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Effects of resistance training on depression and cardiovascular disease risk in Black men: Protocol for a randomized controlled trial

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Abstract

Background: Depression is severely undertreated in Black men. This is primarily because Black men are less likely to seek traditional psychiatric treatment, have less access and more barriers to treatment, and perceive more stigma associated with treatment. Depression contributes to cardiovascular disease (CVD), and Black men have the highest rate of mortality from CVD.

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Declarations

Ethics approval and consent to participate

This trial was reviewed and approved by the Institutional Review Board of Teachers College, Columbia University on 9/27/16 under the reference number 17-005. All participants included in the study will provide written informed consent.

Competing interests

The authors report no conflicts of interest.

Resistance training (RT) can have beneficial effects on both depression and CVD. This study will be the first randomized controlled trial to test the effects of RT on depression and cardiovascular health in a sample of depressed Black men.

Method/Design: Fifty Black men with clinically significant symptoms of depression will be randomized to either (a) a 12-week RT or (b) an attention-control group. Behavioral Activation techniques will be used to support adherence to home-based RT goals. Both groups will meet on-site twice/week during the 12-week program, and follow-up assessments will occur at the end-of-treatment and 3 months post-treatment. Qualitative interviews will be conducted after the 3-month follow-up. The objectives of this study are (1) to assess the feasibility and acceptability of recruitment, retention, and intervention procedures, (2) to obtain preliminary evidence of efficacy, and (3) to explore potential mediators of the effects of RT on depression.

Discussion: This study will advance the field of minority men's health by producing new data on the effects of RT for depression, the potential mechanisms of action that may support its use, and its effects on markers of CVD risk in Black men.

Trial registration: ClinicalTrials.gov (NCT03107039)

Keywords

Depression; cardiovascular disease; weight lifting; strength training; resistance training; behavioral activation

Background

Depressive disorders account for the most significant percentage of the global burden of disease (Ferrari et al., 2013; Vos et al., 2013; Whiteford et al., 2013). In the United States, an estimated 16 million individuals suffer from depression (Substance Abuse and Mental Health Services Administration, 2014), which contributes to high levels of premature morbidity, disability, and mortality. Despite its important health consequences, depression remains underrecognized and untreated in men (Addis & Mahalik, 2003; H. M. González et al., 2008; González et al., 2010). This is in part because men often find traditional psychiatric treatments for depression (i.e., medication or psychotherapy) unacceptable (Addis & Mahalik, 2003). The lack of recognition and treatment is particularly problematic among Black[1] men who are less likely to seek psychiatric treatment, have less access to quality treatment, experience more social and contextual barriers to seeking treatment, perceive the greatest stigma to seeking treatment and are unlikely to engage in treatment even when recommended by a provider (Barksdale & Molock, 2009; H. M. González et al., 2008; Holden, McGregor, Blanks, & Mahaffey, 2012; Holden & Xanthos, 2009; Latalova, Kamaradova, & Prasko, 2014; National Institute of Mental Health, 2001; Sirey, Franklin, McKenzie, Ghosh, & Raue, 2014; Vogel, Heimerdinger-Edwards, Hammer, & Hubbard, 2011; Wallace & Constantine, 2005). Moreover, the negative social correlates of depression (e.g., unemployment, incarceration, low educational attainment, and poverty)

[1]The term "Black" is used throughout the paper to include the diverse ways people with origins in any of the Black racial groups of Africa self-identify (e.g., Black, African American, Afro-Caribbean, and African). Many of these groups are well represented in the recruitment area (i.e., New York City); therefore, the recruitment and study materials will use the term "Black."

disproportionately affect Black men (Hudson, Eaton, Banks, Sewell, & Neighbors, 2018; Harper et al., 2002; Ward & Mengesha, 2013; Williams, 2003).

Although findings from epidemiological surveys indicate lower lifetime prevalence of rates of depression in Black men compared to White men, depression is more persistent, severe, and disabling among Black men (González et al., 2010; Williams et al., 2007). Further, Black men are at the greatest risk of non-detection of depression and have more negative attitudes towards psychiatric care than men of other races and Black women (Borowsky et al., 2000; Das, Olfson, McCurtis, & Weissman, 2006; Latalova et al., 2014; Miranda & Cooper, 2004; Sirey et al., 2014; Vogel et al., 2011). The endorsement of traditional masculine norms (e.g., self-reliance, stoicism, and confidence) has been consistently linked to psychiatric treatment underutilization among men (Addis & Mahalik, 2003; Mahalik, Good, & Englar-Carlson, 2003), and the relationship between these norms and negative attitudes toward depression treatment is stronger in Black men (Vogel et al., 2011).

When taken together, the intersection between race and gender represents a unique risk profile for depression in Black men that might inform treatment needs. This profile is further complicated by the established links between depression and cardiovascular disease (CVD) (Heron, 2013). Depression prospectively predicts the onset and course of CVD, as well as CVD mortality (Davidson, Jonas, Dixon, & Markovitz, 2000; Roose, Glassman, & Seidman, 2001; Rugulies, 2002). Black men have the highest mortality rate from CVD and stroke (Go et al., 2014), and are more likely than other men to be diagnosed with hypertension (Mensah, Mokdad, Ford, Greenlund, & Croft, 2005). Multiple studies have found links between depression and CVD among Black samples (Mwendwa et al., 2013; Weinstein, Abraham, Diao, Zeno, & Deuster, 2011) and the depression-CVD interaction may be particularly strong among Black individuals when compared to other groups (Jonas & Mussolino, 2000; Lewis et al., 2011). For example, depression is a stronger predictor of CVD and stroke death in Blacks than Whites (Lewis et al., 2011). There are many causes for this disparity (e.g., socioeconomic status, community characteristics, access to care), but lower fitness and rates of exercise among Black men are contributing factors (Swift et al., 2013).

