuals) met study eligibility criteria, were enrolled, and were distributed among their respective enrolled church (N=41 in Group 1, N=44 in Group 2). Of the 85 participants enrolled, 76 completed both the baseline health assessment and electronic survey. A total of 68 participants completed both the baseline and follow-up health assessments (80% participant retention rate from time of enrollment) as the basis of the primary statistical analytic sample. No enrolled churches withdrew from the trial (0% attrition rate). Baseline characteristics of study participants are summarized in Table 2. The cluster-ran-

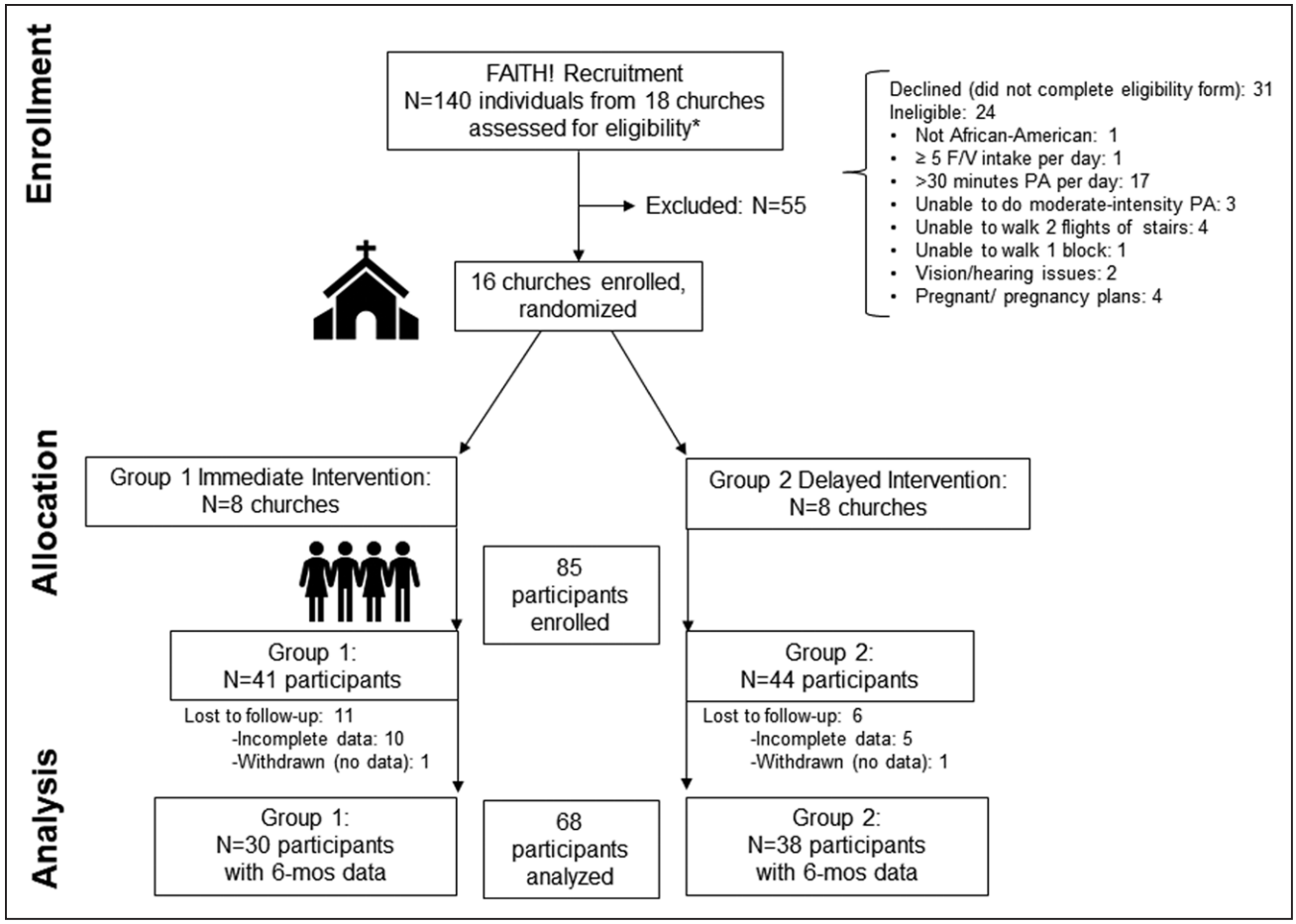

Figure 2. Modified CONSORT flow diagram: screening, enrollment, and follow-up of church participants.
FAITH! indicates Fostering African-American Improvement in Total Health!; F/V, fruit/vegetable; and PA, physical activity. *Among the 18 churches with participants assessed for eligibility, 2 churches were excluded because all individuals within them either declined participation or were deemed ineligible.

domized churches and groups were overall balanced on key sociodemographics. The majority of churches were at the moderate stage of PREACH readiness to engage in research and health promotion programming (mean score [SD], 36.1 [14.2]) and had a large congregation size (75% with >75 members). Eighty percent of churches included in the assessment reported that the majority of their members were age 54 years or younger. Participants were majority female (70.6%), had a lower education level (59% with less than 4-year college degree), and had