University of CINCINNATI
Institutional Review Board
FWA #: 00003152

APPROVAL

February 11, 2022

Holly Jones
CON AD for Nursing Research

Dear Holly Jones,

Type of Submission:	Continuing Review
Title:	Improving Healthy Lifestyle Behaviors in Midlife Black Women to Lower Heart Disease Risk.
Investigator:	Holly Jones
IRB ID:	CR03_2019-0426
Funding:	Name: National Institutes of Health - NIH
IND, IDE, or HDE:	None
Study Risk Level:	No greater than minimal risk
Documents Reviewed:	DSMP report August 2021_2.docx JONES_2021_Continuing Review_revised 2.5.2022.docx

On **1/28/2022**, the IRB reviewed the above submission using an EXPEDITED review procedure in accordance with 45 CFR 46.110(b)(1) which was given approval pending the response to modifications required. Response to the modifications required provided to the IRB were reviewed and approved on **2/9/2022** under the following category(ies):

- (4) Noninvasive procedures
- (7)(a) Behavioral research
- (7)(b) Social science methods
- (mm) Minor modification

CONTINUING REVIEW REQUIREMENT:
The IRB approved the protocol from **1/28/2022** to **1/27/2023**. Thirty days before **1/27/2023**, you are to submit a completed continuing review and required attachments to request continuing approval or closure. You can submit a continuing review by navigation to the active study and clicking Create Modification/CR. If continuing review approval is not granted before the expiration date of **1/27/2023**, approval of this study expires on that date.

PI NOTIFICATIONS:
This approval is through the IRB only. You may be responsible for reporting to other regulatory officials. Please check with your institution and department to ensure you have met all reporting requirements.

WHERE CAN I FIND MY IRB APPROVED DOCUMENTS?
Approved and/or final versions of documents submitted to the IRB can be found under the **documents tab** of the study's RAP submission. Watermarked ("stamped") versions of the consent form will appear in the right-side column as a pdf document. The approval or acknowledgement letter can be found in the top right section of the submission's main study page under **letter**.

INTERNATIONAL CONFERENCE ON HARMONIZATION AND GOOD CLINICAL PRACTICES STATEMENT:
The Institutional Review Board is duly constituted (fulfilling FDA requirements for diversity), has written procedures for initial and continuing review of clinical trials: prepares written minutes of convened meetings and retains records pertaining to the review and approval process all in compliance with requirements defined in 21 CFR Parts 50, 56 and 312 Code of Federal Regulations. This institution is in compliance with the ICH GCP as adopted by FDA/DHHS.

Thank you for your cooperation during the review process.

University of CINCINNATI

Research Protocol Template

PROTOCOL TITLE:

Improving Healthy Lifestyle Behaviors in Midlife Black Women to Lower Heart Disease Risk.

PRINCIPAL INVESTIGATOR:

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VERSION NUMBER/DATE:

Version 6. November 25, 2020

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
5	9/23/2020	Changes to approach due to COVID	Yes
6	12/4/2020	Changes to title to maintain blinding among participants. Increase value of gift provided at 12 weeks. Clarify the purpose of audiotaping for the Zoom sessions. It is used for quality assurance. On page 22, found an area of inconsistency with prior approval of use of information sheet.	Yes

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1.0 Study Summary

Study Title	Improving Healthy Lifestyle Behaviors in Midlife Black Women to Lower Heart Disease Risk.
Study Design	Developmental research study and pilot.
Primary Objective	The primary objective of this research is to develop a midlife **B**lack women's **S**tress-reduction **WELL**ness intervention, **B-SWELL**, for midlife Black women based on the stressors and themes identified in the PI's preliminary research.
Secondary Objective(s)	Determine the feasibility of the B-SWELL intervention with a trial of 50 midlife Black women randomized to the B-SWELL intervention (25) or to a wellness education (WE) control group (25)**:**
Research Intervention(s)/ Investigational Agent(s)	8-week community-based, behavioral intervention
IND/IDE #	N/A
Study Population	Midlife Black women
Sample Size	50
Study Duration for individual participants	8 weeks
Study Specific Abbreviations/ Definitions	B-SWELL: **B**lack women's **S**tress-reduction **WELL**ness Intervention WE: Wellness attention control group CBPR: Community-Based Participatory Research C-RAB: Community Research Advisory Board

2.0 Objectives*

2.1 Describe the purpose, **specific aims**, or objectives.

Purpose: The purpose of this research is to develop a midlife **B**lack women's **S**tress-reduction **WELL**ness intervention, **B-SWELL**, to promote healthy lifestyle behaviors based on the stressors and themes identified in the PI's preliminary research and consistent with the American Heart Association's *Life Simple 7 Success Plan (LS7) behaviors.*

Aim 1: Develop the B-SWELL intervention for midlife Black women through the innovative leveraging of CBPR methodology and LS7 modifiable healthy lifestyle behaviors.

a) To develop components of the B-SWELL intervention prototype for midlife Black women.
b) Obtain ratings of the new components of the B-SWELL from an expert panel consisting of four midlife Black women laypersons, three researchers and three integrative health care specialists for degree of accuracy, relevance, and feasibility to inform further refinements.

Aim 2: Determine the feasibility of the B-SWELL intervention with a trial of 50 midlife Black women randomized to the B-SWELL intervention (25) or to a wellness education (WE) control group (25):

a) Obtain recruitment, retention, treatment fidelity ratings, and satisfaction ratings for the intervention procedures for both groups, including technology;
b) Compare mediator measures (stress, self-efficacy) for participants in the B-SWELL intervention group with those in the WE group at 8 and 12 weeks.
c) Compare outcome measures (LS7 summary scores, unhealthy days, general health, depressive symptoms) for participants in the B-SWELL intervention group with those in the WE attention control group at 8 and 12 weeks.

2.2 State the hypotheses to be tested.

Our hypothesis proposes that B-SWELL (intervention) participants will show improved self-efficacy in managing life stress and adopting the LS7 behaviors, compared to an attention control group (WE group) receiving traditional wellness education.

3.0 Background*

3.1 Describe the relevant prior experience and gaps in current knowledge.

Cardiovascular disease (CVD) is the primary cause of death in all women, and as women transition through midlife, the prevalence of CVD exceeds that of men.(American Heart Association, 2016) Midlife Black women, defined as ages 40-64, unduly shoulder the burden of CVD (49%), hypertension (40%), and heart failure (50% greater risk).(Go et al., 2013; Gudmundsdottir, Hoieggen, Stenehjem, Waldum, & Os, 2012) Midlife Black women also report higher levels of chronic stress and greater numbers of stressful life events in comparison to midlife White women,(Schulz et al., 2000; Turner & Avison, 2003) putting them at greater risk for CVD. In addition to the physical impact, coping with chronic stress takes time and energy away from self-care, functioning as a barrier to the adoption of healthy lifestyle behaviors.(Pedersen, von Kanel, Tully, & Denollet, 2017; Pogosova et al., 2015) Existent interventions do not fully address the unique factors contributing to the experience of stress, lifestyle behaviors, and CVD risk in midlife Black women.

In the PI's prior research, we identified the particularities of stress and how they manifest in the lives of midlife Black women. Key stressors included: workplace stress, parenting, finances, and media stress.(Jones, Sternberg, Janson, & Lee, 2016; H. J. Jones, Norwood, & Bankston, 2018) The theme, 'Strong Black Woman', was identified along with the subthemes of 'gendered racism and discrimination' and 'life balance'.(H. J. Jones et al., 2018) The Strong Black Woman persona explains the elevated risk for morbidity and persistent chronic stress in Black women due to simultaneous exposures to racism and sexism and the gendered expectations of being the primary familial care-giver and supporter of others and the community alike.(Mullings, 2000; Woods-

Giscombe, Lobel, Zimmer, Wiley Cene, & Corbie-Smith, 2015) This persona serves as a coping mechanism under extremely oppressive conditions, cultivating strength and resilience among Black women, but leads to a deterioration of health due to chronic active coping.(Geronimus, 2001; Lekan, 2009)

Many Black women internalize characteristics of the 'Strong Black Woman' and while these characteristics are generally positive, it is easy to envision how a 'Strong Black Woman' can become stressed, overwhelmed, and isolated.(Beauboeuf-Lafontant, 2009) Much research has been done to provide a voice and understanding to the Black female experience in America however, none have used that voice to identify and target the unique perceived stressors that may serve as barriers to the adoption of healthy lifestyle behaviors. The purpose of this research proposal is to develop a midlife **B**lack women's **S**tress-reduction **WELL**ness intervention, **B-SWELL**, to promote healthy lifestyle behaviors based on the stressors and themes identified in preliminary research.(Jones et al., 2016; H. J. Jones et al., 2018) Community-based participatory research (CBPR) methods will be used to engage the community and include midlife Black women in the development of the B-SWELL. We propose that the skills and knowledge gained through participation in the B-SWELL program will increase receptivity to the healthy lifestyle behaviors outlined in the American Heart Association's Life Simple 7 Success Plan (LS7). The LS7 targets seven risk factors known to increase cardiovascular related health risk: cholesterol, fasting glucose, blood pressure, body mass index, physical activity, diet, and smoking.(Windham et al., 2017) By the age of 40, the prevalence of CVD is equal between men and women but by the age of 60, more women are affected.(Mozaffarian et al., 2016) This noted increased risk of CVD across midlife warrants the need for intervention.

