Study Protocol and Statistical Analysis Plan

Official Title	Feasibility of a Yoga Intervention in Sedentary African-American Women
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Table of Contents

ABBREVIATIONS/DEFINITIONS

- African-American (AfAm)
- Data Safety and Monitoring Board (DSMB)
- National Institutes of Health (NIH)
- Physical Activity (PA)
- Principal Investigator (PI)
- Randomized Controlled Trial (RCT)

1.0 Objectives

1.1 Purpose:

The primary objective of this study is to test the feasibility, acceptability, safety and targeted outcomes of a 3-month hatha and restorative yoga intervention to decrease sedentary behavior (primary outcome), stress and blood pressure in 60 sedentary (<30 minutes of moderate-to-vigorous PA per week) African-American women. The proposed study has four aims:

Aim 1: To refine a promising and innovative intervention to enhance its feasibility. Based on our previously developed intervention, I HEART Yoga!, and subsequent experience, we will refine intervention strategies to incorporate findings from the pilot research and theoretically ground the intervention using an integrated model incorporating constructs from the Social Cognitive Theory and collectivism (i.e., social connectedness, sense of belonging, and community cohesion). We will conduct two focus groups of sedentary African-American women (n=16) to seek feedback on the intervention strategies (e.g., yoga sequences).

Aim 2: Assess feasibility of a hatha and restorative yoga intervention (n=30) compared to a control group (n=30). We will examine feasibility of participant recruitment, retention and adherence; fidelity of intervention delivery; and intervention materials.

Aim 3: Evaluate the acceptability and safety of a hatha and restorative yoga intervention (n=30) compared to a control group (n=30). We will examine the acceptability of intervention location and strategies, class format, enjoyment of sessions, and safety of the intervention.

Aim 4: To test feasibility and appropriateness of the targeted outcomes (i.e., primary: sedentary behavior and secondary: blood pressure and stress) for subsequent trials. It is important to properly measure expected outcomes but not make comparisons between intervention and control groups.

2.0 Background

2.1 Significance of Research Question/Purpose:

A sedentary lifestyle is associated with chronic cardiovascular and physiological diseases and psychological disorders.[1,2] Indeed, the 2018 Physical Activity Guidelines for Americans emphasize targeting sedentary time (i.e., waking behaviors in a seated or reclining posture at low energy expenditure[8]), independent of total activity.[1,2] The Guidelines state: "Adults should move more and sit less throughout the day. Some physical activity is better than none."[2] The U.S. has now joined at least six other countries in adopting guidelines to reduce sedentary time.[3-9] Persuasive evidence has emerged in the last 10 years: (a) adults spend inordinate time sedentary (~7.5 hr/day on average);[10-16] (b) physiological mechanisms linking sedentary time to increased chronic disease risk are understood;[17-19] and (c) excess mortality due to sedentary behavior is substantial.[20,21] The current Guidelines are calling for evidence-based interventions to reduce sedentary time.[2] For African-American women who disproportionately have sedentary lifestyles,[22] a "move more and sit less" philosophy to target decreasing sedentary behavior is appropriate. Sedentary lifestyle has contributed to African-American women being 80% more likely to be overweight or obesity compared to non-Hispanic white women,[23] and

suffering from high rates of heart disease,[24] hypertension,[25,26] and other conditions. These statistics present a significant public health problem that must be addressed. Decreasing sedentary time has many mental, social, and psychological health benefits.[25,27] Given the current state of health statistics among African-American women, it remains critical to find innovative ways to decrease sedentary time in this population.

2.2 Preliminary Data:

Co-PI Barr-Anderson conducted a 6-month, randomized controlled, pilot yoga intervention, *I HEART Yoga!,* with 59 overweight, sedentary African-American women.[28] Thirty women were randomized to the intervention group and offered in-person and online yoga classes; the 29 women in the usual care, control group received a 3-month membership at a local yoga studio after post-intervention data collection was completed. The aim of this pilot was to engage participants in yoga at least 3 times per week and to examine the effects on blood pressure, stress, and physical activity. A post-intervention focus group revealed that participants enjoyed the intervention and posted several affirmations on a private Facebook group page. Although the feedback was positive, there were several areas of *I HEART Yoga!* pilot study that participants recommended improving and enhancing, thus warranting the proposed *YogaMoves* feasibility study to test refined strategies.

2.3 Existing Literature:

Previous interventions to decrease sedentary behavior in African-American women. Previous interventions for African-American women to address sedentary lifestyles have mainly included traditional physical activity strategies such as walking, aerobics and dance.[29-31] Walking programs, the most utilized of the interventions, are easy to implement, require minimum equipment, and usually are safe and acceptable for high-risk populations,[32] such as sedentary adults carrying excess weight. However, focus groups with African-American women reported that the repetitiveness and monotony of traditional exercise interventions (i.e., walking and aerobics) may reduce motivation[33] or cause musculoskeletal issues that may make typical, repetitive weight-bearing exercise uncomfortable or painful.[34]

Increasing interest of yoga to address health outcomes. Yoga is a well-established Eastern practice that is promoted as a safe and effective way to encourage less sedentary behavior; improve strength, balance, and flexibility,[35] and decrease depression and stress. Like walking, yoga is a minimal equipment activity, can be practiced almost anywhere at a variety of intensities, and can be used to decrease inactivity.[36] However, yoga introduces not only physical movement, but also mindfulness and deep breathing that can lead to mental and psychological benefits,[37] and may be as effective as higher intensity activity for improving some health-related outcomes.[38]