Despite clear evidence of health disparities in depression and CVD by race, research on depression and CVD risk in Black men is scant and few controlled trials have been conducted. To address this gap, the current randomized controlled trial will investigate the effects of resistance training (RT; i.e., weight lifting) on depressive symptoms and CVD risk in a sample of depressed Black men.

RT was chosen as the mode of exercise in this study for several reasons. RT has significant effects on both cardiovascular health (Braith & Avery, 2013; Braith & Stewart, 2006) and depression (Gordon et al., 2018; Rethorst, Wipfli, & Landers, 2009; Singh, Clements, & Fiatarone, 1997; Singh, Clements, & Singh, 2001). More specifically, RT has well known beneficial effects on hypertension (MacDonald, et al., 2016) and is associated with a significant reduction in cardiovascular disease morbidity and mortality (Liu Y, et al., 2019). With respect to depression, a recent meta-analysis found RT to be associated with a significant reduction in depression across 33 RCTs (Gordon et al., 2018). Moreover, the

antidepressant benefits of RT reported in the literature are equivalent to those observed for aerobic exercise (e.g., walking; Rethorst et al., 2009), with effects persisting one year post-intervention (Singh et al., 1997). Finally, acute bouts of RT reduce many of the acute negative affective states frequently reported by those with depression (e.g., depressed mood, tension, anxiety; Doyne et al., 1987). To date, the majority of work on exercise for depression has been performed in primarily White and female samples (Cooney, Dwan, & Mead, 2014; Rethorst et al., 2009) and outcomes are rarely reported separately by race or gender. As such, the acceptability and efficacy of RT for depression in Black men remains unknown.

Research suggests that depressed Black men are unlikely to seek out psychiatric treatment because of stigma, masculine norms, and distrust of medical professionals resulting from historical abuses (e.g., Tuskegee study; Brandon, Isaac, & LaVeist, 2005; Rencher & Wolf, 2013). This RT intervention attempts to circumvent these barriers. Fitness trainers will be used to provide the intervention rather than medical professionals. Moreover, RT increases physical strength, which may be perceived as enhancing (rather than detracting from) masculinity (Grogan & Richards, 2002 ; Klomsten, Skaalvik, & Espnes, 2004), and the intervention involves RT exercises individuals can do in their homes. Some data suggest that Black individuals engage in RT more than other racial groups (National Center for Health Statistics, 2015) and a recent study found that depressed men preferred RT at more than double the rate of women, (Busch et al., 2016) suggesting that RT may be particularly acceptable to Black men. Thus, RT is promising as a culturally congruent intervention for Black men who are depressed. Of note, there have been a few exercise intervention studies conducted exclusively with Black men (Akinpelu, 1990; Bond et al., 2008; Bond et al., 2002; Hanson et al., 2012; Kokkinos et al., 1995; Taylor, Makambi, Sween, Roltsch, & Adams-Campbell, 2011). These studies show that physical activity reduces several physical health problems associated with depression in this population such as CVD, cancer, and diabetes. However, these interventions focused primarily on aerobic exercise and none enrolled a depressed sample or targeted depressive symptoms as an outcome.

Those with depression are less likely to make health behavior changes and attend exercise intervention appointments (Berlin & Covey, 2006; Ellard, Thorogood, Underwood, Seale, & Taylor, 2014; J. S. Gonzalez et al., 2008; Mazzeschi et al., 2012; Wing, Phelan, & Tate, 2002; Ziegelstein et al., 2000); in addition, they show motivational deficits for exercise (Krämer, Helmes, Seelig, Fuchs, & Bengel, 2014). To address these barriers, we will integrate brief (approximately 10 minutes per session) Behavioral Activation (BA) counseling into the RT protocol to facilitate engagement in and maintenance of RT. BA is an evidenced-based behavioral therapy that has been used to promote and maintain health behavior changes (including exercise) among those with depressed mood (Daughters, Magidson, Schuster, & Safren, 2010; MacPherson et al., 2010; Magidson et al., 2011; Mimiaga et al., 2012; Pagoto et al., 2008; Schneider et al., 2011). BA is a good fit for this purpose because BA techniques address the common motivation, concentration, and cognitive limitations common among those with depression. BA has been used successfully in minority samples (Gitlin et al., 2013; Kanter, Dieguez, Rusch, Busch, & Santiago-Rivera, 2008) and can be provided by bachelors-level practitioners (Ekers, Dawson, & Bailey, 2013). In this study, brief BA counseling will focus on countering the known barriers to

exercise adherence (Searle et al., 2011; Seime & Vickers, 2006) by: (a) providing structured, graded goal setting for at-home RT goals, (b) actively problemsolving idiographic barriers to RT session attendance and completion of at-home RT goals, and (c) promoting maintenance of RT during follow-up.

