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ABSTRACT

Introduction: Colorectal cancer (CRC) is preventable, as screening leads to identification and removal of pre-cancerous polyps. African-American men consistently have the highest CRC mortality rates, and their CRC screening uptake remains low for complex reasons. Culture-specific masculinity barriers to care may contribute to the low uptake among African-American men. Examining these barriers to care is vital as CRC screening may challenge cultural role expectations of African-American men, whose tendency is to delay help-seeking medical care. Barbershops provide a pathway for reaching African-American men with masculinity barriers to care who are not regularly receiving healthcare services and CRC screening, specifically. This study aims to develop and pilot-test a theory-driven, culture-specific, barbershop-based intervention specifically targeting masculinity barriers to care and CRC screening uptake among African-American men ages 45–75.

Methods and analysis: Guided by the Theory of Planned Behavior and the Behaviour Change Wheel, we will use a multi-stage mixed-methods study design, beginning with an exploratory sequential approach to validate items for subsequent use in a pilot mixed-methods intervention. First, we will collect and analyze qualitative data from focus groups and cognitive interviews to validate and test a culture-specific Masculinity Barriers to Care Scale (MBCS) among African-American men. Next, we will administered the MBCS to our target population as an online quantitative survey and evaluate the association between scores and CRC screening uptake. Then, we will consider existing evidence-based approaches, our integrated results (qualitative+quantitative), and community input to design a culture-specific, behavioral intervention aimed at increasing CRC screening uptake among African-American men and

feasible for barbershop delivery. We will test the peer intervention in a pilot study with a 2-arm cluster-randomized design (6 barbershops, randomized by site) to reduce contamination and account for barbershop culture differences. Our primary outcomes for the pilot study are recruitment, sample size estimation, preliminary efficacy, and acceptability.

Keywords: African-Americans, colonic neoplasms, community-based participatory research, men's health, minority health

Ethics and dissemination: Ethics approval was obtained from the University of Utah Institutional Review Board (00113679). Study results will be disseminated through publications in peer-reviewed journals, community dialogue sessions, and presentations at conferences.

Registration: ClinicalTrials.gov identifier: NCT03733197; https://clinicaltrials.gov/ct2/show/NCT03733197

Article Summary

Strengths and limitations

- By drawing on constructs of the Theory of Planned Behavior and the Behaviour Change Wheel, our study will be among the first to offer a structured approach to designing a behavior-change–focused, culture-specific arm for our pilot intervention, while taking into account a range of psychosocial factors associated with CRC screening among African-American men.

- Our study proposes a new, culture-specific Masculinity Barriers to Care Scale for understanding and reducing CRC screening disparities among African-American men.
- Given the rising CRC burden among young adults, our study engages African-American men starting at age 45 years.
- Though self-report questionnaires are a common behavioral-science methodology, social desirability and non-response bias are potential concerns that we will offset by testing the reliability and validity of the data, while collecting it electronically and securely.
- Additional research will be needed to ascertain the generalizability of the findings to other settings, since this study limits involvement to African-American men from 2 metropolitan areas in Utah and Minnesota.

INTRODUCTION

Colorectal cancer (CRC) is one of the most treatable and preventable cancers. Despite CRC screening's life-saving potential, however, nearly 28% of Americans aged 50–75 years have not received timely screening.[1] Across all gender and racial/ethnic groups, African-American men have the highest CRC mortality and shortest survival.[2] In 2010, national CRC screening uptake rates among African Americans (56%) were significantly lower than among non-Hispanic whites (62%).[3,4,5] CRC incidence and mortality rates are 27% and 52% higher, respectively, among African-American men than among non-Hispanic white men.[2,6]

Recommendations for CRC Screening

The U.S. Preventive Services Task Force endorses a CRC-screening age range of 50–75 years for average-risk men and screening initiation at age 40 years for those with a family history of CRC.[7] Because African-American men are more likely than non-Hispanic white men to be diagnosed at both a younger age and a more-advanced disease stage,[3] the American College of Gastroenterology has lowered its recommended age of screening initiation to 45 years for African-American men.[2,3,8] The proportion of CRC cases diagnosed in individuals aged under 55 years has doubled in the past 2 decades, and CRC incidence among younger adults (aged 35–49 years), including African-American men, is predicted to increase 28% to 46% by 2030.[9]

Masculinity may contribute to low CRC screening

Masculinity is an important aspect of gendered and cultural identity for men[10-12] and plays a critical role in African-American men's healthcare use, health behaviors, and mortality.[13-17] Because CRC screening challenges some cultural role expectations of African-American men, who tend to delay seeking medical care, examination of masculinity barriers to care is perilous. However, the specific influence of cultural masculinity perceptions on African-

American men's CRC screening rates is not well studied. An unacknowledged sense of vulnerability that conflicts with culturally accepted gender norms is also often inherent in men's experience of CRC screening. Further, no validated masculinity measures have been developed for African-American men in the context of CRC screening uptake or medical care.[18-20]

Low CRC screening rates may be influenced by psychosocial factors

Consideration of how psychosocial factors relate to CRC screening uptake is also critical. Previous research[18,21-24] with African-American men has documented the influence of factors such as attitudes, knowledge, racism, and perceived barriers (e.g., embarrassment, fear) on CRC screening. Medical mistrust is a widely cited attitudinal barrier to CRC screening and treatment seeking[23,25,26] and is related to the low health services utilization among African-American men,[23] yet it is unclear whether trust-related barriers are related to CRC screening.[18,25-30] Previous research suggests that inadequate existing validated measures and biases toward Western culture (norms, values, customs, etc., associated with Europe and European descent) may explain the absence of a significant association between masculinity and CRC screening attitudes among African-American men.[18,21-24,31] In a systematic review of the literature examining connections between masculinity, racism, social support, and CRC screening uptake among African-American men,[7] few studies have examined how masculinity relates to poor CRC screening uptake and, of these, none used validated measures.

Barbershops as a site for interventions to improve CRC screening

Barbershops serving African-American men are favorable settings for reaching our target population.[32] Previous multi-component, barbershop-based trials have been conducted with African-American men on HIV risk reduction, prostate cancer education, heart disease control, and hypertension detection.[33-35] Few trials of CRC screening uptake among African-

American men have found significant results. The MISTER B study, the first and to date only barbershop-based CRC screening trial, tested a phone-based patient-navigation intervention to urge CRC screening among older (mean age 57 years), low-income African-American men with uncontrolled hypertension.[36] Intervention completion was associated with a 16-fold increase in the odds of CRC screening uptake by 6 months; however, although nearly 70% of participants voiced the intent to obtain colonoscopy screening in the next 6 months, only 17% in the intervention groups and 8% in the control group did so. Our study will help fill this gap between uptake and intention by creating a new, culture-specific intervention that directly addresses masculinity barriers to care, psychosocial factors, and CRC screening uptake among African-American men beginning at age 45, then test its feasibility and acceptability in a cluster-randomized pilot intervention (at the barbershop level).

Study objectives

Disparities associated with CRC screening uptake for African-American men, the failure of previous interventions to significantly increase screening rates, and the novel idea of using the barbershop as an intervention setting led to the current study, with the following objectives: (1) validate and test a culture-specific Masculinity Barriers To Care Scale (MBCS) relative to psychosocial factors and CRC screening uptake among African-American men; and (2) develop and pilot-test a theory-driven, culture-specific peer intervention that targets masculinity barriers to care, psychosocial factors, and uptake of CRC screening (specifically, of the fecal immunochemical test [FIT]) among African-American men. *Culture-specific* refers to the embodiment of "an [African-American male's] real-life experiences within a given cultural context (e.g., neighborhood) and his understanding of those experiences."[37]

METHODS AND ANALYSIS

Overall Study Design

We will use a multi-stage mixed-methods design that is shown in Figure 1. We will begin with an exploratory sequential approach intended to validate items for subsequent use in a pilot mixed-methods intervention. For Objectives 1A and 1B (Years 1–2), we will collect and analyze qualitative data from focus groups and cognitive interviews to validate and test a culture-specific MBCS among African-American men. Next, we will administer the MBCS as an online quantitative survey of our target population to evaluate the association between scale scores and CRC screening uptake.