How can yoga decrease sedentary behavior? Preliminary research suggests that there are several mechanisms proposed for yoga to lead to better health outcomes. Biological mechanisms related to the autonomic nervous system have been connected to lowering blood pressure.[39] Stress has been positively impacted through a biological mechanism of improved circadian patterns in cortisol release,[40] and through psychological mechanisms such as increased positive attitudes towards stress, self-awareness, coping mechanisms, appraisal of control, spirituality,

compassion, and mindfulness.[39] Lastly, it is plausible for yoga to positively impact sedentary behavior as evidence supports that yoga aids in behavioral self-regulation.[41]

Yoga as a potential intervention for African-American women. Much of the research on yoga has not focused on African-American populations despite the potential for suitability and effectiveness. Yoga research studies including African-Americans have primarily targeted those with breast cancer,[42,43] heart failure,[44,45] metabolic syndrome,[46] arthritis,[47] or low back pain.[48-50] These studies found yoga to be an effective strategy[42-45,48,49] or acceptable form of activity.[46,47] Based on these previous studies and pilot work by our research team,[28] yoga appears to be well-suited to engage African-American women to have less sedentary lifestyles.

In the U.S., yoga has become increasingly popular in recent years. From the 2017 National Health Interview Survey (NHIS) Adult Complementary and Alternative questionnaire, over 14 million people stated they have practiced yoga in the past year.[51] Although yoga has the reputation of attracting college-educated, white populations[52] and is sometimes viewed as exclusionary to those outside that community, it has become increasingly popular among African-Americans with the growth of Afrocentric yoga (i.e., focusing on Black or African culture),[53] establishment of Black yoga organizations,[54] and expansion of social media presence of African-American yoga practitioners.[55,56] Furthermore, data from the NHIS questionnaire reported that almost 10% of African-Americans have practiced yoga in the past year compared to 13.5% of white Americans.[51]

African-American women attend mainstream (i.e., majority white) yoga classes, but they do not always continue, partially due to unfamiliarity with various aspects of yoga.[47] Chanting, use of Sanskrit instead of English to name poses, and "religious" sounding music can stimulate preconceived notions that yoga conflicts with religious beliefs.[47] An additional barrier to adopting and sustaining a yoga practice is not feeling included due to the lack of representation of fuller-body, African-American yoga practitioners.[47] Previous yoga studies that targeted African-Americans and modified classes to make it more culturally acceptable[46,47] (i.e., no chanting, generic instrumental music, English names for poses, matching yoga instructors by race with participants), reported that participants found yoga to be more acceptable. One study even reported that 100% of the participants were still practicing yoga three months after the intervention.[47] These culturally appropriate modifications have been critical in African-American women being open to practicing yoga and subsequently recognizing the health benefits.[57]

In summary, the ***scientific premise*** of our proposed pilot study is that African-American women are highly affected by a sedentary lifestyle, and yoga is an engaging activity with biological and psychological mechanisms[39-41] having promise to reduce sedentary behavior and improve health outcomes such as blood pressure and stress. The proposed study is highly significant given that it will address the need for innovative and culturally acceptable approaches to reduce sedentary time among those at elevated risk for chronic diseases.

3.0 Study Endpoints/Events/Outcomes

3.1 Primary Endpoint/Event/Outcome:

This is a feasibility study, therefore the primary endpoints of interests are related to feasibility and acceptability of the intervention.

- Feasibility: Recruitment of participants - 200 women recruited and screened; 76 women (16 for Aim 1 focus groups and 60 for pilot intervention) enrolled and consented
- Feasibility: Retention and adherence - ≥ 80% of intervention participants attend ≥ 80% of intervention sessions
- Feasibility: Fidelity of intervention delivery - ≥90% of each videotaped session is delivered as planned based on training
- Feasibility: Intervention materials and resources - 100% of intervention materials and resources are delivered as planned
- Feasibility: Assessment measures - ≥80% intervention and control participants rate the assessments as not too burdensome; ≥90% intervention and control participants will complete baseline, post-intervention and 3-month follow-up assessments
- Acceptability: Intervention location, in-person classes, instructors, home-based resources - ≥90% intervention participants rate the various intervention components as acceptable
- Acceptability: Yoga intervention - ≥90% intervention participants rate intervention acceptable
- Safety: Adverse events - Zero severe adverse events (causes major disruption to participant's life, e.g., sprain, broken bone, CV event, death), zero moderate adverse events (causes minor inconvenience to participant, e.g., fainting spell, sore muscles for more than 3 days) and <10% of participants report mild adverse events (no major impact, e.g., headache, sore muscles for 2-3 days)

3.2 Secondary Endpoint(s)/Event(s)/Outcome(s):

- Sedentary behavior
- Blood pressure
- Stress

4.0 Study Intervention(s)/Interaction(s)

4.1 Description:

Formative assessment focus groups: After the research team revises the intervention strategies, the newly revised intervention strategies, including yoga sequence, will be presented and discussed during two focus groups of 6-8 sedentary African-American women. Please note that if the focus group participants propose intervention strategies different from what is expected by the MPIs, the MPIs will submit modifications to the IRB. Due to COVID-19 restrictions, these focus groups will take place virtually approximately in April - June 2021.

Yoga intervention: Please note that although we are anticipating conducting the yoga pilot intervention in-person, it is dependent on whether it is safe to have face-to-face contact due to COVID-19. If it is deemed unsafe to have face-to-face contact, the MPIs will submit a modification to IRB to reflect this change. Additionally, if it is safe to conduct the intervention face-to-face, the MPIs will submit the University-required "Sunrise Plan" outlining risk mitigation related to COVID-19.