In sum, the high disease burden of CVD and depression and persistent barriers to care among Black men warrant the development of novel interventions for depression in Black men. In particular, there is need for culturally acceptable interventions that simultaneously improve depression and CVD risk. The purpose of this study is to address this gap in the literature and advance the field of minority men's health. To our knowledge, this will be the first randomized controlled trial testing RT as a dual intervention for depression and CVD risk reduction with depressed Black men. The objectives of this study are to (1) assess the feasibility and acceptability of recruitment, retention, and intervention procedures, (2) obtain preliminary evidence of efficacy, and (3) explore potential mediators of the effects of RT on depression.

Method

Study Design Overview

This study will utilize a parallel group, single blind (i.e., assessors blind to condition), randomized efficacy design to analyze the effects of RT on interviewer assessed depressive symptoms (primary outcome), self-reported depression, anxiety, and stress (secondary outcomes), and a variety of CVD risk factors (secondary outcomes) in a sample of depressed black men. The design complies with the requirements of the Consolidated Standards of Reporting Trials (CONSORT) guidelines. The trial has been registered at clinicaltrials.gov (NCT03107039) Fifty participants will be randomized into either (a) a 12-week RT or (b) an attention control condition (Health, Wellness, and Education; HWE). Follow-up assessments will occur at end-of-treatment (i.e., week 13) and three months after treatment is complete (i.e., 6 months post-randomization). Both RT and HWE conditions will meet on-site twice per week during the 12-week program (24 sessions lasting 60-minutes). RT participants will be provided with the instruction and equipment needed to complete between-visit exercises and to continue RT at-home between end-of-treatment and 3-month follow-up. Participants will be compensated for completing the assessments at baseline ($20), end-of-treatment ($50) and 3-month follow-up ($50). At the 3-month follow-up, a subset of participants will complete a qualitative interview about their experience with the program and will be compensated an additional $25. Figure 1 displays the conceptual model that informed the design of this study, which informed the assessments and outcomes measures.

Study Setting

The majority of study activities will be conducted at a private university in New York, NY. Blood draws will be done at a retail lab with a variety of locations throughout the city.

Participants

Individuals who self-report being cisgender men and Black or African American will be recruited for this study. Epidemiological studies indicate that a significant proportion of

transgender individuals receive hormone therapy to induce changes in physical appearance (i.e., testosterone or estrogen supplements; James et al., 2016; Mepham, Bouman, Arcelus, Hayter, & Wylie, 2014; Reback, Simon, Bemis, & Gatson, 2001). Sex hormones are linked with the regulation of skeletal muscle mass and adipose tissue, glucose homeostasis, lipid metabolism, and cardiovascular processes (Lundsgaard & Kiens, 2014; Mattsson & Olsson, 2007; Vitale, Fini, Speziale, & Chierchia, 2010; Weinand & Safer, 2015; Wiik et al., 2018). As such, the physiological dynamics of hormone therapy could introduce unintended confounds to analyses of primary outcomes; therefore, transgender individuals will not be included in the study.

Participants must be ≥ 21 years of age and have clinically significant symptoms of depression as determined by reporting a score of ≥10 on the Patient Health Questionnaire (PHQ-9; Kroenke, Spitzer, & Williams, 2001). Participants currently receiving therapy or medication to treat depression will be included if they still meet the depressive symptoms criterion. Potential participants will be excluded if they report acute psychosis, mania, or suicidality, are currently engaged in any RT or other exercise for more than 60 minutes/week during the prior month, or report a medical condition that would make exercise unsafe without medical screening. In this regard, and consistent with the American College of Sports Medicine guidelines, we will exclude those with prior myocardial infarction, coronary artery disease, stroke, blood clots, aneurysm, peripheral artery or vascular disease, chronic obstructive pulmonary disease, emphysema, chronic bronchitis, diabetes, renal or kidney disease, liver disease (e.g., cirrhosis or hepatitis), or mobility impairment (e.g., walks with a cane).

Procedure

Recruitment—Participants will be recruited using a variety of methods, including advertisements online (e.g., Craigslist, Instagram) and in free local newspapers, flyers in local venues (e.g., churches, barbershops), and booths/presentations at community events.

Phone screening—Interested participants will call a study number staffed by a Research Assistant (RA). The RA will describe the study and complete a phone screener, 2-question Patient Health Questionnaire (PHQ-2; Kroenke, Spitzer, & Williams, 2003), questions about demographics, medical history, and physical activity to determine eligibility.

Orientation/In-Person Screening—Interested participants who are eligible following the phone screen will attend an orientation session. At orientation, they will be provided with a presentation from an RA who will introduce the research team, goals of the study, time commitment, compensation, and an outline of all assessments. There will be an opportunity for interested participants to clarify any questions they may have. Following this, the Informed Consent and HIPAA documents will be explained and provided for signature.

Questionnaires will be administered to establish final eligibility based on inclusion/exclusion criteria provided above. Specifically, participants will complete a Demographics Questionnaire (to confirm age and that participant identifies as a cisgender Black man), Medical History Questionnaire (to determine exclusionary medical and psychiatric

conditions), the Patient Health Questionsaire-9 (Kroenke et al., 2001), and the Modifiable Activity Questionnaire (MAQ; to determine current minutes per week of exercise; Pettee Gabriel, McClain, Schmid, Storti, & Ainsworth, 2011) .

