A Culturally Tailored mHealth Intervention to Promote Physical Activity in African American Men: A Protocol for a Comparative Effectiveness Trial of MobileMen

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Abstract

Background: African American men are at a higher risk for serious health conditions like cardiovascular disease, diabetes, and stroke compared to non-Hispanic White men. Physical activity (PA) is a modifiable health behavior that has been shown to decrease chronic disease risk, yet PA engagement is alarmingly low in African American men. Interventions to improve PA engagement are effective in a number of populations; very few have been tailored to the unique needs of African American men. Even fewer have leveraged mobile health applications (apps), despite African American men's interest in and willingness to use such technologies for health improvement.

Objective: This comparative effectiveness trial aims to evaluate MobileMen, a PA promotion app tailored to the needs and preferences of African American men. The trial will compare MobileMen to a commercially available PA promotion app with similar features but lacks culturally tailored components.

Methods: We will recruit a sample of "low active" (accumulating < 7,500 steps per day) African American men (n=100) aged > 30 years from Baton Rouge, Louisiana and surrounding communities. All participants will be given a Fitbit Charge 6 wearable activity tracker to assess daily PA and steps, and will be randomized to either the intervention app, MobileMen), or the comparator app, a commercially available PA tracking app called Stridekick. Stridekick has similar features to MobileMen but was not intentionally designed for African American men. The intervention period is 6 months during which participants will interact with their assigned mobile app. MobileMen includes features such as digital badges earned for PA, tangible prizes like exercise equipment, challenges among participants, goal setting, and nutrition, PA, and behavior change educational information in text, audio, and video formats. Participants will complete assessments at baseline and 6-months post-randomization. Assessments include objective measurements of daily steps and minutes of moderate to vigorous PA, quality of life, dietary measures, self-efficacy for fruit and vegetable consumption and PA, and autonomous motivation for PA.

Results: This trial is in the start-up phase. MobileMen development and usability testing was completed in August 2024. Recruitment efforts began in October 2024. The trial and associated data analyses and interpretation are planned to be completed by Fall 2025.

Conclusions: Mobile apps are a widely accessible means to disseminate culturally tailored PA promotion interventions to various populations, including African American men. MobileMen has the potential to impact PA engagement in African American men, which would dramatically improve the overall health and chronic disease risk in this underrepresented group.

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Trial Registration: ClinicalTrials.gov NCT05621044

Keywords: Physical activity; motivation; mHealth; African American men

Introduction

African American men experience disproportionately high rates of obesity, cardiovascular disease, hypertension, stroke, diabetes, and prostate cancer when compared with their non-Hispanic white counterparts.[1–4] Increased levels of physical activity (PA) and fitness have been associated with reduced risk of these chronic conditions.[5–11] However, there is a lack of regular PA in the African American community[12] and African American men's rates of PA are well below national guidelines.[13–15] Comparatively, research consistently shows that African American men engage in lower levels of PA than their non-Hispanic White counterparts.[13,16–18] Thus, PA is one of the major modifiable risk factor for these chronic diseases in African American men and novel interventions to support PA initiation and persistence in this population are needed.

Mobile health (mHealth), which is the use of mobile phones in providing medical care,[19] has been increasingly used to change and maintain health behaviors, such as PA, across various populations.[20,21] Smartphones create enormous potential for intervention delivery because they are compact, portable, normally "on," readily available to individuals, affordable, user-friendly, offer advanced functionality, and allow online access on demand any day or time.[22–27] mHealth interventions[28] have been used to successfully increase PA[29] across several settings and health conditions, including in health care settings[30] and among cancer survivors.[31]

African American men appear to have a positive attitude toward mHealth interventions [27] and approximately 44% of African American men who received five months of PA training were willing to receive a mHealth maintenance intervention.[27] This was especially encouraging because the sample had a mean age of 53 and mobile application (app) usage and acceptability is typically lower in men 50 years of age and older.[27] African American men also demonstrated a willingness to engage in mHealth interventions specifically targeting chronic disease risk reduction.[27] Moreover, evidence suggests that mHealth interventions are effective with African American men. A recent study of a

comprehensive health app for African Americans indicated that users improved their minutes of moderate PA after 10 weeks of use.[32] Other studies have utilized text messaging to influence health behaviors in African Americans, also resulting in increased PA.[33,34] However, the samples in these studies were majority female and none of analyzed outcome data by sex, [32–34] further elucidating the need for development and testing of mHealth interventions specific to African American men.