Participants engaged in the formative assessment focus groups may be invited to be a part of the pilot RCT. 60 participants will be randomly assigned to the yoga intervention (n=30) or control condition (n=30). It is anticipated that the yoga intervention will be a hybrid delivery (combination of in-person and virtual) (June – August 2022) at two intervention locations, 612 Jungle and The Zen Bin. There will be no contact with control participants during the implementation of the yoga intervention. The yoga intervention components are:

- Hybrid, 60-minute yoga sessions will take place three times per week for 12 weeks to include a sharing circle at the end of each session. Participants will unite in a sharing circle to provide feedback as a group on how the practice felt and strategies for integration into ones' daily life. Specifically, each session will include gentle hatha yoga which includes physical poses combined with stretching, breathing and some meditation. A proposed session would include:
    - Warm-Up: Controlled Breathing Meditation & Mindfulness (10 minutes): Mindful breathing (4-6 second inhales/exhales) through nose to increase focus on yoga practice and to build internal heat to better prepare the body for movement
    - Warm-Up: Gentle Movement (5 minutes): Child's, Cat/cow, Thread the needle, Side puppy
    - Active Movement: Strength, Flexibility & Balance Poses (20 mins):
    - Cool Down: Stretching Poses (10 mins): Cobbler's, Seated forward fold, Legs up the wall, Happy baby, Spinal twist
    - Cool Down: Resting Pose (5 mins): Final resting pose on back using props
    - Sharing Circle & Wrap-Up (10 mins): Group gathers in circle and share feedback about yoga session

  These classes will be held in-person, but there will be a synchronous option for participants to join virtually. Yoga sessions will be led by certified yoga instructors from the greater Twin Cities metro area. As preparation for the pilot RCT, they will participate in intervention-specific training developed by research staff regarding (1) instructing yoga as part of a scientific study, and (2) the practice of restorative yoga for race-based trauma. They will be provided yoga sequences outlined by research staff and quality control data will be collected as described in section 15.2.

- A private Facebook group will be set up to keep participants connected to each other, thus further promoting collectivism, and for the research staff to maintain contact and share information with participants. Participants will be able to post freely to the Facebook page to stay connected, offer encouragement, and provide accountability to attend the weekly yoga sessions. Research assistants will keep track of the number of posts and "likes" each participant makes. Research staff will use Facebook to maintain contact and to share information with participants: 1) provide a weekly reminder for upcoming yoga sessions and workshops; 2) inform/remind participants of the biweekly themes of the sessions – there will be a new theme every other week (i.e., weeks 1, 3, 5, 7, 9, 11); and 3) remain accessible to participants for assistance or requested information participants may need. This contact will be virtual.

- To align with and reinforce the biweekly themes established for the weekly yoga sessions (i.e., common yoga poses, the importance of breath, strengthening your core), biweekly, hybrid workshops will be offered. These workshops will take place during weeks 2, 4, 6, 8, 10, and 12 and will be specialty classes that allow participants additional exposure to meditation and breathing and longer class formats so they can delve deeper into yogic philosophy and practice. These workshops will be held in-person, but there will be a synchronous option for participants to join virtually.

Data collection: Yoga intervention and control participants (n=60) will complete baseline (March – May 2022), post-intervention (September – October 2022), and 3-month follow-up measures (January – February 2023) in-person at the University of Minnesota's Epidemiology Clinical Research Center.

Post-intervention focus groups: Four groups (high attendance and low attendance from each intervention location) of randomly chosen intervention participants (anticipated n~20) will be invited to participate in a post-intervention focus group to assess intervention feasibility, acceptability, and safety with the overall program and specific components, and in order to inform program improvements. Focus groups will take place at the Epidemiology Clinical Research Center.

5.0 Procedures Involved

5.1 Study Design:

Our proposed feasibility study will be two-arm, RCT with 60 participants randomly assigned to either an intervention group (n=30) or control group (n=30).

5.2 Study Procedures:

Formative assessment focus groups will be conducted in April - June 2021. Data collected from these focus groups will be qualitative feedback on the proposed intervention strategies. The focus group guide is submitted with this IRB application.

Data collected directly related to the pilot RCT yoga intervention will be:

- Quality control data to make sure the yoga movements follow protocol and are safe for participants will be collected during the implementation of the yoga intervention. One yoga session will be randomly selected biweekly (during weeks 2, 4, 6, 8, 10, and 12) and videotaped so the content can be analyzed based on the established criteria related to poses, breathing and meditation. During these videotaped quality control sessions, participants will be asked to wear the activPAL to assess activity intensity.
- Acceptability of yoga classes will be assessed during the yoga intervention via a short self-reported survey after each yoga session. The survey is included with this application.
- Three, in-person data collection time points: baseline (March – May 2022), post-intervention (September – October 2022), and 3-month follow-up measures (January – February 2023). Data to be collected during these time points are:
    - Sedentary behavior will be assessed with the activPAL3 micro accelerometer (PAL Technologies, Glasgow, United Kingdom) for seven consecutive days at

baseline before the start of the intervention, during three randomly selected weeks over the course of the 3-month intervention, and for one week at both the post-intervention and 3-month follow-up periods. The activPAL provides a valid and reliable measure of posture (sitting/lying vs. standing) for free-living settings[58,59] and uses a transducer suitable for detecting lower intensity movements.[60] The activPAL will be waterproofed using medical grade adhesive covering and attached to the midline of the thigh using a breathable, hypoallergenic tape. This method allows for the monitor to be worn continuously without removing for bathing or other water-based activities (a valuable feature that reduces missing data).