Baseline measures—After confirmation of eligibility, participants will complete several baseline self-report questionnaires at the end of the orientation visit. The rest of baseline data will be collected at three additional baseline assessment visits to the university as well as a baseline blood draw at a local retail laboratory. All of the data gathered at baseline is detailed below and listed in Table 1.

Medical history, demographics, as well as height and weight will be collected at baseline to describe the sample. The primary outcome of this study is interviewer-rated depressive symptoms (the gold standard for assessing depressive symptoms) as measured by the clinicianrated version of the Quick Inventory of Depressive Symptomatology (QIDS; Rush et al., 2003). Assessors will receive regular supervision from a licensed clinical psychologist experienced in assessment of depressive symptom severity. Secondary outcomes include self-reported depressive symptoms as measured by the Patient Health Questionniare-9 (Kroenke et al., 2001), self-reported anxiety measured by the Generalized Anxiety Disorder-7 scale (Spitzer, Kroenke, Williams, & Lowe, 2006), self-reported stress measured by the Perceived Stress Scale (PSS-10; Cohen & Williamson, 1988), resting heart rate and blood pressure, waist to hip ratio, and body composition measured with BodPod (a whole-body air displacement plethysmograph) (Baracos et al., 2012). Blood lipids (total cholesterol, HDL, LDL, triglycerides) and high sensitivity C-reactive protein (CRP) will be tested with a blood sample drawn at local retail laboratories and a saliva sample will be obtained by RAs to test for interleukin-6 (IL-6). Hypothesized mediators include sleep quality, exercise enjoyment, physical self-concept, and self-esteem, and will be measured using the scales indicated in Table 1. Physical fitness measures will be utilized as manipulation checks, and include exercise behavior assessed by the Modifiable Activity Questionnaire (Pettee Gabriel et al., 2011) and muscular strength assessed by the American College of Sports Medicine's 1-Rep Max test (chest press and leg extension; American College of Sports Medicine, 2014). Assessors will be trained to conduct and receive regular supervision regarding strength testing assessments and other anthropomorphic measures from a PhD-level Exercise Scientist. Drug use, alcohol use, smoking, and diet will be assessed by self-report as potential confounders of primary and secondary outcomes and will be measured using the scale indicated in Table 1.

Randomization—Those who complete all baseline assessments will be randomized in a 1:1 ratio to one of the two treatment groups. The randomization scheme will be based on a permutated block randomization procedure with small random sized blocks. Randomization will be stratified by baseline self-reported depressive symptom severity (PHQ-9: 10-14 vs. ≥15). The randomization sequence was generated by an off-site biostatistician. Study staff will open blinded randomization envelopes at the point of randomization.

Treatment—Both groups will be seen on the same schedule (60 minute sessions two times a week with at least one day between sessions) and next sessions will be scheduled at the end of each session. Participants will be encouraged to contact study staff by phone or text

message should they need to reschedule. The same interventionist will conduct both treatment groups.

Resistance Training (RT).: The RT program is designed to reduce depression and cardiovascular risk, while also adhering to the American College of Sports Medicine's guidelines for developing and maintaining muscular fitness (American College of Sports Medicine, 2009). As there is not yet an established dose or total volume (intervention length x frequency x session duration) of RT that is required to reduce depression (Gordon et al., 2018), we will have participants attend two onsite, 50-minute sessions per week, and complete up to 50 minutes of exercise at home per week. This dose both meets the threshold for the amount of time and number of sessions per week of RT associated with a reduction in cardiovascular events (Liu Y, et al., 2019) and also allows for comparisons to the efficacy of traditional depression treatments, which often test initial efficacy after 12-16 weeks of treatment.

Safety and proper form will be central components of the program. Each session will be at least one day apart to allow sufficient recovery, and all will be scheduled at a time/day that is most convenient for participants. All sessions will have two components: (a) 50 mins of exercise and (b) 10 mins of BA counseling, including reviewing previous and setting new at-home RT goals. The 50 minutes of exercise will be individualized based on results of the initial strength test, and will involve a full-body routine that can be accomplished in the participants' home environments. For many participants, this will consist of movements that can be done in small spaces and do not require a lot of equipment (i.e., it combines dumbbells, resistance bands, and bodyweight exercises). For a minority of participants who will have regular access to traditional RT equipment (e.g., have a gym membership) more equipment dependent movements will be prescribed (e.g., lateral pull downs, barbell bench press, or barbell squat on squat rack). This allows participants to complete the same movements during coached sessions and at-home goals.

The format for the 50 minutes of RT will be a 5-minute aerobic warm-up, 40-minutes of RT, and a 5-minute cool-down (stretching). The routine will be progressive and the key RT program variables of volume (sets/repetitions) and intensity (load; percentage of repetition maximum) will be manipulated according to American College of Sports Medicine's guidelines. For weeks 1-3, participants will be introduced to RT and learn proper form, movement techniques, and become accustomed to feelings of muscular fatigue. Then, in a personalized manner, increases to weight/resistance and volume will be prescribed across the remaining weeks (4-12). Participants will learn a large variety of bodyweight, dumbbell, and resistance band exercises that will be first mastered in the presence of the interventionist and then practiced at home. Later sessions will focus on how to use the knowledge, skills, experience, and equipment provided by the program to continue RT at home and uncoached during the follow-up period.

