The HARMONY Study- A Culturally Relevant, Randomized-Controlled, Stress Management Intervention to Reduce Cardiometabolic Risk in African American Women

NCT number NCT04705779
Document Date 05/27/2022

CONFIDENTIALITY STATEMENT

This document is confidential communication. Acceptance of this document constitutes agreement by the recipient that no unpublished information contained herein will be published or disclosed without prior approval of the Principal Investigators or other participating study leadership and as consistent with the NIH terms of award.

Table of Contents

1 STATEMENT OF COMPLIANCE

The trial will be carried out in accordance with International Council on Harmonisation Good Clinical Practice (ICH GCP) and the following:

- United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 312, and/or 21 CFR Part 812).

National Institutes of Health (NIH)-funded investigators and clinical trial site staff who are responsible for the conduct, management, or oversight of NIH-funded clinical trials have completed Human Subjects Protection and ICH GCP Training.

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form(s) must be obtained before any participant is consented. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form(s) will be IRB approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.]

1 PROTOCOL SUMMARY

1.1 SYNOPSIS

Title:	The HARMONY Study- A Culturally Relevant, Randomized-Control, Stress Management Intervention to Reduce Cardiometabolic Risk In African American Women
Grant Number:	1 R01 MD015388-01A1
Study Description:	The HARMONY study is a randomized controlled trial (RCT) to test a culturally-tailored mindfulness-based stress management intervention. This RCT is designed to help African American Women (AAW) build on their strengths to promote stress management and improved cardiometabolic (CM) health by enhancing positive reappraisal, self-regulation, and self-efficacy, all of which are cognitive-behavioral facilitators of self-management and positively impacted by mindfulness training. This 2- arm CM-risk reduction RCT with 200 AAW ≥ 18 years old with CM risk, will be powered to detect group differences in exercise and healthy eating behavior.
Objectives*:	Primary Objective: The primary objectives are listed in section 3. Secondary Objectives: The secondary objectives are listed in section 3.
Endpoints*:	Primary Endpoint: The primary endpoints are listed in section 3. Secondary Endpoints: The secondary endpoints are listed in section 3.
Study Population:	200 African American or Black women who are greater than 18 years old will be enrolled in the study. Participants must have at least one cardiometabolic risk factor.
Phase* or Stage:	Phase II
Description of Sites/Facilities Enrolling Participants:	All participants will be enrolled by study personnel at UNC Chapel Hill.
Description of Study Intervention/Experimental Manipulation:	The HARMONY intervention is a combination of a culturally tailored mindfulness program with a culturally tailored exercise and nutrition education CM risk-reduction program.
Study Duration*:	3.5 years
Participant Duration:	Approximately 13 months

1.2 SCHEDULE OF ACTIVITIES

Schedule of Activities: Outcome Visits:

	Screening (by telephone)	Pre-Baseline Period	Baseline	Randomization (when groups fill)	Week 16 (+/- 14 Days)	Week 32 (+/- 14 Days)	Week 48 (+/- 14 Days)
Informed consent (telephone)	X						

	Screening (by telephone)	Pre-Baseline Period	Baseline	Randomization (when groups fill)	Week 16 (+/- 14 Days)	Week 32 (+/- 14 Days)	Week 48 (+/- 14 Days)
Informed consent (in-person)			x				
Inclusion/exclusion criteria review	x		x				
CM Risk Questionnaire	x						
Physical Activity Readiness Questionnaire (PAR-Q)	x						
Superwoman Schema Questionnaire (SWS)	x				x	x	x
Perceived Stress Scale (PSS-14)	x				x	x	x
General Stress Assessment	x				x	x	x
Demographics Questionnaire	x						
Health History Questionnaire			x				
University of RI Change Assessment Scale			x				
Provide ActiGraph Activity Monitor (with mailer for participant to mail back)			x		x	x	x
Provide Fitbit device			x				
Dietary Risk Assessment			x		x	x	x
Veggie Meter Procedure			x		x	x	x
Weight/Height (Height only required at baseline)			x		x	x	x
Hip circumference			x		x	x	x
Waist circumference			x		x	x	x
Blood draw			x		x	x	x
Fingerstick			x		x	x	x
Blood Pressure			x		x	x	x
Five Facet Mindfulness Scale			x		x	x	x
Contextualized Stress Scale			x		x	x	x
Network Stress		x			x	x	x
Mindful Eating Questionnaire		x			x	x	x
Mindful Self-Care Scale			x		x	x	x
Cognitive Emotion Regulation Questionnaire		x			x	x	x
PROMIS Self-Efficacy for Managing Emotions		x			x	x	x
PROMIS emotional distress-depression scale		x			x	x	x
Connor-Davidson Resilience Scale		x			x	x	x

	Screening (by telephone)	Pre-Baseline Period	Baseline	Randomization (when groups fill)	Week 16 (+/- 14 Days)	Week 32 (+/- 14 Days)	Week 48 (+/- 14 Days)
Self-Efficacy for Exercise Scale			X		X	X	X
Diet Self-Efficacy Scale			X		X	X	X
Buddy System Assessment					X	X	X
Mindfulness Practice Assessment (HARMONY group only)					X	X	X
Interview					X		X
Randomization				X			
Adverse Event Check			X		X	X	X

Schedule of Activities: Group Sessions:

	Session 1	Session 2	Session 3	Session 4	Session 5	Half-Day Retreat	Session 6	Session 7	Session 8	Booster Session 1	Booster Session 2	Booster Session 3	Booster Session 4	Booster Session 5	Booster Session 6
University of RI Change Assessment Scale	X					X									
Group Cohesion Questionnaire		X						X							
Credibility Scale		X						X							
Nutrition Survey	X								X						
Mindfulness Practice Assessment (HARMONY group only)		X	X	X	X	X	X	X	X	X	X	X	X	X	X
Buddy System Assessment		X	X	X	X	X	X	X	X	X	X	X	X	X	X
HARMONY/NEEW Session	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Adverse Event Check	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

2 INTRODUCTION

2.1 STUDY RATIONALE

African American Women (AAW) are at high risk for illness and death from serious cardiometabolic (CM) conditions – cardiovascular disease (CVD), diabetes, stroke and other health sequelae of constant, ongoing exposure to excessive stress, a top 10 determinant of health disparities.[1-3] Health statistics for AAW are alarming: 50% of adult AAW have CVD, of which 50,000 die annually. AAW's rate of stroke is double that of White women. Approximately 80% are overweight or obese.[2] Of AAW > 55 years old, 25% have diabetes, and they have higher complication rates from poorer glucose control.[2, 4-5] Preventive efforts are critical: heart disease, cerebrovascular disease, and diabetes are leading causes of death and disability in the US, with yearly direct (medical) and indirect (disability, work loss, premature death) costs estimated at $561 billion.[1, 2]