- Blood pressure will be objectively measured using BpTRU BPM-200 (VSM MedTech Ltd, Coquitlam, Canada), an automated blood pressure recorder that has been validated against the mercury sphygmomanometer.[61] Two blood pressures will be collected and averaged at each data collection time point following a five minute period of rest.
- Stress will be measured in two different ways: biomarkers of physiological stress using cortisol saliva and perceived stress using questionnaires. Acute stress will be assessed using salivary cortisol levels taken at three different times (upon waking, 30 minutes after waking, and before going to bed) for 2 days at each data collection time point (assayed by UMN ARDL).[62] Participants will be provided detailed instructions. Kits will be sent home with participants with clear instructions for capturing saliva samples in the morning and evening, and storing the date- and time-labeled plastic vials in their home freezer to be carried with them to their next clinic visit. Chronic stress will be assessed using common, valid self-report measures.[63-65]
- Additional measures: Trained research staff will collect height, weight, and body fat % using a Shorr Height measuring board and Tanita BF-350 scale, respectively, to calculate BMI. Diet will be assessed using NCI's web-based dietary recall, ASA-24, which has been validated in adults.[66] A self-reported survey will be completed that inquiries on demographic characteristics (age, sex, marital status, education level, income), physical activity-related psychosocial variables (social support,[67] self-efficacy,[68] barriers,[69] enjoyment[70]), eating-related behaviors (intuitive eating,[71] eating as a coping mechanism[72]), and additional variables (collectivism,[73] social connectedness,[74] sense of belonging,[75] community cohesion[76]and embodiment[77]). The survey with the listed measures is included with this application.

Post-intervention focus groups to assess intervention feasibility, acceptability, and safety with the overall program and specific components, and in order to inform program improvements will be completed September 2022. The focus group guide is submitted with this IRB application.

5.3 Follow-Up:

The data to be collected at follow-up are outlined in the previous section: sedentary behavior using activPAL, blood pressure using an automated blood pressure recorder, stress using

salivary cortisol samples and a survey, height, weight, and body fat % measured by trained research staff, and a survey of additional measures.

5.4 Individually Identifiable Health Information:

PHI will not be collected from any participants.

6.0 Data Banking

N/A

7.0 Sharing of Results with Participants

7.1

Formative assessment and post-intervention focus groups: After each set of focus groups, research staff will summarize the findings in a report that will be shared with respective focus group participants. This methodology is referred to as member checking and allows the focus group participants the opportunity to provide feedback on whether the content of the summary accurately depicts what they wanted to share with the research staff.

Pilot RCT results: Findings from the pilot RCT will be shared with the participants through a presentation. Participants will have the opportunity to provide additional feedback and the research team will discuss plans for next steps. Additionally, the research team will utilize other online and media platforms, such as social media, infographics, videos, and podcasts, to disseminate our findings to a broader audience.

8.0 Study Duration

8.1

The duration anticipated for an individual participant's participation in the study is:

- Three months (April – June 2021) for 16 participants engaged in the formative assessment focus groups
- One year (March 2022 – February 2023) for the 60 participants enrolled in the pilot RCT who will also participate in the post-intervention focus groups

The duration anticipated to enroll all study participants is:

- Two months (April – May 2021) for the 16 participants engaged in the formative assessment focus groups
- Four months (February – May 2022) for the 60 participants enrolled in the pilot RCT who will also participate in the post-intervention focus groups

The duration anticipated to complete all study procedures and data analysis:

- Three years (November 2020 – October 2023)

9.0 Study Population

9.1 Inclusion Criteria:

- Self-identified as an African-American woman at least 18 years old;
- Engaging in less than 30 minutes/week of moderate-to-vigorous physical activity;
- If employed, working in a sedentary occupation that requires primarily seated work;
- If unemployed, typical day involves sedentary, primarily seated activities;
- Able to exercise for 20 minutes continuously;
- No pre-existing condition that limits physical activity;
- Have access to a computer (or mobile device) and internet service; and
- Vaccinated against COVID-19 *or* willing to provide proof of a negative test to attend any in-person components.

9.2 Exclusion Criteria:

- Diagnosed with heart disease, diabetes, cancer, kidney, liver disease, major depression or bipolar disease;
- Take more than two daily medications for lipids or blood pressure; and
- Current smoker.

9.3 Screening:

Participants will be initially screened via phone call for all participants (formative assessment focus group and pilot RCT participants). For pilot RCT participants only, eligibility will be verified during baseline data collection, which will take place at University of Minnesota's Epidemiology Clinical Research Center. Verification is not occurring for the formative assessment focus group participants because their involvement is 100% virtual and not in-person.