The BA component will follow established BA goal-setting procedures (Kanter, Busch, & Rusch, 2009), but will focus on at-home RT as the target behavior. Each study session will include approximately 5 minutes of BA counseling at the beginning of session and 5 minutes

at the end of session. Participants will be provided with a variety of resistance bands at RT session 4 and a set of dumbbells at session 10 to use to complete at-home RT goals.

At the beginning of the first session the interventionist will provide a rationale for the BA-based goal setting, orient the participant to a workbook to facilitate at-home RT goals, and conduct a brief values assessment to assess how engaging in RT is in line with the participants' personal life values. Participants' values will be revisited throughout treatment as motivators for engaging in in-session and at-home RT. At the end of Session 1, the interventionist will take 5 minutes to work in a BA-consistent style with the participant to collaboratively set at-home RT goals to be completed before the next session. Generally, these will consist of basic, body weight RT movements that the participant can do with proper form during the first session (e.g., pushups, squats). For the severely deconditioned participant or a participant particularly worried about muscle soreness, these first at-home goals may consist of recovery activities (e.g., stretching) or simply getting to the next session.

All subsequent RT visits will start with 5 minutes of BA counseling focused on reviewing level of completion of goals from the previous session. If the at-home RT goals were not met, the interventionist will assess what interfered with completion (e.g., forgot how to do movement, forgot to exercise, space issues) and reinforce any effort the participant made (regardless how much was completed). At the end of sessions, the interventionist will again work in a BA-consistent style with the participant to collaboratively set new at-home RT goals.

All BA based at-home goal setting will share the following characteristics (a) goals will be set collaboratively with the participant, (b) goals will only include movements the participant can do with proper form, (c) goals be set concretely with regards to details (e.g., sets and repetitions) and logistics (e.g., where and when participant plans to complete), (d) foreseeable barriers to completion will be assessed and briefly problem solved, and (e) goals and solutions to barriers will be written down and provided to participant in the RT workbook. Starting with the second in-person RT session, level of completion of at-home goals (e.g., completed without issue, patient forgot to do RT, patient forgot how to do movement) will be taken into consideration when setting new goals. Over time, at-home goals will gradually increase in intensity (i.e., more weight, more reps), the number of at-home movements assigned (i.e., 1-2 in early sessions; up to 6 in later sessions), and the complexity of movements (i.e., simple body weight movements early on, more complex movements that incorporate dumbbells or available equipment later on). Final sessions (weeks 10-12) will also include discussion of strategies for maintaining RT during follow-up. Problem-solving of barriers to RT will include explicit attention to social and contextual barriers to exercise commonly experienced by Black, urban men (e.g., lack of space, competing family and work responsibilities).

Health, Wellness, and Education (HWE).: Participants randomized to the control group will participate in a HWE time- and attention-matched control program. Sessions will consist of an informational/educational video (approximately 30 minutes) followed by a discussion of video content including solicitation of the participant's reaction to the video

and thoughts about if and how it applied to him. Interactive worksheets will be used to facilitate discussion for some topics.

HWE content was curated from content that had been successfully used as attention control in multiple previous clinical trials: R03CA132475 (Ciccolo et al., 2011), R01HL117345 (Ciccolo et al., 2014). No content related to depression, exercise, diet, or sleep will be provided, as these topics may affect outcomes and/or hypothesized mediators. Topics will include brain health and function, sex and relationships, music history, creativity, personality types, and minimalism (e.g., decluttering). The previous studies from which these topics were pulled were not specifically designed for Black men. In recognition of this, we will allow some flexibility in topics in order to tailor the content to the needs of Black men. Specifically, if participants report that offered topics did not apply to them, we will allow participants to request topics that they would be interested in and the study team will work to develop content that matches their interests, but will be unlikely to directly affect outcomes and/or mediators. These added topics will then be offered to subsequent participants. The goal of this process is to make the HWE condition culturally relevant and acceptable to Black men.

Following the 3-month follow-up assessment, HWE participants will be offered the same exercise equipment provided to RT group participants. This will be done to create equity between conditions.

Data Collection at Treatment Sessions—Some data will be collected during treatment visits in both groups. The PHQ-9 will be administered every 2 weeks during the intervention to assess for worsening of depressive symptoms and suicidality. Sleep quality and diet will be assessed at sessions 7 and 15 to allow for future exploratory analyses. Exercise behavior will be assessed at sessions 7 and 15 as a manipulation check (e.g., to determine if the HWE group increased their exercise during the treatment period or if the RT group engaged in significant outside of protocol exercise). Self-reported pre- and post-session acute affect will be measured once per week (following odd numbered sessions) using the single-item feeling scale and the felt arousal scale (Hardy & Rejeski, 1989; Svebak & Murgatroyd, 1985). Acute change in affect is hypothesized to be a mediator of the effect of RT on depression symptoms (See Figure 1). Measures collected at treatment sessions will be collected by the interventionist who will not be blind to condition. None of the variables collected in this manner will be included in primary outcome analyses.

Follow-up Assessments—At end-of-treatment (13 weeks after randomization) and 3-month follow-up (6 months after randomization) assessments, all outcome measures, mediators, manipulation checks, and potential confounders completed at baseline will be repeated (See Table 1). In addition, treatment acceptability will be assessed at the end-of treatment assessment using the Client Satisfaction Questionnaire (Attkisson & Zwick, 1982). Feasibility will be assessed through rates of recruitment (i.e., patients enrolled over time), refusal (i.e., qualified patients that chose not to participate), treatment adherence (i.e., number of scheduled sessions attended, rate of completion of RT homework), and study drop-out.