high cardiometabolic risk (71% with overweight/obesity) with a mean age (SD) of 54.2 (12.3) years. Both mean electronic health literacy and mobile technology/internet skills scores were in the relatively high range (mean [SD], 27.8 [6.3]; 4.0 [1.1], respectively).

Primary Outcomes

LS7 Score (CVH)

The primary outcome, mean LS7 score and distribution of its associated individual LS7 components by metric category (poor, intermediate, ideal) are presented for the intervention and control groups and the overall sample in Table S2. At baseline (among participants with complete LS7 data at baseline and 6 months post-intervention), the mean (SD) LS7 scores were 6.5 (1.9) in the intervention group and 7.0 (1.9) in the control group. At 6-months post-intervention, the mean LS7 score increased to 8.4 (SD 2.0; +Δ1.9) in the intervention group versus 7.7 (SD 2.0; +Δ0.7) in the control group ($P<0.0001$ between and within-group differences; Figure 3A). The average change in mean LS7 score was 1.1 point greater in the intervention group than the control group (95% CI, 0.6–1.7; $P<0.0001$; Table 3). When assessing LS7 score by participant-selected lifestyle journey paths within the intervention group (14 selected the diet path, 16 selected the PA), both the diet and PA paths had statistically significant average increases in mean LS7 score from baseline to 6 months post-intervention (+Δ 2.2 [SD 1.8], $P<0.001$; +Δ1.6 [SD 1.9], $P=0.003$, respectively).

As a secondary LS7 end point, the proportion of intervention participants in the ideal category increased from 12.5% to 54.2% ($P=0.004$) at 6

