The FAITH! Trial: A mHealth Intervention to Improve Cardiovascular Health Among African-Americans

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General Study Information

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Study Title: The FAITH! Trial: A mHealth Intervention to Improve Cardiovascular Health Among African-Americans

Protocol version number and date: V3 (01-OCT-2021)

Research Question and Aims

Hypothesis:
The purpose of this project is to apply a community-based participatory research (CBPR) approach to rigorously refine and test the feasibility and preliminary efficacy of our existing cardiovascular (CV) health and wellness digital application (app) prototype to improve CV health according to the American Heart Association Life's Simple 7 (LS7) framework among African-American (AA) adults within faith communities. We hypothesize that our app-based intervention will be feasible and improve LS7 among AAs from baseline to 6-months post-intervention.

Aims, purpose, or objectives:
Aim 1: Refine an existing general CV health and wellness app that promotes the AHA LS7 by incorporating user-individualized and interpersonal features.
Aim 2: Assess the feasibility and preliminary efficacy of the culturally relevant digital app for promoting the AHA LS7 among AA adults within faith communities within a randomized controlled trial (RCT).

We will **adopt and test behavioral theory-informed and empirically-supported** mobile health (mHealth) **strategies to influence CV health.** Research demonstrates the efficacy of personalization, brief motivational/praise messages, goal-setting, positive behavioral prompts, self-assessments, and interpersonal connection in promoting healthy lifestyle in mHealth interventions.[1] We know of no study that integrates these components into an app to synergistically target multiple CV risk factors. **B2.** This is among the **1st community-based mHealth lifestyle interventions for AAs utilizing LS7.** The widely used Framingham Risk score is based on research conducted almost exclusively in homogeneous white populations.[2] Our work adopts the LS7 assessment, which has been examined in more racially diverse cohorts[3-5] but has yet to be used for the design/assessment of a community-based intervention. Our project represents the 1st series of community-based studies to use LS7 as the primary outcome variable in AAs at high-risk for CVD. **B3.** We **address the need for culturally tailored mHealth lifestyle interventions in underserved populations aimed at multiple levels of the Social Ecological Model (SEM).[6-8]** A recent review[9] suggests that culturally tailored behavioral components in the SEM context of the population (individual, interpersonal, community) may lead to better CV risk outcomes among AAs. Our intervention moves from a one-size-fits all approach to culturally tailor a mHealth intervention within the psychosocial context of AAs to improve their CV health.

Background (*Include relevant experience, gaps in current knowledge, preliminary data, etc*.):
AAs are more likely to die from cardiovascular disease (CVD) than the overall US population and have significantly poorer CV health than whites as defined by the AHA LS7. Our proposed study aims to refine and test the feasibility and preliminary efficacy of a culturally relevant mHealth intervention (a CV health and wellness digital application) to promote the AHA LS7 among AAs within faith communities. This research will allow us to design more effective mHealth interventions to improve CV health in AAs.

Importance of the Problem: CV health disparities in African-Americans (AAs) persist.[10] Approximately three-quarters of absolute disparities between AAs and non-Hispanic whites in CVD mortality are attributed to differences in multiple CV risk factors such as hypertension, diabetes, obesity, physical inactivity, and poor diet.[11] Many of these CVD-related deaths are preventable through improvements in modifiable lifestyle behaviors and risk factors, and addressing the social determinants of health. The American Heart Association (AHA) outlined 7 "simple" targets, Life's Simple 7 (LS7) to improve CV health.[12] This metric is inclusive of 4 health behaviors and 3 biological risk factors (physical activity [PA], diet, smoking, body mass index [BMI], blood pressure [BP], total cholesterol, and glucose), which are further classified into 3 categories: ideal, intermediate, and poor. Recent epidemiologic studies unmasked striking disparities in ideal LS7 between AAs and whites.[3,4] AAs have significantly fewer ideal LS7 components than whites, and 82% lower odds of meeting ≥5 ideal LS7 components.[4] In MN, AAs also have poorer CV health than whites.[13] In recent years, numerous culturally tailored, community-based, health interventions have shown effectiveness in improving general health knowledge and health behaviors among AAs.[14-20] These interventions have largely targeted single CV risk factors (eg, PA, obesity); thus, have less potential to significantly reduce CV health disparities than those targeting multiple risk factors.[11,21] Many of these interventions have been unsustainable and inadequately disseminated in AA communities.[22-25] AAs face multi-level psychosocial and structural barriers including reduced access to quality healthcare/health information and trusted providers, and financial/environmental constraints that limit their abilities to focus on their own health/wellness.[6,26,27]

Overcoming Critical Barriers to Progress: Novel methods for overcoming barriers to ideal CV health in AAs are warranted. AAs are embracing mobile technologies with rapid smartphone-use expansion and frequent Internet use to search for health information including CVD-related topics.[28] *A window of opportunity exists in integrating mobile health (mHealth) technologies, digital communication, and devices for the diffusion of CV health promotion in AA communities as these modalities are readily adaptable, engaging, scalable, cost-effective*,[29,30] *and effective in improving CV risk factors.*[31,32] Thus, mHealth lifestyle interventions hold potential for improving CV health in AAs; however, there are few effective, culturally relevant, evidenced-based interventions at their avail.[33,34]

Improvement of Scientific Knowledge: To date, no community-based mHealth lifestyle intervention has assessed the impact of risk-based prevention by targeting multiple CV risk factors among a high CVD risk, underserved racial/ethnic minority group as recommended by the AHA.[12,33,35] Our study fills this gap by enhancing our existing general CV health/wellness digital application (app) to more effectively address the LS7 through a community-based participatory research (CBPR) approach.[36,37] Our integration of rigorous qualitative and quantitative methods will allow us to further culturally tailor and personalize the app by considering the unique needs and preferences of AAs to facilitate their achievement and maintenance of ideal CV health. Community input will provide a better understanding of essential digital communication features and health promotion delivery methods required by a mHealth intervention to improve CV health in AAs. A growing body of evidence shows the benefits of mHealth interventions in CVD prevention through behavior change[33,38,39] and

provides a strong **scientific premise** for the proposed work. This work addresses the need for comprehensive mHealth lifestyle interventions among AAs and other underserved racial/ethnic minority populations with the lowest ideal CV health rates. The scientifically sound LS7 framework provides additional evidence to support our approach.[40]