10.0 Vulnerable Populations

10.1 Vulnerable Populations:

Population / Group	Identify whether any of the following populations will be targeted, included (not necessarily targeted) or excluded from participation in the study.
Children	Excluded from Participation
Pregnant women/fetuses/neonates	Included/Allowed to Participate
Prisoners	Excluded from Participation
Adults lacking capacity to consent and/or adults with diminished capacity to consent, including, but not limited to, those with acute	Excluded from Participation

medical conditions, psychiatric disorders, neurologic disorders, developmental disorders, and behavioral disorders	
Non-English speakers	Excluded from Participation
Those unable to read (illiterate)	Excluded from Participation
Employees of the researcher	Excluded from Participation
Students of the researcher	Excluded from Participation
Undervalued or disenfranchised social group	Targeted Population
Active members of the military (service members), DoD personnel (including civilian employees)	Excluded from Participation
Individual or group that is approached for participation in research during a stressful situation such as emergency room setting, childbirth (labor), etc.	Excluded from Participation
Individual or group that is disadvantaged in the distribution of social goods and services such as income, housing, or healthcare.	Excluded from Participation
Individual or group with a serious health condition for which there are no satisfactory standard treatments.	Excluded from Participation
Individual or group with a fear of negative consequences for not participating in the research (e.g. institutionalization, deportation, disclosure of stigmatizing behavior).	Excluded from Participation

Any other circumstance/dynamic that could increase vulnerability to coercion or exploitation that might influence consent to research or decision to continue in research.	Excluded from Participation

10.2 Additional Safeguards:

By nature of the study, all participants will be minority women, specifically African-American women over the age of 18 years. African-American women are disproportionately affected with a sedentary lifestyle, excessive weight, hypertension, and stress. Over 60% of African-American women report being sedentary, and 80% are more likely to be at higher weight status (BMI$\geq$25 kg/m^2) compared to non-Hispanic white women. These statistics underscore that a significant public health problem, a sedentary lifestyle, coupled with overweight/obesity, is associated with chronic diseases (e.g., hypertension) and psychological disorders. Decreasing sedentary behavior has mental, social, and psychological health benefits in adults, independent of total physical activity. Given the current state of health statistics in African-American women, finding innovative ways to decrease sedentary time in this population are of particular interest. Inclusion of African-American women is essential to the success of this project.

Pregnancy is an exclusion criterion at recruitment and during the intervention due to the possible risk of engaging in yoga if a participant is randomized to the yoga intervention group. However, if a participant becomes pregnant after the intervention has ended which overlaps with the post-intervention and follow-up data collection periods, they will be retained and included in the study. Data collection at all time points include completing an electronic survey, wearing an activity monitor that tracks physical activity with the request for participants not to alter their usual behavior, and collecting salivary samples which entails collecting less than an ounce of saliva over two days. All of the data collection are of minimal risk to pregnant women.

The potential adverse events anticipated in our pilot RCT would be injuries due to participation in yoga (e.g., muscle strain, fainting, falling) as well as other complications from comorbidities such as obesity, hypertension, diabetes and medication use. Participants will be instructed to call their healthcare provider and notify the research staff if they experience an injury or any adverse event. As a proactive measure, a detailed plan for monitoring risks, tracking and reporting adverse events will be established at the start of the study. Adverse events will be classified as severe (cause major disruption to participant's life, e.g. sprain, broken bone, cardiovascular event, death), moderate (causes minor inconvenience to participant, e.g. fainting spell, sore muscles for >3 days), and mild (no major impact on participant, e.g. headache, sore muscles for 2-3 days). The PIs will implement the data collection form for monitoring side effects and adverse events on a routine basis. The research assistants will administer this questionnaire weekly during the study to track any side effects or adverse events.

A Data Safety and Monitoring Board (DSMB) has been mandated by the funding agency, NIH. Members of the DSMC will be three senior PhD-level researchers including a biostatistician. The research staff will submit a written monitoring report to the DSMB twice a year (April and October).

To further protect participants, participants will clearly know that they can end participation at any time, researchers will provide information to participants for UMN IRB advisors to report any activity that the find troublesome, and research staff will undergo cultural sensitivity training.

11.0 Number of Participants

11.1 Number of Participants to be Consented:

For formative assessment focus groups, a maximum number of 16 (minimum of 12) participants will be enrolled for an average of 6-8 participants for each of the two focus groups.

For the pilot RCT, a maximum number of 60 (minimum of 54) participants will be enrolled for an average of 27-30 participants for each of the intervention and control groups. Participants enrolled in the intervention condition will be consented to participate in the yoga intervention eligible and the post-intervention focus groups.

12.0 Recruitment Methods

12.1 Recruitment Process:

Participants will be recruited using radio and print newspaper advertisements in media outlets with a predominantly African-American audience; social media (e.g., Facebook, Instagram, and Twitter) posts targeting local, African-American individuals, groups and organizations; email blasts distributed to local churches, community centers, libraries, and community organizations (particularly health organizations such as NorthPoint Health & Wellness Center, Smiley's Clinic, Whittier Clinic) that serve African-Americans and/or women in the North Minneapolis area of Minnesota. All recruitment materials will have culturally appropriate representations of African-American women and examples are provided in this application.

12.2 Source of Participants:

Participants will be drawn from the greater Twin Cities, MN area.

12.3 Identification of Potential Participants:

All recruitment materials will have contact information (phone number and email address) that interested participants will use to express their desire to be involved in the study. All potential participants must self-identify as an African-American woman over the age of 18.

Initial contact with prospective participants will be made by study team members listed on the IRB application; these research staff members will be trained by the PIs to properly screen participants.

12.4 Recruitment Materials:

Materials that will be used to recruit participants and are included in this application are:

- Flyer to be distributed via email and social media
- Text for social media posts
- Text for print newspaper posts
- Transcript for recorded radio posts

12.5 Payment:

For the formative assessment focus groups, each participant will receive $25 as a thank you for their feedback and time.

For each data collection timepoint, each participant will receive $50 for completing assessments, which includes wearing activPAL for 7 days; collecting two salivary samples; having blood pressure, height, weight, and body fat % measured by trained staff; and completing an electronic survey. After completing the in-person baseline assessment, each participant will receive $5 to complete an online survey. There are three data collection timepoints: baseline, post-intervention, and 3-month follow-up. Therefore, pilot RCT participants (both intervention and control participants) are able to receive up to $255 for completing measurements.