AAW experience unique, chronic stress phenomena that occur at the intersection of race and gender, such as overt discrimination and micro-aggressions[6, 7] Stress phenomena include, but are not limited to, two specific types. First, contextualized stress (CS) is the exposure to pervasive, negative race- and gender-based sociocultural constraints experienced by AAW.[8] Second, network stress (NS) is the vicarious experience of stresses encountered by family and close others, which to some AAW are as distressing as their own problems.[9] In response to these two stress phenomena, AAW may feel obliged to present an image of strength, suppress emotions, resist dependence on others, succeed despite limited resources, and prioritize care of family and community over care of self. [10-17] Known as Superwoman Schema (SWS), these stress responses have paradoxical features: SWS may increase life stress, depression, emotional eating, self-sacrifice, delayed health promoting behaviors, and burdensome allostatic ("wear and tear") load,[18-20] while also promoting survival and adaptation in context of disproportionately high rates of exposure to toxic stress and trauma.[10,11] Survey research and media profiles of SWS indicate its broad relevance to the stress and coping experiences of AAW in the US. A recent Al Jazeera media report on SWS in AAW had >4.8 million views, 2,500 comments, and 57,000 shares, demonstrating its salience and importance to the health of AAW.[21] A significant feature of our study, thus, is that we address SWS, contextualized stress and network stress. The prevailing paradigm of intervention research related to CM risk reduction inadequately addresses stress as a barrier to adherence to healthy exercise and eating goals.[22]

Physiological responses to stress, particularly hypothalamic-pituitary-adrenal (HPA)-axis activation and dysregulation, may affect CM risk directly. Constant, excessive demands on regulatory systems compromise cardiovascular, autonomic, metabolic, and neuro-endocrine activity, leading to illnesses such as diabetes.[8, 23] Furthermore, allostatic load[24-25] and the related concept of weathering may explain stress-related physiologic responses as the impact of *cumulative risk* from chronic exposure to life challenges and stress. As Geronimus noted "the cumulative impact of repeated experience with social, economic, or political exclusion" [26,p.133] among AAW is a stressor responsible for current health disparities. African Americans may cope with chronic stress by engaging in unhealthy behaviors rather than making recommended lifestyle changes, a perspective supported by research.[27] Because stress typically cannot be eliminated, this intervention will be tested to manage (rather than control) chronic stress exposure, which may alter the stress response and in turn decrease CM risk.[28-31] Interventions addressing adherence to healthy eating and exercise goals should target motivation and address self-efficacy and self-regulation. In the landmark 2017 Stress and Health Disparities Report, the American Psychological Association (APA) noted that interventions with elements to manage stress show promise to produce greater success in improving health equity for AAW and other populations.[6]

Mindfulness-based stress reduction (MBSR) is an evidence-based approach to manage stress and improve self-efficacy, positive reappraisal, and self-regulation, through which cognitive-emotional and physiological effects of stress are improved [32-37] MBSR involves training persons in intentional self-regulation of attention by learning to place awareness on present-moment experiences and to let go of fixation on thoughts of past and future.[12] Tested in RCTs, mindfulness training is an effective intervention for reducing stress and increasing well-being in a variety of healthy and clinical

populations,[18,38] including those at risk for cardiometabolic conditions.[39-48] Mindfulness also moderates intrinsic motivation and physical activity, and is associated with success in fulfilling intentions[49-50.] Research suggests that mindfulness training may be a culturally relevant intervention for stress-related conditions in African Americans; [50] a growing body of research demonstrates the potential for effective use of mindfulness for stress-related conditions in AAW.[52-53] Researchers have found that mindfulness is effective for improving perceived stress, addiction severity, anxiety, blood pressure, depressive symptoms, self-acceptance, and growth in samples that include AAW[54-57]. Two studies have been successful in incorporating informal mind-body and other stress reduction techniques into lifestyle programs to promote weight loss by AAW.[58-59] Despite demonstrated effectiveness of prevention strategies to delay onset or reduce development of CM conditions, AAW have been the least successful at reaching behavioral lifestyle change goals compared with women and men of other racial/ethnic groups.[60-63] These findings strongly suggest the need for enhanced evidence-based interventions to overcome barriers to lifestyle changes among AAW.[1, 64-73] This study proposes that a culturally–tailored mindfulness intervention addressing AAW's distinct, unique experiences of stress and coping holds potential to increase engagement in healthy behaviors critical for preventing CM conditions. Through a culturally-tailored[74] mindfulness training program, informed by awareness of the SWS, AAW will be encouraged to reconceptualize strategies such as self-care, aerobic and weight training exercise, and healthy eating as means to promote self-management. In contrast to a focus solely on weight loss, these strategies provide resilience, strength and fuel to meet life demands. This mindfulness intervention will be implemented at both individual and community levels, thus meeting NIH recommendations to address social-ecological factors influencing health disparities.[75]

2.2 BACKGROUND

The HARMONY intervention shifts the prevailing paradigm, from a focus on encouraging diet and exercise in isolation of the influence of stress and other contextual factors that affect AAW's ability to adhere to such recommendations, to an improved model in which AAW learn effective management of stressors through a culturally–tailored mindfulness intervention that raises awareness of AAW's potential strengths and that emphasizes the importance of self-care and being healthy for improving coping and stress management. Through culturally-relevant mindfulness training, exercise, and nutrition education, AAW will benefit from stress management and improved self-regulation and adherence to mindfulness practice recommendations, exercise and diet, thus reducing CM risk.[75, 22] HARMONY builds on findings from studies conducted by Drs. Giscombe, Gaylord and collaborators.[9,10,12,18,20 33, 36,38,51, 52,76, 77] Overall, research has demonstrated feasibility and acceptability of conducting a RCT to reduce cardiometabolic risk in African Americans using a mindfulness-based healthy lifestyle intervention (NIH/R21 We Can Prevent Diabetes Study).[77,52] Importantly, the control condition was a culturally-tailored exercise and healthy eating intervention. HARMONY extends the impact of the exercise and nutrition education intervention with a culturally-tailored mindfulness stress management intervention, by enhancing stress management and self-regulation facilitating adherence to exercise and diet lifestyle changes. The mindfulness stress management training in HARMONY is designed to raise awareness of how culturally-prevalent stress-related phenomena such as SWS can be transformed from being barriers to being facilitators of health. This transformation occurs through improvements in mindfulness, positive reappraisal, self-regulation, and self-efficacy; these efforts can sustain improvements in exercise and healthy eating behaviors and reduce risk for chronic cardiometabolic illnesses compared to those who do not receive the HARMONY program.

The previous studies that provide the foundation for this clinical trial are as follows:

Study 1: The African American Women's Well-Being Study, with 189 AAW from diverse socioeconomic

backgrounds. This cross-sectional study demonstrated the importance of incorporating multidimensional and culturally relevant factors (e.g., gender- and race-related stress) into research on health disparities in AAW[7] and showed significant, positive associations among culturally relevant stress, stress-related eating, and obesity.[12] In a follow-up study with African American college women, Giscombe et al. found associations between stress, contextualized stress, eating behaviors, and BMI.[97] Another study demonstrated that AAW experienced a higher number of NS events than self-stress events; AAW perceived NS occurrences as bothersome as self-stress and both were significantly and positively associated with psychological distress symptoms.[98]

Study 2: The SWS conceptual framework and the SWS Questionnaire was developed.[10,19, 20,38] AAW focus group participants (n=48) described the experience of SWS, the associated resilience, and risk factors including stress and delayed health-promoting behaviors. The five SWS characteristics were identified: obligation to project an image of strength, obligation to suppress emotions, resistance to admitting vulnerability or accepting help from others, motivation to succeed despite limited resources, and prioritization of caregiving over self-care.[10] Subsequently, using structural equation modeling in a secondary data analysis, it was demonstrated that significant positive relationships among race, gender, generic stressors, SWS, and obesity.[12]

Study 3: Semi-structured interviews were conducted with 15 AA adults with experience in mindfulness meditation[50] to examine cultural relevance of mindfulness. Participants reported that mindfulness could help AAs enhance stress management, reduce depressive symptoms, reduce blood pressure and rates of diabetes, and increase self-awareness and purposefulness. Participants recommended that mindfulness for AAs be adapted to enhance cultural relevance and therapeutic value. Suggested adaptations included emphasizing health benefits, connecting it to culturally specific practices and values in the AA community, and implementing a "buddy system" to sustain mindfulness practice.