Improvement of Scientific Knowledge: To date, no community-based mHealth lifestyle intervention has assessed the impact of risk-based prevention by targeting multiple CV risk factors among a high CVD risk, underserved racial/ethnic minority group as recommended by the AHA.3,27,29 Our study fills this gap by enhancing our existing general CV health/wellness digital application (app) to more effectively address the LS7 through a community-based participatory research (CBPR) approach.30,31 Our integration of rigorous qualitative and quantitative methods will allow us to further culturally tailor and personalize the app by considering the unique needs and preferences of AAs to facilitate their achievement and maintenance of ideal CV health. Community input will provide a better understanding of essential digital communication features and health promotion delivery methods required by a mHealth intervention to improve CV health in AAs. A growing body of evidence shows the benefits of mHealth interventions in CVD prevention through behavior change27 ,32 ,33 and provides a strong **scientific premise** for the proposed work. This work addresses the need for comprehensive mHealth lifestyle interventions among AAs and other underserved racial/ethnic minority populations with the lowest ideal CV health rates. The scientifically sound LS7 framework provides additional evidence to support our approach.34

Preliminary Work:

I. **Using CBPR to design and test FAITH! intervention.** The original focus of the FAITH! (Fostering African-American Improvement in Total Health) Program was chronic disease prevention through nutrition education. Through formative development in partnership with an AA church in Baltimore, MD, the behavioral theory-based multicomponent intervention included 2 face-to-face education sessions on healthy eating with health professional-led, evidence-based lectures, videos, cooking demonstrations (demos), and culturally tailored, spiritually-motivating, educational materials.[41] Key Findings: We enrolled 27 AA adults (74% women, mean age 50). Over the study course, there was a >20% increase in participants reporting ≥5 fruit/vegetable intake/day (17% baseline, 40% 6-months post-intervention) and a 10% increase in healthy diet self-efficacy.[42] A sustainable, church-run healthy food pantry was also established. Relevance to Proposed Work: A CBPR approach with an AA church congregation to jointly develop our evidence-based intervention is feasible and can influence health behaviors.

Figure 1: FAITH! App Prototype Homepage

II. **Adapting FAITH! intervention to CV health focus among new community partners.** In 2013, we began to build a rich and dynamic CBPR academic-community partnership with 6 predominantly AA churches within Rochester and Minneapolis-St. Paul (MSP), MN. It was mutually agreed upon by our study team and community partners to better address health disparities within the AA faith community by shifting the FAITH! Program's focus to CV health promotion through the LS7 framework, maintaining key intervention components (C1a, face-to-face education sessions). Supportive educational and social support resources included an NHLBI CVD prevention for AAs manual and heart healthy

cookbook,[43,44] cooking demos and fitness classes. We enrolled 37 participants (70% women) in the 16-week [wk] program of 8 biweekly, 90-minute education sessions at participating churches. Key Findings: Participants had improvements in CV health knowledge/LS7 metrics[45] along with positive trends between self-efficacy and health behaviors. *Participant evaluations indicated a keen interest in program sustainability and dissemination through integration of mobile technology or the Internet.*[46] Relevance to Proposed Work: FAITH!, with a new CV health focus was expandable to a new AA faith community and improved CV health knowledge/LS7. Participant feedback guided the intervention formatting from a face-to-face program to an app to increase its access and be less resource-intensive.

III. **Developing and testing app prototype (*FAITH! App* Pilot Study).** Employing a CBPR approach, we co-developed an app prototype, *FAITH! App* (**Figure 1**) focused on general CV health/wellness. It included 10 core education modules on CVD risk as a video series from health professionals and basic functionality of diet/PA self-monitoring and a sharing board. We enrolled and retained 50 participants (26 in MSP, 24 in Rochester, 70% women) into a single group, 10-wk intervention centered on the modules with adjunct live sessions (cooking demos, fitness classes, meet-the-experts forum).[47,48] Key Findings (**Table 1**): Analyses revealed positive perceptions and high user-satisfaction of the *FAITH! App* with feedback to include individually-tailored, interpersonal features to support CV health. Participants had: high mobile technology use, high eHealth literacy and overall high CVD risk with multiple risk factors at baseline (overweight/obese, 85%; physical inactivity, 40%; hypertensive, 40%; poor diet, 30%). At 28-wks post-intervention, there were significant improvements in LS7 factors/behaviors, LS7 composite score and psychosocial variables influencing behavior change. Relevance to Proposed Work: It is crucial to refine and rigorously test the app as a standalone intervention with LS7, individualized/interpersonal features, building logically to the proposed study.

Table 1. Summary of key findings: FAITH! App Pilot Study

Mean (SD), unless otherwise noted	**Baseline (N=50)**	**Post-intervention 28 wks (N=49)**	***P*-Value**
LS7 CV health factors			
Systolic BP (mmHg)	132.9 (18.8)	127.1 (19.3)	**0.005**
Diastolic BP (mmHg)	82.6 (10.3)	77.1 (12.0)	**0.0003**
Triglycerides (mg/dL)	104.3 (58.1)	88.7 (44.7)	**0.03**
LS7 CV health behaviors			
Fruit/vegetable intake (servings/d)	3.6 (1.6)	4.5 (1.8)	**<0.0001**
Moderate PA (min/wk)1	40 (0, 100)	60 (0, 225)	**0.04**
LS7 composite score	8.4 (2.1)	9.0 (2.1)	**0.05**
Psychosocial measures			
Diet regulation	2.2 (0.8)	2.7 (0.8)	**<0.0001**
PA regulation	2.4 (0.7)	2.7 (0.7)	**<0.0001**
Diet social support-discouragement	11.0 (4.7)	8.9 (3.3)	**0.0006**
PA social support-encouragement	17.5 (9.2)	21.5 (9.5)	**0.02**
Barriers to healthy diet	2.4 (0.8)	2.2 (0.6)	**<0.0001**
1Median (25th, 75th percentile)			

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Study Design and Methods

Methods: *Describe, in detail, the research activities that will be conducted under this protocol*:

Overall Strategy and Design:
Aim 1: We will obtain community input through an iterative, semi-structured focus group series. Their feedback will bolster cultural relevance for the AA faith community and encourage optimal user engagement as we incorporate individually-tailored messaging based on individual LS7 and psychosocial factors and a moderated group sharing board, features deficient or absent within the existing *FAITH! App*. A formative research process will provide key information for *FAITH! App* prototype refinement to a LS7 theme for use in a RCT (Aim 2) and is essential to our ongoing CBPR process.[37]

Table 2. Projected content and structure of refined FAITH! App

Feature	Description; Theoretical Framework
Dashboard *(New)*	User-specific display of baseline LS7 metrics, tailored stage-based messaging, modules/tracking progress meter; PAPM
Social incentive *(New)*	Thermometer goal chart by church for tracked diet (fruit/vegetable intake) and PA (no. of steps, minutes); SEM
Education modules *(Refined)*	10 modules with core video series on key LS7 components from health professionals, pre-post quizzes of CV health knowledge and relevant brochure content in each module
Self-monitoring *(Refined)*	Interactive tracking of fruit/vegetable intake and PA via a monthly calendar
Sharing Board *(Refined)*	Moderated discussion platform and feed for participant interaction by posting healthy lifestyle practices and associated psychosocial factors through text, photographs and video; SEM
Testimonials *(Refined)*	Church leadership and past FAITH! Program participant video accounts of their personal experiences with heart disease or healthy lifestyle change with motivational messaging; SEM
Recipes	Cookbooks including heart-healthy traditional AA cuisine

Theoretical framework. (**Table 2**) We will integrate a theory-based approach into refining the *FAITH! App* to provide users with personalized educational content and support to encourage ideal CV health behaviors. Individual participant LS7 and the Precaution Adoption Process Model (PAPM) will be used to promote

behavior change based on stage-of-change (facilitate stage movement, Stages 1-6) according to a classification algorithm to deliver predetermined decision rule-based messages.[49] For instance, individuals in early stages (1-2) will receive messages to increase their awareness and readiness to act (eg, "Following 7 simple steps can improve your heart health and help you live longer"); whereas, those in advanced stages (5-6) will receive messages focused on performance capacity-building and positive reinforcement (eg, "Reducing portion size and increasing PA will help you lose weight" or "Keep up the good work, you've eaten >5 fruit and vegetable servings today!"). Tailored messages unique to each individual's PAPM stage will be delivered via their app dashboard to inform and persuade toward consistent healthy behaviors.[24] The existing app sharing board allows participants to post testimonials of their healthy lifestyle practices. We will modify this feature by including moderated weekly posts to foster discussion on psychosocial factors (self-efficacy, self-regulation, social support, and barriers/facilitators to healthy lifestyle) by incorporating SEM concepts.[6,7] Furthermore, we will integrate a social incentive at the church level (motivator for behavior change based on social ties)[50-52] with a thermometer goal chart tracking diet/PA by church over the 1-year study. Top-ranked churches will be acknowledged during a post-study community-wide dissemination event.

Aim 2:
We will use a cluster RCT design to evaluate app preliminary efficacy with participants randomized into the intervention or delayed intervention (control) group. This strategy ensures that all participating churches receive the intervention as mutually-preferred by our ongoing CBPR partnership. Health assessments of LS7 measures will be conducted for both groups at baseline and 6-month follow-up.

Recruitment:

Aim 1:

We will recruit 15 participants (5/series) for the focus group series from AA churches in Rochester and MSP through church flyers, announcements and advertisements, our existing contacts (FAITH! Community Steering Committee [CSC] members) and the assistance of established FAITH! Partners (church liaisons identified by the church pastors). Recruitment materials will contain a brief description of the study, key contact information (study team telephone number and email address) and inclusion criteria for interested participants to review. The study team will recruit participants using a recruitment telephone script. Oral consent will be obtained from eligible individuals who wish to participate.

Aim 2: Churches
Churches will be recruited primarily through our existing contacts (FAITH! CSC members). Churches will also be identified by city-wide congregational and business listings.

Aim 2: Participants
Participants will be recruited from partnering congregations into the cluster RCT through church announcements, advertisements and flyers with similar procedures as Aim 1. We will seek assistance from FAITH! Partners with recruitment through community kickoff events, review of church rosters and involvement of church auxiliary groups (e.g. men's, women's, senior's and young adult ministries). See **Other Clinical Trial-related Attachments** for sample community kickoff event flyer.

The study team will organize joint congregation community kickoff events (1 in Rochester, 2 in MSP), which will include a project overview and open discussion.[48] Interested individuals will complete a Registration/Program Interest Form and return it to the church designated FAITH! Partner, who will then forward it to the study team. The FAITH! Partner will assist with recruitment and will NOT conduct research. The study team will contact interested individuals to reiterate study details and complete eligibility screening while ensuring at least 10 participants/church.

Study Enrollment:
Aim 1:

At the end of the recruitment telephone conversation, oral consent will be obtained from eligible individuals who wish to participate in the study. Documentation of HIPAA authorization will involve the use of Electronic Informed Consent for the HIPAA authorization form. This is an institutionally approved process for documenting HIPAA authorization using an on-line process. The subject may print or electronically save the HIPAA authorization form, or may contact the study team to provide a copy of the form.

Note: If the subject prefers not to use Electronic Informed Consent, the study team will either have the subject review and sign a paper HIPAA authorization form at the Orientation Session OR mail the subject the HIPAA form for them to review, sign and return via pre-paid envelope.

Consented participants will be instructed to attend an Orientation Session (1 in Rochester, 1 in MSP) where they will receive instructions on how to install the app prototype to their personal smartphones. As an alternative to the face-to-face Orientation Session, a virtual Orientation Session will be held (via an online meeting platform such as Zoom, Go-To-Meeting, etc.). Only if requested due to preference of use, tablet devices will be securely mailed directly to participants with signature required on delivery by the participants. As proven successful for participant retention with our previous community discussion sessions within other studies, we will establish rapport with the participants at the orientation sessions, to ensure that they feel welcome and comfortable engaging with the study team to share their experiences.

Following the Orientation Session, participants will be emailed a 20-item survey capturing sociodemographics, mobile technology use, and digital health information sources to complete prior to Focus Group 1.

The electronic screener will be delivered through a secure, HIPAA-compliant survey software (Qualtrics (https://www.qualtrics.com)) that transmits data to and from secure firewalled data centers using Transport Layer Security encryption.