To address the gap in mHealth applications developed specifically for African American men, we developed a smartphone app, *MobileMen*, to support PA engagement in this population. The process to develop this app is described elsewhere.[35] *MobileMen* is grounded in two behavior change theories: Social Cognitive Theory (SCT) and Self Determination Theory (SDT). SCT states the environment and a person's behavior interact to shape behavior, and that self-efficacy is a key component to behavior change.[36] SCT was the foundation of the PA adoption content focusing on self-monitoring, goal setting, and social support in the *MobileMen* app. We chose SCT[37–39] because SCT-grounded interventions have been effective at increasing and maintaining PA in African Americans.[40–42] In addition, SDT posits that satisfying three fundamental needs contributes to behavior change: perceived competence, a feeling of relatedness (feeling connected to others), and autonomy (feeling that change is a choice and not coerced).[43–47] When an activity fulfills these three needs, people can become more autonomously motivated, and resulting in more PA initiation and persistence.[48] In African American men, specifically, intrinsic motivation associates PA engagement with personal values and overall health goals, increasing the likelihood that they will persist with the behavior.[49] In the *MobileMen* app, we included features like reminders and goal setting to support the development of autonomy.[50] To support competence, we included activity history and feedback such as cumulative exercise statistics aggregated over weeks and months, logging of weight training workouts and health metrics, and tangible and digital rewards.[50] We also included the ability to participate in competitions with other users and a message function to support the basic need of relatedness.[50]

Additionally, the *MobileMen* app was culturally tailored to African American men. The culturally tailored content was based on the model established by Kreuter.[51] Kreuter describes five strategies to culturally tailor an intervention including 1) peripheral, 2) evidential, 3) linguistic, 4) constituent-involving, and 5) socio-cultural. Peripheral strategies involve matching the materials and messaging to the observable characteristics of the target population (e.g. utilization of images of African American men), analogous to face validity and like Resnicow's "surface structure."[52] Evidential strategies seek to put into context the health impact for a target population (e.g. notifications such as "African American men have higher rates of diabetes compared to men from other ethnic groups. Engaging in regular physical activity can reduce your risk of developing diabetes."). Linguistic strategies involve using language to make materials more accessible to the target audience (e.g. "Beast Mode" badge). Constituent-involving strategies are informed by experiences or input from the population of interest (e.g. utilizing focus groups with African American men). Socio-cultural strategies reflect the underlying beliefs, values, and norms of a group, like Resnicow's "deep structure."[52] Socio-cultural strategies involve how cultural, social, psychological, environmental, and historical factors affect health behaviors specifically within the target population. It is concerned with the target population's conceptualization of the need for intervention and accurate incorporation of this information into the treatment model. Commonly noted facilitators of PA include the need for peer support and camaraderie specifically from men[53,54] and competition.[53] African American men's gender role responsibility and commitment to family, friends, and community also play a role in the adoption and maintenance of PA. Although the men noted these factors during focus groups for the development of the app, they were unable to be incorporated into the prototype due to the limited scope. However, these factors largely contribute to the current app development. For example, educational content was included that explicitly acknowledges gender role expectations and provides practical strategies based on SCT (e.g. cognitive restructuring, social support techniques, etc.) and SDT (e.g. fostering relatedness through

competition) to assist men with incorporating family and friends into physical activity as part of the adoption and maintenance strategies.