Study 4: 68 AA adults were enrolled to compare a mindfulness-based pre-diabetes (MPD) prevention program to a conventional diabetes prevention program for AA adults (>80% AAW) with pre-diabetes (Grant # R21 AT004276-03),[76,51] using a mixed-methods, two-arm RCT. Participants reported acceptability, credibility, and cultural-relevance of the intervention. Enrollment of eligible participants (79%), session attendance (76.5%), retention (90%), and attendance at three post-intervention data collection sessions (83%, 82%, and 78%, respectively) demonstrated feasibility. MPD resulted in reductions in perceived stress and BMI, reduced calorie, fat, and carbohydrate intake, and improved quality of life. Both groups reported increased knowledge about strategies to improve diet and exercise. MDP participants reported using mindfulness, breathing techniques, and conscious eating behaviors, and were more aware of stress. Participants recommended improvements that form the basis for this proposal: 1) explicit discussion of the potential impact of culturally-relevant, contextualized stressors for AAW; 2) incorporation of strategies in the mindfulness sessions for overcoming guilt and resistance to self-sacrifice by enhancing self-compassion; and 3) incorporating strategies to help AAW overcome physical and psychological barriers to home-based mindfulness practice, exercise, and healthy eating (e.g., accountability partners).

Study 5: The SWS Questionnaire was evaluated in a mixed-methods study in three samples of demographically diverse AAW across the US. (n=48; n=561; n=130)[20] . A a five-factor structure was confirmed consistent with the SWS conceptual framework (see above in Study 2) and strong psychometric properties[20,38] The majority of participants endorsed SWS. Significant, positive associations between SWS and use of food to cope with stress, poor sleep, and physical inactivity, among others were found– all factors associated with increased CM risk.[20,38] Participants were also engaged in identifying strategies to improve feasibility and engagement of MPD. AAW wanted more mindfulness, diet and fitness education, more classes, and support for new habit development followed by maintenance support. Participants suggested increased motivational support, fun physical activities as exercise, and a "buddy system." Participants discussed culturally-relevant stress (i.e., SWS, NS) and desires to balance caregiving responsibilities with stress reduction and better health. We integrated all suggestions into the proposed intervention and are using the SWS conceptual framework and

questionnaire.[38]

3 OUTCOMES AND ENDPOINTS

OUTCOMES	ENDPOINTS
Primary	
1.1 Change in amount of moderate to vigorous physical activity from baseline to 48 weeks after first group session	The participant's moderate to vigorous physical activity will be measured by triaxial accelerometry. Results will be reported in minutes, with higher numbers indicating a higher amount of moderate to vigorous physical activity.
1.2 Change in the dietary risk assessment score from baseline to 48 weeks after first group session	The participant's dietary intake will be assessed using the dietary risk assessment, which includes 54 items. The dietary risk assessment measures the healthiness of a participant's eating habits. Score ranges from 0 to 108, with higher scores associated with less healthy dietary intake.
1.3 Change in veggie meter score from baseline to 48 weeks after first group session	The participant's nutrition will be assessed using the veggie meter, which uses light reflectance spectroscopy to provide an estimate skin carotenoid composite score. Score ranges from 0 to 800, with higher scores associated with greater fruit and vegetable intake.
Secondary	
2.1 Change in BMI from baseline to 48 weeks after first group session	The participant's BMI is calculated as weight (kg) divided by height (cm).
2.2 Change in weight from baseline to 48 weeks after first group session	The participant's weight will be measured using a digital scale.
2.3 Change in waist-to-hip ratio from baseline to 48 weeks after first group session	The participant's waist to hip ratio is calculated by using the mean of two waist circumference measurements divided by mean of two hip circumference measurements. Waist circumference will be measured at the midpoint between the upper iliac crest and lower costal margin in the midaxillary line. Hip circumference will be measured at the maximum width of the buttocks or gluteo-femoral fold.
2.4 Change in percent body fat from baseline to 48 weeks after first group session	The participant's percent body fat is measured using lange skinfold calipers. The final measurement will be the mean of three measurements on the right side of the body.
2.5 Change in in blood pressure (systolic blood pressure/diastolic blood pressure) from baseline to 48 weeks after first group session	The participant's blood pressure is measured using an electronic sphygmomanometer. The final measurement will be the mean of three measurements.
2.6 Change in high sensitivity C-reactive protein amount from baseline to 48 weeks after first group session	The participant's high sensitivity C-reactive protein levels will be obtained via phlebotomy.

OUTCOMES	ENDPOINTS
2.7 Change in IL-6 amount from baseline to 48 weeks after first group session	The participant's IL-6 levels will be obtained via phlebotomy.
2.8 Change in glycosylated hemoglobin amount from baseline to 48 weeks after first group session	The participant's glycosylated hemoglobin levels will be obtained via phlebotomy.
Tertiary/Exploratory	
3.1 Change in Five Facet Mindfulness Scale from baseline to 16 weeks after first group session	The participant's level of mindfulness will be measured using the Five Facet Mindfulness Scale, which includes 39 items on a 5-point scale. The Five Facet Mindfulness Scale measures observing, the ability to verbally express one's experience, acting with awareness, nonjudging of inner experience, and non-reacting to one's inner experience. Score ranges from 1-5, with higher scores associated with a higher level of mindfulness.
3.2 Change in Five Facet Mindfulness Scale from baseline to 32 weeks after first group session	The participant's level of mindfulness will be measured using the Five Facet Mindfulness Scale, which includes 39 items on a 5-point scale. The Five Facet Mindfulness Scale measures observing, the ability to verbally express one's experience, acting with awareness, nonjudging of inner experience, and non-reacting to one's inner experience. Score ranges from 1-5, with higher scores associated with a higher level of mindfulness.
3.3 Change in Five Facet Mindfulness Scale from baseline to 48 weeks after first group session	The participant's level of mindfulness will be measured using the Five Facet Mindfulness Scale, which includes 39 items on a 5-point scale. The Five Facet Mindfulness Scale measures observing, the ability to verbally express one's experience, acting with awareness, nonjudging of inner experience, and non-reacting to one's inner experience. Score ranges from 1-5, with higher scores associated with a higher level of mindfulness.
3.4 Change in Perceived Stress Scale from baseline to 16 weeks after first group session	The participant's general stress will be measured using the PSS-14, which includes 14 items on a 5-point scale. Scores range 0-56, with higher scores indicating greater perceived stress.
3.5 Change in Perceived Stress Scale from baseline to 32 weeks after first group session	The participant's general stress will be measured using the PSS-14, which includes 14 items on a 5-point scale. Scores range 0-56, with higher scores indicating greater perceived stress.
3.6 Change in Perceived Stress Scale from baseline to 48 weeks after first group session	The participant's general stress will be measured using the PSS-14, which includes 14 items on a 5-point scale. Scores range 0-56, with higher scores indicating greater perceived stress.
3.7 Change in Network Stress Scale from baseline to 16 weeks after first group session	The participant's indirect and self-stress will be measured using the Network Stress Scale, which includes 10 items on a 4-point scale. The Network Stress scale assesses both exposure and appraisal of events that happened to both