For Objective 2 (Years 3–5), we will consider existing evidence-based approaches (e.g., motivational interviewing), our integrated results (qualitative + quantitative) from Objectives 1A and 1B regarding masculinity barriers to care, and community input to design a novel, culture-specific, behavioral intervention that is (1) aimed at increasing CRC screening uptake (via FIT) among African-American men and (2) feasible for delivery in barbershops. To reduce contamination and account for differences in barbershop culture, we will pilot-test the peer intervention in a 2-arm cluster-randomized intervention (6 barbershops, with participants randomized by site). Our primary outcomes for the pilot are recruitment, sample size estimation, preliminary efficacy, and acceptability. We will also conduct post-intervention interviews with participants from both arms to evaluate acceptability (i.e., why and how each arm was or was not successful). This study protocol has received ethics approval from the University of Utah Institutional Review Board (00113679), who will also be responsible for receiving communication updates regarding important protocol modifications. To ensure confidentiality,

data dispersed to project team members will be blinded of any identifying participant information.

Patient and Public Involvement

Neither patients nor the public were involved in the design of the study.

Theoretical Foundation

A conceptual framework integrating constructs of the Theory of Planned Behavior (TPB) will guide our work. The TPB posits that behavior is a function of intention, which is influenced by attitudes and beliefs.[38] **Figure 2** illustrates how masculinity barriers to care and other psychosocial factors may influence CRC screening intention and uptake among African-American men. We will also assess demographic characteristics (e.g., age, marital status, health insurance status) that are known to influence African-American men's masculinity, and CRC screening perceptions and behaviors.[6,21,23,24]

Evidence-based cultural grounding to facilitate understanding of African-American men's culture and engage community stakeholders as trial-development partners is best achieved by an iterative, participatory, and reflexive research process.[39,40] Hence, we will use the Behaviour Change Wheel (BCW) as the conceptual framework driving our study's intervention-development phase. Developed from 19 behavior-change frameworks, the BCW offers a structured approach to inclusively analyzing available intervention options and designing behavior-change interventions.[41]

Setting

We will conduct this research in the Salt Lake City, Utah, and Minneapolis–St. Paul (Twin Cities), Minnesota, metro areas, regions notable for having the largest populations of African-Americans in their respective states.[42,43] Moreover, in both states, CRC screening rates among African Americans are well below statewide averages (53% vs 72% for all ethnic and racial groups combined in Utah; 57% vs 73% for both non-Hispanic whites and all ethnic and racial groups combined in Minnesota).[12-14] Nationally, African-American men exhibit a lower screening likelihood than African-American women.[3,5,44-46]

Focus Groups

Participants & Procedures

To inform MBCS development, we will conduct twelve 2-hour focus groups (a sufficient number to reach saturation),[47,48] each involving 8 men who (1) self-identify as non-Hispanic Black/African American; (2) were born in the United States; (3) are aged 45–75 years; (4) have a working telephone; (5) speak English; and (6) reside in the Salt Lake City or Twin Cities metro area. Six focus groups will be conducted in each metro area. Because participants may be more comfortable with other African-American men of similar age who either have or have not completed CRC screening, each group will be clustered by age and CRC screening status (**Table 1**). Men aged 45–49 years will be included because African-American men are diagnosed with CRC at both an earlier age and a more advanced disease stage.[3,7,8]

Table 1. Focus Group Composition

Groups	Age Range	CRC Screening Status
1–2	45–49	Never Completed
3–4	50–65	Not Current
5–6	66–75	Not Current
7–8	45–49	Completed/Current
9–10	50–65	Completed/Current
10–12	66–75	Completed/Current

We will use culture-specific marketing materials to promote the study through existing social networks, including newspaper advertisements, social media, predominantly African American churches, air time on 2 radio stations (1 in Minneapolis, 1 in Salt Lake City) with a predominantly African-American male audience, and African-American male–serving barbershops. The principal investigator (PI), CRR, has a record of success in recruiting African-American men using these strategies.[21,23,24]

Potential participants will be encouraged to visit www.cuttingCRC.com to express interest in focus-group participation. Basic demographic information will be collected (and kept confidential) to enable research-team members to contact participants by phone to confirm eligibility and discuss participation arrangements. Food and drink will be provided during each session. Each participant will receive a gift card and participants may choose to be entered into a random drawing to win 1 of 3 incentives.

Data Collection and Analyses

CRR will facilitate the focus groups, using an interview guide stemming from modifications to existing measures that examine masculinity as well as attitudes and practices precluding men from seeking healthcare access. Another team member will assist with consenting and note-taking. The 2-hour sessions will be audio-recorded with 2 voice recorders, transcribed, and checked for accuracy. De-identified transcripts will be imported into NVivo 11 software (QSR International Pty. Ltd., Melbourne, Australia). Our NVivo-proficient coding team (TNR, CRR, and the research assistant) will use constant comparative and content-analysis

methods to independently code transcripts for themes.[49,50] After identifying themes relevant to our research questions from a sample reading and initial coding, we will automate term searches, code all documents, and run reports to ascertain the code text related to study themes. NVivo can organize data by participant characteristics, allowing us to compare the responses of participants who have or have not undergone CRC screening. To interpret and discuss findings and develop a codebook depicting how our codes interrelate, we will track coding decisions in NVivo and adjudicate them at team meetings. MF and/or SZ will referee coding deviations, as needed. Key themes will be identified and incorporated into the new MBCS.[51,52]

Cognitive Interviews

Participants and Procedures

We will pilot-test the MBCS with 30 CRC advocates and survivors from across the United States (men and women who speak English, have a working telephone, and are aged 18–75 years), using 1-hour cognitive interviews (conducted in person or by phone) to elicit input as participants respond to the survey in real time.[53,54] Interviews will probe (1) how participants understand each question and response option; (2) whether the questions are likely to elicit an honest response; (3) the clarity of question wording; (4) the user-friendliness of the online survey setup; and (5) the questions' cultural specificity. Participants will engage in a thinking-aloud process with follow-up probes such as "How did you arrive at that answer?" These approaches will improve feasibility, reduce response error, and enhance face validity (an estimate of the degree to which the scale is clearly tapping the desired construct we aim to assess, i.e., culture-specific masculinity barriers to care).[55-57] Cognitive interviews also allow us to assess participants' comfort with online survey completion via PsychData (PsychData LLC, State

College, PA), a secure, web-based application that supports data capture for research Objective 1B. Interviewees will receive a gift card. RJT will provide expert item review of the final MBCS.

Online Survey

Participants and Procedures

During Year 2, we will recruit 400 African-American men to complete an online survey, administered via smartphone, to test the relationship between masculinity barriers to care and CRC screening. Eligible respondents are men who (1) self-describe as non-Hispanic Black/African American; (2) were born in the United States; (3) are aged 45–75 years; (4) reside in the Salt Lake City or Twin Cities metro area; (5) have a telephone with internet access; and (6) speak English. With the aid of barbers and culture-specific marketing materials, we will recruit participants from African-American male–serving barbershops. Survey participants will have the opportunity to participate in drawings for 1 of 5 incentives.

Barbershops are cultural hubs of trust essential in the growth and development of African-American men. Men usually spend at least 30 minutes waiting for or getting a haircut or chatting with others in the barbershop. Using PsychData, participants will be able to complete our survey within 15 minutes on their smartphones while waiting for or getting a haircut in participating barbershops. PsychData prevents survey alterations and eliminates transcription errors.[58] The PI has a successful record of recruiting African-American men to complete surveys using mobile technology,[21,23,24] and African Americans outpace all groups for smartphone use.[59] For men who want to complete the survey but do not own a smartphone, each participating barbershop will be provided 1 smartphone courtesy of the study.

Dependent variables. We will use 2 Behavioral Risk Factor Surveillance System (BRFSS) questions to assess CRC screening uptake: (1) "A blood stool test is a test that may use a special kit at home to determine whether the stool contains blood. Have you ever had this test using a home kit?"; and (2) "Sigmoidoscopy and colonoscopy are exams in which a tube is inserted in the rectum to view the colon for signs of cancer or other health problems. Have you ever had either of these exams?"[60]

Independent variables. In accordance with our conceptual model illustrated in Figure 2 and the PI's Male Role Norms, Knowledge, Attitudes, and Perceptions associated with Colorectal Cancer Screening tool,[1,18,21-24] our independent variables will be masculinity barriers to care from our new scale and 5 factors known to influence CRC screening uptake among African-American men: knowledge, medical mistrust, social support, beliefs, and attitudes towards CRC and 2 CRC screening exams (FIT, colonoscopy).[13,18,24,27]

Demographic covariates. Age, educational level, marital status, and other covariates will be included as previous studies by the PI and others have found these factors to be related to CRC screening among African-American men.[2,18,21-24,61]

Sample Size and Power Considerations

With a sample of 400 African-American men, we will have 80% power at the 0.05 level to detect a masculinity barriers to care effect on the odds of having had CRC screening, assuming 35% of men with a masculinity barriers to care index equal to the mean have had CRC screening compared with 25% of men with a masculinity barriers to care index 1 standard deviation above the mean. We estimate that the average screening rate will be 35%, as the screening rate for African Americans is 53.1% in Utah and 52% in Minnesota and African-

American men in both states tend to have lower CRC screening rates than women.[4,6,12,42] This assumes a moderately strong relationship between the masculinity barriers to care index and confounders (i.e., $R^2 = 0.25$ for the linear model that regresses the masculinity barriers to care index on the confounders). If the relationship between the confounders and the masculinity index is weaker, the power will be higher: 82% power with $R^2 = 0.2$ and 87% power with $R^2 = 0.1$. Power calculations were performed using PASS 15 (NCSS, LLC, Kaysville, Utah).