Another incentive pilot RCT participants will receive yoga equipment that they will own. Participants assigned to the intervention group will receive a yoga mat, a yoga strap, a yoga bolster, a pair of yoga blocks, and a bag for carrying at the first in-person yoga session. Participants assigned to the control condition will receive their yoga equipment at the 3-month follow-up data collection as a thank you for participating in the study. Furthermore, since the control participants were not involved in the face-to-face yoga intervention, they will receive a three-month membership to a local yoga studio and a catalog of virtual yoga classes led by the intervention yoga instructors. The membership and catalog may assist the control participants in establishing a regular yoga practice.

Additionally, intervention participants who engage in the post-intervention focus groups will receive a meal during the focus group and a $25 Tango Gift Card as a thank you for their feedback and time.

13.0 Withdrawal of Participants

13.1 Withdrawal Circumstances:

Because participants will be rigorously screened for participating, we will not withdraw any participants from the study. Only participants who are eligible and pass the screening will be recruited for the study. However, participants can assent or withdraw from the study at any given point, they will not be questioned nor will face penalty.

13.2 Withdrawal Procedures:

This is a voluntary study, so participants can withdraw at any time during the study without any penalty or consequences. Once a participant withdraws from the study, there will be no attempt to collect additional data from them.

13.3 Termination Procedures:

It is highly unlikely that any one would be terminated from the study by the research staff, but participants may choose to withdraw and terminate their participation. In those cases, all available data may potentially still be used in data analysis.

14.0 Risks to Participants

14.1 Foreseeable Risks:

Formative assessment and post-intervention focus groups: N/A

Pilot intervention: The potential risks to participants assigned to the yoga intervention, including psychological, social, and legal, are considered minimal. The potential adverse events anticipated in our intervention would be injuries due to participation in yoga (e.g., muscle strain, fainting, falling) as well as other complications from comorbidities such as obesity, hypertension, diabetes and medication use. Participants will be instructed to call their healthcare provider and notify the research staff if they experience an injury or any adverse event. As a proactive measure, a detailed plan for monitoring risks, tracking and reporting adverse events will be established at the start of the study. Adverse events will be classified as severe (cause major disruption to participant's life, e.g. sprain, broken bone, cardiovascular event, death), moderate (causes minor inconvenience to participant, e.g. fainting spell, sore muscles for >3 days), and mild (no major impact on participant, e.g. headache, sore muscles for 2-3 days). Any adverse events will be reported to the DSMB and IRB. If an adverse event does occur, the only alternative to participation in the intervention is not to participate, which eligible participants are able to opt out.

14.2 Reproduction Risks:

N/A

14.3 Risks to Others:

N/A

15.0 Incomplete Disclosure or Deception

15.1 Incomplete Disclosure or Deception:

There is no incomplete disclosure or deception to be utilized in this study.

16.0 Potential Benefits to Participants

16.1 Potential Benefits:

Formative assessment focus groups: No direct benefits are expected.

Pilot RCT: Participants enrolled in the yoga intervention will potentially receive the direct health benefits associated with regularly practicing yoga.

17.0 Statistical Considerations

17.1 Data Analysis Plan:

Aims 1-3. Feasibility, acceptability, and safety. Descriptive statistics of survey variables will be compared to the benchmarks in Table 6. For *recruitment*, we will record: a) the count of women

who express interest, b) weeks elapsed to screen 200 women, and c) number enrolled and consented as a *% of the targets* – 16 for focus groups and 60 for the pilot intervention. For *retention and adherence*, we will compute *% of participants* who attend ≥ 80% of the yoga sessions by tracking attendance to all in-person sessions. For *intervention fidelity*, Dr. Barr-Anderson will *analyze the videotaped yoga sessions* using established criteria to enumerate the number of planned specific yoga components that were *completed as a percentage of the total*. For *feasibility* we will compute the *percentage of participants* who: a) receive the materials and resources throughout the intervention, b) rate the assessments as 'not too burdensome' on a multiple choice question, and c) complete baseline, post-intervention, and follow-up assessments. For *acceptability* we will compute the *percentage of participants* who rate the various intervention components as acceptable. For *safety* we will track all adverse events experienced by participants, report them to the UMN IRB, and compare to the benchmarks. If benchmark goals are not met, we will explore why they were not met during the post-intervention focus groups in hopes of gaining substantive information to address the missed benchmark goals in the future trial.

Aim 4. Targeted Outcomes. Per the NCCIH's "Pilot Studies: Common Uses and Misuse",[77] the research team do not intend to evaluate the efficacy of the intervention. The behavioral and biological outcome data will be used to inform the design of the future trial by identifying feasibility/adherence problems with measures and suggesting effect size expectations. Data will be cleaned for errors and outliers, checked for normality, and transformed if necessary. The primary behavioral outcome will be time spent sitting/lying down from the activPAL3 as the gold standard measure of sedentary time. The research team will also analyze standing, stepping, sit-stand transitions, and moderate and vigorous physical activity data from the activPAL. Blood pressure (systolic and diastolic average of three measurements), perceived stress, anthropometry and other exploratory measures will be analyzed similarly. If **missing data** exceed 10% multiple imputation will be performed in addition to complete case analysis. For this pilot, we will report 95% confidence intervals.

Proposed statistical analyses are outlined above.