Blinding.: All follow-up assessments will be conducted by a master's level staff member who is blind to treatment condition.

Qualitative Interviews—Immediately after the 3-month follow-up, approximately 15-20% of the sample will be offered the opportunity to complete a qualitative interview about their experience in the study. The interviews will be 30-60 minutes and semi-structured (to allow for flexibility and probing). HWE and RT participants who showed a range of study engagement will be sought out for interviews in order to obtain a breadth of experiences.

Program Adherence—A comprehensive maintenance program will be used to aid adherence. This includes scheduling same, next day, or weekend appointments, text message reminders, and make-up sessions (i.e., to make up for a missed session, limited to one per week). In addition, participants will receive financial compensation for (a) completing all four pre-randomization contacts ($20); (b) transportation (i.e., bus, subway) costs for all randomized on-site contacts ($5.50/session); and (c) completing end-of-treatment and 3-month follow-up assessments ($50 each). Those who complete the qualitative interview will receive an additional $25. Financial incentives for the two conditions will be identical.

Interventionist Background and Training—Interventionists will either be applied exercise physiology or kinesiology doctoral students, certified personal trainers, or certified strength and conditioning specialists. The intervention manuals were written with the aim that professionals without a college degree (e.g., certified personal trainers, certified strength and conditioning specialists, or similar professionals) would have the background necessary to provide the manuals with fidelity. The same interventionists will provide treatment in both conditions. Interventionists will receive several hours of training from study leaders on how to conduct both the HWE and RT content before providing treatment. Interventionists will also complete directed readings and receive a minimum of 10 hours of BA training from a licensed clinical psychologist before providing treatment. During the study, the interventionists will receive regular supervision on all BA-related issues from a licensed clinical psychologist with expertise in BA, and supervision from a PhD level exercise scientist on RT condition issues not related to BA components and all HWE related issues.

Intervention Fidelity—Interventionists will complete a fidelity checklist of all treatment components at the end of each session. All BA content will be audio recorded, and 10% of BA components will be reviewed by a licensed clinical psychologist and BA expert using a fidelity checklist. These audio tapes will be reviewed throughout the trial to ensure that any deviation from the manual is corrected.

Safety, Data Management, and Confidentiality—The proposed research is a single site pilot study and therefore does not meet National Institutes of Health (NIH) criteria requiring establishment of a formal Data and Safety Monitoring Board at the time of its funding. However, we have a detailed data and safety monitoring plan.

All adverse events will be reported by to the Teachers College Institutional Review Board (IRB) and serious adverse events will be reported within 24 hours. NIH will be informed in

cases when any significant action is taken as a result of an adverse event or by direction of the IRB. Any unanticipated problems involving risks to participants will be reported to the IRB, who will report such events to NIH the sponsor. A summary of the SAEs that occurred during the previous year will be included in the annual progress report to NIH.

Contact between participants and study staff will be initiated by the participants. Potential participants will respond to community advertisements that contain a study description and the study phone number. All participant records and assessment data from this study will be treated as confidential, including participants' names and the fact they are participating in the study. The records and assessments will be safeguarded according to the policy of Teachers College IRB, a policy that is based on New York law and which promotes the protection of confidential health information. Confidentiality will be maintained by numerically coding all data, disguising identifying information, and keeping data (e.g., participant contact information) in locked file drawers. More specifically, the master list linking names with code numbers will be locked in the PI's office, and all information obtained from participants will be accessible only by research staff. In addition, all investigators and staff will undergo human subjects' ethics training as required by Teachers College, and are fully conversant with relevant ethical principles around confidentiality.

Complications associated with blood collection.: To protect against this risk, all blood draws will be conducted by LabCorp laboratory, which is a well-established national chain of laboratories that provides phlebotomy and testing services, and is HIPAA compliant. Thus, the blood draw will be conducted by an experienced phlebotomist, reducing the likelihood that a participant will incur a bruise or other adverse outcome.

Complications associated with fitness testing and strength training intervention.: We will only enroll patients that can engage in RT safely per American College of Sports Medicine guidelines. Participants will be screened for orthopedic problems and other conditions that may make strength training unsafe, difficult, or uncomfortable prior to enrolling. Perceived exertion will be monitored during RT to maximize safety. Finally, only highly trained and carefully supervised staff will conduct the fitness testing and strength training protocols. Each staff member conducting these will have training in Cardiopulmonary Resuscitation (CPR) and Automated External Defibrillator (AED) use.

Worsening of depressive symptoms and emergent suicidality.: There is no evidence indicating that strength training can worsen depressive symptoms or cause suicidality. However, given that all of our participants will have depressive symptoms at baseline, it is likely that some will experience worsening of their symptoms or episodes of suicidality during this study. To protect against this risk, we will: (a) Not restrict treatment seeking in any way during the study (i.e., we will not ask participants to refrain from starting depression counseling or medication during the study). (b) Monitor depressive symptom severity every two weeks during the intervention and at each assessment. If a participant reports severe levels (i.e., PHQ-9 ≥20) or passive suicidal thoughts at any time point, staff will inform the participant that he is reporting severe depressive symptoms, encourage the participant to discuss these symptoms with his medical provider, and provide a list of low cost community psychiatric treatment referrals if the participant does not have a primary

healthcare provider. (c) Call 911 and take any other appropriate actions to protect that participant if he reports active suicidality. The study participation of patients who report active suicidality will be put on hold so they can seek psychiatric treatment. Such patients will be allowed to rejoin the study after treatment if their active suicidality has resolved.