Data Collection and Analyses

We will test for associations between masculinity barriers to care, psychosocial factors, and CRC screening uptake. Our central hypothesis is that masculinity barriers to care will be negatively associated with CRC screening uptake. The masculinity barriers to care items emerging from Objective 1 will be utilized to create a latent variable that represents the construct being measured. The CRC screening-uptake outcome will be a binary variable that indicates whether a participant self-reported CRC screening uptake (i.e., answered Yes to either BRFSS dependent-variable question). We will fit a structural equation model with CRC screening uptake as the outcome and masculinity barriers to care as the predictor. We will adjust for potential confounders (e.g., age, educational level). We will also present the estimate and 95% confidence interval for the odds ratio comparing the odds of CRC screening uptake between participants with a 1-point difference in masculinity barriers to care scores. Descriptive statistics will summarize participants' characteristics.

Two-Arm Intervention

Integration

In an exploratory sequential–designed study, a key step is to apply the qualitative data captured in Objective 1A to assist with building Objective 1B's quantitative phase. As described by Fetters et al.,[62] we will "merge" qualitative and quantitative data from Objective 1 to identify content areas for contrasting, comparing, and synthesizing results. During the first 6 months of Year 3, 2 team members (MF and CRR) will determine to what degree and how the results from the combined qualitative and quantitative datasets yield a richer and more comprehensive understanding of the impact of masculinity barriers to care on CRC screening uptake among African-American men. Through this process, we will apply what we learn about the role of our variable of interest on CRC screening to develop a pilot intervention for overcoming these barriers.

Development

During the first 6 months of Year 3, we will adopt the BCW approach, working with Community Advisory Board members (2-hour small-group discussions via conference call and/or in person, 3 members per meeting) to develop the culture-specific intervention arm of our pilot intervention. We will use information from (1) our integrated Objective 1 results, (2) existing CRC screening intervention evidence, and (3) study-team expertise to apply the APEASE criteria *(**A**cceptability, **P**racticability, **E**ffectiveness/cost-effectiveness, **A**ffordability, **S**afety/side-effects, **E**quity)* (**Table 2**). Our hypothesis is that CRC screening uptake will be higher in the culture-specific arm than in the control arm.

Table 2. BCW Activities to Drive Development of Culture-Specific Trial Arm

[1] Behavioural Diagnosis	Utilize the BCW to determine what needs to change for CRC screening uptake to increase among African-American men
[2] Intervention Strategy Selection	Utilize **[1]** to decide which intervention functions to apply (e.g., Education, Persuasion, Enablement)

[3] Behaviour Change Technique Identification	Develop a detailed culture-specific arm plan by selecting from among a range of specific, evidence-based behavior change techniques (e.g., intervention components such as barbers as motivational interviewers plus barbers distributing FIT kits; info about health consequences related to negating CRC screening).
[4] Draft Full Intervention Specifications	Create the detailed intervention specifications covering all aspects of content and delivery of the intervention structured around **[3]**.

We anticipate that the culture-specific arm will include at least 2 core components: barbers as motivational interviewers and InSure® FIT™ kits distributed by barbers. Motivational interviewing (MI) is "a collaborative conversation style for strengthening a person's own motivation and commitment to change."[63] Telephone-based MI is an effective way to improve cancer screening among underrepresented groups. Community-member–led MI has proved successful, but it is unknown if barbers as motivational interviewers can assist with reducing CRC screening inequalities among African-American men.[64-67] Also, randomized trials have shown that the FIT is the first-choice fecal occult blood test for CRC screening, is less invasive, less costly, and may be better accepted than other CRC screening tests.[67] If we choose this route for the culture-specific arm, preliminary data from our barbers suggest that the PI may teach the barbers the MI technique using content stems from Objective 1 findings. Additional components for this arm may be developed during the APEASE process.

Based on the PI's research[18,21-24] and evidence-based strategies,[68] the control arm will include an informational CRC screening brochure developed by the American Cancer Society[69] plus a FIT kit distributed by the barbers. Since the FIT kits will be free and the study will cover postage and processing fees, participants will be able to complete screening regardless of whether they have health insurance. Participants will mail the completed FIT kits to our local

laboratory for processing. We will refer participants with positive FIT results to collaborator Huntsman Cancer Institute for a colonoscopy.

Participants and Procedures

Intervention participants will be non-Hispanic Black/African-American men (n = 60) who (1) have never completed CRC screening ; (2) are aged 45–75 years; (3) were born in the United States; (4) reside in the Salt Lake City metro area; (5) have a telephone with internet access, and (6) speak English. As a feasibility intervention, sample size is not based on the power to detect a certain effect size.[65] Rather, n = 60 (30 per arm) was chosen based on practical considerations (e.g., cost, recruitment).

The intervention will comprise a *recruitment phase* and an *implementation phase*. The recruitment phase will occur during the last 6 months of Year 3. With the assistance of barbers and culture-specific marketing materials, we will enroll 10 eligible African-American men at each of 6 barbershops. At baseline, participants will complete the demographic portion of our online survey. Once total enrollment is reached and consent obtained, the 6 barbershops will be randomized to the culture-specific or control arm using a permuted block size of 6. Then the implementation phase will begin. These distinct phases provide advantages in a cluster-randomized design. First, we eliminate recruitment bias as we blind participants to the intervention at enrollment.[70] Second, the distinct phases allow each man to be exposed to the intervention for the same amount of time. We foresee the recruitment phase lasting 3 months and the implementation phase 7 months, resulting in a 10-month intervention, allowing ample time for participants to obtain CRC screening.

During the last 6 months of Year 4, our coding team will conduct exit interviews. Prior literature documents that 6 to 12 individual interviews per homogeneous group are sufficient to reach data saturation.[71,72] Thus, 18 in-depth, 60-minute participant interviews (2 participants from each of the 6 barbershops plus 3 barbers from each arm) will permit us to obtain rigorous outcomes data as well as participant accounts of what worked well and what did not.

Analyses

Descriptive statistics will summarize participants' baseline characteristics. Continuous variables will be summarized by mean (standard deviation) or median (interquartile range), and categorical variables in contingency tables. Feasibility of the study protocol will be evaluated as follows:

1) *Recruitment.* We will calculate the number of days needed to reach full enrollment at each barbershop, the percentage of men meeting eligibility criteria and, of those, the percentage who chose to enroll.

2) *Sample Size Estimation.* The intraclass correlation coefficient will be estimated from our study data and inflated (due to the expected downward bias) to estimate the necessary sample size for the full trial.[73]

3) *Preliminary Efficacy.* By treatment arm, we will calculate the percentage for whom we can ascertain FIT uptake. We will assess intervention adherence 7 months after the recruitment phase by FIT kits returned to our laboratory for processing. Because we will have only 3 barbershops per arm, no formal statistical analysis of FIT uptake will be performed. Instead, percentages for these outcomes will be calculated by barbershop. We will perform this as intent-to-treat, with men included based in the arm to which their shop was randomized. A

per-protocol analysis will also be performed. Many more barbershops are needed to accurately account for the correlation of African-American men within the same barbershop and achieve a cluster-level confounding balance.[74] In our pilot trial, a logistic mixed-effects model with a random intercept for each barbershop will be used to estimate the odds ratios comparing CRC screening uptake between our control and culture-specific arms.

4) ***Acceptability.*** After the 7-month intervention phase, we will conduct 18 post-intervention interviews to obtain rigorous outcomes data. The audio-recorded and transcribed post-intervention interviews will be analyzed by our coding team using NVivo[57] and Creswell's methods.[72] To increase our findings' internal validity, data will be triangulated or compared from the perspectives of the 2 study arms.[75]

Conclusion

African-American men have the highest CRC mortality across all gender and racial/ethnic groups. Moreover, national findings predict a 28% to 46% increase in CRC incidence among adults ages 35-49 years, including African-American men, by 2030.[9] Our study aims to aid in reducing CRC screening inequities among African-American men by creating a new, culture-specific intervention that directly addresses masculinity barriers to care, psychosocial factors, and CRC screening uptake among African-American men beginning at age 45 years. Subsequently, we will test its feasibility and acceptability in a cluster-randomized pilot intervention.