3.2 Describe any relevant preliminary data.

Two preliminary studies conducted by the PI will inform this research.(Jones et al., 2016; H. J. Jones et al., 2018) These studies sought to understand the complexity of stress as a health indicator for midlife Black women. The first study used mixed methods to assess changes in perceived stress across midlife and identify significant life stressors.(Jones et al., 2016) The sample of 15 midlife Black women from the San Francisco Bay area (mean age 61years) had high-perceived stress scores that persisted across midlife. Although stress scores were consistent over time (between ages 40 and 60), the sources of stress changed. Significant life stressors included finances, caring for family members, relationships, personal health and aging, race and gender-based discrimination, and raising children.(Jones et al., 2016)

"Race is the hidden in plain view stressor in USA life. I am Black and that has caused me stress working in a White world. Equal, or perhaps worse, is the fight to have my voice heard as a woman."

This sample of midlife Black women was part of a larger cohort of Black and White midlife women. In the cohort (N=39), midlife Black women had higher perceived stress scores, a greater number of depressive symptoms and, were more likely to be obese and have elevated blood pressures compared to White women of similar age and demographics.(Jones et al., 2016) Higher perceived stress scores correlated with older biological age, indicating a greater health risk profile;[19] a finding that is consistent with the literature.

The second study conducted by the PI(H. J. Jones et al., 2018) used community engagement and focus groups to identify stress-related themes in the lives of midlife Black women residing in the Greater Cincinnati area. Key stressors were identified within six major themes: workplace, parenting, finances, social media, gendered racism and discrimination, and life imbalance(H. J. Jones et al., 2018). The participants also identified stress-reduction strategies and barriers to adopting those strategies. The six themes highlighting key life stressors in this second study were similar to those reported by the PI in the first study.(Jones et al., 2016) Two new sources of stress also emerged: social media and life imbalance.(H. J. Jones et al., 2018) Stress-reduction strategies were also similar between the two studies and included exercise, prayer, hobbies and other self-care activities, and fellowship.(H. J. Jones et al., 2018) The 'Strong Black Woman' theme was prevalent in the Cincinnati cohort:

"...we fail to seek assistance...sometimes you have to step back and recognize you might be a little bit in over your head and you need some help"

The focus group discussions in this second study generated ideas for the content (i.e., finances, parenting) and delivery (i.e., lectures, demonstrations) of a culturally tailored stress reduction program. The women also recommended the use of technology (social media, websites) for continued access to information and support. A manuscript authored by the PI and her primary mentor that highlights the ideas for content and delivery of the B-SWELL intervention is under peer review.

The findings for these preliminary studies are notable for their similarities. Midlife Black women in the San Francisco Bay area shared similar experiences with stress and sources of stress with midlife Black women from the Midwest.(Jones et al., 2016; H. J. Jones et al., 2018) Furthermore, the women reported similarities in preferred coping strategies.(Jones et al., 2016; H. J. Jones et al., 2018) The stress reduction strategies reported reflect culturally acceptable approaches for midlife Black women. This preliminary research underscores the importance of using the voices of midlife Black women to inform the design of interventions intended to improve behavior. CBPR methodology will facilitate the collaboration between the research team and the targeted population. This proposed research aims to fill that gap in the current intervention literature; themes identified in the PI's preliminary research(Jones et al., 2016; H. J. Jones et al., 2018) will inform the development of a stress-reduction wellness program for midlife Black women, B-SWELL. This project has the potential to improve our knowledge about the complex relationship between stress and behavior while decreasing CVD risk in a high-risk population.

The work of the mentoring team is essential to the success of this research. The primary mentor, Dr. Tamilyn Bakas, has a body of research that focuses on the care of the family caregiver. She developed the Telephone Assessment and Skill-building Kit (TASK) for stroke family caregivers through a K01 Award, then tested efficacy of this innovative program (TASK II) through an R01-funded randomized controlled clinical trial (RCT). (Bakas et al., 2015; Bakas et al., 2009) She has a currently funded R21 designed to optimize the TASK III program using technology (i.e., Task III website and eBook) and goal setting strategies to further improve caregiver health. Dr. Bakas has invited the PI to join her R21 research team where she will take an active role in helping to optimize the TASK III program. The PI will learn essential skills as a member of Dr. Bakas' research team (i.e., intervention development, clinical trial management, use of technology for intervention delivery). Many midlife Black women serve in caregiving roles, making her involvement in Dr. Bakas' research highly relevant to the current project.

Dr. Butsch Kovacic has a body of research grounded in CBPR and the health of under-represented communities.[64] She is the faculty liaison for the community research advisory board identified in this study and has a currently funded NIH R25 SEPA grant. Her expertise in epidemiology is an excellent complement to this research, as she understands the intersectionality of environment, person, and health; stress-related illness; and the challenges facing midlife Black women. The PI served as a co-investigator on Dr. Butsch Kovacic's recent research that used recreational music making to decrease stress in midlife Black women.

3.3 Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.

3.3.1. *Cardiovascular Health Disparities for Midlife Black Women.*

Black women are projected to have the lowest life expectancy of all racial/ethnic groups in the U.S. by 2060. This lower life expectancy projection is attributed to health problems that occur across the life span but in midlife Black women (ages 40-64), is commonly attributed to cardiovascular disease (CVD). It is estimated that 49% of adult black women have heart disease and over 40% have been diagnosed with hypertension.1 African American women are more likely to be obese, increasing their risk for Type 2 diabetes, hypertension and CVD.29 Although CVD is the number one cause of death in all women, African American women over the age of 60 have the greatest incidence of heart failure30 and 64% of Black women do not know that heart disease is their greatest health risk.1 Despite these statistics, studies show that intervention in midlife can aide in the prevention of chronic conditions like CVD and increase life expectancy.31,32

Midlife Black women are exposed to multiple and competing daily stressors resulting from role changes, major life events, and menopause, in addition to microaggressions and discriminatory acts related to their age,

gender, and ethnicity. The unique stressors experienced by midlife Black women contribute to the development of chronic conditions such as CVD because they tend to occur persistently and over prolonged periods of time. This chronic exposure has been associated with inflammation and plaque development in the vasculature 33. These stressors also function as barriers to the adoption of lifestyle behaviors that can prevent and even reverse these conditions 34. Coping with multiple stressors requires time that could otherwise be devoted to exercise, preparation of healthy foods, sleep, or fellowship; behaviors that have been shown to minimize, and possibly reverse, the effects of chronic stress 6,35. In fact, recent literature supports the need for tailored interventions for midlife Black women based upon observed health disparities and the strong relationship between health deterioration and chronic active coping 13,36

3.3.2. *Theoretical underpinnings*

In the effort to conceptualize and design a stress-reduction wellness intervention for midlife Black women, two theoretical frameworks will be used: Black Feminist Thought and Social Cognitive theory. Black Feminist Thought is a theoretical point of view that seeks to clarify the ideas and experiences of Black women from the perspective of Black women.37 Black Feminist Thought and its related constructs explain the elevated health risks and morbidity within the context of racism, sexism, and gendered expectations experienced by midlife Black women.10,11 The "Strong Black Woman" is a cultural construct arising from the Black Feminist perspective and was a major theme identified in the PI's preliminary work.8,37 The 'Strong Black Woman' persona, encapsulates a set of characteristics, beliefs, and behaviors that have been historically associated with the 'Strong Black Woman' (independence, resilience, perseverance) and deemed necessary for survival. This persona also contributes to a deterioration of health12 as women struggle to meet the expectations and needs of others with little regard for their own needs.29

Bandura's Social Cognitive Theory39 will guide the development of this intervention. Self-efficacy, a construct arising from Bandura's theory, has been shown to influence the adoption of healthy lifestyle behaviors.40,41 Self-efficacy is defined as "an individual's judgement of his or her capabilities to organize and execute courses of action."42 Self-efficacy recognizes that the intersectionality between person, behavior, and environment is key to understanding the motivations, perceptions, and barriers that influence decisions and the adoption of healthy lifestyle behaviors.39,42 In understanding and recognizing the significant stressors in the lives of midlife Black women, we can make steps to change perceptions and behaviors For this research study, self-efficacy will be viewed as a mediator for the adoption of healthy lifestyle behaviors.