OUTCOMES	ENDPOINTS
	self and close family members and friends. Higher scores represent higher exposure and appraisal. Score ranges from 0, with 10 scores associated with a higher amount of indirect and self-stress.
3.8 Change in Network Stress Scale from baseline to 32 weeks after first group session	The participant's indirect and self-stress will be measured using the Network Stress Scale, which includes 10 items on a 4-point scale. The Network Stress scale assesses both exposure and appraisal of events that happened to both self and close family members and friends. Higher scores represent higher exposure and appraisal. Score ranges from 0, with 10 scores associated with a higher amount of indirect and self-stress.
3.9 Change in Network Stress Scale from baseline to 48 weeks after first group session	The participant's indirect and self-stress will be measured using the Network Stress Scale, which includes 10 items on a 4-point scale. The Network Stress scale assesses both exposure and appraisal of events that happened to both self and close family members and friends. Higher scores represent higher exposure and appraisal. core ranges from 0, with 10 scores associated with a higher amount of indirect and self-stress.
3.10 Change in Giscombe Superwoman Schema Questionnaire from baseline to 16 weeks after first group session	The participant's endorsement of Superwoman Schema will be measured using the Giscombe Superwoman Schema Questionnaire, which includes 35 items, divided in 5 subscales, on a 4-point scale, ranging from 0 to 3. The Giscombe Superwoman Schema Questionnaire measures obligation to present an image of strength, obligation to suppress emotions, resistance to vulnerability, intense motivation to succeed, obligation to help others. There are 5 different subscales for the superwoman schema, so participants will report 5 different scores. Score ranges for each subscale are 0-18 (strength), 0-21 (suppress emotions), 0-21 (resistance to vulnerability), 0-18 (motivation to succeed), 0-27 (obligation to help others), with higher scores associated with a greater endorsement of the selected superwoman schema scale characteristic.
3.11 Change in Superwoman Schema Questionnaire from baseline to 32 weeks after first group session	The participant's endorsement of Superwoman Schema will be measured using the Giscombe Superwoman Schema Questionnaire, which includes 35 items, divided in 5 subscales, on a 4-point scale, ranging from 0 to 3. The Giscombe Superwoman Schema Questionnaire measures obligation to present an image of strength, obligation to suppress emotions, resistance to vulnerability, intense motivation to succeed, obligation to help others. There are 5 different subscales for the superwoman schema, so participants will report 5 different scores. Score ranges for each subscale are 0-18 (strength), 0-21 (suppress

OUTCOMES	ENDPOINTS
	emotions), 0-21 (resistance to vulnerability), 0-18 (motivation to succeed), 0-27 (obligation to help others), with higher scores associated with a greater endorsement of the selected superwoman schema scale characteristic.
3.12 Change in Superwoman Schema Questionnaire from baseline to 48 weeks after first group session	The participant's endorsement of Superwoman Schema will be measured using the Giscombe Superwoman Schema Questionnaire, which includes 35 items, divided in 5 subscales, on a 4-point scale, ranging from 0 to 3. The Giscombe Superwoman Schema Questionnaire measures obligation to present an image of strength, obligation to suppress emotions, resistance to vulnerability, intense motivation to succeed, obligation to help others. There are 5 different subscales for the superwoman schema, so participants will report 5 different scores. Score ranges for each subscale are 0-18 (strength), 0-21 (suppress emotions), 0-21 (resistance to vulnerability), 0-18 (motivation to succeed), 0-27 (obligation to help others), with higher scores associated with a greater endorsement of the selected superwoman schema scale characteristic.
3.13 Change in the Mindful Eating Questionnaire from baseline to 16 weeks after first group session	The participant's mindful eating will be measured using the Mindful Eating Questionnaire, which includes 28 items on a 4-point scale. Score ranges from 1 to 4, with higher scores associated with more mindful eating.
3.14 Change in the Mindful Eating Questionnaire from baseline to 32 weeks after first group session	The participant's mindful eating will be measured using the Mindful Eating Questionnaire, which includes 28 items on a 4-point scale. Score ranges from 1 to 4, with higher scores associated with more mindful eating.
3.15 Change in the Mindful Eating Questionnaire from baseline to 48 weeks after first group session	The participant's mindful eating will be measured using the Mindful Eating Questionnaire, which includes 28 items on a 4-point scale. Score ranges from 1 to 4, with higher scores associated with more mindful eating.
3.16 Change in the Mindful Self-Care Scale from baseline to 16 weeks after first group session	The participant's self-care will be measured using the Mindful Self-Care scale, which includes 42 items on a 5-point scale. The Mindful Self-Care scale assesses 6 domains of self-care: physical care, supportive relationships, mindful awareness, self-compassion and purpose, mindful relaxation, and supportive structure. Score ranges from 1 to 5, with higher scores higher associated with more self-care.
3.17 Change in the Mindful Self-Care Scale from baseline to 32 weeks after first group session	The participant's self-care will be measured using the Mindful Self-Care scale, which includes 42 items on a 5-point scale. The Mindful Self-Care scale assesses 6 domains of self-care: physical care, supportive relationships, mindful awareness, self-compassion and purpose, mindful relaxation, and supportive structure. Score ranges from 1 to 5, with higher scores associated with more self-care.