Completing our objective will provide the preliminary data needed for an R01 application to test the new intervention's efficacy in a large-scale, well-powered, cluster-randomized controlled trial. More broadly, this research will demonstrate that decisions regarding CRC

screening uptake are not detached from cultural and other influences. We will use the culture-specific survey instrument we create to more rigorously assess the association between masculinity barriers to care and CRC screening uptake. This will strengthen our scale's predictive utility while endorsing optimal health for African-American men as warranted by Healthy People 2020.[76] Additionally, our scale could be adapted for use in research on other types of cancer (e.g., prostate cancer) that disproportionately affect African-American and other underrepresented men.

Overall, our efforts will serve as a model for more culture-specific tailored approaches to prevention, diagnosis, and treatment, a goal aligned with the NCI's Cancer Moonshot initiative.

Ethics and dissemination

Signed informed consent will be obtained from all participants prior to any data collection. Study results will be disseminated through publications in peer-reviewed journals, discourse sessions with the community, and presentations at national and international professional conferences.

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Authors' and data access statement

KO, EDP, MH, SZ, RJT, and MF serve as data monitoring committee (DMC) members for this study, while additional data monitoring, harms, and auditing logistics are available from the University of Utah Institutional Review Board. Only the DMC will have access to the full pilot trial dataset in order to ensure that the overall results are not disclosed by an individual study site prior to the main publication.

CRR is the study PI, wrote the first draft of the study protocol, and edited every draft thereafter. KO is a Primary Mentor for the study and edited the study protocol with the PI. EDP is a Secondary Mentor of the study and edited the study protocol with the PI. Study Co-Mentors MH, SZ, and RJT edited the study protocol with the PI. CR and TNR are Co-Investigators of the study and edited the study protocol with the PI. All authors read and approved the final manuscript. In addition to being a mixed-methods expert, MDF is a Co-Mentor on the study who edited the study protocol extensively with the PI as a senior co-author. All authors read and approved the final manuscript, and the SPIRIT checklist was used when writing this manuscript[77].

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Conflicts of Interests

None declared.

Figure legends

Figure 1. Exploratory Sequential Intervention Design

Figure 2. Conceptual model of factors influencing CRC screening uptake among African-American men

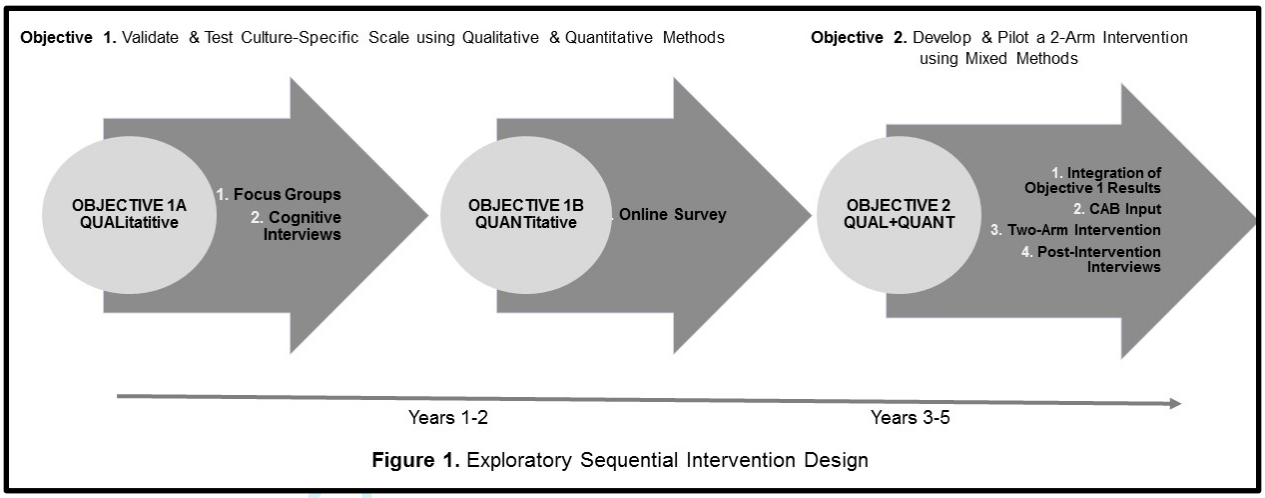

Figure 1. Exploratory Sequential Intervention Design

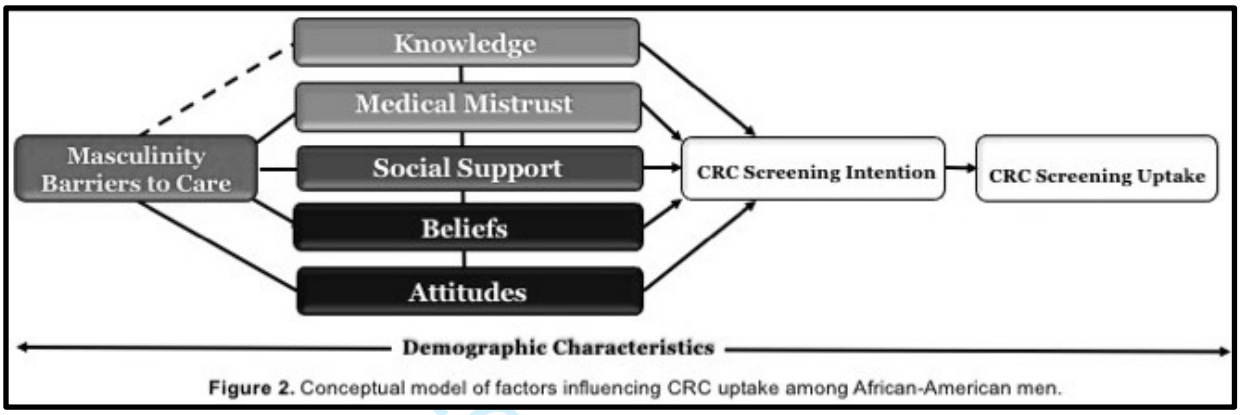

Figure 2. Conceptual model of factors influencing CRC uptake among African-American men.

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

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Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

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		Reporting Item	Page Number
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	4
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	4
Protocol version	#3	Date and version identifier	1
Funding	#4	Sources and types of financial, material, and other support	30
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	29
Roles and responsibilities:	#5b	Name and contact information for the trial sponsor	30

sponsor contact information			
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	30
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	6
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	6
Objectives	#7	Specific objectives or hypotheses	8
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	9
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	10
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	11
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	16
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	17
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return;	19

		laboratory tests)	
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	20
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	20
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	19
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	15
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	11
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	19
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	19
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	19
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	19
Blinding (masking): emergency	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during	N/A

unblinding		the trial	
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	12
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	12
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	12
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	16
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	18
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	13
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	29
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	29
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	29
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and	29

		whether the process will be independent from investigators and the sponsor	
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	4
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	9
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	12
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	19
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	12
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	30
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	29
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	21
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	22
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/A
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	N/A

Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

BMJ Open

Study Protocol for Developing a Barbershop-Based Trial on Masculinity Barriers to Care and Colorectal Cancer Screening Uptake among African-American Men Using an Exploratory Sequential Mixed-Methods Design

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Study Protocol for Developing a Barbershop-Based Trial on Masculinity Barriers to Care and Colorectal Cancer Screening Uptake among African-American Men Using an Exploratory Sequential Mixed-Methods Design

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ABSTRACT

Introduction: Colorectal cancer (CRC) is preventable, as screening leads to identification and removal of pre-cancerous polyps. African-American men consistently have the highest CRC mortality rates, and their CRC screening uptake remains low for complex reasons. Culture-specific masculinity barriers to care may contribute to the low uptake among African-American men. Examining these barriers to care is vital as CRC screening may challenge cultural role expectations of African-American men, whose tendency is to delay help-seeking medical care. Barbershops provide a pathway for reaching African-American men with masculinity barriers to care who are not regularly receiving healthcare services and CRC screening. This study aims to develop and pilot-test a theory-driven, culture-specific, barbershop-based intervention targeting masculinity barriers to care and CRC screening uptake among African-American men ages 45–75.