17.2 Data Integrity:

There are two PIs for this study and the leadership plan helps to maintain the integrity of this study. Dr. Barr-Anderson will be responsible for overseeing intervention development, implementation, and qualitative evaluation and will not be involved with data collection and analyses. Dr. Pereira, along with our analyst and biostatistician, will lead quantitative data collection and analyses at baseline, post-intervention, and 3-month follow-up and will be blinded to the intervention conditions.

18.0 Health Information and Privacy Compliance

18.1 Select which of the following is applicable to your research:

☒ My research does not require access to individual health information and therefore assert HIPAA does not apply.

☐ I am requesting that all research participants sign a HIPCO approved HIPAA

Disclosure Authorization to participate in the research (either the standalone form or the combined consent and HIPAA Authorization).

☐ I am requesting the IRB to approve a Waiver or an alteration of research participant authorization to participate in the research.

Appropriate Use for Research: N/A

☐ An external IRB (e.g. Advarra) is reviewing and we are requesting use of the authorization language embedded in the template consent form in lieu of the U of M stand-alone HIPAA Authorization. Note: External IRB must be serving as the privacy board for this option.

18.2 Identify the source of Private Health Information you will be using for your research (Check all that apply)

☐ I will use the Informatics Consulting Services (ICS) available through CTSI (also referred to as the University's Information Exchange (IE) or data shelter) to pull records for me

☒ I will collect information directly from research participants.

☐ I will use University services to access and retrieve records from the Bone Marrow Transplant (BMPT) database, also known as the HSCT (Hematopoietic Stem Cell Transplant) database.

☐ I will pull records directly from EPIC.

☐ I will retrieve record directly from axiUm / MiPACS

☐ I will receive data from the Center for Medicare/Medicaid Services

☐ I will receive a limited data set from another institution

☐ Other. Describe: N/A

18.3 Explain how you will ensure that only records of patients who have agreed to have their information used for research will be reviewed.

N/A

18.4 Approximate number of records required for review:

N/A

18.5 Please describe how you will communicate with research participants during the course of this research. Check all applicable boxes.

N/A

☐ This research involves record review only. There will be no communication with research participants.

☐ Communication with research participants will take place in the course of treatment, through MyChart, or other similar forms of communication used with patients receiving treatment.

☐ Communication with research participants will take place outside of treatment settings. If this box is selected, please describe the type of communication and how it will be received by participants.

18.6 Access to participants

N/A

18.7 Location(s) of storage, sharing and analysis of research data, including any links to research data (check all that apply).

☐ In the data shelter of the Information Exchange (IE)

☐ Store ☐ Analyze ☐ Share

☐ In the Bone Marrow Transplant (BMT) database, also known as the HSCT (Hematopoietic Stem Cell Transplant) Database

☐ Store ☐ Analyze ☐ Share

☒ In REDCap (recap.ahc.umn.edu)

☒ Store ☒ Analyze ☐ Share

☒ In Qualtrics (qualtrics.umn.edu)

☒ Store ☒ Analyze ☐ Share

☐ In OnCore (oncore.umn.edu)

☐ Store ☐ Analyze ☐ Share

☒ In the University's Box Secure Storage (box.umn.edu)

☒ Store ☒ Analyze ☒ Share

☒ In an AHC-IS supported server. Provide folder path, location of server and IT Support Contact: Epidemiology & Community Health secured encrypted server managed by Jeff Johnson (johns260@umn.edu): \\files.epi.umn.edu\Pereira\YogaMoves

☒ Store ☒ Analyze ☒ Share

☐ In an AHC-IS supported desktop or laptop.

Provide UMN device numbers of all devices:

☐ Store ☐ Analyze ☐ Share

☐ Other.

Indicate if data will be collected, downloaded, accessed, shared or stored using a server, desktop, laptop, external drive or mobile device (including a tablet computer such as an iPad or a smartform (iPhone or Android devices) that you have not already identified in the preceding questions

☐I will use a server not previously listed to collect/download research data

☐I will use a desktop or laptop not previously listed

☐I will use an external hard drive or USB drive ("flash" or "thumb" drives) not previously listed

☐I will use a mobile device such as an tablet or smartphone not previously listed

N/A

18.8 Consultants. Vendors. Third Parties.

N/A

18.9 Links to identifiable data:

As participants are enrolled in the study, they will receive a unique identifier that will be attached to all of their research materials (i.e., data collection and assessments, intervention materials). A password-protected document will contain identifying information and will only be accessible by authorized research staff will have access to subject identities. In accordance with NIH guidelines (i.e., the funding agency), identifiable data will be destroyed 5 years after the conclusion of the study.

18.10 Sharing of Data with Research Team Members.

Electronic files will be stored in the University's Box Secure Storage and only authorized research staff will have access to a given file (i.e., measurement staff, but not intervention staff, will be able to access baseline data files).

18.11 Storage and Disposal of Paper Documents:

We do not anticipate any paper documents as we will use electronic forms only. However, in the case that we have to use paper documents, we will keep all paper data collection forms in locked filing cabinets housed in the School of Kinesiology or Division of Epidemiology and Community Health and will destroy 5 years after the conclusion of the study.

19.0 Confidentiality

19.1 Data Security:

All data collected, especially participant information, during the study will be treated with strict confidentiality. Information will be entered into our data files by coded numbers (without recording individual names), thus assuring anonymity. Only authorized research staff will have access to participant identities or condition allocation (i.e., Dr. Pereira and the measurement team will be blind to condition allocation). When the research team reports study results,

participants will not be named or identified in any way. All research team members have (or will) completed human subjects training.