OUTCOMES	ENDPOINTS
3.18 Change in the Mindful Self-Care Scale from baseline to 48 weeks after first group session	The participant's self-care will be measured using the Mindful Self-Care scale, which includes 42 items on a 5-point scale. The Mindful Self-Care scale assesses 6 domains of self-care: physical care, supportive relationships, mindful awareness, self-compassion and purpose, mindful relaxation, and supportive structure. Score ranges from 1 to 5, with higher scores associated with more self-care.
3.19 Change in the Cognitive Emotion Regulation Questionnaire from baseline to 16 weeks after first group session	The participant's cognitive emotion regulation strategies will be measured using the Cognitive Emotion Regulation questionnaire, which includes 20 items on a 5-point scale. The Cognitive Emotion Regulation Questionnaire assesses the sub-scales of self-blame, other-blame, rumination, catastrophizing, positive refocusing, planning, positive reappraisal, putting into perspective and acceptance. Scores for each sub-scale ranges from 2 to 10, with higher scores associated with an increased usage of a specific cognitive strategy.
3.20 Change in the Cognitive Emotion Regulation Questionnaire from baseline to 32 weeks after first group session	The participant's cognitive emotion regulation strategies will be measured using the Cognitive Emotion Regulation questionnaire, which includes 20 items on a 5-point scale. The Cognitive Emotion Regulation Questionnaire assesses the sub-scales of self-blame, other-blame, rumination, catastrophizing, positive refocusing, planning, positive reappraisal, putting into perspective and acceptance. Scores for each sub-scale ranges from 2 to 10, with higher scores associated with an increased usage of a specific cognitive strategy.
3.21 Change in the Cognitive Emotion Regulation Questionnaire from baseline to 48 weeks after first group session	The participant's cognitive emotion regulation strategies will be measured using the Cognitive Emotion Regulation questionnaire, which includes 20 items on a 5-point scale. The Cognitive Emotion Regulation Questionnaire assesses the sub-scales of self-blame, other-blame, rumination, catastrophizing, positive refocusing, planning, positive reappraisal, putting into perspective and acceptance. Scores for each sub-scale ranges from 2 to 10, with higher scores associated with an increased usage of a specific cognitive strategy.
3.22 Change in the PROMIS Self-Efficacy for Managing Emotions- Short Form from baseline to 16 weeks after first group session	The participant's management of emotions will be measured using the PROMIS Self-Efficacy for Managing Emotions, which includes 4 items on a 5-point scale. The PROMIS Self-Efficacy for Managing Emotions assesses the participant's confidence to manage and control symptoms stress, discouragement, disappointment, and negative feelings. Score ranges from 5 to 20, with higher scores associated with a higher confidence level in managing symptoms.

OUTCOMES	ENDPOINTS
3.23 Change in the PROMIS Self-Efficacy for Managing Emotions- Short Form from baseline to 32 weeks after first group session	The participant's management of emotions will be measured using the PROMIS Self-Efficacy for Managing Emotions, which includes 4 items on a 5-point scale. The PROMIS Self-Efficacy for Managing Emotions assesses the participant's confidence to manage and control symptoms stress, discouragement, disappointment, and negative feelings. Score ranges from 5 to 20, with higher scores associated with a higher confidence level in managing symptoms.
3.24 Change in the PROMIS Self-Efficacy for Managing Emotions- Short Form from baseline to 48 weeks after first group session	The participant's management of emotions will be measured using the PROMIS Self-Efficacy for Managing Emotions, which includes 4 items on a 5-point scale. The PROMIS Self-Efficacy for Managing Emotions assesses the participant's confidence to manage and control symptoms stress, discouragement, disappointment, and negative feelings. Score ranges from 5 to 20, with higher scores associated with a higher confidence level in managing symptoms.
3.25 Change in the PROMIS Emotional Distress- Depression Short Form 4a from baseline to 16 weeks after first group session	The participant's depressive symptoms will be assessed using the PROMIS Emotional Distress- Depression Scale, which includes 4 items on a 5-point scale. The PROMIS Emotional Distress-Depression Scale assesses self-reported negative mood, views of self, social cognition, and decreased positive affect and engagement. Scores range from 5 to 20, with higher scores associated with a higher degree of depressive symptoms.
3.26 Change in the PROMIS Emotional Distress- Depression Short Form 4a from baseline to 32 weeks after first group session	The participant's depressive symptoms will be assessed using the PROMIS Emotional Distress- Depression Scale, which includes 4 items on a 5-point scale. The PROMIS Emotional Distress-Depression Scale assesses self-reported negative mood, views of self, social cognition, and decreased positive affect and engagement. Scores range from 5 to 20, with higher scores associated with a higher degree of depressive symptoms.
3.27 Change in the PROMIS Emotional Distress- Depression Short Form 4a from baseline to 48 weeks after first group session	The participant's depressive symptoms will be assessed using the PROMIS Emotional Distress- Depression Scale, which includes 4 items on a 5-point scale. The PROMIS Emotional Distress-Depression Scale assesses self-reported negative mood, views of self, social cognition, and decreased positive affect and engagement. Scores range from 5 to 20, with higher scores associated with a higher degree of depressive symptoms.
3.28 Change in the Connor-Davidson Resilience Scale from baseline to 16 weeks after first group session	The participant's resilience will be measured using the Connor-Davidson Resilience Scale, which includes 10 items on a 4-point scale. The Connor-Davidson Resilience Scale assesses ability to adapt to change, achievement of goals

OUTCOMES	ENDPOINTS
	despite obstacles, and how participants handle strong feelings. Score ranges from 0 to 40, with higher scores associated with increased resiliency.
3.29 Change in the Connor-Davidson Resilience Scale from baseline to 32 weeks after first group session	The participant's resilience will be measured using the Connor-Davidson Resilience Scale, which includes 10 items on a 4-point scale. The Connor-Davidson Resilience Scale assesses ability to adapt to change, achievement of goals despite obstacles, and how participants handle strong feelings. Score ranges from 0 to 40, with higher scores associated with increased resiliency.
3.30 Change in the Connor-Davidson Resilience Scale from baseline to 48 weeks after first group session	The participant's resilience will be measured using the Connor-Davidson Resilience Scale, which includes 10 items on a 4-point scale. The Connor-Davidson Resilience Scale assesses ability to adapt to change, achievement of goals despite obstacles, and how participants handle strong feelings. Score ranges from 0 to 40, with higher scores associated with increased resiliency.
3.31 Change in the Contextualized Stress Measure from baseline to 16 weeks after first group session	The participant's racial and gendered stress exposure will be measured using the Contextualized Stress Measure, which includes 69 items on a 5-point scale. The Contextualized Stress Measure is divided into six subscales, including race/racism, burden, personal history, workplace, coping and support, and stress states. Score ranges from 0 to 345, with higher scores associated with increased stress exposure.
3.32 Change in the Contextualized Stress Measure from baseline to 32 weeks after first group session	The participant's racial and gendered stress exposure will be measured using the Contextualized Stress Measure, which includes 69 items on a 5-point scale. The Contextualized Stress Measure is divided into six subscales, including race/racism, burden, personal history, workplace, coping and support, and stress states. Score ranges from 0 to 345, with higher scores associated with increased stress exposure.
3.33 Change in the Contextualized Stress Measure from baseline to 48 weeks after first group session	The participant's racial and gendered stress exposure will be measured using the Contextualized Stress Measure, which includes 69 items on a 5-point scale. The Contextualized Stress Measure is divided into six subscales, including race/racism, burden, personal history, workplace, coping and support, and stress states. Score ranges from 0 to 345, with higher scores associated with increased stress exposure.
3.34 Change in the Diet Self Efficacy Scale from baseline to 16 weeks after first group session	The participant's perceived self-efficacy for healthy eating will be measured using the Diet Self-Efficacy scale, which includes 11 items on a 5-point scale. The Diet Self Efficacy Scale assesses high caloric food temptations, social and internal factors, and negative emotional events which