Aim 2: Churches

We will assess readiness to engage of each church by the PREACH (Predicting Readiness to Engage AA Churches in Health) model (i.e. infrastructure, prior health programming) and telephone survey of health-related church activities (goal screening of at least 30 churches in Rochester and MSP areas).[53,54] Churches meeting our inclusion criteria and screened at readiness Stage 3 (substantial infrastructure capacity for health promotion programming) will be invited to participate and interested churches will sign a letter of mutual intent to enroll within the study.

Aim 2: Participants

To maximize participant recruitment and retention, the study team will organize joint congregation community kickoff events (one in Rochester, two in MSP) which will include an introduction to the study team, prior research study findings/accomplishments, an overview of the current research project (timeline, intervention components, health assessments, etc.), a promotional video and open discussion. Healthy refreshments will be provided at all events. Interested participants will complete a "Registration/Program Interest Form" (including name, address, telephone number and email address) and return it to the church designated FAITH! Partner, who will then forward it to the study team. FAITH! Partners will assist with recruitment and will NOT conduct research. The study team will contact the interested participants to reiterate study details and complete eligibility screening while ensuring at least 10 participants per church. Documentation of informed consent will involve the use of Electronic Informed Consent for research informed consent. This is an institutionally approved process for documenting consent using an on-line process. The subject may print or electronically save the consent form, or may contact the study team to provide a copy of the form.

Note: If the subject prefers not to use Electronic Informed Consent, the study team will either have the subject review and sign a paper consent form when they report for the Baseline Health Assessment OR mail the subject the informed consent form to review, sign and return via pre-paid envelope.

Subject Participation:

Aim 1

Participants will remain in the study for 3 months. Participants will test the app prototype with the proposed refined features for a 2-wk period prior to Focus Group 1. At least 3 focus groups will be convened over a 3-month period. Each session (up to 90 minutes) will be led by a trained moderator from the Mayo Clinic Qualitative Research Center, will be audio-recorded and transcribed. A co-moderator (either another moderator from the Mayo Clinic Qualitative Research Center or the study PI) will record field notes and manage room equipment. The discussion will follow a semi-structured moderator guide, informed by preliminary studies and the Health Information Technology Usability Evaluation Model/Scale (Health-ITUEM[55]/Health-ITUES[56,57]), on app prototype features, proposed revisions, and LS7 incorporation. The Health-ITUEM and Health-ITUES are systematic rubrics for evaluating mHealth intervention usability, particularly for health-related apps.[55] Questions will be structured by category[58] and sessions will integrate attentiveness to AA faith community cultural norms and values.[59] The series will inform sequential revisions of the app prototype components by the study team and software developers (CareHubs, Inc.) for review at subsequent focus groups.

Focus groups will be held at local churches, community venues and Mayo Clinic. As an alternative to the face-to-face focus groups, we have outlined potentially two strategies to receive feedback from participants: 1) virtual focus groups will be held (via an online meeting platform such as Zoom, Go-To-Meeting, etc.) or 2) semi-structured interviews to participants individually will be conducted by the trained moderator from the Mayo Clinic Qualitative Research Center.

Aim 2
Participants will remain in the study for 18 months: Intervention phase (2.5 months each/group, total 5 months), Maintenance phase (6 months each/group, total 12 months). Participants will then complete a baseline electronic survey and health assessment. Two 1-hour, hands-on instructional training sessions on the app login process, basic features and navigation will be delivered by the study team (1 each in Rochester and MSP). Participants will be provided with a step-by-step instructional manual to support independent use.

Schedule of Assessments				
Data Collected	**# Items**	**Baseline**	**Immediate Post-intervention**	**6 months**
Sociodemographics				
eHealth literacy: eHEALS[61,62]	10	X		
Mobile technology use skills[82]	13	X		
CV health (LS7) measures				
BP	--	X		X
Fasting lipid panel	--	X		X
Fasting glucose	--	X		X
Height/weight (BMI)	--	X		X
Cigarette smoking status	--	X		X
Diet quality: Delta Nutrition Intervention FFQ[79,80]	158	X	X	X
PA patterns: International PA Questionnaire[81]	7	X	X	X
Feasibility measures				
App engagement	--		X	X
App usability[64,65]	20		X	X
Psychosocial measures				
Diet/PA self-efficacy[83,84]	12/12	X	X	X
Diet/PA self-regulation[85,86]	16/10	X	X	X
Diet/PA social support[9,87]	10/13	X	X	X
Religiosity/spirituality: Daily Spiritual Experiences Scale[88]	6	X		X
Optimism: Life Orientation Test-Revised[89]	6	X		X
Perceived stress: Global Perceived Stress Scale[90-93]	8	X		X

Randomization (Figure 2). We will use a cluster RCT design with 2 waves of implementation inclusive of 2 groups: intervention (Group 1) and delayed intervention (Group 2, control group). We will randomize clusters of churches in Rochester and MSP to receive the intervention immediately following baseline health assessments including LS7 measures (Time 1, Group 1) or at post-maintenance (Time 3, Group 2). Groups 1 and 2 will complete post-intervention assessments by electronic survey of CV health behaviors, feasibility and psychosocial measures (Times 2 and 4). Both groups will complete a second health assessment at post-maintenance (Time 3), to allow for comparison of LS7 measures between Groups 1 and 2. Times 4 through 5 are data collection points following the intervention (post-intervention and post-maintenance) for Group 2. The study statistician will randomize churches, ensuring the number of participants in Groups 1 and 2 is balanced. Churches will be told their group assignment after baseline assessments.