Power and Data Analyses—With 25 men in each condition and two-sided α=.05, this study will have 80% power to detect between-group differences in depressive symptoms from baseline to end-of-treatment. As this study is focused on assessing feasibility, acceptability, and preliminary efficacy, it will not be fully powered to detect group differences in depressive symptoms at 3-month follow-up, secondary outcomes, or mediation effects. The power estimate is based on (a) meta-analytic results (Rethorst et al., 2009) regarding RT vs. control on depressive symptom severity in clinical samples (g= −1.00, SE=.22), and (b) two RCTs of RT for depressive symptoms that also used contact control conditions (g=−2.44 and g=−1.40; Singh et al., 1997; Singh et al., 2001). Thus, the effect size is conservatively estimated to be g=−0.70 at end-of-treatment.

It is hypothesized that the RT condition will experience a greater improvement in primary and secondary outcomes. All analyses will be conducted in a modified intent-to-treat manner. To estimate the effects of RT vs. HWE on interviewer assessed depression symptoms, a longitudinal linear mixed effects regression model will be used which simultaneously regresses depressive symptoms at end-of-treatment and 3-month follow-up on intervention (RT vs. HWE), time, intervention x time, baseline depressive symptoms, and potential confounders (e.g., variables not balanced by randomization). Models will include a subject-specific intercept, to adjust for repeated, correlated measures within individual. Estimation takes a likelihood-based approach using all data without directly imputing missing outcomes. Estimates will be compared to other assumptions of the missing data mechanism. Interest is in estimating effect sizes and confidence intervals rather than strict statistical hypothesis testing. A similar analysis approach will be used to estimate intervention effects on all secondary outcomes. Mixed effects models allow for flexible specification of the time effect (e.g., linear, quadratic) and outcome distribution (e.g., normal, zero-inflated).

To test the hypothesized mediators of depressive symptom improvement (at end-of-treatment), two mediational models will be used. Model 1 will consider sleep quality, exercise enjoyment, physical self-concept, and self-esteem as mediators. Model 2 will consider acute changes in affect during intervention sessions as a mediator. For Model 1, a multiple mediation approach will be used, in which all potential mediators are tested simultaneously, using a product of coefficients method (Preacher & Hayes, 2008) with bootstrapped standard errors (5000 samples with replacement). Path coefficients (*a* path: effects of intervention on changes in mediators from baseline to end-of-treatment, and *b* path: effects of changes in the mediators on depressive symptoms at end-of-treatment, controlling for baseline), as well as the indirect effect of intervention (*ab* path: effect of intervention on depressive symptoms through the mediators) will be considered. Interest is in estimating the path coefficients, effect sizes, and confidence intervals, rather than strict hypothesis testing. In Model 2, the path coefficients and indirect effects of intervention on depressive symptoms (at end-of-treatment) through changes in acute affect (measured during

weekly during intervention sessions, pre and post treatment session) will be estimated. The mediator is time-varying and it is the trajectory of acute affect that is hypothesized to mediate the intervention-depressive symptom association.

Discussion

If the proposed trial indicates that RT has promise for depression and CVD risk reduction in Black men, it will lay the groundwork for a fully powered efficacy trial. Such a trial would have the sample size to (a) detect significant changes in *both* depressive symptom and CVD outcomes over long-term follow-up, and (b) test hypotheses regarding the dynamic relationships among ST, depressive symptoms, and inflammatory markers over time. If efficacy is supported by a fully powered trial, the proposed RT intervention is well poised to be "taken to scale," as it could be done by strength coaches or personal trainers in the community with modest cost and training.

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Abbreviations

CVD	Cardiovascular disease
RT	Resistance training
BA	Behavioral activation
HWE	Health, wellness, and education attention control condition
PHQ	Patient Health Questionnaire
RA	Research Assistant
HIPAA	Health Insurance Portability and Accountability Act
QIDS	Quick Inventory of Depressive Symptomatology
HDL	High-density lipoprotein
LDL	Low-density lipoprotein
CRP	C-reactive protein
RCT	Randomized controlled trial
NIH	National Institutes of Health

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Highlights:

- Black men experience high rates of heart disease morbidity and mortality
- Depression contributes to heart disease and is undertreated in Black men
- Current psychiatric depression treatments are unacceptable to many Black men
- Weight lifting may improve both depression and heart health
- This study will test the effect of weight-lifting in depressed black men