Table 2. Church and Trial Participant Baseline Characteristics*

	Intervention	Control	Total	*P* Value
Churches				
No. of churches	8	8	16	
PREACH readiness score, mean (SD)	38.0 (14.6)	34.1 (14.6)	36.1 (14.2)	0.49
Congregation size >75 members	5 (62.5)	7 (87.5)	12 (75.0)	0.57
Congregation member age ≤54	6/8 (75.0)	6/7 (85.7)	12/15 (80.0)	1.0
Participants				
No. of participants†	30	38	68	
Sex				0.92
Male	9 (30.0)	11 (28.9)	20 (29.4)	
Female	21 (70.0)	27 (71.1)	48 (70.6)	
Age, y				0.22
Mean (SD)	56.3 (13.4)	52.6 (11.4)	54.2 (12.3)	
Range	31.0-86.0	21.0-70.0	21.0-86.0	
Marital status				0.14
Single	8 (26.7)	9 (25.0)	17 (25.8)	
Divorced	1 (3.3)	7 (19.4)	8 (12.1)	
Widowed	0 (0.0)	1 (2.8)	1 (1.5)	
Married or committed relationship	21 (70.0)	19 (52.8)	40 (60.6)	
Education				0.70
High school graduate or less	4 (13.3)	3 (8.3)	7 (10.6)	
Some college	7 (23.3)	13 (36.1)	20 (30.3)	
Technical or Associate's degree	6 (20.0)	6 (16.7)	12 (18.2)	
College graduate or higher	13 (43.3)	14 (38.9)	27 (40.9)	
Employment status				0.77
Employed, at least part-time	23 (76.7)	29 (80.6)	52 (78.8)	
Unemployed or retired	7 (23.3)	7 (19.4)	14 (21.2)	
Household income				0.56
<$35 000	6 (23.1)	5 (15.6)	11 (19.0)	
$35 000–$49 999	2 (7.7)	11 (34.4)	13 (22.4)	
$50 000–$74 999	11 (42.3)	8 (25.0)	19 (32.8)	
≥$75 000	7 (26.9)	8 (25.0)	15 (25.9)	
Health care insurance				1.0
Yes	26 (86.7)	32 (88.9)	58 (87.9)	
No/Don't know	4 (13.3)	4 (11.1)	8 (12.1)	
Regular health care provider				0.78
Yes	22 (73.3)	29 (76.3)	51 (75.0)	
No	8 (26.7)	9 (23.7)	17 (25.0)	
Cardiovascular risk factors‡				
Overweight/Obesity	19 (63.3)	29 (76.3)	48 (70.6)	0.24
Hypertension	17 (56.7)	24 (63.2)	41 (60.3)	0.59
Diabetes	11 (36.7)	8 (21.1)	19 (27.9)	0.15
Cholesterol	14 (46.7)	16 (42.1)	30 (44.1)	0.71
Current cigarette smoker	1 (3.3)	1 (2.7)	2 (3.0)	0.71
Electronic health literacy score§				0.77
Mean (SD)	27.3 (7.2)	28.1 (5.5)	27.8 (6.3)	

(*Continued*)

Table 2. Continued

	Intervention	Control	Total	*P* Value
Range	9.0–38.0	14.0–40.0	9.0–40.0	
<26 (Low)	9 (30.0)	8 (21.1)	17 (25.0)	
≥26 (High)	21 (70.0)	30 (78.9)	51 (75.0)	
Mobile technology/internet use skills‖				0.72
Mean (SD)	3.9 (1.3)	4.1 (1.0)	4.0 (1.1)	
Range	1.0–5.0	1.0–5.0	1.0–5.0	

PREACH indicates Predicting Readiness to Engage African American Churches in Health.
*N (%) shown unless otherwise specified.
†Frequencies not adding to column total indicate missing data.
‡Cardiovascular risk factors are by self-report.
§Possible range 8 (low) to 40 (high).
‖Possible range 1 (low) to 5 (high).

months (Figure 3B). For individual LS7 component categories within the intervention group, there were statistically significant improvements in the proportion of participants in the intermediate/ideal categories from baseline to 6 months post-intervention for diet (31% to 62.1%, *P*=0.003) and PA (61.5% to 84.6%, *P*=0.03; Figure 4). Distributions for smoking, body mass index, and glucose were stable within the intervention group during the study period. There were no statistically significant within-group changes in the control arm for the intermediate/ideal categories, and the degree of change in these categorical LS7 components did not differ significantly between the groups. Change in the individual LS7 components (except smoking) between the intervention and control groups during the study period as continuous measures are presented in Table 3. The average change in mean healthy diet score was 0.9 points greater in the intervention group than the control group (95% CI, 0.5–1.2; *P*<0.0001). Also, the average change in weekly PA (moderate and vigorous intensity) was 143.6 minutes higher than the control group (*P*=0.04).

Within last observation carried forward sensitivity analyses, the size of the intervention effect for the LS7 score was lessened slightly, but remained consistent and statistically significant. The intervention effect using the last observation carried forward approach for LS7 score was 0.8 (95% CI, 0.2–1.3; *P*=0.01).