Methods and analysis: Guided by the Theory of Planned Behavior and the Behaviour Change Wheel, we will use a multi-stage mixed-methods study design, beginning with an exploratory sequential approach to validate items for subsequent use in a pilot mixed-methods intervention. First, we will collect and analyze qualitative data from focus groups, cognitive interviews, and expert item review to validate and test a culture-specific Masculinity Barriers to Care Scale (MBCS) among African-American men. Next, we will administer the MBCS to our target population as an online quantitative survey and evaluate the association between scores and CRC screening uptake. Then, we will consider existing evidence-based approaches, our integrated results (qualitative+quantitative), and community input to design a culture-specific, behavioral intervention aimed at increasing CRC screening uptake among African-American men and

feasible for barbershop delivery. We will test the peer intervention in a pilot study with a 2-arm cluster-randomized design (6 barbershops, randomized by site) to reduce contamination and account for barbershop culture differences. Our primary outcomes for the pilot are recruitment, sample size estimation, preliminary efficacy, and acceptability.

Keywords: African-Americans, colonic neoplasms, community-based participatory research, men's health, minority health

Ethics and dissemination: Ethics approval was obtained from the University of Utah Institutional Review Board (00113679). Study results will be disseminated through publications in peer-reviewed journals, community dialogue sessions, and presentations at conferences.

Registration: ClinicalTrials.gov identifier: NCT03733197; https://clinicaltrials.gov/ct2/show/NCT03733197

Article Summary

Strengths and limitations

- By drawing on constructs of the Theory of Planned Behavior and the Behaviour Change Wheel, our study will be among the first to offer a structured approach to designing a behavior-change–focused, culture-specific arm for our pilot intervention, while considering a range of psychosocial factors associated with CRC screening among African-American men.
- Our study proposes a new, culture-specific Masculinity Barriers to Care Scale for understanding and reducing CRC screening disparities among African-American men.

- Given the rising CRC burden among young adults, our study engages African-American men starting at age 45 years.
- Though self-report questionnaires are a common behavioral-science methodology, social desirability and non-response bias are potential concerns that we will offset by testing the reliability and validity of the data, while collecting it electronically and securely.
- Additional research will be needed to ascertain the generalizability of the findings to other settings, since this study limits involvement to African-American men from 2 metropolitan areas in Utah and Minnesota.

INTRODUCTION

Colorectal cancer (CRC) is one of the most treatable and preventable cancers. Despite CRC screening's life-saving potential, however, nearly 28% of Americans aged 50–75 years have not received timely screening.[1] Across all gender and racial/ethnic groups, African-American men have the highest CRC mortality and shortest survival.[2] In 2010, national CRC screening uptake rates among African Americans (56%) were significantly lower than among non-Hispanic whites (62%).[3,4,5] CRC incidence and mortality rates are 27% and 52% higher, respectively, among African-American men than among non-Hispanic white men.[2,6]

Recommendations for CRC Screening

The U.S. Preventive Services Task Force endorses a CRC-screening age range of 50–75 years for average-risk men and screening initiation at age 40 years for those with a family history of CRC.[7] Because African-American men are more likely than non-Hispanic white men to be diagnosed at both a younger age and a more-advanced disease stage,[3] the American College of Gastroenterology has lowered its recommended age of screening initiation to 45 years for African-American men.[2,3,8] The proportion of CRC cases diagnosed in individuals aged under 55 years has doubled in the past 2 decades, and CRC incidence among younger adults (aged 35–49 years), including African-American men, is predicted to increase 28% to 46% by 2030.[9]

Masculinity and psychosocial factors may contribute to low CRC screening

Masculinity is an important aspect of gendered and cultural identity for men[10-12] and plays a critical role in African-American men's healthcare use, health behaviors, and mortality.[13-17] Because CRC screening challenges some cultural role expectations of African-American men, who tend to delay seeking medical care, examination of masculinity barriers to care is perilous. However, the specific influence of cultural masculinity perceptions on African-

American men's CRC screening rates is not well studied. An unacknowledged sense of vulnerability that conflicts with culturally accepted gender norms is also often inherent in men's experience of CRC screening. Previous research suggests that inadequate existing validated measures and biases toward Western culture (norms, values, customs, etc., associated with Europe and European descent) may explain the absence of a significant association between masculinity and CRC screening attitudes among African-American men.[18 – 23] In a systematic review of the literature examining connections between masculinity, racism, social support, and CRC screening uptake among African-American men,[7] few studies have examined how masculinity relates to poor CRC screening uptake and, of these, none used validated measures. Further, no validated masculinity measures have been developed for African-American men in the context of CRC screening uptake or medical care [18, 24-25]

Consideration of how psychosocial factors relate to CRC screening uptake is also critical. Previous research[18-22] with African-American men has documented the influence of factors such as attitudes, knowledge, racism, and perceived barriers (e.g., embarrassment, fear) on CRC screening. Medical mistrust is another widely cited attitudinal barrier to CRC screening and treatment seeking[21,26,27] and is related to the low health services utilization among African-American men,[21] yet it is unclear whether trust-related barriers are related to CRC screening.[18,26-31] Since each of the aforementioned factors represent deeply intricate aspects of the social milieu in which African-American men make health decisions, the first author lead the creation and psychometric evaluation of the reliability and validity of his *Male Role Norms, Knowledge, Attitudes, and Perceptions associated with CRC Screening* (MKAP-CRCS) survey.[21] On average, our sample of young adult African-American men (ages 19-45) disagreed with traditional masculinity ideology—as measured by the 21-item Male Role Norms Inventory-Short

Form (MRNI-SF) scale.[32] Our principal component analysis revealed the MKAP-CRCS measure was psychometrically sound, but some participants may have withdrawn prematurely from the MRNI-SF portion as they found the measures' norms offensive/taboo, or felt awkward sharing beliefs about the roles expected of men. We concluded that research focused on developing a scale explicitly considering African-American men's masculinity beliefs in the medical care context and with more rigorous psychometric assessments (e.g., exploratory factor analysis) is needed.

Barbershops as a site for interventions to improve CRC screening

Barbershops serving African-American men are favorable settings for reaching our target population.[33] Previous multi-component, barbershop-based trials have been conducted with African-American men on HIV risk reduction, prostate cancer education, heart disease control, and hypertension detection.[34-36] Few trials of CRC screening uptake among African-American men have found significant results. The MISTER B study, the first and to date only barbershop-based CRC screening trial, tested a phone-based patient-navigation intervention to urge CRC screening among older (mean age 57 years), low-income African-American men with uncontrolled hypertension.[37] Intervention completion was associated with a 16-fold increase in the odds of CRC screening uptake by 6 months; however, although nearly 70% of participants voiced the intent to obtain colonoscopy screening in the next 6 months, only 17% in the intervention groups and 8% in the control group did so. Our study will help fill this gap between uptake and intention by creating a new, culture-specific intervention that directly addresses masculinity barriers to care, psychosocial factors, and CRC screening uptake among African-American men beginning at age 45, then test its feasibility and acceptability in a cluster-randomized pilot intervention (at the barbershop level).

Study objectives

Disparities associated with CRC screening uptake for African-American men, the failure of previous interventions to significantly increase screening rates, and the novel idea of using the barbershop as an intervention setting led to the current study, with the following objectives: (1) validate and test a culture-specific Masculinity Barriers To Care Scale (MBCS) relative to psychosocial factors and CRC screening uptake among African-American men; and (2) develop and pilot-test a theory-driven, culture-specific peer intervention that targets masculinity barriers to care, psychosocial factors, and uptake of CRC screening (specifically, of the fecal immunochemical test [FIT]) among African-American men. *Culture-specific* refers to the embodiment of "an [African-American male's] real-life experiences within a given cultural context (e.g., neighborhood) and his understanding of those experiences."[38]

METHODS AND ANALYSIS

Overall Study Design

The SPIRIT checklist was utilized while developing this manuscript.[39] For the proposed study, a multi-stage mixed-methods design that is shown in Figure 1 will be employed. We will begin with an exploratory sequential approach intended to validate items for subsequent use in a pilot mixed-methods intervention. For Objectives 1A and 1B (Years 1–2), we will collect and analyze qualitative data from focus groups, cognitive interviews, and expert item review to validate and test a culture-specific MBCS among African-American men. Questions for the MCBS will stem from modifications to the (a) the *Barriers to Help Seeking Scale* developed by Mansfield, Addis, and Courtenay [38], (b) the *Group-Based Medical Mistrust Scale* developed by Thompson et al. [40], (c) Mincey and colleagues' *Masculinity Inventory Scale* [41], (d) the *Male Role Norms Inventory-Short Form* by Levant, Hall, and Rankin [31],

Bowleg and colleagues' *Black Men's Experiences Scale* [42], and the *Masculinity Salience* scale developed by Hammond et al. [13]. Six factors are expected for the underlying structure of the 21 items in the MBCS: (1) Need for Control and Self-Reliance, (2) Minimizing Health Problems and Resignation (3) Medical Mistrust, (4) Privacy, (5) Emotional Control, and (6) Black Masculinity. For all factors, individual items will be assessed on a Likert-type scale. Higher scores will indicate a greater degree of endorsement of masculinity barriers to care. Next, we will administer the MBCS as an online quantitative survey of our target population to evaluate the association between scale scores and CRC screening uptake.