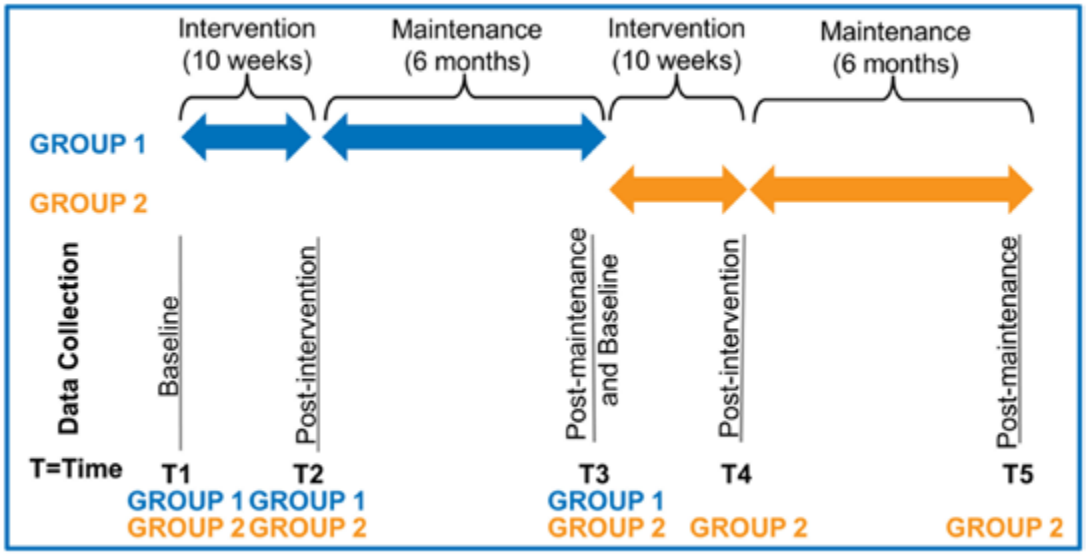

Figure 2. RCT with delayed intervention

Baseline and 6 month Health Assessment: Enrolled and consented participants will then complete a baseline assessment with screening of CVD risk profiles. CVD risk profiles will be assessed by measurement of height (without shoes to the nearest centimeter by a stadiometer), weight (using a calibrated scale in kilograms), blood pressure (average blood pressure of three sitting readings with an oscillometric automated device), lipid panel (by Cholestech system fingerstick measurement), random glucose (by fingerstick measurement).

Optional Group Meeting Following Maintenance: 15 participants from both Group 1 and Group 2 will be selected on a first-come, first-serve basis to participate in an optional group meeting, lasting about 2-hours, to be conducted at the post-maintenance phase. Participants will provide more information about the program and how it could be changed or improved.

Intervention condition. The app-based intervention is an individually-tailored program to promote LS7 through health education to increase awareness and skill development while enhancing self-efficacy, self-regulation, and social support for healthy behavior change. The app includes a 10-wk core series of multimedia education modules with a LS7 focus and other features including interactive self-quizzes, self-monitoring (diet/PA), and social networking (sharing board). The intervention is intended for participants to follow a weekly schedule of each module concentrating on each LS7 component. Personalized messages guided by the theory-based models (PAPM, SEM) will be delivered to each participant 3-4 times weekly over the intervention phase through the app dashboard and by text message or email as per participant preferences. Messages will be either informational, cues to action, reminders or motivational/praise for healthy behavior change. The sharing board will be moderated weekly by Mayo Social Media with posts to foster discussion on behavior change influences (barriers, facilitators) and participant successes/challenges to healthy lifestyle. Moderated posts will include messages, videos and images from reputable sources (eg, AHA, Mayo) and those cultural relevant to the AA faith community[60,61] . Participants will be notified of new posts via the app homepage. Participants will maintain app access for the duration of the study.

Control condition (Delayed intervention group). The delayed intervention group will not receive additional materials while under the "control" timepoint (intervention group within intervention/maintenance phases).

Subject Retention:
We will remind participants of outlined program events/milestones at multiple time points during recruitment, assessment and after randomization to support our retention efforts and to reiterate requirements of the study to participants. The communication plan for reminders will include a variety of means of contact (i.e. church announcements, flyers, telephone calls and automated emails). These strategies have enhanced our adherence/retention rates to interventions and health assessments in prior studies. In addition, there will be mandatory meetings with the study team at Mayo Clinic and collaborating sites to discuss progress and problem solve issues related to retention and data collection. Quarterly FAITH! CSC meetings will also review these items in detail to inform any necessary protocol modifications.

Subject Participation Remuneration:
Aim 1
Participants will receive a total of $100 by Visa gift card ($50 at enrollment, $50 at completion) and a personal PA monitor (i.e. Fitbit). Participants are only eligible to participate within this phase of the proposed project (i.e. focus group series only).

Aim 2: Churches
Churches are not considered subjects in FAITH! Trial, but it is worth mentioning that churches completing the screening survey will receive a health ministry starter kit by mail.[62] Churches meeting our screening and inclusion criteria as well as signing a letter of mutual intent will receive a $250 incentive for committing to participate in the study (goal distribution to church by completion of intervention post-maintenance phase for respective study arm).

Aim 2: Participants
Participants will receive a total of $150 by Visa gift card ($50 at enrollment, $50 at immediate post-intervention and $50 at 6-months follow-up), a cookbook with healthy recipes, a Mayo Clinic-published heart healthy book along with a personal PA monitor (FitBit). Participants who are selected to participate in optional group meeting will receive a $50 cash card at the conclusion of the meeting.

Dissemination Plan:
We have identified five key audiences for dissemination of our research findings which include the following:

1. **FAITH! CSC**
2. **Partnering AA churches (Rochester and MSP, MN)**
3. **Local AA community (Rochester and MSP, MN)**
4. **State-wide to regional public health organizations (e.g. Olmsted County and Minnesota Departments of Health, Midwest local affiliate AHA)**
5. **Academia (nationally and internationally)**

To ensure that the findings from our research informs community level health interventions to promote CV health and thereby maximizing the benefit to underserved AA communities, the following dissemination strategy has been developed by the study team:

First, the PI (Dr. Brewer) and study consultant (Mr. Clarence Jones) will formally co-present an executive summary of the study primary and secondary outcome findings to the FAITH! CSC at a regularly scheduled quarterly meeting, not only as an informative session but to also receive feedback and advice on the most

appropriate dissemination plans at the local, state and national levels. The study team will utilize this feedback to further inform and strengthen the dissemination strategy.

Second, the next audience for dissemination is the partnering AA congregations which encompass the church leadership, FAITH! Partners and last but not least--the study participants. We will hold at least three faith community-wide events (one in each city-Rochester, Minneapolis, St. Paul) at the end of the study to provide the overall results in a clear and succinct manner with incorporation of slide and video presentations and culturally appropriate infographics. As outlined in the Overall Strategy and Design section, the top-ranked church for highest levels of tracked fruit/vegetable intake and PA (by the app thermometer goal chart) will be acknowledged. In addition, a FAITH! Program-specific newsletter (paper and digital) will be created to provide ongoing updates about research plans, publications and church/participant testimonials.