3.3.3. Intervention Research Studies:

Targeting Interventions to Black Women: In general, intervention studies designed to improve healthy lifestyle behaviors are not focused on Black women. However, recommendations on how to tailor and target this population exist.29,43 Interventions targeted to vulnerable populations such as midlife Black women are advised to incorporate theory and take into account cultural and social factors that influence the decision to adopt (or avoid) specific behaviors.44 Mwenda et al. used the 'Transtheoretical Model' stages of change to evaluate factors associated with increased physical activity in a sample of hypertensive Black women.45 In another study, researchers concluded that the inclusion of social networks and a variety of behavioral strategies is imperative when designing interventions intended to improve the adoption of healthy lifestyle behaviors in Black women.46 Social networks, in particular, are key cultural factors of importance to midlife Black women. Finally, a literature review of interventions to promote exercise in Black women recommended that intragroup differences and communal resources be assessed in the design and implementation of interventions.47 The results of these highlighted studies can be applied to future interventions.

Interventions to Improve Health: Intervention studies focused on healthy lifestyle behaviors in Black women tend to target specific health behaviors such as cancer screening or exercise. Few target general health or well-being.50,51 Napholz developed a psychoeducational intervention for Black working women with the goal of reducing role conflict and improving well-being.50 This research focused solely on work role experiences for Black women. Napholz acknowledged the work role as a major life domain and discussed the

impact of prejudicial racial attitudes and other harmful stimuli encountered during daily work place interactions.50 She proposed that gender- and culture-appropriate content improved the receptivity of her intervention and she advocated for the use of tailoring to improve interventions. Work stress was a significant stressor in the preliminary research focus group study conducted by the PI. The proposed research will look beyond work stress to include the multiple, competing stressors experienced by midlife Black women.

Gaston, Porter, & Thomas 52 created an intervention designed to improve knowledge about major illness and nutrition for midlife Black women. This intervention used a support group approach to increase awareness and engagement. In another study, civic engagement was used to promote participation in lifestyle behaviors that reduce CVD risk. The adapted intervention was conducted in churches and 'change clubs' were formed. The 'change clubs' created a social network and group dynamic centered on improving lifestyle behaviors. Both studies aimed to improve general health. Culturally relevant approaches were identified but specific risk factors (i.e. stress) were not addressed.

Stress Interventions: Stress-reduction intervention studies aimed at Black women have targeted health problems such as pre-term labor, high blood pressure, and obesity. These health problems have demonstrated strong associations with stress and alarming disparities for Black women. In a study by Wesley,56 on-to-one sessions using deep breathing exercises or guided imagery were successful in decreasing perceived stress scores in pregnant Black women. Another study by Lechner and colleagues,57 used cognitive behavioral stress therapy to improve psychological adaptation in a sample of Black female breast cancer survivors. Alternatively, Cox and colleagues did not find significant success in their stress-augmented weight loss intervention program for adult Black women.55 Engagement was a key mediator related to lack of adherence to the intervention55 and is often proposed as a rationale for gender and cultural tailoring. These studies demonstrate a willingness of Black women to use a variety of stress-reduction strategies and highlights the importance of culture and inclusion when delivering interventions. No intervention studies were found that focus on the life stressors relevant to midlife Black women and the mechanisms through which these stressors serve as barriers to health lifestyle behavior.

*3.3.4. **Technology Use During COVID-19 Pandemic.***

There has been a steady increase in the use of technology in behavioral interventions. The addition of technology has shown effectiveness in several areas that increase its popularity. Technology has potential to reach a wider scope of people, ease access to information, decrease barriers to participation, improve collection and retention of research data, and eliminate internal bias, among others. Technology used for information and communication in behavioral interventions has been shown to improve outcomes when combined with other methodologies such as face-to-face (Lau, Lau, Wong, & Ransdell, 2011). Several systematic reviews focus on the use of technology in interventions designed to assess the effectiveness of physical activity and/or dietary behavior change. In the majority of systematic reviews (Kroeze, Werkman, & Brug, 2006; Lau et al., 2011; van den Berg, Schoones, & Vliet Vlieland, 2007; Vandelanotte, Spathonis, Eakin, & Owen, 2007), positive effects were noted with the addition of technology while others reported mixed results (Norman et al., 2007). Due to the COVID-19 pandemic, the B-SWELL RCT will be conducted remotely online. The use of technology in this study has the potential to improve our knowledge about technology in behavioral research studies.

4.0 Study Endpoints*

4.1 Describe the primary and secondary study endpoints.

The primary endpoint is to develop the B-SWELL intervention for midlife Black women using theory-based research, community engagement, and CBPR methods.

The secondary endpoint is to decrease stress and eliminate barriers to the adoption of healthy lifestyle behaviors in midlife Black women, ultimately reducing CVD risk in this vulnerable population.

4.2 Describe any primary or secondary safety endpoints.

N/A

5.0 Study Intervention/Investigational Agent

5.1 FDA-Related, Select Applicable:

☐	Drugs or Biologics	The proposed research involves the administration of an article (e.g. drug, biologic, herbal preparation, dietary supplement, etc.) to a human where the article is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or is intended to affect the structure or any function of the body. For both FDA and non-FDA approved article.
☐	Devices	Any research that involves the use of a device (medical or other devices, approved or investigational) to test the safety or effectiveness of the device or the device is the focus of the research. **Note:** This includes research that will use human samples to test the safety or effectiveness of a device.
☐	Data Collection	Any research that involves the collection of data or other results from individuals that will be submitted to, **OR** held for inspection by, the FDA. In general this would include research that involves any data that will be provided (in any form) to a pharmaceutical, medical device or biotech company.
☐	Specimens	Any research activity where specimens (of any type) from individuals, regardless of whether the specimens are identifiable, are used to test the safety or effectiveness of any device (medical or other devices, approved or investigational) and the information will be submitted to, or held for inspection by, the FDA.
☒	None of the Above	None of the above describes my research.

1.1

1.2 Describe the study intervention and/or investigational agent *(e.g., drug, device)* that is being evaluated.

N/A

5.2 Drug/Device Handling: If the research involves drugs or device, describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators.

N/A

5.3 If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:

N/A

6.0 Procedures Involved*

6.1 Describe and explain the study design.

This is a development and feasibility study. It will take place in two parts as outlined in Aims 1 & 2. In accordance with Aim 1, we will develop a stress reduction wellness intervention for midlife Black women and rate its accuracy, relevance, and feasibility using an expert panel and a community research

advisory board. We will then pilot the intervention using a sample of 50 women randomized to either the B-SWELL group or the WE (attention control) group. Satisfaction ratings will be obtained from participants. The study findings will be used to determine feasibility of the intervention and support a larger trial.

6.2 Provide a description of all research procedures being performed and when they are performed, including procedures being performed to monitor subjects for safety or minimize risks.

6.2.1 *Methods for Aim 1*

Aim 1: Develop the B-SWELL intervention for midlife Black women through the innovative leveraging of CBPR and LS7 modifiable healthy lifestyle behaviors. In Aim 1, the content for both the intervention (B-SWELL) and control groups (WE) will be developed. The B-SWELL intervention is proposed as an 8-week community-based intervention, culturally tailored to decrease stress in midlife Black women while simultaneously addressing key risk factors associated with CVD (Figure 1). The B-SWELL program will address key stressors and cultural themes identified in the PI's preliminary research [8,9] to provide a unique approach tailored to midlife Black women. Each module in the 8-week intervention will focus on the adverse effects of stress on health, in particular CVD, and the importance of minimizing these effects through healthy lifestyle behaviors (LS7). Links will be drawn between stress and CVD risk factors such as lack of exercise, poor diet, smoking, sleep deprivation, and non-adherence to treatment regimens. Stress reduction strategies included in the B-SWELL will be presented with emphasis on the needs and preferences of midlife Black women. For example, culturally relevant images will be used in guided imagery exercises. The tools learned in the B-SWELL will enable participants to be self-directed and create personalized plans to adopt healthy lifestyle behaviors. Content will be delivered by lecture, demonstration, and interactive exercises to increase engagement and promote inclusivity.

Consider this scenario: a midlife Black woman desires to improve her health and lifestyle habits. Through the B-SWELL program, she gains an understanding of how personal beliefs, culture, and socialized expectations inform her lifestyle decisions and affect her risk factors for CVD. She learns strategies to address the key stressor in her life: poor life balance. She receives support and validation from other participants in the program and takes steps to adjust her schedule and make time for exercise. She joins a carpool at her daughter's school that frees her up 2 times a week to participate in a morning walking group while also allowing her extra time in the afternoon to relax before her daughter and husband return home. Empowered by this positive change, she decides that she will next create a personalized plan to stop smoking.

Collaboration with the West End C-RAB and other community partners is critical to Aims 1 & 2. In CBPR, the community is recognized as a vital stakeholder to be included at every stage of the research. The C-RAB's participation will ensure that the B-SWELL reflects the needs of midlife Black women. The final intervention, including its materials and processes, will reflect knowledge gained from the PI's training plan, input from community collaborators, and refinements dictated by the initial ratings.