The purpose of this paper is to describe the study protocol for examining the effectiveness of *MobileMen.* The trial will test the hypothesis that the *MobileMen* app will increase PA in African American men in comparison with a popular fitness app, *Stridekick.*

Methods

Study Design

A comparative effectiveness trial (CET) will be conducted to assess the effectiveness of the *MobileMen* app at increasing PA in African American men compared to a similar fitness app, Stridekick. The participants will be assigned to one of two arms, intervention (*MobileMen)* or comparator (Stridekick*)*, and will use the assigned app on their personal smartphones for the duration of the 6-month trial. The study was registered with ClinicalTrials.gov (NCT05621044). The protocol was approved by the Pennington Biomedical Research Center Institutional Review Board on July 31, 2024.

MobileMen

MobileMen[55] is a mobile application tailored to the needs of African American men who aspire to increase their PA engagement. *MobileMen* was developed using an extensive and iterative process described elsewhere.[35] The development of the *MobileMen* app was completed in July 2024 and is available for use on both iOS and Android platforms. See **Table 1** for *MobileMen* features.

Comparator App

The Stridekick app is intended to increase PA in users through a variety of functions. Stridekick is a free app available on iOS and Android platforms. See **Table 1** for Stridekick features**.**

Table 1: Features of *MobileMen* and Stridekick

Feature	MobileMen	Stridekick
Syncs to Fitbit Device	✔	✔
Displays Physical Activity Data	✔	✔

Message Boards	✔*	✔
Goal Setting	✔	✔
Challenges	✔	✔
Educational Content (PA, Nutrition, and Behavior Change Articles)	✔	-
Allows Tracking of Health Metrics (Blood Pressure, Blood Glucose, Body Weight, and Cholesterol)	✔	-
Incentives (Virtual Badges and Tangible Prizes)	✔	✔**
Designed with a Behavior Change Theory Framework	✔	-
Designed Specifically for African American Men	✔	-

*= MobileMen will utilize a private Facebook group for the message board feature during the CET
**= Stridekick offers virtual badges but not tangible prizes

Participants

Eligibility criteria include: self-identification as an African American male, a resting systolic BP ≤159 mmHg and a diastolic BP ≤99 mmHg (to reduce risk of exercise-induced cardiovascular events), free of significant medical problems that would impact their ability to engage in aerobic and/ or resistance training, smartphone ownership, age ≥ 30 years, and “low active” at baseline (defined as having an average daily accelerometer assessed step count of < 7500 steps).[56]

Protocol

Recruitment and Screening

Community-based efforts, including advertising at churches, health fairs, YMCAs, and fraternities, social media posts, and advertisements on paid, owned, and earned media, will be used to recruit study participants. Potential participants will undergo a telephone screening to assess initial eligibility.

Study Visit One

Men who meet the inclusion criteria will be invited for an in-person orientation visit with study staff. Study staff will review the study protocol and facilitate an informed consent process.

Consented participants will receive an Actigraph WGT3X+BT (ActiGraph LLC, Pensacola, FL) and a Fitbit to wear for one week to assess baseline PA levels. At the conclusion of the week, study staff will evaluate the accelerometer data and will invite participants who meet PA eligibility criteria to return for a second study visit.

Study Visit Two

During the second study visit, participants will complete several baseline assessments, including a sociodemographic questionnaire and height, weight, and resting blood pressure measurements. We will calculate body mass index (BMI) using lab measured body weight and height (kg/m^2). To assess quality of life, participants will complete the 36-Item Short Form Health Survey (SF-36) which has been validated in African Americans.[57] To assess PA and dietary habits, participants will complete the International Physical Activity Questionnaire (IPAQ) [58] and National Cancer Institute's (NCI) Automated Self-Administered 24-hour (ASA24) Dietary Assessment Tool,[59] respectively. Self-efficacy for fruit and vegetable consumption will be measured with seven items that measure participants' confidence in their ability to consume fruits and vegetables in different context like when away from home or in a rush.[60] Self-efficacy for PA will be measured using the Self-Efficacy for Exercise Scale.[61] Self-Determination Theory based motivation for PA will be measured using the Behavioral Regulations in Exercise Questionnaire v.3 (BREQ-3).66,67 This 24-item questionnaire assesses the six SDT subtypes of motivation, with each item scored on a five-point Likert scale ranging from 0 (not true for me) to 4 (very true for me).