Next, at the local AA community level, we will hold two community-wide outreach events (one in Rochester and one in MSP) to promote ideal CV health in the form of a "Walk by FAITH!" 5K event which will start and end with testimonials from the study team, FAITH! CSC and partnering church leadership on the importance of healthy lifestyle practices. We will also capitalize on social media (i.e. Facebook, Twitter), local newspapers (including *Minnesota Spokesman-Reporter*, *Insight News*) and radio shows (Mr. Jones' weekly radio program, *Community Health Dialogues,* KMOJ FM Radio, Minneapolis) for proactive dissemination of our study findings to our prioritized population.

On a statewide level, the PI and Mr. Jones will jointly present executive summaries of the FAITH! mHealth intervention components and study findings to key influential organizations to inform health policy, environmental and systems change in the Rochester and MSP areas (Departments of Health and local-affiliate AHA). Two of our FAITH! CSC members are closely aligned as leadership and stakeholders within these organizations and will be fully engaged to ensure that robust and actionable recommendations are generated to maximize their uptake. Central to our meetings with these organizations are to identify the potential benefits/role of the FAITH! intervention and program as a whole in improving the CV health of MN AA communities as a part of ongoing community-based programming within these entities. As a reciprocal dialogue, we also hope to collaboratively assess the quality of the current community health programs and services in meeting the needs and priorities of the AA community and how the FAITH! Program can assist in transforming program delivery models and facilitating ideal CV health outcome benchmarking.

Lastly, the PI, Co-Is and community partners will present study findings within academia both nationally and internationally. Anticipated conferences include the following: AHA Scientific Sessions, AHA Epi Lifestyle, American Public Health Association Annual Meeting, AcademyHealth, European Cardiology Society, American Society of Preventive Cardiology and the Mixed Methods International Research Association Global Conference. This level of dissemination also includes peer-reviewed publications in high impact academic journals and research summaries for professional journals all written and co-authored with our community partners. The PI will ensure that the study is registered and that its results are submitted to ClinicalTrials.gov in compliance with NIH specific timelines and policies and our own institutional policy at Mayo Clinic. All informed consent documents will include a specific statement relating to posting of information related to this study at ClinicalTrials.gov. The lessons learned from our research can be translated and adapted to other racial/ethnic minority groups and underserved populations to enhance efforts to effectively promote CV health

Resources: *Describe the available resources to conduct the research (personnel, time, facilities, mentor commitment, etc.)*:

Expertise of the Study Team:

Our study team is uniquely suited to conduct the proposed study. Dr. Brewer (PI) has expertise in *preventive CV medicine,*[63] *CBPR,* and *faith-based* and *mHealth interventions*.[48] Co-Is, Drs. Patten[64] and Cooper[65] are the PI's KL2 mentors and are internationally recognized experts in *CBPR* and *health disparities research*. Other Co-Is and Consultants are: Dr. Burke, *mHealth/digital communication expert*[66,67]; Dr. Radecki Breitkopf, *social/behavioral sciences expert*[68]; Dr. Hayes, *cardiologist and health disparities expert*[69]; Mr. Jones, former *community outreach director* of a federally qualified health center[48]; and Ms. Jenkins, *biostatistical expert.*[45]

CSC:
As infrastructure for the overarching CBPR partnership for CV health promotion within the AA community, a FAITH! Program-specific CSC was established including 10 members from diverse community organizations in MN.[70] It will inform all research phases, meet quarterly with the study team, and receive an honorarium.

☐ (1a) This is a multisite study involving Mayo Clinic and non Mayo Clinic sites. *When checked, describe in detail the research procedures or activities that will be conducted by Mayo Clinic study staff.*

Locations:

Mayo Clinic study staff will be the lead coordinating center, and responsible for oversight of study conduct, training appropriate personnel, communication, facilitating the use of the most current and IRB approved study processes, subject recruitment and data analysis.

☒ (1b) Mayo Clinic study staff will be engaged in research activity at a non Mayo Clinic site. *When checked, provide a detailed description of the activity that will be conducted by Mayo Clinic study staff.*

Please see the methods for additional information on the inclusion of community partners.

Subject Information

Target accrual is the proposed total number of subjects to be included in this study at Mayo Clinic. A "Subject" may include medical records, images, or specimens generated at Mayo Clinic and/or received from external sources.

Target accrual: 215 participants
Aim 1: 15 participants
Aim 2: 16 churches, 200 participants

Subject population (children, adults, groups):
Adult community members affiliated with the partnering AA churches in Rochester and MSP, MN

Inclusion Criteria:
Aim 1

- Men and women 18 years of age and older
- AA race/ethnicity

- Basic Internet navigation skills
- Active email address

Aim 2: Churches
- predominantly AA parishioners
- church size >50 members
- commitment from church pastor/senior leadership to promote the study at church
- willingness of church member to serve as church liaison (FAITH! Partner)

Aim 2: Participants
- Men and women 18 years of age and older
- AA race/ethnicity
- Basic Internet navigation skills (at least weekly access)
- Active email address
- Ownership of smartphone (supporting iOS or Android systems)
- Minimal fruit/vegetable intake (<5 servings/day)
- No regular PA program (<30 minutes/day of moderate PA)
- Able to engage in moderate PA (such as brisk walking, dancing, aerobics, gardening, weight lifting without restrictions including physical disability, use of a wheelchair daily or serious medical condition)

Exclusion Criteria:
Aim 1
- Unable to commit to participating in at least 3 focus groups over 3 month period.
- Have visual/hearing impairment or mental disability that would preclude independent use of the app.

Aim 2
- Unable to walk up at least two flights of stairs or walk at least one city block without assistance or stopping
- Pregnant or planning to become pregnant within 2 years (due to associated hormonal and weight changes)
- Have visual/hearing impairment or mental disability that would preclude independent use of the app.
- Participant in Aim 1 focus groups

Research Activity

Check all that apply and complete the appropriate sections as instructed.

1. ☐ **Drug & Device**: Drugs for which an investigational new drug application is not required. Device for which (i) an investigational device exemption application is not required; or the medical device is

cleared/approved for marketing and being used in accordance with its cleared/approved labeling. (Specify in the Methods section)

2. ☒ **Blood**: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.