Data Collection Procedures: Aim 1. Data collection will occur during the development phase in Aim 1. Data will be collected using survey ratings about materials and components of the B-SWELL intervention from 10 identified experts. The expert panel will include four midlife Black women laypersons, three researchers (identified as experts by having a doctoral degree and strong record of publication), and three integrative health care specialists. Rating surveys will be similar to those used by Dr. Bakas in her feasibility study 22 to assess accuracy, relevance, and feasibility. Ratings will be averaged across the experts, with possible scores ranging from 1=strongly disagree to 5=strongly agree.

Recruitment and Informed Consent. Following approval from the UC IRB, research activities will begin. In Aim 1, the intervention will be developed and expert raters will be recruited to assess and evaluate the intervention materials and content. Experts will be recruited by word of mouth and by special invitation from the researchers by email, mail, telephone, or flyers. They will receive a study information sheet explaining that participation is voluntary and that their decision will not affect their relationship with the University of

Cincinnati, their employer, or the researchers. Full information will be provided and questions answered prior to consent. Incentives will be provided to the experts for participation.

6.2.2. *Methods for Aim 2*

Aim 2: Determine the feasibility of the B-SWELL intervention with a trial of 50 midlife Black women randomized to the B-SWELL intervention (25) or to a general wellness education (WE) control group (25). Aim 2 will focus on conducting a successful trial of the 8-week B-SWELL intervention for midlife Black women. The preliminary conceptual model in Figure 2 will guide this phase of the research. We anticipate that the model will be refined as we synthesize the new knowledge and feedback from the community (Aim 1). During Aim 2, community-based activities will focus on the recruitment, trial, data collection, and dissemination. Midlife Black women will be recruited and randomized into one of two groups: B-SWELL intervention group or a wellness education control group, WE group. Sessions will be held online using the Zoom online platform which has been approved and is supported by the university for research. Participants will be asked not to share intervention materials or experiences with midlife Black women outside of their assigned group. Participants in both groups will be introduced to AHA's LS7 behaviors, LS7 materials, and the LS7 website using B-SWELL tablets. Participants in the B-SWELL intervention group will also receive education about stress, with a focus on unique stressors experienced by midlife Black women.

Program evaluation will be ongoing. Data collection telephone interviews will occur at three time points: baseline (pre-intervention), 8 weeks (completion of the study), and 12 weeks (4 weeks post intervention) for both the B-SWELL and WE groups. Outcome measures will include LS7 scores, number of unhealthy days, depressive symptoms, and perceived general health. Ratings will be obtained from community collaborators to evaluate recruitment, retention, and treatment fidelity for both groups. Qualitative feedback and satisfaction ratings for the B-SWELL groups, WE groups, and technology will be obtained from participants at completion.

Recruitment and Eligibility: Aim 2: The sample of participants for Aim 2 will consist of 50 Black or African-American women randomized to a B-SWELL group (n=25) or to a WE attention control group (n=25). Inclusion criteria include being Black or African-American, between the ages of 40 and 64, fluent in the English language, ability to hear and speak well enough to engage in everyday conversation, access to a telephone, access to WIFI and willingness to participate. Exclusion criteria include recent immigration to the U.S., prisoner or on house arrest, pregnant, terminal illness (i.e., late stage cancer, end-of-life condition, renal failure requiring dialysis), history of Alzheimer's, dementia, or severe mental illness (i.e., suicidal tendencies, schizophrenia, or severe untreated depression), or any other major health conditions or disabilities (i.e. visual impairment, blindness, deafness) prohibiting safe or full participation in the program. Recruitment will involve use of fliers, referral, snowballing, and purposeful sampling in targeted communities. Fliers may be posted in businesses, on list serves, or group websites to increase distribution. The 8-week trial will take place virtually using a Zoom account established through the UC CON for the PI. Dates and times of the online virtual sessions will be established based on availability of the participants following randomization.

Interventions and Treatment Fidelity Methods: The B-SWELL intervention will follow procedures such as those proposed in Figure 1 and will be refined prior to trial based on feedback from the community collaborators and expert ratings (Aim1). Participants will be randomized to either the B-SWELL or WE groups. Both groups will be introduced to the LS7 materials. The B-SWELL will receive additional instruction about stress. B-SWELL and WE group sessions will occur on different dates and times and, participants will be asked not to share experiences with women outside of their assigned group. Participants will also be asked to secure private location when attending the virtual sessions to ensure privacy and confidentiality. Treatment fidelity of both groups will be monitored using Borrelli's Treatment Fidelity Checklist (Design, Training, Delivery, Receipt, Enactment). Facilitators of the intervention and control groups will be trained prior to the start of the trials.. Zoom meetings will be audio taped for quality assurance.

Data Collection Procedures: Aim 2. Data collection will occur at baseline, 8 weeks, and 12 weeks. Baseline data will be collected from B-SWELL and WE participants using telephone interviews conducted by trained, blinded research assistants. Data collection at 8 and 12 weeks may be collected via phone interview or through a REDCap link on the B-SWELL study tablets provided to B-SWELL and WE participant. Completion

of the surveys (interview or via REDCap link) is expected to last 30-45 minutes for each timepoint. Instruments are listed in Table 5. 3.4.d.

Randomization Procedures: Following baseline data collection, participants will be randomized to either the B-SWELL or WE group using 1:1 block randomization to promote equal group sizes. The randomization allocation sequence will be blinded to data collectors to avoid bias during follow-up data collection telephone interviews. Following randomization, the PI or research assistant will notify the participant of their group assignment and upcoming group meetings. Treatment fidelity will be monitored using the Borrelli's Treatment Fidelity Checklist (Design, Training, Delivery, Receipt, Enactment).

Recruitment and Informed Consent. In Aim 2, trial of the intervention will be conducted. Participants for the trial of the intervention will be recruited using fliers, referral, snowballing, and purposeful sampling in targeted communities. Fliers may be posted on list serves or group websites to increase distribution. A letter of introduction and study information sheet will be the first contact made for the study. A telephone number is provided for potential participants to call if they wish to participate. The PI or trained research staff will make the calls from a private location to protect confidentiality of the participant. If eligible and interested in participating, the person will be invited to participate and receive informed consent. All participants will be given full information about the nature, purpose, and possible risks and benefits of the study. Participants will be informed that participation in the study is voluntary, and they are free to discontinue participation at any time. Those who are eligible and who have signed the informed consent will be enrolled. The PI or research staff trained by the PI will obtain consent. Upon completion of the study, participants will receive a gift valued at $40 and keep all study materials. Study materials will consist of a study binder, AHA and LS7 informational materials, and a Fire 8 tablet.

6.3 Describe: Procedures performed to lessen the probability or magnitude of risks.

This study has minimal risk. Some survey items asked during the phone interviews may focus on negative emotions or experiences. There is a risk of loss of confidentiality for participants involved in the study given the online Zoom platform used for each session. Audiotapes of the Zoom sessions are for quality assurance. Transcriptions will be de-identified. There are no anticipated physical, social, legal, or other potential risks connected with the proposed procedures. The alternative to participating in the study is not to participate in the study. Participants and experts may withdraw at any time or may choose not to answer items during the interviews that make them uncomfortable.

Protections against risk. Participants may choose not to answer items during interviews or participate in portions of the intervention program with which they are uncomfortable. In the unlikely event that a participant appears to be distressed, she will be referred to appropriate resources or be given the telephone number for the national Suicide Hotline (800-784-2433; 800-SUICIDE) if appropriate. The PI will inform the IRB of any adverse events and/or any amendments to the protocol. Training for data collectors also will include how to respond to any potential adverse events experienced by participants, such as suicidal tendencies or severe depression. Participants with these types of problems will be given information about how to seek help and will be encouraged to inquire whether medication and/or psychological counseling would be helpful. In the event of suicidal thoughts, the PI or research staff may contact a health care provider on the participant's behalf so that they can contact the participant directly to determine if treatment is necessary.

To avoid loss of confidentiality during the online Zoom sessions, participants will be asked to find a private location from which to attend the online Zoom sessions. Additionally, participants will be required to attend Zoom sessions with video and will be asked to keep session discussions and activities private.

Only authorized study personnel will have access during the Zoom sessions, Zoom audiotapes or transcriptions, REDCap data, database, or contact information for study participants and expert panel members. For data analysis, study ID numbers will be generated to protect the identity of the participants in the final data set. Participants will not be identified in any way in reports or manuscripts from the study. Data from surveys will input directly into a REDCap database either manually or via the link on the study tablets. REDCap is backed up nightly by the university. Only authorized study personnel will have access to REDCap. Any calls to participants will be made to a telephone number provided by the participant at a time that is convenient for the

participant. Research staff will make calls from a private location in order to protect confidentiality. Informed consent forms and contact information from participants will be stored separately in a locked file cabinet to protect confidentiality.

Tablets will be programmed with content and links relevant to the B-SWELL study and appropriate restrictions. Programming will be conducted by the B-SWELL research team under guidance of UC CATER staff. All study materials, including tablets, will be handled in accordance with UC COVID-19 protocols (i.e. gloves and masks).

