Study Protocol and Statistical Analysis Plan

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Study Title: Still Climbin': A Randomized Controlled Trial to Improve Coping, Medical Mistrust, and Healthcare Engagement Among Black Sexual Minority Men

KEY PERSONNEL

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Abbreviations

SMM	Sexual minority man/men
BSMM	Black sexual minority man/men
HIV	Human Immunodeficiency Virus
CVD	Cardiovascular disease
CBT	Cognitive Behavior Therapy

RAND

Study Protocol

1. What the study will do

This study is a randomized controlled trial of Still Climbin', an 8-session cognitive behavior therapy (CBT) group intervention that addresses coping and medical mistrust among Black sexual minority men (SMM). Designed to be flexible for use in community settings, this intervention was developed in partnership with community stakeholders who emphasized the need for a community-based program outside of the health care system, without a specific disease focus. It intends to give Black SMM a safe space to receive support for the whole of their identity and to openly discuss barriers to health care. Participants will be followed for 12 months. The effectiveness of the Still Climbin' intervention will be assessed on health care engagement and receipt of evidence-based preventive care, through surveys administered at multiple points throughout the intervention period. These outcomes will be confirmed with information from medical records. The intervention is hypothesized to show increased health care engagement and receipt of evidence-based preventive care, in addition to better coping than the control group.

The Specific Aims is to conduct a randomized controlled trial to test the effects of *Still Climbin'*, a culturally congruent CBT group intervention, on the primary outcomes of healthcare engagement (e.g., at least one ambulatory care visit in the past 6 months) and receipt of evidence-based preventive care (e.g., chronic disease screenings) among Black SMM, and the secondary coping outcome.

2. How it will be done

A total of 370 Black participants will be recruited; approximately half will be randomly assigned to receive the coping intervention and half to a no-treatment control condition. There will be about 10 cohorts of about 15 participants each for both intervention and control. Participants will be randomized to an intervention or control group after they complete the baseline survey. Participants will complete four surveys, starting with the baseline survey, and followed by 4-, 8-, and 12-month post-baseline follow-up surveys to assess health care engagement and receipt of evidence-based preventive care (e.g., cancer and diabetes screening, cardiovascular disease prevention, immunization, HIV prevention), and other topics such as coping strategies.

3. Why it is being done

This study's primary purpose is to address health issues that affect Black men, especially Black sexual minority men (SMM). Large racial/ethnic and sexual minority health and healthcare differences exist for preventable conditions in the U.S. Black men show higher mortality rates and lower healthcare engagement than nearly all other racial/ethnic subgroups. SMM, including Black SMM, are at high risk for poor physical health, including hypertension and cardiovascular disease (CVD), and have low access to care. Black SMM display high rates of HIV and other sexually transmitted infections. To date, there are no evidence-based prevention programs addressing overall health and wellness among Black sexual minority men; the few evidence-based interventions specifically tailored for Black SMM focus only on HIV.

4. How many people will be in the study?

We will enroll 370 participants at baseline. This sample size was determined in a priori power analyses to be sufficient to detect small to moderate intervention effect sizes for all primary and secondary outcomes.

5. Who is eligible to take part in it?

Eligibility criteria include: 18 years of age or older; Biologically male at birth; Identify as male; Self-identify as a Black/African American; Report having sex with men in the past 24 months; Anticipate being available for the next 12 months to attend study visits; Able to interact and communicate in written and spoken English.

6. What study therapy or other interventions will be given?

The intervention is an 8-session CBT group intervention that addresses coping with discrimination and medical mistrust among Black SMM in order to improve health care utilization, receipt of evidence-based care, and overall health and wellness.

7. What tests will be done and how often?

We will administer surveys at baseline, and 4-, 8-, and 12-mont follow-up.

8. What information will be collected

1. From baseline to 12-month post-baseline we will assess the Primary Outcome Measure: Proportion of Participants Who Have Inadequate Healthcare Utilization (self-reported). The survey will assess number of medical care visits in different settings (usual source of medical care, primary care visits, missed visits, urgent care, emergency department, hospital inpatient, residential care facility, hospital outpatient clinic, other type of clinic, dental care provider, home healthcare). We will construct measures of inadequate service utilization as having: (1) fewer than 1 ambulatory visit, (2) at least 1 emergency department visit (without subsequent hospitalization), or (3) at least 1 hospitalization in the past 6 months. Higher numbers of hospital visits and emergency department use likely results from not receiving indicated outpatient treatment, which can prevent complications, even among those who experience multiple chronic conditions.