For Objective 2 (Years 3–5), we will consider existing evidence-based approaches (e.g., motivational interviewing), our integrated results (qualitative + quantitative) from Objectives 1A and 1B regarding masculinity barriers to care, and community input to design a novel, culture-specific, behavioral intervention that is (1) aimed at increasing CRC screening uptake (via FIT) among African-American men and (2) feasible for delivery in barbershops. To reduce contamination and account for differences in barbershop culture, we will pilot-test the peer intervention in a 2-arm cluster-randomized intervention (6 barbershops, with participants randomized by site). Our primary outcomes for the pilot are recruitment, sample size estimation, preliminary efficacy, and acceptability. We will also conduct post-intervention interviews with participants from both arms to evaluate acceptability (i.e., why and how each arm was or was not successful). This study protocol has received ethics approval from the University of Utah Institutional Review Board (00113679), who will also be responsible for receiving communication updates regarding important protocol modifications. To ensure confidentiality, data dispersed to project team members will be blinded of any identifying participant information.

Patient and Public Involvement

Neither patients nor the public were involved in the design of the study.

Theoretical Foundation

A conceptual framework integrating constructs of the Theory of Planned Behavior (TPB) will guide our work. The TPB posits that behavior is a function of intention, which is influenced by attitudes and beliefs.[43] **Figure 2** illustrates how masculinity barriers to care and other psychosocial factors may influence CRC screening intention and uptake among African-American men. We will also assess demographic characteristics (e.g., age, marital status, health insurance status) that are known to influence African-American men's masculinity, and CRC screening perceptions and behaviors.[6,19,21,22]

Evidence-based cultural grounding to facilitate understanding of African-American men's culture and engage community stakeholders as trial-development partners is best achieved by an iterative, participatory, and reflexive research process.[44,45] Hence, we will use the Behaviour Change Wheel (BCW) as the conceptual framework driving our study's intervention-development phase. Developed from 19 behavior-change frameworks, the BCW offers a structured approach to inclusively analyzing available intervention options and designing behavior-change interventions.[46]

Setting

We will conduct this research in the Salt Lake City, Utah, and Minneapolis–St. Paul (Twin Cities), Minnesota, metro areas, regions notable for having the largest populations of African-

Americans in their respective states.[47,48] Moreover, in both states, CRC screening rates among African Americans are well below statewide averages (53% vs 72% for all ethnic and racial groups combined in Utah; 57% vs 73% for both non-Hispanic whites and all ethnic and racial groups combined in Minnesota).[12-14] Nationally, African-American men exhibit a lower screening likelihood than African-American women.[3,5,49-51]

Focus Groups

Participants & Procedures

To inform MBCS development, we will conduct twelve 2-hour focus groups (a sufficient number to reach saturation),[52,53] each involving 8 men who (1) self-identify as non-Hispanic Black/African American; (2) were born in the U.S.; (3) are aged 45–75 years; (4) have a working telephone; (5) speak English; and (6) reside in the Salt Lake City or Twin Cities metro area. Six focus groups will be conducted in each metro area. Because participants may be more comfortable with other African-American men of similar age who either have or have not completed CRC screening, each group will be clustered by age and CRC screening status (**Table 1**). Men aged 45–49 years will be included because African-American men are diagnosed with CRC at both an earlier age and a more advanced disease stage.[3,7,8]

Table 1. Focus Group Composition

Groups	Age Range	CRC Screening Status
1–2	45–49	Never Completed
3–4	50–65	Not Current
5–6	66–75	Not Current
7–8	45–49	Completed/Current
9–10	50–65	Completed/Current
10–12	66–75	Completed/Current

We will use culture-specific marketing materials to promote the study through existing social networks, including newspaper advertisements, social media, predominantly African-American churches, air time on 2 radio stations (1 in Minneapolis, 1 in Salt Lake City) with a predominantly African-American male audience, and African-American male–serving barbershops. The principal investigator (PI), CRR, has a record of success in recruiting African-American men using these strategies.[19,21,22]

Potential participants will be encouraged to visit www.cuttingCRC.com to express interest in focus-group participation. Basic demographic information will be collected (and kept confidential) to enable research-team members to contact participants by phone to confirm eligibility and discuss participation arrangements. Food and drink will be provided during each session. Each participant will receive a $20 Target gift card and participants may choose to be entered into a random drawing to win 1 of 3 incentives: (1) an $100 pre-paid Visa gift card, (2) two tickets to a Utah Jazz or Minnesota Timberwolves basketball game in Fall 2019 (respective of your home state), or (3) a Samsung 55” 4K UHDTV.

Data Collection and Analyses

CRR will facilitate the focus groups, using an interview guide stemming from modifications to existing measures [13, 40-42] that examine masculinity as well as attitudes and practices precluding men from seeking healthcare access. Another team member will assist with consenting and note-taking. The 2-hour sessions will be audio-recorded with 2 voice recorders, transcribed, and checked for accuracy. De-identified transcripts will be imported into NVivo 11 software (QSR International Pty. Ltd., Melbourne, Australia). Our NVivo-proficient coding team (TNR, CRR, and the research assistant) will use constant comparative and content-analysis

methods to independently code transcripts for themes.[54,55] After identifying themes relevant to our research questions from a sample reading and initial coding, we will automate term searches, code all documents, and run reports to ascertain the code text related to study themes. NVivo can organize data by participant characteristics, allowing us to compare the responses of participants who have or have not undergone CRC screening. To interpret and discuss findings and develop a codebook depicting how our codes interrelate, we will track coding decisions in NVivo and adjudicate them at team meetings. MDF and/or SZ will referee coding deviations, as needed. Key themes will be identified and incorporated into the new MBCS.[56,57]

Cognitive Interviews

Participants and Procedures

We will pilot-test the MBCS with 20 CRC advocates and survivors from across the U.S. (men and women who speak English, have a working telephone, and are aged 18–75 years), using 1-hour cognitive interviews (conducted in person or by phone) to elicit input as participants respond to the survey in real time.[58,59] Interviews will probe (1) how participants understand each question and response option; (2) whether the questions are likely to elicit an honest response; (3) the clarity of question wording; (4) the user-friendliness of the online survey setup; and (5) the questions' cultural specificity. Participants will engage in a thinking-aloud process with follow-up probes such as "How did you arrive at that answer?" These approaches will improve feasibility, reduce response error, and enhance face validity (an estimate of the degree to which the scale is clearly tapping the desired construct we aim to assess, i.e., culture-specific masculinity barriers to care).[60-62] Cognitive interviews also allow us to assess participants' comfort with online survey completion via PsychData (PsychData LLC, State

College, PA), a secure, web-based application that supports data capture for research Objective 1B. Our MBCS will be modified as a result of the cognitive interviews when necessary. Interviewees will receive a $20 Amazon gift card. RJT and two additional leaders in African-American men's health will provide expert item review of the final MBCS utilizing a questionnaire appraisal system [63].

Online Survey

Participants and Procedures

During Year 2, we will recruit 400 African-American men to complete an online survey, administered via smartphone, to test the relationship between masculinity barriers to care and CRC screening. Eligible respondents are men who (1) self-describe as non-Hispanic Black/African American; (2) were born in the U.S.; (3) are aged 45–75 years; (4) reside in the Salt Lake City or Twin Cities metro area; (5) have a telephone with internet access; and (6) speak English. With the aid of barbers and culture-specific marketing materials, we will recruit participants from African-American male–serving barbershops. Survey participants will have the opportunity to participate in drawings for 1 of 5 incentives: (1) a $50 Target gift card, (2) a $75 Amazon gift card, (3) an $100 Trader Joe's gift card, (4) an Apple iPad, or (5) Samsung 43" 4K UHDTV.

Barbershops are cultural hubs of trust essential in the growth and development of African-American men. Men usually spend at least 30 minutes waiting for or getting a haircut or chatting with others in the barbershop. Using PsychData, participants will be able to complete our survey within 15 minutes on their smartphones while waiting for or getting a haircut in participating barbershops. PsychData prevents survey alterations and eliminates transcription errors.[64] The PI

has a successful record of recruiting African-American men to complete surveys using mobile technology,[19,21,22] and African Americans outpace all groups for smartphone use.[65] For men who want to complete the survey but do not own a smartphone, each participating barbershop will be provided 1 smartphone courtesy of the study.