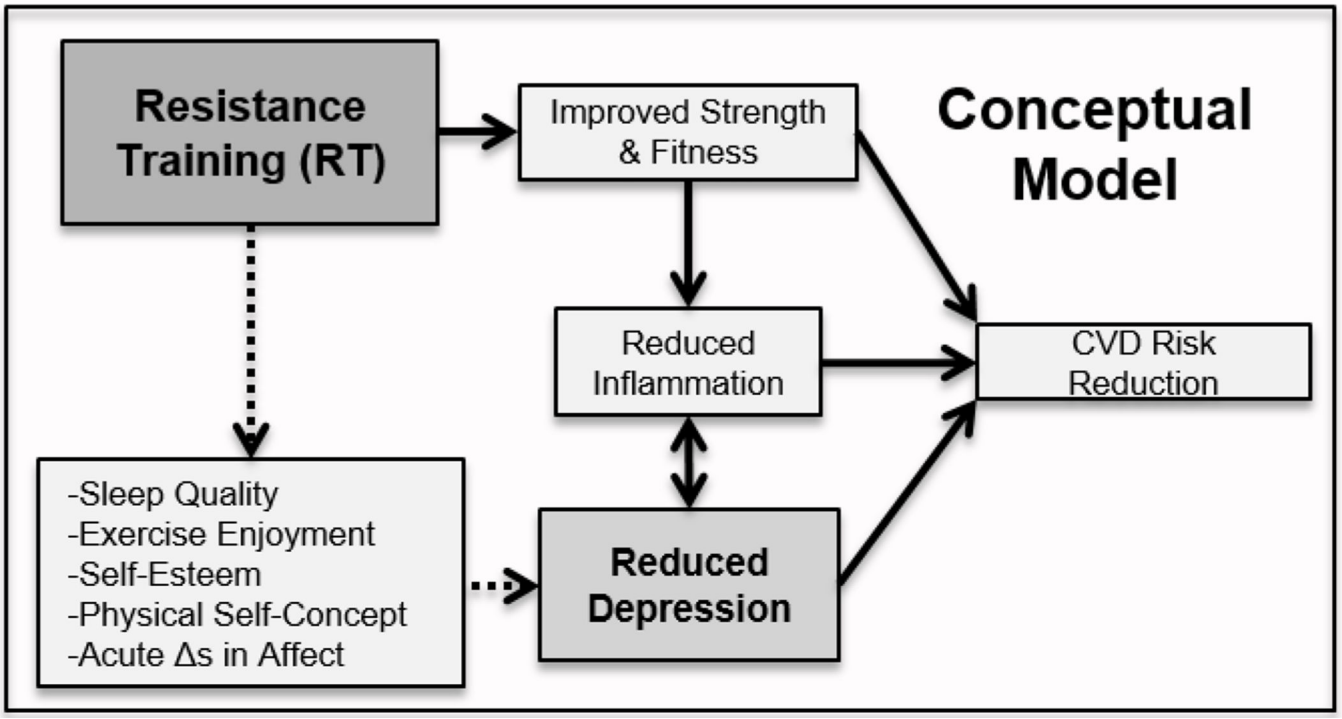

Figure 1.
Conceptual model for this study.

Table 1:

Study Measures and Assessment Time Points

Study Assessments	Screen	Baseline	Weeks 1-12	End-of-Treatment	3-month Follow-up
Participant Characteristics					
Medical History	X	X		X	X
Demographics (age, race/ethnicity, perceived SES, etc.)	X	X			
Height (stadiometer) and Weight (calibrated electronic scale)		X		X	X
Male Role Norms: Masculinity Ideology Scale-21[a]		X			
Primary Outcome					
Interviewer Rated Depression (Quick Inventory of Depressive Symptomatology; QIDS)		X		X	X
Secondary Outcomes					
Self-reported Depression (Patient Health Questionaire-9; PHQ-9)	X	X	X	X	X
Self-Reported Anxiety (Generalized Anxiety Disorder-7)		X		X	X
Perceived Stress Scale (PSS-10)		X		X	X
Resting Heart Rate (seated, after 5 min rest)		X		X	X
Blood pressure (seated, after 5 min rest)		X		X	X
Waist-to-hip ratio (directly above iliac crest/max circumference of hip)		X		X	X
Body composition (BodPod; whole-body air displacement plethysmography)		X		X	X
Full blood lipid panel (total cholesterol, HDL. LDL, triglycerides)		X		X	X
C-reactive protein (CRP)		X		X	X
Interleuken-6 (IL-6)		X		X	X
Hypothesized Mediators					
Pittsburgh Sleep Quality Index		X	X	X	X
Single item Exercise Enjoyment Scale		X		X	X
Self-esteem: Rosenberg Self Esteem Scale		X		X	X
Physical self concept: Physical Self Description Questionnaire		X		X	X
Acute Affect: Feeling Scale, Felt Arousal Scale			X		
Fitness Outcomes/Manipulation Checks					
Exercise behavior: Modifiable Activity Questionnaire	X	X	X	X	X
Muscular strength: American College of Sports Medicine's 1-Rep Max test; chest press, leg extension		X		X	X
Potential Confounders					
Drug Abuse: Drug Abuse Screening Test (DAST)		X		X	X
Alcohol Abuse: Alcohol Use Disorders Identification Test (AUDIT)		X		X	X
Smoking: Fagerstrom Test of Nicotine Dependence (FTND)		X		X	X
Diet: NIH Quick Food Scan		X	X	X	X

Study Assessments	Screen	Baseline	Weeks 1-12	End-of-Treatment	3-month Follow-up
Acceptability/Feasibility					
Qualitative Interviews (with ≈10 participants)					X

[a] Only the status/rationality, tough image, and violent toughness subscales we assessed