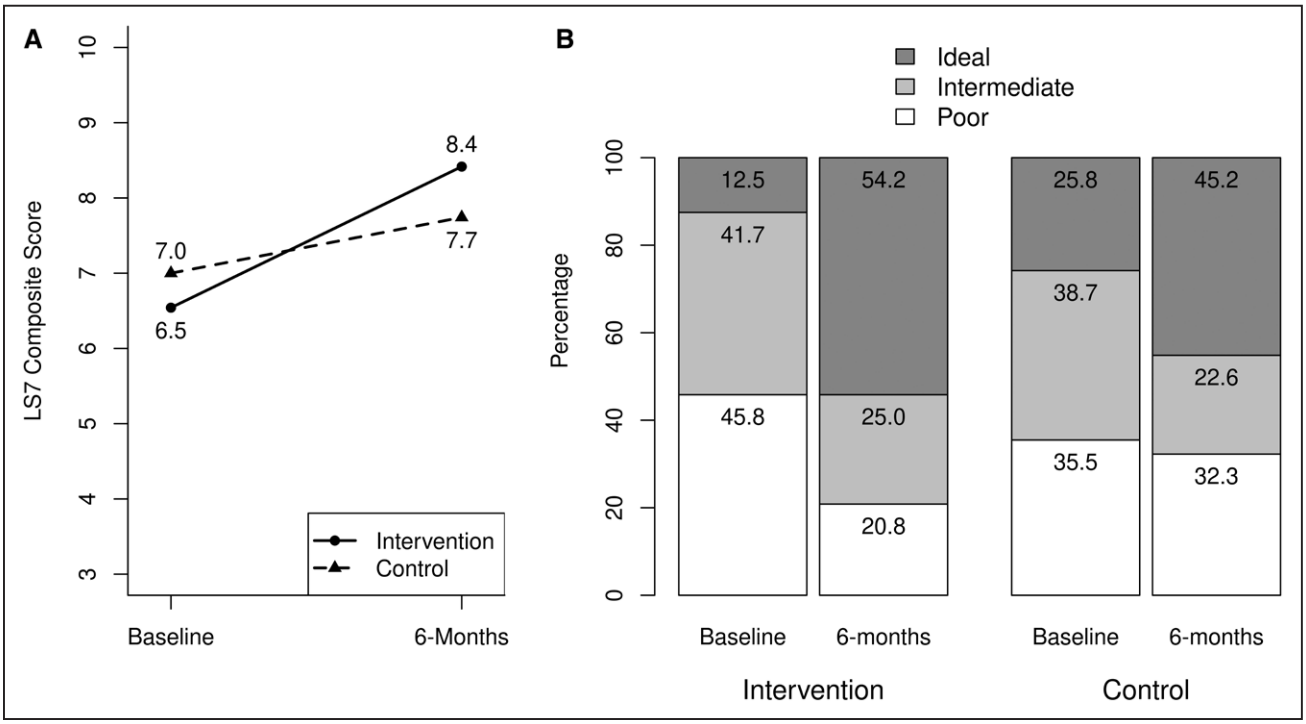

Figure 3. Primary outcome measure: change in Life's Simple 7 score, baseline to 6 months post-intervention.
A, Mean change in LS7 score. *P*<0.0001 between and within-group differences. **B**, Comparison of LS7 score categories. LS7 categories: Poor (0–6), Intermediate (7–8), Ideal (9–14). Difference in proportion of intervention group participants in the Ideal category from baseline to 6 months post-intervention, *P*=0.004. LS7 indicates Life's Simple 7.