- *All drugs and devices used in the research and the purpose of their use, and their regulatory approval status.*

N/A

- *The source records that will be used to collect data about subjects. (Attach all surveys, scripts, and data collection forms.)*

All study data and tracking will be entered into an electronic data system, REDCap (www.REDCap.org), a secure research electronic data management system with validated data entry, audit trails for tracking data manipulation, and export procedures. It is HIPAA complaint satisfying all local, state, and federal regulation for the capture and storage of private health information for research purposes.

Zoom accounts have been purchased by the UC CON. Zoom accounts will be supported by the UC CON CATER technology experts. Zoom links have been determined to be secure and appropriate for research by the UC depart of research. Members of the B-SWELL research team will be trained in the use and management of online Zoom group sessions, privacy, and technical issues.

The surveys used to collect data are included in the chart below and attached.

Construct	Survey Tool	Time	Baseline	8wks	12wks
Moderators	Demographic data: income, marital status, children, education, health problems, and community of residence (among others).	5	X		
Mediator	Cohen's Perceived Stress Scale (PSS-10): measures perception of general stress. Items are rated on a scale of 0–4 (Max score =40). [66,67] Higher stress levels correspond with higher scores.	5	X	X	X
Mediator	General Self-Efficacy Scale (GSE): 10-item psychometric scale that assesses optimistic self-beliefs to cope with life demands.[68]	5	X	X	X
Primary Outcome	AHA Life's Simple 7 (LS7): developed to promote cardiovascular health in accordance with the organization's 2020 Impact Goals.[69] Risk behaviors scored 0 to 2. Higher scores indicate trend towards optimal health behaviors and lower risk for CVD.	5	X	X	X
Secondary Outcome	Number of Unhealthy Days (UD): Number of days in past month participant felt physical/mental health was not good.[70]	2	X	X	X
Secondary Outcome	Perceived General Health: Uses the general health perception item from the Short Form Health Survey (SF36). Health rated as 'excellent', 'very good', 'good', 'fair' and 'poor'.[71]	2	X	X	X
Secondary Outcome	Patient Health Questionnaire (PHQ-9): A diagnostic instrument for depressive symptoms. Scores each of the 9 DSM-IV criteria as '0' (not at all) to '3' (nearly every day).[72]	5	X	X	X
Program Evaluation	Satisfaction (Adapted from Satisfaction questionnaire): Measures usefulness, ease of use, and acceptability ratings.(Bakas et al., 2009)	10			X
Technology Evaluation	Satisfaction (Adapted from Satisfaction questionnaire): Measures usefulness, ease of use, and acceptability ratings.(Bakas et al., 2009)	5			X
Total Minutes	Total data collection minutes each visit	40 min	30 min	25 min	35 min

6.4 What data will be collected during the study and how that data will be obtained?

Rating surveys, self-report survey data, and satisfaction ratings will be gathered from the expert panel and participants (Aims 1 & 2) and entered directly into a REDCap database via laptop computer or REDCap survey link. Intake data will be labeled with study ID numbers and stored separately. Names, contact information, or any other identifiers will be stored separately from all data that is collected. Access to the database, contact information, or links between study ID numbers and participants enrolled in the study will be limited to the investigators. Participants will not be identified in reports or manuscripts from the study. All paper forms and study materials will be stored in locked file cabinets accessible only to authorized study personnel. All computers, servers, and electronic files used in the study will be password protected and accessible only to authorized study personnel. Authorized study personnel will include the investigators and research staff involved in the study.

6.5 If there are plans for long-term follow-up, what data will be collected during this period.

A third and final data collection time point will occur 4 weeks after the completion of the intervention (12 weeks).

6.6 For Humanitarian Use Device (HUD) uses provide a description of the device, a summary of how you propose to use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures.

N/A

7.0 Data and Specimen Banking*

7.1 If data or specimens will be banked for future use, describe where the specimens will be stored, how long they will be stored, how the specimens will be accessed, and who will have access to the specimens.

N/A

7.2 List the data to be stored or associated with each specimen.

N/A

7.3 Describe the procedures to release data or specimens, including: *the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.*

N/A

8.0 Sharing of Results with Subjects*

8.1 Describe whether results will be shared with subjects or others and if so, describe how the results will be shared.

We anticipate that there will be manuscripts, not only from the findings addressing Specific Aims 1 and 2, but also from secondary analyses from data generated from this study. We will disseminate results from Specific Aims 1 and 2, as well as results from secondary analyses, in peer-reviewed journals. We will also make the data available to others. Data will be shared with undergraduate honors students, MSN students, DNP students, PhD students, post-doctoral students, and interested faculty members at the University of Cincinnati, College of Nursing, and other institutions. Special measures will be taken to ensure that participants are not identifiable by any data that are shared. Close collaboration between the PI and her research team will be necessary for the use of shared data.

This is a community-based participatory research plan and dissemination efforts will include community presentations to share the findings of the research and discuss its relevance and usefulness to the community. Measures will be taken to de-identify any data that is shared. Feedback and ideas from the community will be taken into consideration with future iterations of this research and larger clinical trials based upon the findings.

This study will be registered and study results will be submitted to ClinicalTrials.gov in accordance with the NIH policy. Informed consent documents will include statements relating to the posting of clinical trial information at ClinicalTrials.gov.

9.0 Study Timelines*

The duration for individual participation in the study is 12 weeks. The duration anticipated to enroll all study participants is 12 months. The estimated date for the investigators to complete primary analysis is April 2022. Please see the study timeline below:

Grant Timeline	**Year 1**				**Year 2**				**Year 3**			
Month	3	6	9	12	15	18	21	24	27	30	33	36
Mentoring												
Didactic Coursework												
Workshops and conferences												
IRB approval process												

Advisory board meetings - quarterly												
Aim 1: Develop the B-SWELL components												
Aim 1: Obtain ratings of B-SWELL components												
Aim 1: Data Analysis												
Aim 1: Refine B-SWELL components												
Aim 2: Recruitment												
Aim 2: Data collection												
Aim 2: Data analysis												
Aim 1&2: Dissemination												
R01 Grant writing												
K01 progress reports												

10.0 Inclusion and Exclusion Criteria*

10.1 Describe how individuals will be screened for eligibility.

Recruitment will involve use of fliers, referral, snowballing, and purposeful sampling in targeted communities (Aim 1 & 2). Potential participants will express their interest by contacting the research team. Screenings will take place via phone. If a potential participant meets the study requirements, and agrees to the terms of the study, they will be randomized to either the intervention (B-SWELL) or control (WE) group (Aim 2).

10.2 Describe the criteria that define who will be included or excluded in your final study sample.

For Aim 2, inclusion criteria include self-identification as Black or African-American, between the ages of 40 and 64, fluent in the English language, ability to hear and speak well enough to engage in everyday conversation, an email address, access to a telephone and WIFI, and willingness to participate. Exclusion criteria include recent immigration to the U.S., prisoner or on house arrest, pregnant, terminal illness (i.e., late stage cancer, end-of-life condition, renal failure requiring dialysis), history of Alzheimer's, dementia, or severe mental illness (i.e., suicidal tendencies, schizophrenia, or severe untreated depression), or any other major health conditions or disabilities (i.e. visual impairment, blindness, deafness) prohibiting safe or full participation in the program.

Indicate specifically whether you will include or exclude each of the following special populations:

- *Adults unable to consent*

Adults who are unable to consent will be excluded from this research study because this intervention focuses on increasing self-efficacy and one's ability to make decisions about lifestyle changes to improve health. An inability to consent for one's self speaks to agency. It is a contraindication for this study and implies that someone else may be deciding for the participant.

- *Individuals who are not yet adults (infants, children, teenagers)*

This research is targeted specifically to midlife Black women. Children and adolescents will not be recruited.

Pregnant women are also excluded from this study. The study focuses on healthy lifestyle behavior and stress reduction; activities which should be beneficial to pregnant women. However, each pregnancy is unique and would require additional supervision. Safety measures for pregnant women are NOT included in the study procedures

- *Prisoners*

Prisoners are excluded from this study as it is community-based research and requires participants to freely participate in virtual group activities, receive B-SWELL study documents in the mail, and have access to WIFI and a private location for group sessions.

11.0 Vulnerable Populations*

11.1 If the research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare.

N/A

12.0 Local Number of Subjects

12.1 Indicate the total number of subjects to be accrued locally.

For Aim 1, ten (10) experts will be selected to review and rate the components developed for the B-SWELL intervention.

For Aim 2, a total of fifty (50) midlife Black women will be recruited for participation in the pilot of the intervention.

12.2 If applicable, distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures.

For Aim 2, statistical power is analyzed based upon assumptions that we have N=50 total or N=25/group complete all 3 data collection time points with complete observations. We will over sample participants at baseline to offset the predicted dropout rate and ensure the proposed sample size in the final visit.