Dependent variables. We will use 2 Behavioral Risk Factor Surveillance System (BRFSS) questions to assess CRC screening uptake: (1) "A blood stool test is a test that may use a special kit at home to determine whether the stool contains blood. Have you ever had this test using a home kit?"; and (2) "Sigmoidoscopy and colonoscopy are exams in which a tube is inserted in the rectum to view the colon for signs of cancer or other health problems. Have you ever had either of these exams?"[66]

Independent variables. In accordance with our conceptual model illustrated in Figure 2 and the PI's Male Role Norms, Knowledge, Attitudes, and Perceptions associated with Colorectal Cancer Screening tool,[1,18,19-22] our independent variables will be masculinity barriers to care from our new scale and 5 factors known to influence CRC screening uptake among African-American men: knowledge, social support, beliefs, and attitudes towards CRC and 2 CRC screening exams (FIT, colonoscopy).[13,18,21,27]

Demographic covariates. Age, educational level, marital status, employment status, and other covariates will be included as previous studies by the PI and others have found these factors to be related to CRC screening among African-American men.[2,18,19-22,67]

Sample Size and Power Considerations

With a sample of 400 African-American men, we will have 80% power at the 0.05 level to detect a masculinity barriers to care effect on the odds of having had CRC screening,

assuming 35% of men with a masculinity barriers to care index equal to the mean have had CRC screening compared with 25% of men with a masculinity barriers to care index 1 standard deviation above the mean. We estimate that the average screening rate will be 35%, as the screening rate for African Americans is 53.1% in Utah and 52% in Minnesota and African-American men in both states tend to have lower CRC screening rates than women.[4,6,12,45] This assumes a moderately strong relationship between the masculinity barriers to care index and confounders (i.e., $R^2 = 0.25$ for the linear model that regresses the masculinity barriers to care index on the confounders). If the relationship between the confounders and the masculinity index is weaker, the power will be higher: 82% power with $R^2 = 0.2$ and 87% power with $R^2 = 0.1$. Power calculations were performed using PASS 15 (NCSS, LLC, Kaysville, Utah).

Data Collection and Analyses

We will test for associations between masculinity barriers to care, psychosocial factors, and CRC screening uptake. Our central hypothesis is that masculinity barriers to care will be negatively associated with CRC screening uptake. The masculinity barriers to care items emerging from Objective 1 will be utilized to create a latent variable that represents the construct being measured. The CRC screening-uptake outcome will be a binary variable that indicates whether a participant self-reported CRC screening uptake (i.e., answered Yes to either BRFSS dependent-variable question). We will fit a structural equation model with CRC screening uptake as the outcome and masculinity barriers to care as the predictor. We will adjust for potential confounders (e.g., age, educational level). We will also present the estimate and 95% confidence interval for the odds ratio comparing the odds of CRC screening uptake between participants

with a 1-point difference in masculinity barriers to care scores. Descriptive statistics will summarize participants' characteristics.

Two-Arm Intervention

Integration

In an exploratory sequential–designed study, a key step is to apply the qualitative data captured in Objective 1A to assist with building Objective 1B's quantitative phase. As described by Fetters et al.,[68] we will "merge" qualitative and quantitative data from Objective 1 to identify content areas for contrasting, comparing, and synthesizing results. During the first 6 months of Year 3, 2 team members (MDF and CRR) will determine to what degree and how the results from the combined qualitative and quantitative datasets yield a richer and more comprehensive understanding of the impact of masculinity barriers to care on CRC screening uptake among African-American men. Through this process, we will apply what we learn about the role of our variable of interest on CRC screening to develop a pilot intervention for overcoming these barriers.

Development

During the first 6 months of Year 3, we will adopt the BCW approach, working with Community Advisory Board members (2-hour small-group discussions via conference call and/or in person, 3 members per meeting) to develop the culture-specific intervention arm of our pilot intervention. We will use information from (1) our integrated Objective 1 results, (2) existing CRC screening intervention evidence, and (3) study-team expertise to apply the APEASE criteria *(**A**cceptability, **P**racticability, **E**ffectiveness/cost-effectiveness, **A**ffordability,*

***S**afety/side-effects, **E**quity)* (**Table 2**). Our hypothesis is that CRC screening uptake will be higher in the culture-specific arm than in the control arm.

Table 2. BCW Activities to Drive Development of Culture-Specific Trial Arm	
[1] Behavioural Diagnosis	Utilize the BCW to determine what needs to change for CRC screening uptake to increase among African-American men
[2] Intervention Strategy Selection	Utilize **[1]** to decide which intervention functions to apply (e.g., Education, Persuasion, Enablement)
[3] Behaviour Change Technique Identification	Develop a detailed culture-specific arm plan by selecting from among a range of specific, evidence-based behavior change techniques (e.g., intervention components such as barbers as motivational interviewers plus barbers distributing FIT kits; info about health consequences related to negating CRC screening).
[4] Draft Full Intervention Specifications	Create the detailed intervention specifications covering all aspects of content and delivery of the intervention structured around **[3]**.

We anticipate that the culture-specific arm will include at least 2 core components: barbers as motivational interviewers and InSure® FIT™ kits distributed by barbers. Motivational interviewing (MI) is "a collaborative conversation style for strengthening a person's own motivation and commitment to change."[69] Telephone-based MI is an effective way to improve cancer screening among underrepresented groups. Community-member–led MI has proved successful, but it is unknown if barbers as motivational interviewers can assist with reducing CRC screening inequalities among African-American men.[70-73] Also, randomized trials have shown that the FIT is the first-choice fecal occult blood test for CRC screening, is less invasive, less costly, and may be better accepted than other CRC screening tests.[74] If we choose this route for the culture-specific arm, preliminary data from our barbers suggest that the PI may teach the barbers the MI technique using content stems from Objective 1 findings. Additional components for this arm may be developed during the APEASE process.

Based on the PI's research[18-22] and evidence-based strategies,[75] the control arm will include an informational CRC screening brochure developed by the American Cancer Society[76] plus a FIT kit distributed by the barbers. Since the FIT kits will be free and the study will cover postage and processing fees, participants will be able to complete screening regardless of whether they have health insurance. Participants will mail the completed FIT kits to our local laboratory for processing. We will refer participants with positive FIT results to Huntsman Cancer Institute for a colonoscopy.

Participants and Procedures

Intervention participants will be non-Hispanic Black/African-American men (n = 60) who (1) have never completed CRC screening ; (2) are aged 45–75 years; (3) were born in the U.S.; (4) reside in the Salt Lake City metro area; (5) have a telephone with internet access, and (6) speak English. As a feasibility intervention, sample size is not based on the power to detect a certain effect size.[77] Rather, n = 60 (30 per arm) was chosen based on practical considerations (e.g., cost, recruitment).

The intervention will comprise a *recruitment phase* and an *implementation phase*. The recruitment phase will occur during the last 6 months of Year 3. With the assistance of barbers and culture-specific marketing materials, we will enroll 10 eligible African-American men at each of 6 barbershops. At baseline, participants will complete the demographic portion of our online survey. Once total enrollment is reached and consent obtained, the 6 barbershops will be randomized to the culture-specific or control arm using a permuted block size of 6. Then the implementation phase will begin. These distinct phases provide advantages in a cluster-randomized design. First, we eliminate recruitment bias as we blind participants to the

intervention at enrollment.[77] Second, the distinct phases allow each man to be exposed to the intervention for the same amount of time. We foresee the recruitment phase lasting 3 months and the implementation phase 7 months, resulting in a 10-month intervention, allowing ample time for participants to obtain CRC screening.

During the last 6 months of Year 4, our coding team will conduct exit interviews. Prior literature documents that 6 to 12 individual interviews per homogeneous group are sufficient to reach data saturation.[78,79] Thus, 18 in-depth, 60-minute participant interviews (2 participants from each of the 6 barbershops plus 3 barbers from each arm) will permit us to obtain rigorous outcomes data as well as participant accounts of what worked well and what did not for our two-arm intervention's implementation.

Analyses

Descriptive statistics will summarize participants' baseline characteristics. Continuous variables will be summarized by mean (standard deviation) or median (interquartile range), and categorical variables in contingency tables. Feasibility of the study protocol will be evaluated as follows:

1) *Recruitment.* We will calculate the number of days needed to reach full enrollment at each barbershop, the percentage of men meeting eligibility criteria and, of those, the percentage who chose to enroll.