3. ☐ **Biological specimens other than blood**: Prospective collection of human biological specimens by noninvasive means that may include: urine, sweat, saliva, buccal scraping, oral/anal/vaginal swab, sputum, hair and nail clippings, etc.

4. ☐ **Tests & Procedures:** Collection of data through noninvasive tests and procedures routinely employed in clinical practice that may include: MRI, surface EEG, echo, ultrasound, moderate exercise, muscular strength & flexibility testing, biometrics, cognition testing, eye exam, etc. (Specify in the Methods section)

5. ☒ **Data** (medical record, images, or specimens): Research involving use of existing and/or prospectively collected data.

6. ☒ **Digital Record**: Collection of electronic data from voice, video, digital, or image recording. (Specify in the Methods section)

7. ☒ **Survey, Interview, Focus Group:** Research on individual or group characteristics or behavior, survey, interview, oral history, focus group, program evaluation, etc. (Specify in the Methods section)

☐ NIH has issued a *Certificate of Confidentiality* (COC). *When checked, provide the institution and investigator named on the COC and explain why one was requested*. _____

Biospecimens – Categories 2 and 3

(2) Collection of blood samples. When multiple groups are involved copy and paste the appropriate section below for example repeat section b when drawing blood from children and adults with cancer.

a. **From healthy, non-pregnant, adult subjects who weigh at least 110 pounds**. For a minimal risk application, the amount of blood drawn from these subjects may not exceed 550ml in an 8 week period and collection may not occur more frequently than 2 times per week.

Volume per blood draw: Fingerstick blood sample only (per lipid panel, glucose sample)

Frequency of blood draw (e.g. single draw, time(s) per week, per year, etc.) Once at baseline assessment and 6-months follow-up assessment

Review of medical records, images, specimens – Category 5

For review of existing data: provide a date range or an end date for when the data was generated. The end date can be the date this application was submitted to the IRB. Example: *01/01/1999 to 12/31/2015* or all records through *mm/dd/yyyy*.

Date Range:

Check all that apply (data includes medical records, images, specimens).

☐ (5a) Only data that exists before the IRB submission date will be collected.

☐ (5b) The study involves data that exist at the time of IRB submission **and** data that will be generated after IRB submission. Include this activity in the Methods section.
Examples

- The study plans to conduct a retrospective chart review and ask subjects to complete a questionnaire.
- The study plans to include subjects previously diagnosed with a specific disease and add newly diagnosed subjects in the future.

☐ (5c) The study will use data that have been collected under another IRB protocol. Include in the Methods section and enter the IRB number from which the research material will be obtained. *When appropriate, note when subjects have provided consent for future use of their data and/or specimens as described in this protocol*.

Enter one IRB number per line, add more lines as needed

☐ Data ☐ Specimens ☐ Data & Specimens _____

☐ Data ☐ Specimens ☐ Data & Specimens _____

☐ Data ☐ Specimens ☐ Data & Specimens _____

☐ (5d) This study will obtain data generated from other sources. Examples may include receiving data from participating sites or an external collaborator, accessing an external database or registry, etc. Explain the source and how the data will be used in the Methods section.

☐ (6) Video audio recording: *Describe the plan to maintain subject privacy and data confidentiality, transcription, store or destroy, etc.*

HIPAA Identifiers and Protected Health Information (PHI)

Protected health information is medical data that can be linked to the subject directly or through a combination of indirect identifiers.

Recording identifiers (including a code) during the conduct of the study allows you to return to the medical record or data source to delete duplicate subjects, check a missing or questionable entry, add new data points, etc. De-identified data is medical information that has been stripped of all HIPAA identifiers so that it cannot be linked back to the subject. De-identified data is **rarely** used in the conduct of a research study involving a chart review.

Review the list of subject identifiers below and, if applicable, check the box next to each HIPAA identifier being recorded at the time of data collection or abstraction. Identifiers apply to any subject enrolled in the study including Mayo Clinic staff, patients and their relatives and household members.

Internal refers to the subject's identifier that will be recorded at Mayo Clinic by the study staff.
External refers to the subject's identifier that will be shared outside of Mayo Clinic.

Check all that apply:	INTERNAL	EXTERNAL
Name	X	
Mayo Clinic medical record or patient registration number, lab accession, specimen or radiologic image number	X (Aim 2)	
Subject ID, subject code or any other person-specific unique identifying number, characteristic or code that can link the subject to their medical data	X	
Dates: All elements of dates [month, day, and year] directly related to an individual, their birth date, date of death, date of diagnosis, etc. **Note:** Recording a year only is not a unique identifier.	X	
Social Security number	X	
Medical device identifiers and serial numbers		
Biometric identifiers, including finger and voice prints, full face photographic images and any comparable images		
Web Universal Resource Locators (URLs), Internet Protocol (IP) address numbers, email address	X	
Street address, city, county, precinct, zip code, and their equivalent geocodes	X	
Phone or fax numbers	X	
Account, member, certificate or professional license numbers, health beneficiary numbers		
Vehicle identifiers and serial numbers, including license plate numbers		
Check 'None' when none of the identifiers listed above will be recorded, maintained, or shared during the conduct of this study. (exempt category 4)	☐ None	☒ None

Data Analysis

Power analyses may not be appropriate if this is a feasibility or pilot study, but end-point analysis plans are always appropriate even if only exploratory. Provide all information requested below, or provide justification if not including all of the information.

Power Statement:
Aim 1
Not applicable.

Aim 2
The primary outcome will be a comparison of average change in the AHA LS7 score from baseline (Time 1) to 6-months post-intervention (Time 3) between Groups 1 and 2. Based on our prior study of 37 participants, including 5 churches, the intracluster correlation (ICC) of this outcome was near zero (<0.01), and the coefficient of variation (CoV) of church sizes was 0.38 (average number of participants/church, 10; SD 3.8; CoV 0.38). Assuming similar ICC (0.01) and slightly higher CoV (0.50) since more churches will be included in the planned study, including a total of 16 churches with an average of 10 participants/church, 80 participants/group will provide 85% power to detect a difference of 1.0 in average LS7 score change between the groups (SD 2; effect size 0.50; 5% type-I error rate). The clinical significance of this 1-unit difference in LS7 score is based on a recent meta-analysis demonstrating that each unit increase in LS7 metrics is associated with an estimated 19% and 11% reduction in CVD and all-cause mortality respectively.[40] We will recruit 200 participants to ensure 160 completers (assuming 20% attrition rate).