Table 3. Primary and Secondary Life's Simple 7 Outcomes*

Outcome		Intervention†	Control†	Intervention Effect‡	*P* Value
LS7 score, range 0–14	N	24	31		
	Baseline	6.54 (1.86)	7.00 (1.88)		
	6 Months	8.42 (2.02)	7.74 (2.03)		
	Change	1.88 (1.85)	0.74 (1.69)	1.13 (0.62 to 1.65)	<0.0001
	Within-group *P* value	<0.0001	<0.0001		
LS7 components					
Healthy diet score, range 0–5	N	29	38		
	Baseline	1.24 (1.02)	1.39 (0.97)		
	6 Months	2.03 (1.24)	1.32 (1.12)		
	Change	0.79 (0.86)	−0.08 (1.19)	0.87 (0.54 to 1.21)	<.0001
	Within-group *P* value	<0.0001	0.58		
PA, min/wk	N	20	23		
	Baseline	36.05 (73.64)	116.96 (180.04)		
	6 Months	255.75 (385.25)	193.04 (230.21)		
	Change	219.70 (396.73)	76.09 (286.67)	143.61 (7.67 to 279.56)	0.04
	Within-group *P* value	<0.0001	0.11		
BMI, kg/m^2	N	27	34		
	Baseline	31.92 (8.07)	36.07 (7.81)		
	6 Months	31.76 (8.09)	36.22 (7.72)		
	Change	−0.16 (1.30)	0.14 (2.24)	−0.30 (−1.23 to 0.62)	0.52
	Within-group *P* value	0.69	0.54		
BP					
Systolic BP, mm Hg	N	27	34		
	Baseline	131.47 (17.00)	137.15 (18.44)		
	6 Months	128.38 (14.05)	129.90 (16.81)		
	Change	−3.09 (11.61)	−7.25 (13.14)	4.16 (−1.38 to 9.70)	0.14
	Within-group *P* value	0.23	<0.0001		
Diastolic BP, mm Hg	N	27	34		
	Baseline	78.88 (10.09)	83.88 (12.21)		
	6 Months	78.35 (9.77)	81.38 (11.16)		
	Change	−0.53 (8.27)	−2.50 (11.85)	1.97 (−2.38 to 6.31)	0.37
	Within-group *P* value	0.73	0.12		
Total cholesterol, mg/dL	N	27	34		
	Baseline	184.85 (43.40)	201.74 (39.69)		
	6 Months	173.89 (36.38)	184.00 (37.29)		
	Change	−10.96 (25.88)	−17.74 (25.93)	6.77 (−6.81 to 20.36)	0.33
	Within-group *P* value	0.07	<0.0001		
Glucose					
Fasting, mg/dL	N	9	11		
	Baseline	90.00 (9.54)	86.82 (12.62)		
	6 Months	92.89 (12.97)	93.55 (14.07)		
	Change	2.89 (18.44)	6.73 (10.64)	−3.84 (−11.73 to 4.05)	0.34
	Within-group *P* value	0.28	0.03		
Nonfasting, mg/dL	N	11	12		
	Baseline	104.09 (31.65)	104.33 (20.34)		
	6 Months	106.45 (22.40)	111.17 (40.53)		
	Change	2.36 (38.79)	6.83 (36.89)	−4.47 (−19.82 to 10.88)	0.57
	Within-group *P* value	0.66	0.23		

BMI indicates body mass index; BP, blood pressure; LS7, Life's Simple 7; and PA, physical activity.
*LS7 components as continuous measures displayed. Smoking status is not displayed given its measurement as a categorical variable.
†Mean (SD) shown.
‡Intervention effect (difference in mean change between intervention and control groups) and 95% CI shown.