2) *Sample Size Estimation.* The intraclass correlation coefficient will be estimated from our study data and inflated (due to the expected downward bias) to estimate the necessary sample size for the full trial.[80]

3) *Preliminary Efficacy.* By treatment arm, we will calculate the percentage for whom we can ascertain FIT uptake. We will assess intervention adherence 7 months after the recruitment phase by FIT kits returned to our laboratory for processing. Because we will have only 3 barbershops per arm, no formal statistical analysis of FIT uptake will be performed. Instead, percentages for these outcomes will be calculated by barbershop. We will perform this as intent-to-treat, with men included based in the arm to which their shop was randomized. A per-protocol analysis will also be performed. Many more barbershops are needed to accurately account for the correlation of African-American men within the same barbershop and achieve a cluster-level confounding balance.[81] In our pilot trial, a logistic mixed-effects model with a random intercept for each barbershop will be used to estimate the odds ratios comparing CRC screening uptake between our control and culture-specific arms.

4) *Acceptability.* After the 7-month intervention phase, we will conduct 18 post-intervention interviews to obtain rigorous outcomes data. The audio-recorded and transcribed post-intervention interviews will be analyzed by our coding team using Nvivo [64] and Creswell's methods.[82] To increase our findings' internal validity, data will be triangulated or compared from the perspectives of the 2 study arms.[83]

Conclusion

African-American men have the highest CRC mortality across all gender and racial/ethnic groups. Moreover, national findings predict a 28% to 46% increase in CRC incidence among adults ages 35-49 years, including African-American men, by 2030.[9] Our study aims to aid in reducing CRC screening inequities among African-American men by creating a new, culture-specific intervention that directly addresses masculinity barriers to care,

psychosocial factors, and CRC screening uptake among African-American men beginning at age 45 years. Subsequently, we will test its feasibility and acceptability in a cluster-randomized pilot intervention.

Completing our objective will provide the preliminary data needed for an R01 application to test the new intervention's efficacy in a large-scale, well-powered, cluster-randomized controlled trial. More broadly, this research will demonstrate that decisions regarding CRC screening uptake are not detached from cultural and other influences. We will use the culture-specific survey instrument we create to more rigorously assess the association between masculinity barriers to care and CRC screening uptake. This will strengthen our scale's predictive utility while endorsing optimal health for African-American men as warranted by Healthy People 2020. [82] Additionally, our scale could be adapted for use in research on other types of cancer (e.g., prostate cancer) that disproportionately affect African-American and other underrepresented men.

Overall, our efforts will serve as a model for more culture-specific tailored approaches to prevention, diagnosis, and treatment, a goal aligned with the NCI's Cancer Moonshot initiative.

Ethics and dissemination

Signed informed consent will be obtained from all participants prior to any data collection. Study results will be disseminated through publications in peer-reviewed journals, discourse sessions with the community, and presentations at national and international professional conferences.

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Authors' contributions and data access statement

KO, EDP, MH, SZ, RJT, and MDF serve as data monitoring committee (DMC) members for this study, while additional data monitoring, harms, and auditing logistics are available from the University of Utah Institutional Review Board. Only the DMC will have access to the full pilot trial dataset in order to ensure that the overall results are not disclosed by an individual study site prior to the main publication.

CRR is the study PI, wrote the first draft of the study protocol, and edited every draft thereafter. KO is a Primary Mentor for the study and edited the study protocol with the PI. EDP is a Secondary Mentor of the study and edited the study protocol with the PI. Study Co-Mentors MH, SZ, and RJT edited the study protocol with the PI. CR and TNR are Co-Investigators of the study and edited the study protocol with the PI. In addition to being a mixed-methods expert, MDF is a Co-Mentor on the study who edited the study protocol extensively with the PI as a senior co-author. All authors agreed to be accountable for all aspects of the study in ensuring that questions related to the accuracy or integrity of any part of the study are appropriately investigated and resolved. Lastly, all authors read and approved the final manuscript.

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Conflicts of Interests

None declared.

Figure legends

Figure 1. Exploratory Sequential Intervention Design

Figure 2. Conceptual model of factors influencing CRC screening uptake among African-American men

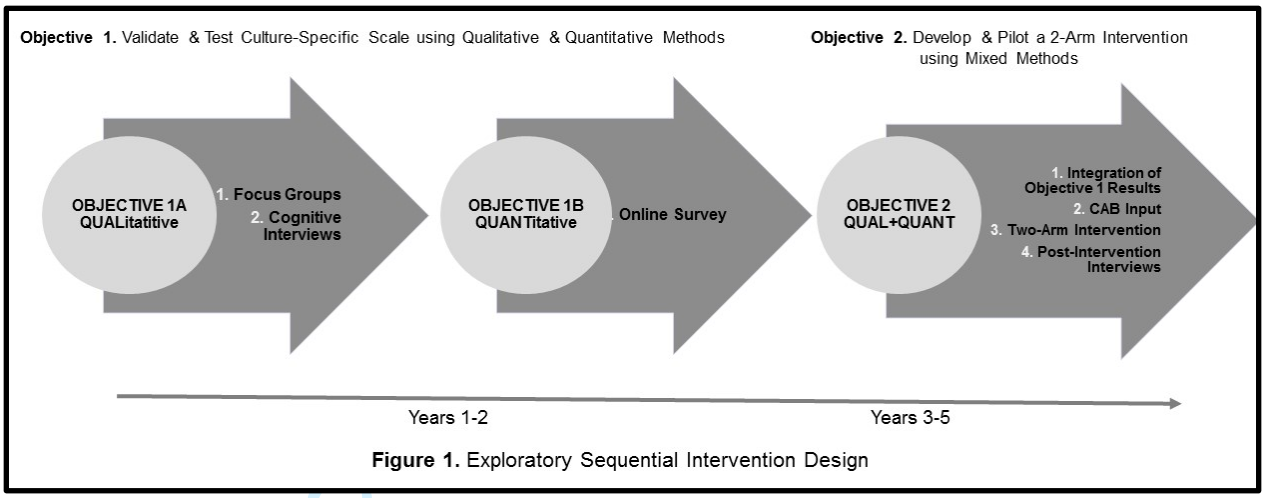

Figure 1. Exploratory Sequential Intervention Design

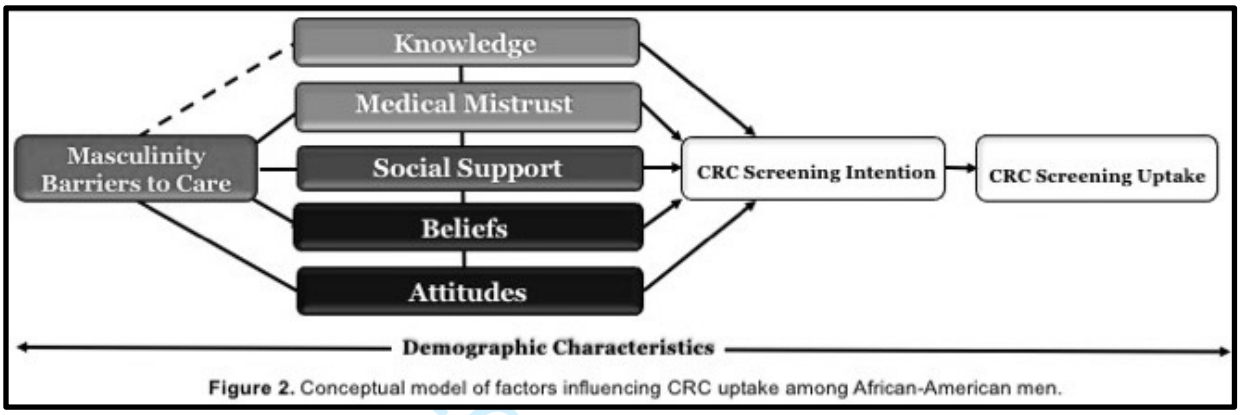

Figure 2. Conceptual model of factors influencing CRC uptake among African-American men.

Reporting checklist for protocol of a clinical trial.

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		Reporting Item	Page Number
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	4
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	4
Protocol version	#3	Date and version identifier	1
Funding	#4	Sources and types of financial, material, and other support	30
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	29
Roles and responsibilities:	#5b	Name and contact information for the trial sponsor	30

sponsor contact information			
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	30
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	6
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	6
Objectives	#7	Specific objectives or hypotheses	8
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	9
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	10
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	11
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	16
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	17
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return;	19

		laboratory tests)	
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	20
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	20
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	19
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	15
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	11
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	19
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	19
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	19
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	19
Blinding (masking): emergency	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during	N/A

unblinding		the trial	
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	12
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	12
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	12
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	16
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	18
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	13
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	29
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	29
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	29
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and	29

		whether the process will be independent from investigators and the sponsor	
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	4
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	9
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	12
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	19
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	12
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	30
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	29
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	21
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	22
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/A
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	N/A

Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A