OUTCOMES	ENDPOINTS
	impact eating behaviors. Scores range from 0 to 44, with higher perceived self-efficacy for healthy eating.
3.35 Change in the Diet Self Efficacy Scale from baseline to 32 weeks after first group session	The participant's perceived self-efficacy for healthy eating will be measured using the Diet Self-Efficacy scale, which includes 11 items on a 5-point scale. The Diet Self Efficacy Scale assesses high caloric food temptations, social and internal factors, and negative emotional events which impact eating behaviors. Scores range from 0 to 44, with higher perceived self-efficacy for healthy eating.
3.36 Change in the Diet Self Efficacy Scale from baseline to 48 weeks after first group session	The participant's perceived self-efficacy for healthy eating will be measured using the Diet Self-Efficacy scale, which includes 11 items on a 5-point scale. The Diet Self Efficacy Scale assesses high caloric food temptations, social and internal factors, and negative emotional events which impact eating behaviors. Scores range from 0 to 44, with higher perceived self-efficacy for healthy eating.
3.37 Change in the Self Efficacy for Exercise Scale from baseline to 16 weeks after first group session	The participant's perceived self-efficacy for healthy exercise will be measured using the Self-Efficacy for Exercise Scale, which includes 9 items on a 11-point scale. Scores range from 0 to 90, with higher scores associated with higher self-efficacy for exercise.
3.38 Change in the Self Efficacy for Exercise Scale from baseline to 32 weeks after first group session	The participant's perceived self-efficacy for healthy exercise will be measured using the Self-Efficacy for Exercise Scale, which includes 9 items on a 11-point scale. Scores range from 0 to 90, with higher scores associated with higher self-efficacy for exercise.
3.39 Change in the Self Efficacy for Exercise Scale from baseline to 48 weeks after first group session	The participant's perceived self-efficacy for healthy exercise will be measured using the Self-Efficacy for Exercise Scale, which includes 9 items on a 11-point scale. Scores range from 0 to 90, with higher scores associated with higher self-efficacy for exercise.
3.40 Change in amount of moderate to vigorous physical activity from baseline to 16 weeks after first group session	The participant's moderate to vigorous physical activity will be measured by triaxial accelerometry. Results will be reported in minutes, with higher numbers indicating a higher amount of moderate to vigorous physical activity.
3.41 Change in amount of moderate to vigorous physical activity from baseline to 32 weeks after first group session	The participant's moderate to vigorous physical activity will be measured by triaxial accelerometry. Results will be reported in minutes, with higher numbers indicating a higher amount of moderate to vigorous physical activity.
3.42 Change in the dietary risk assessment score from baseline to 16 weeks after first group session	The participant's dietary intake will be assessed using the dietary risk assessment, which includes 54 items. The dietary risk assessment measures the healthiness of a participant's eating habits. Score ranges from 0 to 108, with higher scores associated with less healthy dietary intake.

OUTCOMES	ENDPOINTS
3.43 Change in the dietary risk assessment score from baseline to 32 weeks after first group session	The participant's dietary intake will be assessed using the dietary risk assessment, which includes 54 items. The dietary risk assessment measures the healthiness of a participant's eating habits. Score ranges from 0 to 108, with higher scores associated with less healthy dietary intake.
3.44 Change in veggie meter score from baseline to 16 weeks after first group session	The participant's nutrition will be assessed using the veggie meter, which uses light reflectance spectroscopy to provide an estimate skin carotenoid composite score. Score ranges from 0 to 800, with higher scores associated with greater fruit and vegetable intake.
3.45 Change in veggie meter score from baseline to 32 weeks after first group session	The participant's nutrition will be assessed using the veggie meter, which uses light reflectance spectroscopy to provide an estimate skin carotenoid composite score. Score ranges from 0 to 800 with higher scores associated with greater fruit and vegetable intake.
3.46 Change in BMI from baseline to 16 weeks after first group session	The participant's BMI is calculated as weight (kg) divided by height (cm).
3.47 Change in BMI from baseline to 32 weeks after first group session	The participant's BMI is calculated as weight (kg) divided by height (cm).
3.48 Change in weight from baseline to 16 weeks after first group session	The participants weight will be measured using a digital scale.
3.49 Change in weight from baseline to 32 weeks after first group session	The participant's weight will be measured using a digital scale.
3.50 Change in waist-to-hip ratio from baseline to 16 weeks after first group session	The participant's waist to hip ratio is calculated by using the mean of two waist circumference measurements divided by mean of two hip circumference measurements. Waist circumference will be measured at the midpoint between the upper iliac crest and lower costal margin in the midaxillary line. Hip circumference will be measured at the maximum width of the buttocks or gluteo-femoral fold.
3.51 Change in waist-to-hip ratio from baseline to 32 weeks after first group session	The participant's waist to hip ratio is calculated by using the mean of two waist circumference measurements divided by mean of two hip circumference measurements. Waist circumference will be measured at the midpoint between the upper iliac crest and lower costal margin in the midaxillary line. Hip circumference will be measured at the maximum width of the buttocks or gluteo-femoral fold.
3.52 Change in blood pressure (systolic blood pressure/diastolic blood pressure) from baseline to 16 weeks after first group session	The participant's blood pressure is measured using an electronic sphygmomanometer. The final measurement will be the mean of three measurements.
3.53 Change in in blood pressure (systolic blood pressure/diastolic blood pressure) from baseline to 32 weeks after first group session	The participant's blood pressure is measured using an electronic sphygmomanometer. The final measurement will be the mean of three measurements.
3.54 Change in high sensitivity C-reactive protein amount from baseline to 16 weeks after first group session	The participant's high sensitivity C-reactive protein levels will be obtained via phlebotomy.

OUTCOMES	ENDPOINTS
3.55 Change in high sensitivity C-reactive protein amount from baseline to 32 weeks after first group session	The participant's high sensitivity C-reactive protein levels will be obtained via phlebotomy.
3.56 Change in IL-6 amount from baseline to 16 weeks after first group session	The participant's IL-6 levels will be obtained via phlebotomy.
3.57 Change in IL-6 amount from baseline to 32 weeks after first group session	The participant's IL-6 levels will be obtained via phlebotomy.
3.58 Change in glycosylated hemoglobin amount from baseline to 16 weeks after first group session	The participant's glycosylated hemoglobin levels will be obtained via phlebotomy.
3.59 Change in glycosylated hemoglobin amount from baseline to 32 weeks after first group session	The participant's glycosylated hemoglobin levels will be obtained via phlebotomy.

4 STUDY DESIGN

4.1 OVERALL DESIGN

The HARMONY study is a two-arm, randomized control, single site trial to test the HARMONY experimental group against an attention control group (Nutrition and Exercise Education Workgroup; NEEW). The study will be conducted in 8 cohorts of 25 participants, group sizes of 12-13 randomly assigned to HARMONY and 12-13 to NEEW. The allocation sequence will be generated using permuted blocks (2,4,6). Participants will be told after baseline assessment to anticipate a brief wait (~4 weeks) until 25 participants are accrued in the cohort, at which time participants will be randomized.[77]

The main study hypothesis is that the HARMONY intervention will promote and sustain improvements in health behaviors that lower CM risk factors in AAW through improved management of stress.