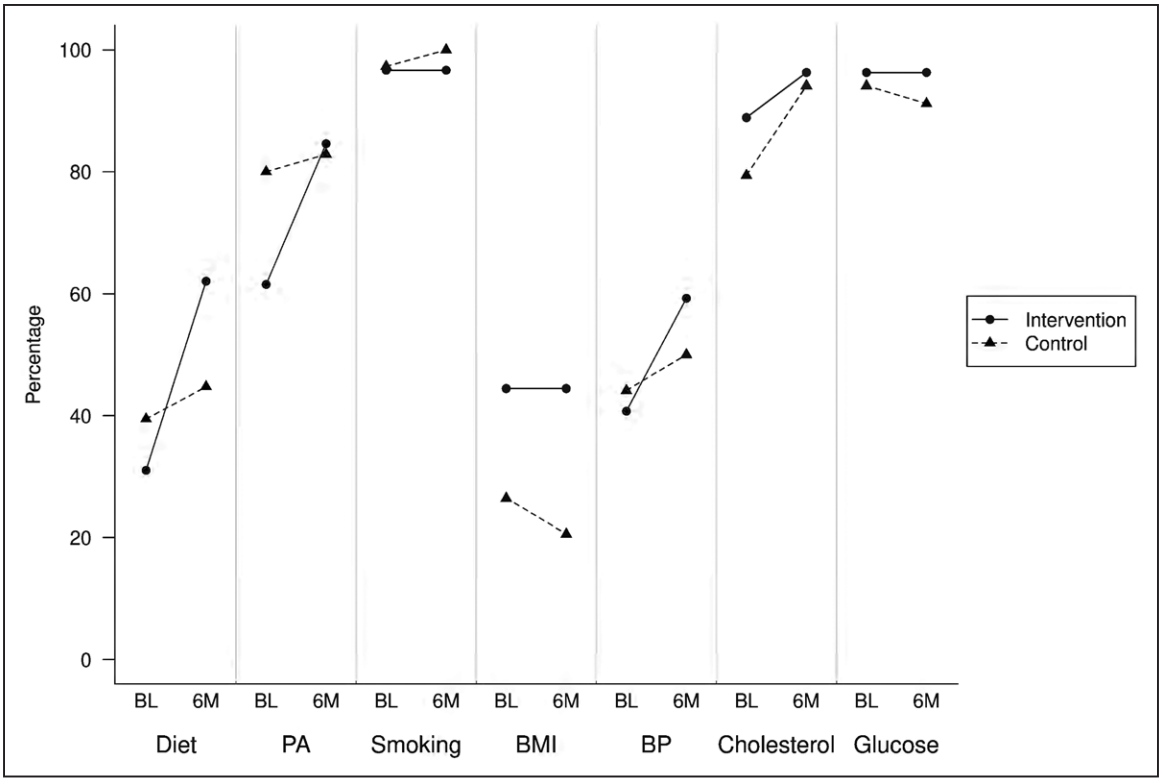

Figure 4. Change in Life's Simple 7 individual components, baseline to 6 months post-intervention.
Proportion of participants in Intermediate/Ideal level of Life's Simple 7 metric at baseline and 6 months post-intervention. Statistical significance achieved for diet (*P*=0.003) and physical activity (*P*=0.03). 6M indicates 6 months; BL, baseline; BMI, body mass index; BP, blood pressure; and PA, physical activity.

Intervention Feasibility

In terms of app engagement for Group 1 only, all participants (100%) successfully connected and logged into the FAITH! App (Table 4). Completion of at least 50% of the 10 education modules was achieved by 40% of participants. Three-fourths of participants completed at least 1 diet and PA tracking during the 10-week course of the intervention. The mean Health-ITUES score was overall high (mean [SD], 4.2 [0.7]). The impact subscale received the highest score (mean [SD], 4.5 [0.6]), whereas the user control subscale received the lowest score (mean [SD], 3.7 [1.0]).

DISCUSSION

In this study of African American churchgoers of overall high cardiometabolic risk, an mHealth intervention promoting CVH resulted in significant improvements in LS7 scores and individual LS7 component indicators during a 6-month follow-up period. These findings suggest that the delivery of culturally tailored, individualized messaging and features via the FAITH! App can foster CVH-promoting behaviors, particularly diet and PA, in a population with a strikingly low prevalence of ideal CVH. The FAITH! App intervention was overall feasible with favorable participant usability ratings, meeting and exceeding our prespecified goals. Excellent study retention (100% and 80% for churches and participants, respectively) was achieved likely through our multipronged recruitment strategy (church leadership commitment, participant prioritization) and overarching CBPR approach (community member oversight, user-centered intervention development). These feats were accomplished even in the face of unanticipated challenges and setbacks from the COVID-19 pandemic.