13.0 Recruitment Methods

13.1 Describe when, where, and how potential subjects will be recruited.

13.2 Describe the source of subjects.

13.3 Describe the methods that will be used to identify potential subjects.

13.4 Describe materials that will be used to recruit subjects.

13.5 Describe the amount and timing of any payments to subjects.

Recruitment will take place in Aim 1 and Aim 2 of this study. For Aim 1, an expert panel will be selected to rate the accuracy, relevance, and feasibility of the intervention. Purposeful recruitment methods will be used. For example, flyers will be placed in strategic locations. Referrals and recommendations will be accepted. The expert panel will include four midlife Black women laypersons, three researchers (identified as experts by having a doctoral degree and strong record of publication), and three integrative health care specialists. $100 is allocated for each reviewer for their time and effort (total $1000).

Aim 2 will include CBPR techniques, such as community engagement, to assist in recruiting midlife Black women in the Greater Cincinnati area. Collaboration with an experienced community research advisory board will guide the recruitment efforts and selection of study sites. Recruitment will involve use of fliers, referral, snowballing, and purposeful sampling in targeted communities. Fliers may be posted in businesses, on list serves, or group websites to increase distribution. All potential participants will be provided with written information about the nature, purpose, and possible risks and benefits of the study. Study participants will receive a $20 incentive per person at each data collection time point: baseline (before the start of the program), 8 weeks (at completion of the study), and 12 weeks. For 50 participants with three data collection time points, the total is $3000.

14.0 Withdrawal of Subjects*

14.1 Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent.

Participants may be withdrawn from the research without consent if they exhibit behaviors that disrupt the study activities, fail to adhere to online confidentiality guidelines, or are disrespectful and/or distressing to other participants in the study.

14.2 Describe any procedures for orderly termination.

The decision for termination will be made by the PI. Any and all communications regarding a termination and related procedures will be initiated by the PI. Only relevant research personnel will be advised and appropriate documentation will be placed in RedCap.

14.3 Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.

When participants choose to withdraw from the research, all data collection and contact will cease. Upon withdrawal, the participant will be required to return the B-SWELL study tablet and materials. Documentation will be updated in RedCap to reflect the change. Only relevant research personnel will be Advised of the participant's status.

15.0 Risks to Subjects*

15.1 List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects' participation in the research.

There is minimal risk in this study. Some items asked during the data collection phone calls or group (intervention or attention control) sessions may focus on negative emotions or experiences. There is also a risk of loss of confidentiality for participants and expert raters involved in the study due to the online Zoom platform used for group sessions. To avoid loss of confidentiality during the online Zoom sessions, participants will be asked to find a private location from which to attend the online Zoom sessions. Additionally, participants will be required to attend Zoom sessions with video and will be asked to keep session discussions and activities private

There are no anticipated physical, social, legal, or other anticipated risks connected with the proposed procedures. There are no investigational drugs or devices associated with the study, and we do not anticipate any serious adverse events. Adverse events attributed to data collection or participation in the group (intervention or attention control) sessions are unlikely. Data collection will take place via phone for each of the third data collection time points (baseline, 8, and 12 weeks). The time estimated for data collection is 24 to 34 minutes. Data collection when be scheduled at the convenience of the participant.

15.2 If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.

N/A

15.3 If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.

N/A

15.4 If applicable, describe risks to others who are not subjects.

N/A

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16.0 Potential Benefits to Subjects*

16.1 Describe the potential benefits that individual subjects may experience from taking part in the research.

Participants involved in the study may perceive benefit by knowing that they are assisting in the development of a novel intervention program tailored to midlife Black women and designed to decrease stress and CVD risk. Participants in this study will have improved knowledge about stress, stress reducing strategies, personal cardiovascular disease risk, and healthy lifestyle behaviors. Participants may also increase their social and support networks and awareness of resources within their communities. In addition, participants who engage in the program may improve their health through the adoption of healthy lifestyle behaviors and decrease their overall CVD risk.

16.2 Indicate if there is no direct benefit. Do not include benefits to society or others.

N/A

17.0 Data Management* and Confidentiality

17.1 Describe the data analysis plan, including any statistical procedures or power analysis.

In Aim 1 and Aim 2a, numerical measures will be summarized using descriptive statistics (i.e., means, standard deviations, and frequencies) regarding expert ratings of degrees of accuracy, relevance and feasibility of new components of the B-SWELL program (Aim 1), and recruitment, retention, treatment fidelity ratings, and satisfaction ratings (Aim 2a). For Aims 2b and 2c, numerical dependent variables (stress, self-efficacy, LS7 scores, unhealthy days, perceived general health, depressive symptoms) will be inspected of empirical distributions to ensure they meet conditions for parametric statistical models. Variable transformation will be used otherwise. All statistical tests will be performed using SPSS Version 25. Parameter estimates with P-values less than .05 will be considered statistically significant. Assumptions related to each statistical test used will be checked using residual plots, qq-plots, and tests for homogeneity of variance/ covariance. In Aim 2b, continuous mediators (stress, self-efficacy) will be compared between groups (B-SWELL vs WE) using t-tests at each visit (baseline, 8 weeks, 12 weeks).

In Aim 2c, using mixed effect models, primary (i.e., LS7 summary scores) and secondary outcome measures (i.e., unhealthy days, perceived general health, depressive symptoms) will be assessed for their associations with time (baseline, 8 weeks, 12 weeks), group (B-SWELL vs. WE), and interaction. In particular, each of the outcome measures will be treated as the dependent variable, and the time effect, group effect, and the interaction will be treated as independent variables or fixed effects of interest in the mixed effect model. Random effects will be used to account for within person correlation due to repeated measurements. Other covariates, such as demographics and attendance rate, will be controlled for by including them in the model and checking for their interaction with the intervention. Post hoc analysis of group means will be compared cross-sectionally, as well as longitudinally between time points (such as week 8 or 12 vs. baseline). Considering the limited sample size for this pilot-type of study, statistical tests will not be adjusted for multiple comparisons in post hoc analyses. Significant findings will be considered preliminary in nature and inspire future research.

Power. Statistical power is analyzed based upon assumptions that we have N=50 total or N=25/group complete all four data collection time points with complete observations. Should there be any concern of dropout from the study, we will over sample participants at baseline to offset the predicted dropout rate and ensure the proposed sample size in the final visit. The statistical tests are two sided with a targeted significance level of 0.05. In Aim2b and Aim2c post hoc analyses when we compare means using a two group t-test with equal variances assumption, we will reach 85% power to detect an effect size (i.e. difference of means/standard deviation of the difference) of 0.87.73 In Aim2c when we compare means using a paired t-test between visits in a group, we will reach the 85% power to detect an effect size of 0.63.73 If possible, and plausible, missing data could be included into analysis after multiple imputation, thus increasing the sample size and statistical power to detect differences. The main emphasis will be on exploring data trends to inform future work, rather than

significance, since this is a feasibility study. Significance will be emphasized when testing efficacy of the B-SWELL intervention compared to the WE attention control group in a future, well-powered RCT.

17.2 Describe the steps that will be taken to secure the data during storage, use, and transmission.

All study data and tracking will be entered into an electronic data system, REDCap (www.REDCap.org), a secure research electronic data management system with validated data entry, audit trails for tracking data manipulation, and export procedures. It is HIPAA complaint satisfying all local, state, and federal regulation for the capture and storage of private health information for research purposes. The PI is familiar with RedCap through prior research projects. The PI is committed to compliance with HIPAA, data safety procedures, NIH recommendations, and CITI trainings. All research personnel will be trained in the use of secure data and RedCap prior to their participation in the study and any communication with participants.

The Zoom platform has been approved by the UC Department of Research. Zoom provides advanced security and infrastructure to provide security during online activities. Administrators have the ability to perform secure log-ins, start a secured meetings with password, and schedule secured meetings with password. Secure meeting capabilities include the following:

- Role-based user security (i.e. waiting room, lock a meeting, end a meeting, expel a participant)
- Host and client authenticated meeting
- Open or password protected meeting
- Edit or delete meeting
- Host controlled joining meeting
- In-meeting security (i.e. all data is encoded)
- Authentication

The account administrator (study PI) will have the following security capabilities:

- Secure login options using standard username and password or SAML SSO
- Add user and admin to account
- Delete user from account Security Guide Zoom Video Communications, Inc. July 2020
- Manage account dashboard and cloud recordings

17.3 Describe any procedures that will be used for quality control of collected data.

For Aim 1, ratings will be obtained using survey tools adapted from a validated satisfaction questionnaire. For Aim 2, data will be collected using validated survey tools. In addition, data will be collected via phone to decrease the risk for missing data. Data collected via the B-SWELL study tablet will be linked directly to the REDCap. REDCap will be used to organize, store, and secure data. Only trained research personnel will handle the data and have access to REDCap.