HARMONY is an intervention to help AAW manage chronic stress and develop and sustainable new healthy habits for exercise and eating as a means of self-care, despite pervasive environmental and sociocultural challenges and caregiving demands. A 16-week program using an approach based on mindfulness, HARMONY is designed to be scaled and translated for use in community settings serving AAW. Unique in length and focus on managing culturally-relevant stressors specific to AAW, who face high CM risk, HARMONY – unlike nutrition and exercise-only active control interventions – focuses specifically on mindful self-management of negative emotions and behaviors that may impact adherence to sufficient self-care engagement, adequate exercise, and/or healthy eating habits.[50,78, 79,] The goal of HARMONY is to provide AAW with strategies to address stress cognitively and emotionally in a way that simultaneously honors their desire to care for their families and communities while harmoniously and successfully integrating sustained engagement in exercise and healthy eating through improvements in mindfulness, positive reappraisal, self-regulation, and self-efficacy. Accordingly, AAW will have reduced psychological distress and improved resilience to stress,[80-82] address barriers to sustaining their healthy lifestyle changes.

The NEEW group includes only the culturally tailored nutrition education and exercise program, which does not address mindfulness, positive reappraisal, self-regulation, and self-efficacy, stress management, or SWS.

Participants will be engaged for approximately 13 months, which includes the following:

- Screening telephone call
- Pre-baseline period
- Baseline visit
- 8 biweekly HARMONY/NEEW sessions over a 16-week period (e.g., weeks 1, 3, 5, 7, 9, 11, 13, 15),
- 6 monthly booster sessions.
- Follow-up assessments at 16, 32, and 48 weeks post first group session

4.2 SCIENTIFIC RATIONALE FOR STUDY DESIGN

The HARMONY study's cohort group sizes (12-13) is consistent with prior mindfulness research yielding moderately high group cohesion, intervention credibility, and information uptake.

To facilitate the attention control design, NEEW participants will have the same amount of contact with interventionist and encouragement to engage in intervention components and at-home activities.

4.3 END-OF-STUDY DEFINITION

A participant is considered to have completed the study if she has completed the 48-week follow-up assessments.

The end of the study is defined as completion of the 48-week follow-up assessments shown in the Schedule of Activities (SoA), **Section 1.3** for all subjects.

5 STUDY POPULATION

5.1 INCLUSION CRITERIA

To be eligible to participate in this study, an individual must meet all the following criteria:

1. Self-reported African American or Black woman
2. BMI= 25-39 kg/m2 (confirmed at baseline assessment)
3. At least one cardiometabolic risk factor:
    a. < 150 minutes of self-reported moderate to vigorous exercise per week
    b. History of gestational diabetes
    c. Parent or sibling with prediabetes or diabetes
    d. Personal or family history of hypertension (≥130/80)
    e. Prediabetes or impaired glucose metabolism (HgbA1c=5.7-≤6.5)
    f. Personal or family history of abnormal cholesterol levels
4. At least 18 years of age
5. Able to read/speak English

6. Willing to attend scheduled classes, complete internet surveys and biomarker assessments
7. Able/willing to engage in moderate to vigorous exercise
8. Ambulatory
9. Superwoman Schema Questionnaire score indicating at least moderate endorsement of one or more subscales (strength: 7; emotional suppression: 7; resistance of vulnerability: 8; motivation to succeed: 7; or helping others: 10) or a total score of 20 or greater.
10. A Perceived Stress Scale-14 score of >5 or self-report at least "some" general stress.
11. Willing to agree to be randomized between the two culturally-tailor programs.
12. Willing to not share group assignment for the study.

5.2 EXCLUSION CRITERIA

An individual who meets any of the following criteria will be excluded from participation in this study:

1. Pregnant/anticipated pregnancy
2. Substance use, mental health or medical condition that will prevent your ability to participate in the intervention
3. Use of weight loss medication
4. Current or recent (<6 months prior to enrollment) engagement in another weight loss or meditation program
5. Impaired cognition (inability to follow and respond appropriately during screening)
6. Diabetes diagnosis
7. Lives in the same household as someone who is currently in the study or was previously in the study.

5.3 LIFESTYLE CONSIDERATIONS

During this study, participants are asked to:

- Refrain from starting weight loss medications/nutritional supplements taken for weight loss
- Refrain from starting any weight loss or meditation program

5.4 SCREEN FAILURES

Screen failures are defined as participants who consent to participate in this study but are not subsequently assigned to the study intervention or control group. Individuals who do not meet the criteria for participation in this trial (screen failure) because of meeting one or more exclusion criteria that are likely to change over time may be rescreened. Examples include a new diagnosis or new family history.

5.5 STRATEGIES FOR RECRUITMENT AND RETENTION

Please refer section B.1 of the UNC IRB application for the recruitment plan.

6 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S)

6.1 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S) ADMINISTRATION

6.1.1 STUDY INTERVENTION OR EXPERIMENTAL MANIPULATION DESCRIPTION

HARMONY INTERVENTION:

The HARMONY intervention is the experimental intervention for this trial. The HARMONY intervention will also be referred to as the "purple group".

The HARMONY intervention uses three strategies:

- Mindfulness, with enhanced content on stressors unique to AAW, mindful self-compassion and mindful loving-kindness (LKM), specifically targeting caregiving, self-sacrifice, guilt related to self-care engagement; [83-86]
- Mindfulness-based positive reappraisal, self-regulation, and self-efficacy strategies to resolve barriers to mindfulness-based positive reappraisal, self-regulation, and self-efficacy strategies to resolve barriers to engagement in mindful self-care practices in context of culturally-relevant stress and/or caregiving obligations; and
- Strategies to address cognitive-emotional barriers to self-care (e.g., guilt related to engaging in self-care)[33-37,86-90] by developing new health-promoting cognitive and behavioral strategies.

The HARMONY intervention will be delivered over 8 every-other-week sessions and 6 booster sessions by trained study interventionists. Each class will have three components:

- Exercise sampler (e.g., Zumba®, African dance, weightlifting)[92-94]
- Mindfulness cool down
- Tailored education on CM condition prevention and risk reduction

NEEW INTERVENTION:

The control intervention is referred to as the NEEW (Nutrition and Exercise Education Workgroup) intervention. The control intervention will be referred to as the "gold group".

The NEEW group includes only culturally tailored nutrition and exercise, and does not address mindfulness, positive reappraisal, self-regulation, self-efficacy, stress management, or SWS.

The NEEW intervention will be delivered over 8 every-other-week sessions and 6 booster sessions by trained study interventionists. Each class will have three components:

- Exercise sampler (e.g., Zumba®, African dance, weightlifting)[92-94]
- Stretching/cool down
- Tailored education on CM condition prevention and risk reduction.

6.1.2 ADMINISTRATION

The HARMONY and NEEW interventions will be delivered over 8 every-other-week sessions and 6 booster sessions. All intervention sessions will be led by various interventionists:

- A personal trainer to facilitate the exercise portion of the session;
- A health educator (not trained in mindfulness) who will deliver the CM prevention and risk-reduction education; and
- A mindfulness instructor who will deliver the mindfulness cool down (for HARMONY group only).

The personal trainer and health educator will lead both the HARMONY and NEEW groups, however they will be instructed to not speak about the other group to ensure blinding.

Participants will interact with others in their group during the study but will not have contact with participants outside of their group. A "buddy system" will also be implemented where participants will be encouraged to communicate with their buddy to enhance accountability.

All intervention sessions will be delivered over secure teleconferencing platforms (e.g. Zoom) due to the COVID-19 pandemic.