In contrast with other community-based intervention trials among African Americans focused on a single cardiovascular risk factor (or within limited clusters),[19] our trial comprehensively promoted and assessed the totality of CVH (all LS7 indicators and composite score) as a conglomerate of multiple cardiovascular risk factors according to the standardized LS7 framework. Although some studies have measured ≥1 cardiometabolic factors, these are often secondary measures and not adequately powered, rendering intervention effects findings inconclusive. Further, there is often wide heterogeneity in the outcome measurement of cardiovascular risk in community-based interventions, and thus clinical significance and translational potential remains uncertain. To our knowledge, our trial is the only study to date rigorously assessing the LS7 within a robust RCT among an underserved African American community in partnership with African American churches. Using a CBPR approach

Table 4. Intervention Feasibility: App Engagement and Usability, N=30*

App engagement, N (%)	
Initial connection, login to homepage/dashboard	30 (100)
≥50% education modules series completion	12 (40.0)
≥1 diet tracking†	23 (76.7)
≥1 PA/steps tracking‡	23 (76.7)
App usability, mean (SD)	
Health-ITUES, overall score	4.2 (0.7)
Impact	4.5 (0.6)
Perceived usefulness	4.4 (0.7)
Perceived ease of use	3.9 (1.2)
User control	3.7 (1.0)

FAITH! indicates Fostering African-American Improvement in Total Health!; Health-ITUES, Health Information Technology Usability Evaluation Scale; and PA, physical activity.

*Immediate intervention, Group 1 participant data only as the delayed intervention. Group 2 participant data were incomplete at time of analysis (data collection ongoing in randomized controlled trial).

†By participant manual entry of daily fruit and vegetable intake within the FAITH! App.

‡By automatic syncing of daily step count from participant physical activity monitor to the FAITH! App.

similar to our trial, Kitzman and colleagues implemented a cluster RCT of a faith-based diabetes prevention program among 211 African American women attending 11 African American churches.[53] There were statistically significant improvements in weight loss (−2.6%, $P<0.01$), health behaviors (diet, PA), and biometrics (BP) at 10 months; however, the study power calculations were based on the primary weight loss outcome. Another landmark trial of a hypertension-focused therapeutic lifestyle intervention with motivational interviewing among New York City African American churches (N=13 churches, N=373 participants) demonstrated a greater reduction in systolic BP (5.79 mm Hg) compared with the control group.[34] In light of empirical evidence showing a graded relationship between number of ideal LS7 components and CVD risk, more inclusive lifestyle interventions with content and assessment of multiple cardiovascular risk factors within a standardized rubric (LS7) are warranted. This could have a greater long-term effect on CVD outcomes among African Americans than single risk factor interventions.[22]

Our findings illustrating improvements in the LS7 by way of engagement with a community-based mHealth intervention among African Americans are novel and unique. These findings are likely resultant from several factors primarily related to intervention and trial design. First, the mHealth component of our intervention is unique in that it was rigorously developed through stepwise formative evaluation to specifically meet the preferences/priorities of African Americans.[26,27] African Americans are overwhelmingly faced with a high negative SDOH burden, which drastically limits their available time and resources to focus on lifestyle change. The digital platform delivery offered convenience, accessibility, and social capital/support to promote healthy behaviors despite these challenges as demonstrated within our work.[54] Further, in retrospect, the FAITH! App was timely for deployment during the COVID-19 pandemic because it provided participants with a reliable resource to maintain a healthy lifestyle without the necessity of in-person programming or recreational facilities. At the heart of the app was an emphasis on tailored messaging and features to support ideal LS7 behaviors (diet/PA). Messaging delivery via mobile technologies has been shown to be a feasible and acceptable avenue for health promotion in African American and Latino churches.[55] To date, no other church-based lifestyle intervention has afforded this mHealth innovation in the context of a global public health crisis. Second, although not intentionally tailored for African American women, the intervention was codesigned by a sector of the African American community predominated by women (the Black church).[26] Given that the majority of participants were women, they likely gravitated to the social networking/cohesion afforded by the intervention and felt a sense of belonging/purpose to better their CVH and that of their families and communities.[56] Last, the collective body of the African American church as a unit of identity potentially fostered enthusiasm for participation in a health promotion program. This was highly personal and relevant during the pandemic—a time when prioritizing spiritual, physical, and mental health is crucial. This was further enriched by the blending of religious and biblical tenets within the education content to enhance app engagement.