Data Analysis Plan:
Aim 1
Sample characteristics from electronic surveys will be summarized by descriptive statistics. Immediately following each focus group, a summary analysis of discussion highlights will be compiled by the moderator.[71,72] Overarching themes and most informative participant commentary will be further summarized to inform sequential intervention development. Subsequently, transcripts of each session will be independently reviewed by 2 study team members for confirmation of summary analysis themes and extraction of additional emergent themes.[73] Each will aggregate (by interview question) a synthesis of major themes of participant feedback and suggested revisions. Initial thematic analysis will incorporate codes from the Health-ITUEM.[55] A 3rd team member will assist with discrepancy resolution to ensure consensus. Content analysis will be facilitated by QSR NVivo software, v10 (Doncaster, Victoria, Australia).

Aim 2
Study measures will be summarized and compared between groups using $\chi 2$ tests for categorical variables and 2-sample *t*-tests for continuous variables. Differences between baseline and each follow-up will be calculated for continuous measures. These differences will be examined overall and within each group, with paired *t*-tests. The average change from baseline will be compared between intervention and control groups with 2-sample *t*-tests. The distribution of categorical outcomes (eg, LS7 component category: poor, intermediate, ideal) will be compared between baseline and each follow-up with McNemar's tests. All variables will be assessed and reported by sex.

Endpoints

Primary:

Aim 1

Focus group series/ App usability (impact, perceived usefulness, ease of use, user control):

App usability will be assessed by the Health-ITUEM/Health-ITUES, on the app prototype features, proposed revisions, and LS7 incorporation. The Health-ITUEM and Health-ITUES are systematic rubrics for evaluating mHealth intervention usability, particularly for health-related apps. At the end of the third focus group, participants will complete the Health-ITUES to assess the readiness of the app prototype. We will proceed to the RCT: if mean overall score of ≥4, the app will be finalized; if <4 an additional focus group will be held to address any remaining usability/satisfaction needs.

App user satisfaction (likes, dislikes, perceived cultural appropriateness):

A semi-structured moderator guide, informed by our preliminary studies will probe for feedback on the app prototype features, proposed revisions, and LS7 incorporation. The questions will be structured by the following categories: likes, dislikes, and perceived cultural appropriateness.

Aim 2: RCT

LS7 score

The LS7 score will be assessed by measurement of BP (average of 3 sitting readings), fasting lipid panel and glucose (by fingerstick), height (to nearest centimeter by stadiometer), weight (with calibrated scale in kilograms), self-reported cigarette smoking status (former, current, never), dietary quality (according to AHA guidelines by validated, culturally appropriate, food frequency questionnaire-FFQ),[74,75] and PA patterns (minutes/wk of moderate and vigorous intensity PA).[76] LS7 component criteria are adapted from AHA standards based on health assessment data. We will calculate a LS7 score as a composite of each LS7 component by assigning 2-pts for ideal, 1-pt for intermediate, or 0-pts for poor.[5] The total sum will allow for a continuous measure of CV health ranging from poor to ideal (0-14 points). For ease of translation and understanding, the LS7 score will be categorized as 0-6 (poor), 7-8 (intermediate), and 9-14 (ideal).

Intervention Feasibility

We will assess feasibility by participant engagement with the app features (goal >50% completion of education modules series, weekly diet/PA tracking and ≥1 sharing board post/month by each participant) and app usability by the Health-ITUES.

Secondary:

Aim 2: RCT

Self-efficacy (diet, PA)

Participant self-efficacy towards healthy behaviors (healthy diet, regular PA) will be assessed by validated instruments. The 12-item scales were previously utilized in our preliminary studies and assess a participant's confidence to maintain a healthy diet (fruit/vegetable intake) or exercise when faced with common barriers.[77,78]

Self-regulation (diet, PA)

Self-regulation for diet (16 items) and PA (10 items) will be adapted from the Health Beliefs Survey which has demonstrated reliability and validity among AA church congregations. [79,80]Participants are asked

questions about strategies they have used in the past three months to eat healthier foods, increase their daily step-count or PA. All items are measured on a five-point scale ("never" [1] to "repeatedly" [5]).

Social support (diet, PA)

Social support for healthy diet (10 items) and PA (13 items) from family, friends, colleagues or church members will be assessed using an adapted Sallis et al. scale previously utilized in our prior studies and in other AA church congregation samples.[16,81] Participants are asked how much encouragement they receive to eat healthier or increase PA. All items are measured on a five-point scale ("never" [1] to "very often" [5]).

Religiosity/spirituality

Religiosity/spirituality will be assessed by the 6-item Daily Spiritual Experiences Scale.[82] Scores range from 1 to 6 (attendance), from 1 to 8 (prayer), from 1 to 4 (religious coping), and from 6 to 36 (spirituality), with higher scores on each measure indicating greater religiosity.

Optimism

The Life Orientation Test-Revised (LOT-R) will be used to measure optimism.[83] The LOT-R is a 6-item scale ranging from 6 (least optimistic) to 24 (most optimistic). Participants respond to 3 positively worded items (e.g. "I'm always optimistic about my future") and 3 negatively worded items (e.g. "If something can go wrong for me, it will").

Perceived stress

Perceived stress will be measured using the Global Perceived Stress Scale which was validated in a population of AA adults with adaptation from standardized stress scales and within our study on stress and CV health in AAs.[84-87] The eight-item instrument measures global perceptions of stressful experiences over the prior 12 months in domains such as employment, legal issues, and racism/discrimination. Participants rate the severity of each domain according to a range of "not stressful" (1) to "very stressful" (3) with a total sum ranging from 0 to 24.

eHealth literacy

eHealth literacy will be evaluated using the eHealth Literacy Scale (eHEALS) which consists of 8 items scored on a 5-point Likert scale which assesses an individual's perception of their ability to understand and apply electronic health information.[88,89] The sum of all items ranges from 8 to 40 with higher scores reflecting a higher level of eHealth literacy.

Mobile technology use skills

Mobile technology use skills will be assessed by adapting 13 items from the "Measuring Digital Skills" instrument by Van Deursen et al with a focus on questions evaluating participant operational and navigation skills.[90]

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