17.4 Describe how data or specimens will be handled study-wide:

Rating surveys, self-report survey data, and satisfaction ratings will be gathered from the expert panel and participants (Aims 1 & 2) and entered directly into a REDCap database via laptop computer or REDCap survey link (for experts). Intake data will be labeled with study ID numbers and stored separately. Names, contact information, or any other identifiers will be stored separately from all data that is collected. Access to the

database, contact information, or linkages between study ID numbers and participants enrolled in the study will be limited to the investigators. Participants will not be identified in reports or manuscripts from the study. All paper forms and study materials will be stored in locked file cabinets accessible only to authorized study personnel. All computers, servers, and electronic files used in the study will be password protected and accessible only to authorized study personnel. Authorized study personnel will include the investigators and research staff involved in the study.

Data will be handled by trained research personnel only. Trained research personnel will be responsible for collecting and logging data. Data will be stored for the duration of the study and for five years following the completion of the study.

18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects*

This section is required when research involves more than Minimal Risk to subjects.

N/A

19.0 Provisions to Protect the Privacy Interests of Subjects

19.1 Describe the steps that will be taken to protect subjects' privacy interests.

Participants may choose not to answer items during interviews or participate in portions of the intervention program with which they are uncomfortable. Participants will be informed that participation in the study is voluntary and that they are free to discontinue participation at any time. Participants will be informed of risks related to privacy using an online format (Zoom).

19.2 Describe what steps you will take to make the subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed

Recruitment and retention of Black women in research studies is a historic problem. Using community-based participatory research (CBPR) methods, our team hopes to achieve optimal recruitment numbers and minimize attrition in this study. CBPR techniques, such as community engagement, will assist in targeting and tailoring the study procedures, thereby increasing its appeal to a large number of midlife Black women in the Greater Cincinnati area. Collaboration with an experienced community research advisory board will guide the recruitment efforts and selection of study sites. Recruitment activities will include the use of fliers and pamphlets, referral, snow balling, and/or remote community presentations. All potential participants will be provided with written information about the nature, purpose, and possible risks and benefits of the study.

Transparency and full disclosure are necessary to improve retention. Participants will be informed that participation in the study is voluntary and that they are free to discontinue participation at any time. Research staff having contact with the participants in the study will be trained using this process in the event that at any time the participant has any questions or wishes to withdraw. To prevent attrition, duplicates will be built into the program when possible to accommodate participant's schedules. Group session times will be selected based on availability of participants. In addition, phone or text messages will be sent to remind participants about the sessions and incentives will be offered after each of the four data collection time-points.

19.3 Indicate how the research team is permitted to access any sources of information about the subjects.

Participants may choose not to answer items during interviews or participate in portions of the intervention program with which they are uncomfortable.

Only authorized study personnel will have access to the database or contact information for study participants and expert panel members. For data analysis, study ID numbers will be generated to protect the identity of the participants in the final data set. Participants will not be identified in any way in reports or manuscripts from the study. Data from surveys will input directly into a REDCap database. REDCap is backed up nightly by the university. Only authorized study personnel will have access to REDCap. All calls to participants will be made to a telephone number provided by the participant at a time that is convenient for the participant. Research staff will make calls from a private location in order to protect confidentiality. Informed consent forms and contact information from participants will be stored separately in a locked file cabinet to protect confidentiality.

20.0 Compensation for Research-Related Injury

N/A

21.0 Economic Burden to Subjects

21.1 Describe any costs that subjects may be responsible for because of participation in the research.

There is no cost to participate in this study.

22.0 Consent Process

22.1 Indicate whether you will you be obtaining consent, and if so describe:

For Aim 1, experts will receive a study information sheet explaining that participation is voluntary and that their decision will not affect their relationship with the University of Cincinnati, their employer, or the researchers. Full information will be provided and questions answered prior to consent. Consent will be obtained prior to the start of the study.

For Aim 2, participants will receive full information about the nature, purpose, and possible risks and benefits of the study. Participants will be informed that participation in the study is voluntary, and they are free to discontinue participation at any time. Those who are eligible and who have signed the informed consent will be enrolled. Eligibility will be determined via phone. Participants will receive an information sheet for their records following screening, receipt of study details, a question/answer period, and verbal consent. Consent will take place prior to collection of baseline data. There may be a brief waiting period between notification of eligibility and consent.

We will be following "SOP: Informed Consent Process for Research.

Ongoing consent is not required. We are seeking consent for participation in the study for a duration of 12 weeks.

Non-English Speaking Subjects

N/A

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

N/A

Subjects who are not yet adults (infants, children, teenagers)

N/A

Cognitively Impaired Adults

N/A

Adults Unable to Consent

N/A

Adults Unable to Consent

N/A

23.0 Process to Document Consent in Writing

23.1 Describe whether you will be following "SOP: Written Documentation of Consent (HRP-091)." If not, describe whether and how consent of the subject will be documented in writing.

We will use the UC template for our consent documentation: HRP-502S University of Cincinnati Social, Behavioral, and Educational consent to participate in Aim 1 of this research study. The HRP-502I University of Cincinnati Information Sheet for Research Study will be used for Aim 2 of his study.

23.2 If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent.

This research presents no more than Minimal Risk of harm to subjects. The research involves no procedures for which written consent is normally required outside of the research context. The research is not FDA-regulated.

The waiver of documentation of consent is required because the study sessions will be held online. Following screening, randomization, and baseline data collection, participants will receive a copy of the study information sheet for their records in the mail. The written script of the information will be provided orally via phone. The information sheet will be provided or electronically displayed and include all required and appropriate additional elements of consent disclosure.

23.3 (If you will document consent in writing, attach a consent document. If you will obtain consent, but not document consent in writing, attach a consent script. Review "CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)" to ensure that you have provided sufficient information.

See attached consent document.

24.0 Setting

24.1 Describe the sites or locations where your research team will conduct the research.

For Aim 1, experts from the Greater Cincinnati Tri-State area will be recruited by word of mouth and by special invitation from the researchers by email, mail, telephone, or flyers. They will receive a study information sheet explaining that participation is voluntary and that their decision will not affect their relationship with the University of Cincinnati, their employer, or the researchers.

For Aim 2, participants for the trial of the intervention will be recruited from the Greater Cincinnati Tri-State area using flyers ad pamphlets, community virtual presentations about the study, referral, and snow balling. A letter of introduction and study information sheet will be the first contact made for the study. A telephone number is provided for potential participants to call if they wish to participate. The PI or trained research staff

will make the calls from a private location to protect confidentiality of the participant. If eligible and interested in participating, the person will be invited to participate and receive informed consent. All participants will be given full information about the nature, purpose, and possible risks and benefits of the study. Participants will be informed that participation in the study is voluntary, and they are free to discontinue participation at any time. Those who are eligible and who have given consent will be enrolled. The PI or research staff trained by the PI will obtain consent.

This is a single-site study with community partnership. All administrative activity, including grant administration, post award budget management, data management, and research and advisory team meetings will take place at UC and the UC College of Nursing. There are no separate lab or testing centers. The study intervention and control group sessions will take place virtually.

This research study will use community-based participatory research methods (CBPR). In CBPR, the community is a vital stakeholder, to be included at every stage of the research. The West End Community Research Advisory Board (C-RAB), consisting of 20 active community residents, has been identified as a community partner. The C-RAB is associated with UC and the UC Center for Clinical & Translational Science & Training. Representatives from the C-RAB will serve as advisors on the PI's advisory team and attend virtual quarterly meetings at the UC CON. The C-RAB's participation will ensure that the B-SWELL intervention reflects the needs of midlife Black women in Cincinnati. The final intervention, including its materials and processes, will reflect knowledge gained from the C-RAB and other community collaborators.

24.2 *Select all applicable UC/UC Health Affiliated Research Sites:*

☐	Barrett Cancer Center (Including IV Therapies & Pancreatic Disease Clinic	☐	Medical Sciences Building
☒	College of Nursing	☐	Shriners Hospital
☐	Crossroads Center	☐	UC Gardner Neuroscience Institute
☐	Drake Center	☐	UCMC (Emergency Department, Inpatient, and Outpatient Units)
☐	Genome Research Institute (Reading Campus)	☐	UCMC (Emergency Department, Inpatient, and Outpatient Units)
☐	Hoxworth: Inpatient Unit	☐	UCMC NICU
☐	Hoxworth: Outpatient Clinics	☐	University of Cincinnati Physicians (UCP)
☐	Infectious Disease Clinic (Holmes-UC Health)	☐	University Pointe Surgical Hospital
☐	Infectious Disease Clinical Trial Unit (Holmes-UC)	☐	VA-Cincinnati Medical Center
☐	Kettering Laboratory	☐	West Chester Hospital
☐	Linder Center of Hope	☐	Other UC Health Affiliated Clinic
☐	Liver Transplant Clinic (Medical Arts Building)		

25.0 Resources Available

25.1 Describe the resources available to conduct the research: For example, as appropriate:

Recruitment Justification:
Recruiting the required number of suitable participants (N=50) to meet the objectives in Aim 2 within the agreed recruitment period is highly feasible. Statistical power is analyzed based upon assumptions that we have N=50 total or N=25/group complete all four data collection time points with complete observations. We will over sample participants at baseline to offset the predicted dropout rate and ensure the proposed sample size in the final visit.