Randomization

At the conclusion of the second visit, eligible participants will be randomized to one of two conditions, the *MobileMen* intervention group or the Stridekick comparator group, as directed by the next assignment letter contained in a randomized sequence of sealed and numbered envelopes. Using a computerized pseudo-random number generator, the statistician will determine the randomization order in advance. The study coordinator will reveal the randomization after the participant is deemed

eligible. Project staff will assist each participant in downloading the designated (*MobileMen* or Stridekick) app onto their smartphone, provide an app orientation, and assist in app navigation.

Study Visit Three

At the conclusion of month three of the intervention period, participants will attend a third visit with study staff and complete a second week of objective PA assessments, using an Actigraph WGT3X+BT (ActiGraph LLC, Pensacola, FL) and a Fitbit following the same protocol as in study visit one.

Study Visit Four

At the conclusion of month six post-randomization, participants will return for a final visit, where they will complete all follow-up assessments, using the same protocols as in study visit two. Participants in the *MobileMen* group will also complete additional measures such as a survey to assess their satisfaction with the mobile app and the System Usability Scale (SUS),[64] a validated 10-item measure that provides a global view of subjective usability for technology, to assess the app's usability. Participants will also complete a brief interview with study staff to collect feedback regarding suggestions for app improvement and users' impressions of the *MobileMen* app content.

Outcome Measures

Primary Outcomes

The primary outcome measure for this study is change in step counts derived from the Acitgraph collected pre- (week 0) and post-intervention (week 24).

Secondary Outcomes

Time spent in moderate-to-vigorous physical activity (MVPA), also derived from the Actigraph pre- and post-intervention data, will be a secondary outcome measure. Other secondary outcomes include changes in body weight, blood pressure, quality of life, and healthy eating index (HEI) score. Daily PA engagement assessed with Fitbit Charge 6 will be another secondary outcome measure. Using the Fitbit Application Programming Interface (API), study staff will access

participant daily steps, time spent engaging in PA, number of PA bouts, and minutes spent in each Fitbit defined heart rate zone. Usability (using SUS) and overall satisfaction with the *MobileMen* app are additional secondary outcomes.

Potential Mediators

We will measure three potential mediators pre- and post-intervention: self-efficacy for fruit and vegetables consumption,[60] self-efficacy for PA[61] and as will autonomous motivation for PA.[62,63]

Potential Covariates

Demographic variables including age, marital status, education, family income, occupation, and employment status will be tested as potential covariates in our statistical models. We will also examine BMI and lab measured blood pressure (mmHg) at baseline as covariates.

Sample Size and Power Calculation

A sample of 50 participants per trial arm was determined based on step count data from a recent meta-analysis.[69] When the sample size per group is n=50, a two-sided 95% confidence interval (CI) for the difference of two means will extend 0.40 standard deviation (SD) units from the observed difference in means, assuming a SD of 1 and the CI is based on the large sample z statistic. Doubling the sample reduces the half width of the CI to 0.28, which reduces the half width by only 30% but disproportionately increases the recruitment time and difficulty. Within the two arms, we can estimate longer-term adherence at 6 months with a width of a two-sided 95% CI equal to 0.289 when the sample proportion adherent is 0.50 and the width shortens as the adherence increases.