Yoga classes will be recorded as part of the intervention and will be stored on a password-protected, view-only Google Drive. Videos will focus on instructors, with the goal of keeping participants out of the frame. Instructors will sign a video release form and participants will consent to being recorded in case of audio being picked up on the video. Only the research team and participants in the pilot RCT will have access to the catalog of yoga videos. No identifiable information will be shared over the videos.

20.0 Provisions to Monitor the Data to Ensure the Safety of Participants

20.1 Data Integrity Monitoring.

Drs. Barr-Anderson and Pereira will be responsible for monitoring the safety of this study, executing the Data and Safety Monitoring Plan (DSMP), complying with any reporting requirements, and consulting with the DSMB about any adverse events that may occur. If funding agency-mandated DSMB will receive formal reports from the research staff twice per year. The DSM report will include the participants' socio-demographic characteristics, expected versus actual recruitment rates, retention rates, quality assurance, or regulatory issues that occurred during the past year, a summary of Adverse Events (AEs) and Serious Adverse Events (SAEs) and any actions or changes with respect to the protocol. The DSM report will also include, when available, the results of any interim outcome analyses. In addition to the annual DSM report, the PIs will be responsible for informing NIH of any IRB actions within two weeks of their occurrence as well as any substantial changes or amendments to the study protocol prior to their implementation.

20.2 Data Safety Monitoring.

No Adverse Events (AEs) or Serious Adverse Events (SAEs) are expected as a result of the study procedures or intervention. If any AEs or SAEs occur during the study, they will be documented by the research staff and reviewed by UMN IRB and DSMB to determine if further action needs to be taken. Quality control videos will be collected biweekly (i.e., every other week – weeks 2, 4, 6, 8, 10, 12). Although these videos are intended to make sure yoga instructors are following the training protocol, the research staff will be able to use the videos to identify any participants who may be performing yoga poses that could put her at an increased risk for injury. Yoga instructors will review and correct any injury risks participants. Please note that all yoga instructors will be 200-hour certified (Yoga Alliance registered) with current CPR certification and at least one year experience teaching yoga. The yoga proposed for this pilot intervention will be a combination of hatha and restorative yoga, which is lower intensity and typical for beginner yoga practitioners. Additionally, the instructors will be trained on the pilot study's yoga protocol by three experienced yoga teachers: two 500-hour and one 250-hour certified yoga teachers.

21.0 Compensation for Research-Related Injury

21.1 Compensation for Research-Related Injury:

This research does not involve greater than minimal risk to participants.

21.2 Contract Language:

N/A

22.0 Consent Process

22.1 Consent Process (when consent will be obtained):

This study will have two separate consent processes. Participants engaged in the formative assessment focus groups will be consented to complete those focus groups only. Participants enrolled in the pilot RCT will be consented to: a) participate in the study and to be randomized to either the intervention or control condition, and b) participate in the post-intervention focus groups, if allocated to the intervention group. After a participant is screened and identified as having met the eligibility criteria, participants will be asked to "consent and sign" the informed consent form. This will take place virtually for the formative assessment focus groups and in-person for the pilot RCT.

22.2 Waiver or Alteration of Consent Process (when consent will not be obtained, required information will not be disclosed, or the research involves deception):

N/A

22.3 Waiver of Written/Signed Documentation of Consent (when written/signed consent will not be obtained):

N/A

22.4 Non-English Speaking Participants:

N/A

22.5 Participants Who Are Not Yet Adults (infants, children, teenagers under 18 years of age):

N/A

22.6 Cognitively Impaired Adults, or adults with fluctuating or diminished capacity to consent:

N/A

22.7 Adults Unable to Consent:

- Permission: N/A
- Assent: N/A

23.0 Setting

23.1 Research Sites:

Formative assessment focus groups: Participants for the formative assessment focus groups will be identified through radio, newspaper, email list and social media posts and will be screened via phone; all other study activities for these focus groups will take place virtually using Zoom as the platform.

Pilot RCT and post-intervention focus groups: Participants for the pilot RCT and post-intervention focus groups will be identified through radio, newspaper, email list and social media posts and will be screened via phone; baseline, post-intervention, and 3-month follow-up data collection will take place at University of Minnesota's Epidemiology Clinical Research Center. Participants randomized to the intervention group will engage in yoga sessions, workshops, and post-intervention focus groups at two intervention locations, 612 Jungle and The Zen Bin.

23.2 International Research:

N/A

23.3 Community Based Participatory Research:

N/A

24.0 Multi-Site Research

N/A

25.0 Coordinating Center Research

N/A

26.0 Resources Available

26.1 Resources Available:

The time devoted in conducting and completing the outlined research is substantial. Funding for this project is for three years with a total of 0.40 FTE per year for PIs and co-investigators and 0.50 FTE for a graduate research assistant in years 1 and 3 and 1.00 FTE for a graduate research assistant in year 2.

The bulk of the research will be conducted remotely from the School of Kinesiology and Division of Epidemiology and Community Health at the University of Minnesota. Both have the technological and computing assistance to support the proposed research. Due to the COVID-19 global pandemic, formative assessment focus groups will be conducted via Zoom, which is fully supported by the UM's Office of Information Technology. The pilot RCT and post-intervention focus groups will take place at two intervention locations, 612 Jungle and The Zen Bin.

All research staff will be IRB-approved and human subjects research-trained. Drs. Barr-Anderson and Pereira will meet with each on a bi-weekly basis to discuss the overall research project. Each of them will meet weekly with their graduate research assistant overseeing research duties and tasks. Meetings with the co-investigators and consultant will take place as

needed (approximately once a month over the life of the study and more often, when appropriate).

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