Recruitment will be facilitated through the use of CBPR methods. Interest in the PI's prior research was great and the high level of interest is anticipated to continue. Use of community resources to assist in recruitment will be beneficial.

Time devoted to research:
This research project will be funded through a NIH K01 (NHLBI) career development award that allows the PI to spend 75% of her time on research.

Facilities:
College of Nursing Physical Facilities: The CON is housed in Procter Hall on the UC Academic Health Center campus which includes the Colleges of Allied Health Sciences, Medicine, and Pharmacy, University of Cincinnati Medical Center, Cincinnati Children's Hospital, and the Cincinnati Veteran's Administration Hospital. The CON has 110 offices for faculty and administration. Lounges for faculty/staff and students, offices for graduate assistants, administrative offices, and storage space are also located in the CON. The Institute for Nursing Research and Scholarship (INRS) is also housed in the CON (see description below).

Office Space and Computer Needs: The PI has a private office at the CON with a telephone for participant enrollment and laptop computers using Microsoft Office Software and SPSS statistical software. The laptop is connected to the UC Academic Health Center Server and is Internet accessible. The PI has access to a secure computer research server for data storage at the CON. There is convenient access to facsimile transmission, email, and photocopying equipment. Administrative assistance is also available.

Center for Academic Technologies & Educational Resources (CATER): The College of Nursing is committed to providing quality information technology (IT) support for students, faculty and staff to facilitate success. For this reason, the college established the Office of Technology-Enhanced Learning which includes the *Center for Academic Technologies and Educational Resources (CATER)*. CATER includes a staff of 10 full-time individuals (instructional designers and information technology specialists) led by the Assistant Dean for Technology. CATER provides services including but not limited to desktop support, help desk support, server administration, eLearning, instructional design, classroom technology, web design/administration, group and one-to-one training, technology seminars and workshops, and continuing education training. The CON has made data storage a priority and houses a separate, secured research server for storage of all research data which is administered by CATER according to University policies and procedures. In addition, CATER is well versed on approved university servers for data storage such as 'box' and 'Redcap'.

Institute for Nursing Research and Scholarship (INRS): The Institute for Nursing Research and Scholarship (INRS) provides the infrastructure to facilitate the scholarly activities of faculty members in the CON. The INRS is directed by the Associate Dean for Research and Translation. Staff members in the INRS include a Statistician, a Program Coordinator, two grant administrators, an accountant and eleven graduate student assistants. The INRS promotes scholarly excellence through research interest groups, a writing support group, a Statistical Consultation Lab, and regularly scheduled INRS educational forums. The INRS staff members offer administrative support, pre-grant and post-award budget management, data entry/management, and grant writing/editing support to principal investigators. Other services include literature reviews, copying and office space for project directors, research assistants, and graduate assistants assigned to funded research projects. The INRS is a locked and secure environment with desks, computers with statistical analysis

capabilities, and qualitative analysis software capabilities, file storage space with locks for confidential research participant data files.

Center for Clinical & Translational Science & Training (CCTST): The CCTST has been funded by the National Center for Advancing Translational Sciences (NCATS) (1UL1TR001425-01). Investigators request services through the CCTST's online "Research Central" portal at http://cctst.uc.edu. The CCTST Center for Improvement Science (CIS) provides an infrastructure to support interprofessional team focused learning and promotes utilizing the principles of team science for translational research. The CCTST has promoted multi-disciplinary collaboration through Integration Committee consultations and topic-based studios to help define solutions for problems encountered during the course of faculty research. The Biostatistics, Epidemiology and Research Design (BERD) program provides all investigators ready access to experts in research methods. Individualized services include review of IRB protocols; advice on study designs, including project implementation and data collection methods; guidance on appropriate statistical methods; development of data safety and monitoring plans; and consultation on clinical research ethics. The Biomedical Informatics (BMI) core serves as the hub for research informatics that provides services that include development of databases and surveys using REDCap (Research Electronic Data Capture), a software toolset and workflow methodology. The Community Engagement core is broadening and strengthening collaborations between the Academic Health Center and community, and has ties with the West End Community Research Advisory Board (C-RAB) for underserved populations.

University of Cincinnati Libraries: The University of Cincinnati library system of eleven libraries houses 3.6 million books and serials, 19,500 journal subscriptions, and 141,000 audio-visual pieces. Access to a larger core collection of books and journal titles is available through University of Cincinnati Libraries Information Database (UCLID), an online public access catalog supporting all University of Cincinnati Libraries. The UC Libraries are a founding member of OhioLINK which provides access to 48 million books, 12,000 electronic journals, 140 online databases, and over 55,000 electronic books. The Donald C. Harrison Health Sciences Library (HSL) is within easy walking distance of the College. The HSL has assigned a librarian to be the primary liaison to the CON.

University of Cincinnati Medical Center (UC Health): The University of Cincinnati Medical Center, University Health, is an urban medical center that serves the Greater Cincinnati Tri-State area and is considered one of the region's top medical facilities. UC Health houses the region's largest group of board-certified physicians that include psychiatrists.

Medical and Psychiatric Resources:

In the unlikely event that a participant appears to be distressed, she will be referred to appropriate resources or be given the telephone number for the national Suicide Hotline (800-784-2433; 800-SUICIDE) if appropriate. The PI will inform the IRB of any adverse events and/or any amendments to the protocol. Training for data collectors also will include how to respond to any potential adverse events experienced by participants, such as suicidal tendencies or severe depression. Participants with these types of problems will be given information about how to seek help and will be encouraged to inquire whether medication and/or psychological counseling would be helpful. In the event of suicidal thoughts, the PI or research staff may contact a health care provider on the participant's behalf so that they can contact the participant directly to determine if treatment is necessary. Alternatively, the participant may be referred to UC Health for immediate evaluation and/or treatment if deemed necessary.

Information Processes:

Training team members in research ethics. All of the research team members have completed their CITI training for the protection of human subjects. The PI will remind the research team of the expected research conduct and required adherence to UC IRB and research sponsored program policies and procedures when conducting the initial research project orientation, and during ongoing research team meetings.

Training team members in research activities. Research assistants will be trained to provide overall study support including clerical activities, participant screening, data collection, preparation of training manuals, coordination of research team meetings, scheduling, monitoring adherence to protocol, and other

study-related tasks as assigned. Team members will be trained through a one day training workshop provided by the PI and co-investigators. Those having direct contact with research participants will be trained in the informed consent process and the IRB approved protocol for the study, with emphasis on the protection of human subjects.

Verification. The PI and Co-investigators will review procedures monthly and complete adherence to protocol checklists on all staff with retraining as necessary. Weekly team meetings will be conducted to verify procedures and to address issues as they arise. IRB approved documentation will be available to all research staff and will be included as an essential part of all training sessions. Audiotapes of Zoom sessions will be reviewed by facilitators and the PI at random for self-evaluation and quality assurance.

26.0 HIPAA

☒ Not using HIPAA-protected information for any research activities.

☐ Through a HIPAA Authorization signed by the participant (or their legally authorized representative).

☐ Requesting that the IRB approve a waiver of authorization in this application. **SUBMIT HIPAA WAIVER REQUEST FORM**.

☐ As a limited data set under a data use agreement.

27.0 Other Reviews

19.1 *Select applicable:*

☐ **Radiation Safety:** *The proposed research involves the research participants being exposed to radiation for research purposes. Note: This includes an increase of frequency of radiological imaging procedure and/or increase duration of clinically indicated radiological imaging procedures.*

☐ **Institutional Biosafety Committee:** *IBC Approval is required for research that will utilize any of the following: infectious agents, select agents (See "Selected Agents for IBC Review"), recombinant DNA or viral gene transfer vectors, select agents or toxins for human gene transfer or an agent (virus, bacteria, etc.) that has been genetically modified. Information regarding submission to the University of Cincinnati IBC can be found at: Institutional Biosafety Committee. The IRB must receive a copy of IBC approval prior to issuing final IRB approval.*

☐ **Infectious Agent:** *The proposed research involves an infectious agent that is administered to a human subject, or that involves a risk of accidental exposure to a member of the research team, other hospital staff or other patients in the hospital.*

19.2 CT.Gov Registration

☒ The PI is responsible for registration of this study on www.clinicaltrials.gov (If yes, contact the IND-IDE Assistance Program at (513) 558-0453).

19.3 Identify where funds are being held:

☒ Funds held in Sponsored Research Services for a Grant or Contract (funds are held internally at UC)

This research will be funded by the NIH National Heart, Lung, and Blood Institute through a K01 career development award. Funds will be held by the UC College of Nursing and dispersed/managed according to federal, state, and institution regulations.

☐ Funds are from a UC department account (held internally at UC)

☐ Funds held in a Corporate account from a Contract (funds held externally at UC)

28.0 Multi-Site Research* (Please complete if you are the lead PI for multi-site research)

N/A

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