Statistical Analyses

Response frequency, proportions, and means will be calculated. Means and standard deviations, medians and interquartile ranges, distributions, frequencies, and percentages will characterize the data. Comparisons on demographics (i.e. age, marital status) will be done using chi-square, t-tests, and correlations, with 2-tailed p=0.05. The changes from baseline (CHG) to all post-

baseline visits until week 24 in steps per day will be estimated using a Mixed Model for Repeated Measures (MMRM) using SAS PROC MIXED. The model includes response data from all post-baseline visits with no imputation for missing data, as the model assumes missingness is at random. The step counts at baseline will be included as a fixed factor in the model. An unstructured covariance structure will be assumed and the denominator degrees of freedom will be computed using the Kenward-Roger method. In case the model will not converge with the unstructured covariance structure, the heterogeneous compound symmetry (CSH) and the heterogeneous Toeplitz structure (TOEPH) will be used instead (in that order). The least-squares mean (LSMEANS) estimates for the mean change from baseline to Week 24, as well as the difference of the estimates at 12 weeks will be displayed with their corresponding standard errors, p-values, and 95% confidence interval. Characteristics of dropouts and/or noncompliant individuals will be intensively examined to shed light on potential weaknesses of the *MobileMen* app (differential dropout overall or within certain subgroups) and assumptions about missingness in the estimates. The evaluation of the app will include its impact using the pre-post data. Examination of the correlation matrices along with the mean changes will inform whether the variables appear to move similarly in both arms and how the interventions are working.

App utilization data will be examined to understand the acceptability and intensity of interactions with *MobileMen* via several criteria including but not limited to logins, notifications sent and received, number of activities inputted, badges earned, tips read, number of health parameters inputted, competitions competed in, and incentives earned. Complier average causal effect models[70] will be used to examine the intensity of intervention app utilization.

Results

Development of the fully functional *MobileMen* app began in September 2022 and the app was completed in July 2024. Design and implementation of the CET are led by the project PI (RN). Rolling recruitment and enrollment of participants began in October 2024 and is planned to be

completed by June 2025. The trial will be completed in the first half of 2025, with analyses completed in the September of 2025.

Discussion

Eighty-four percent of African Americans own a smartphone, with access to the internet and mobile apps.[21] In addition, this population reports higher use of mHealth apps to access information about their health than any other ethnicity or race, besides Hispanics.[20] Further, African American men report willingness to utilize mHealth interventions to support PA habits.[27] It is surprising that despite health and fitness apps being downloaded nearly 21 million times in January 2023 alone[67], there are no PA promotion apps designed specifically for African American men. The *MobileMen* app seeks to fill this gap by becoming the first smartphone app that aims to support PA adoption and maintenance in African American men. If successful, *MobileMen* has the potential to profoundly impact the health of African American men.

Strengths and Limitations

The planned CET has several strengths including a multidisciplinary research team with combined expertise in African American men's health, mHealth app development, PA assessment, wearable technology use in interventions, and psychological mediators of PA behavior change. The primary outcome of the CET, change in daily step count, will be assessed using accelerometry, rather than self-report, which is a study strength due to the reliability and validity of objectively measured step counts.[68] Further, this study not only aims to assess the primary PA outcome (steps) but also the hypothesized mediating construct (autonomous motivation), addressing the question of how *MobileMen* might support PA behavior change.

However, due to the small sample size, we are unable to conduct statistical mediation tests, leaving us unable to assert if behavioral changes associated with *MobileMen* use can be attributed to changes in potential mediators. At present, mechanisms of action for PA behavior change, or most health behavior change, are not well understood as they have not been closely examined.[69] Therefore,

this is a critical next step for PA research in this population. Further, the location from which African American men will be recruited, the Southern United States, presents a limitation in the generalizability of the results of the study. As such, a larger study with a more geographically diverse sample of African American men should be considered. Finally, the mobile app is available to men who have use of a mobile phone; non-mobile phone users will need other methods for accessing PA tailored interventions.

Conclusions

To date, no mobile PA and health app exists that is specifically tailored to the needs of African American men. *MobileMen* seeks to fill this gap with culturally tailored content and foundations in health behavior change theory. This CET will test its efficacy compared to a popular mobile health app, providing the research team with important data for app modifications before testing the final version in a large-scale effectiveness trial.

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