Limitations

There are several limitations to this study. The sample size was much smaller than anticipated, which was largely complicated by pandemic-related constraints and the need to move forward with the trial given limited resources and to maintain accountability to our community partners. However, despite these challenges, we maintained overall favorable retention rates that were similar to or better than those previously noted in community-based intervention[19,57] and app-based intervention[58] studies. We also acknowledge the lower enrollment of African American men than women within the trial. We also recognize that it takes intentional, tailored strategies to successfully recruit African American men and will be mindful to incorporate these in future studies.[59] Further, the LS7 health behaviors (diet and PA) were assessed by self-report and subject to social desirability and recall bias; however, instruments previously validated among similar African American communities were used. There is also potential for bias in the LS7 score outcome assessment given some participants with incomplete LS7 component data at the 6-month post-intervention follow-up. To account for this missing data, we

conducted sensitivity analyses with integration of the last observation carried forward imputation approach for participants with incomplete LS7 component data. There was a slightly lessened but concordant positive intervention effect (it remained statistically significant) compared with the complete-case approach. The inherent limitation of cluster randomized design with delayed intervention is the inability to blind participants. However, as a means to buffer potential Hawthorne effects, the study team reiterated participant expectations through study timelines. Also, pre- and post-intervention health assessments were conducted by clinical staff blinded to the study arms. In any case, the study design allowed for all enrolled participants the opportunity to gain access to the intervention, which is important to cultivating trustworthiness in research with this often marginalized demographic.

Further, we acknowledge that our study was not designed to capture external study factors including intensification of medical therapies by clinicians or improved participant adherence to recommended medical therapies or lifestyle changes from clinicians. These factors could potentially explain the demonstrated significant changes in LS7 clinical factors (systolic BP, total cholesterol, and glucose) in the control group. We also recognize that this study was performed during a relative short time period and may not have had sufficient follow-up duration to detect changes in the objective LS7 clinical factors or to achieve sustained improvements in these parameters. We recommend prudence to not overemphasize or interpret the improvements in diet and PA or minimize the lack of change in clinical factors within the intervention arm, but rather to examine the use of our intervention to improve overall CVH in the community-based setting among African Americans, a group highly underrepresented in mHealth research.[25] Future directions for mHealth interventions should include assessments of their utility and efficacy at the clinical care and health system levels.[60,61] The study team is currently examining the FAITH! App in federally qualified health centers to improve hypertension management in African American patients.[62]

Another limitation is the lack of in-depth assessment of specific features within the multicomponent FAITH! App intervention (eg, modules, tracking, sharing board, etc) associated with changes in LS7 score and the individual components. This is beyond the scope of the current study because sophisticated analyses of user engagement categories (eg, frequency of use versus interaction with features) are required. Future dismantling studies[63–65] including data from both study arms (immediate and delayed intervention) are planned to identify the influence (active mechanism) of discrete intervention components on CVH.

Generalizability is limited because this study was conducted in the MN African American community and may not be reflective of other regions. However, our data suggest that this Midwest population has equivalent or greater CVD risk than other, larger population-based cohorts of African Americans, including the Jackson Heart Study.[66] Future studies are warranted to assess the replicability of these findings in other geographic areas (both urban and rural) and the sustainability potential of the FAITH! App within a broader network of national and international faith-based organizations traditionally prioritizing individuals of African descent. African American churches have been the trusted institutional backbone of the African American community given their substantial influence, health promotion, and outreach efforts. Thus, they may continue to serve as agents of change in the health behavior realm to promote favorable changes in CVH among African Americans.[25,67]

Conclusions

The FAITH! Trial demonstrated preliminary findings to suggest that a culturally relevant mHealth lifestyle intervention may be efficacious in promoting ideal CVH among African Americans. The study also provides a community-informed, evidence-based model for best practices to assess, promote, and attain ideal CVH in minoritized and socioeconomically disadvantaged populations at greatest risk for CVD.

ARTICLE INFORMATION

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Disclosures

None.

Supplemental Material

Tables S1 and S2

Figures S1–S3

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