2. From baseline to 12-month post-baseline we will assess the Primary Outcome Measure: Proportion of Participants Receiving Evidence-based Care Across Conditions and Assessments (self-reported). We will calculate receipt of evidence-based care as receipt of all eligible services within health condition categories (cancer screening, CVD prevention, immunization, diabetes care, HIV prevention, HIV treatment), and create an “all-or-none” measure across all categories.

3. From baseline to 4 months, to 8 months, and to 12 months, we will measure change the Secondary Outcome Measure, Adaptive Coping Strategies (Social Support Seeking; e.g., “I get emotional support from others”). Relevant items on the Brief Cope a general measure of coping strategies, will be adapted to assess frequency of use of each strategy, using the instructions, “indicate the extent you do what the item says when you are faced with discrimination,” and response options 1 = “I haven't been doing this at all,” 2 = “I've been doing this a little bit,” 3 = “I've been doing this a medium amount” and 4 = “I've been doing this a lot.”

Note: The study team originally planned to validate self-reported health care behaviors and outcomes with medical records data, but the grant was terminated before the team could collect these objective data.

Statistical Analysis Plan

1. Statistical aspects of the clinical trial design

Intention-to-treat analyses will be used to test intervention efficacy.

2. Process of data selection for analyses

Data were selected for analysis in order to address study aims focused on evaluating the intervention in terms of primary and secondary outcomes as well as determining mediating mechanisms of change as well as moderators. (Due to premature study termination, only analyses with respect to primary and secondary outcomes will be conducted.)

3. Detailed analyses of data items

Descriptive statistics will be performed on all study variables. We will transform any outcomes with skewed distributions (log or other as appropriate) to stabilize error variances and reduce the influence of outliers in regression models. To address potential bias from differential randomization and drop-out, we will use covariates and non-response weights. Socio-demographic characteristics that significantly differ by intervention condition at will be included as covariates. Nonresponse weights will be used to address any potential differences between participants with complete data for at least one follow-up wave versus participants with only baseline data. Weights will be created using the inverse of the estimated probability of completing any follow-up survey, based on a multivariable logistic regression using socio-demographic and psychosocial variables that were not missing for any participant.

4. Procedures and methods employed for analyzing the data

Analysis Plan. To test intervention effects under the Study Aim, we will use intention-to-treat analyses comparing intervention to control group outcomes. For inadequate healthcare engagement (<1 ambulatory visit, ≥1 emergency department visit, or ≥1 hospitalization in past 6 months) and receipt of evidence-based preventive care, we will conduct logistic regressions predicting whether participants had inadequate health care utilization or received evidence-based care within the entire follow-up period (yes/no). For coping, we will analyze all follow-up responses with repeated-measures linear regressions that include fixed effects for intervention condition, baseline value of the outcome, and covariates, employing a sandwich estimator to account for within-participant clustering; each participant can contribute up to three follow-up responses (from the 4-, 8-, or 12-month surveys).

Statistical Power. Based on our prior research, we anticipate medium effect sizes (0.5 SD). For analyses comparing intervention vs. control on continuous outcomes (e.g., coping) at follow-up, with a very conservative estimate of 240 participants (120 per group), there will be 80% power to

detect a difference of .36 SD (a small-to-medium effect size). For receipt of evidence-based preventive care, we used percentages from an analysis of our preliminary data, in which receipt of evidence-based care for CVD prevention and treatment ranged from 5.1% to 58.4% (and was lower for people living with HIV vs. people who were HIV-negative) [Ladapo JA, Richards AK, DeWitt CM, Harawa NT, Shoptaw S, Cunningham WE, Mafi JN. Disparities in the quality of cardiovascular care between HIV-infected versus HIV-uninfected adults in the United States: a cross-sectional study. J Am Heart Assoc. 2017;6(11):e007107. PubMed PMID: 29138182; PMCID: 5721786]. Thus, we estimated 80% power at 12-month follow-up to detect minimum between-groups difference representing small-to-medium effect sizes:

Control Group %	Minimum Detectable Difference	Effect Size (Cohn's D)
5%	11.0%	.37
30%	17.6%	.36
60%	16.8%	.36

5. Planned presentation of results in formats such as tables, listings, and figures

Results will be depicted in tables.

6. Plans for interim and final analysis and statistical analysis of the primary and secondary variables and other data

All analyses detailed above including timepoint specific follow-up as well as overall longitudinal models will compare intervention conditions on change in primary and secondary outcomes.