6.2 FIDELITY

6.2.1 INTERVENTIONIST TRAINING AND TRACKING

All intervention (NEEW and HARMONY) sessions will be audio-recorded for fidelity purposes. The fidelity lead will listen to or observe these sessions and will report blinded findings to the PIs. If necessary, the PIs will review findings with the interventionists and address barriers to adherence.

Interventionists will review all session outlines and complete mock Zoom sessions with the study team prior to the first group session. Further details about the interventionist training are in the interventionist training plan.

6.3 MEASURES TO MINIMIZE BIAS: RANDOMIZATION AND BLINDING

The study statistician will generate the allocation sequence using permuted blocks (2, 4, 6).

The study PIs, statisticians, and participants will be blinded to intervention assignment. The blind may be intentionally broken in case of an unexpected SAE or for other safety reasons. If the blind is broken intentionally, it will be recorded in the report of the event that caused the broken blind. The blind may also be broken intentionally for participants at the end of their participation by providing them with a debriefing statement to explain the two interventions. If the blind is broken unintentionally (e.g. an interventionist accidentally revealing a study group assignment to a PI), this will be reported to the appropriate regulatory authorities if applicable.

To keep participants blinded, participants will be told during the recruitment and consenting process that they will be placed into one of two culturally tailored nutrition and exercise groups. The participants will be provided a debriefing statement at the end of their participation to explain the difference between the two groups, and to ask them not to disclose information to others about the different assignments.

To prevent accidental unblinding, it will be very clear who is blinded to all members of the study team. The study team will be encouraged to take all questions and comments to an unblinded study team member prior to presenting them to blinded study team members, to ensure that the content of the question or comment would not inadvertently unblind them. In addition, documents that list intervention assignments will be limited and labeled appropriately to ensure blinded team members do not accidentally review them. Appropriate study team personnel will be trained to ensure the integrity of the study blind.

6.4 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION ADHERENCE

Participants' adherence to study procedures will be tracked in the following ways:

- Documenting attendance at all sessions
- Documenting attendance at data collection visits (4, 8, 12 months post first session)
- Review of data in the Fitabase system

6.5 CONCOMITANT THERAPY

During their participation in the study, subjects will be asked to refrain from taking any weight loss medication or supplements or enrolling in weight loss or meditation programs.

7 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

7.1 DISCONTINUATION OF STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

When a subject discontinues from HARMONY/NEEW but not from the study, remaining study procedures will be completed as indicated by the study protocol. If a clinically significant finding is identified

(including, but not limited to changes from baseline) after enrollment, the investigator or qualified designee will determine if any change in participant management is needed. Any new clinically relevant finding will be reported as an adverse event (AE).

The data to be collected at the time of study intervention discontinuation will include the reason(s) for discontinuing the participant from the intervention.

7.2 PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

Participants are free to withdraw from participation in the study at any time upon request.
An investigator may discontinue a participant from the study for the following reasons:

- Significant study intervention non-compliance
- If the participant does not complete their pre-baseline assessments in a timely manner (per investigator judgement)
- Lost-to-follow up; unable to contact subject (see **Section 7.3, Lost to Follow-Up**)
- Any event, medical condition or situation that occurs such that continued collection of follow-up study data would not be in the best interest of the participant or might require an additional treatment that would confound the interpretation of the study
- The participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation

The reason for participant discontinuation or withdrawal from the study will be recorded. Subjects who sign the informed consent form and are randomized but do not receive the study intervention may be replaced. Subjects who sign the informed consent form, are randomized, receive the study intervention, and subsequently withdraw, or are discontinued from the study, will not be replaced.

If a participant becomes pregnant during the study, they will temporarily stop all study procedures. Both the study investigator and the patient's maternity care provider will be consulted to determine if the participant should continue with the study. If those parties agree that it is safe and appropriate, the participant will be allowed to continue with the study if they are willing. If the participant is either unwilling to continue or if the investigator or maternity care provider deem it unsafe for the participant to continue, they will be withdrawn from the study.

7.3 LOST TO FOLLOW-UP

A participant will be considered lost to follow-up if she fails to return for 2 scheduled intervention sessions, or 1 data collection session and study staff are unable to contact the participant after at least 3 attempts.

The following actions must be taken if a participant fails to attend a data collection visit or intervention session (unless there is a documented reason why they were absent):

- The study team will attempt to contact the participant, reschedule the missed visit, counsel the participant on the importance of maintaining the assigned visit schedule and ascertain if the participant wishes to and/or should continue in the study
- Before a participant is deemed lost to follow-up, the investigator or designee will make every effort to regain contact with the participant (where possible, 3 telephone calls and, if necessary, a certified letter to the participant's last known mailing address or local equivalent methods). These contact attempts will be documented in the participant's study file.
- Should the participant continue to be unreachable, she will be considered to have withdrawn from the study with a primary reason of lost to follow-up.

8 STUDY ASSESSMENTS AND PROCEDURES

8.1 ENDPOINT AND OTHER ASSESSMENTS

The procedures and assessments described in this section will be performed at the time points described in the schedule of activities in section 1.3.

Endpoint Assessments

Superwoman Schema Questionnaire

The participant's endorsement of Superwoman Schema will be measured using the Giscombe Superwoman Schema Questionnaire, which includes 35 items, divided in 5 subscales, on a 4-point scale, ranging from 0 to 3. The Giscombe Superwoman Schema Questionnaire measures obligation to present an image of strength, obligation to suppress emotions, resistance to vulnerability, intense motivation to succeed, obligation to help others. There are 5 different subscales for the superwoman schema, so participants will report 5 different scores. Score ranges for each subscale are 0-18 (strength), 0-21 (suppress emotions), 0-21 (resistance to vulnerability), 0-18 (motivation to succeed), 0-27 (obligation to help others), with higher scores associated with a greater endorsement of the selected superwoman schema scale characteristic.

This questionnaire will be performed at telephone screening and 16, 32, and 48 weeks post first group session. The data will be entered electronically by the patient through REDCap survey; however, paper copies of the questionnaire may be used if necessary.

Perceived Stress Scale

The participant's general stress will be measured using the PSS-14, which includes 14 items on a 5-point scale. Scores range 0-56, with higher scores indicating greater perceived stress.

This questionnaire will be performed at telephone screening and 16, 32, and 48 weeks post first group session. The data will be entered electronically by the patient through REDCap survey; however, paper copies of the questionnaire may be used if necessary.

Actigraphy

Participants will be given a triaxial ActiGraph Activity Monitor at baseline and 16, 32, and 48 weeks post first group session. Participants will be instructed to wear the ActiGraph Activity Monitor for 7 consecutive days. Participants will be instructed how to wear the ActiGraph Activity Monitor and special instructions for care by study personnel.

For the purposes of this study, the participant's moderate to vigorous physical activity will be measured. Moderate to vigorous physical activity is defined as activities that are strenuous enough to burn off three to six times as much energy per minutes as one does when sitting quietly, or exercises that clock in at 3 to 6 METs.

Dietary Risk Assessment

The participant's dietary intake will be assessed using the dietary risk assessment, which includes 54 items. The dietary risk assessment measures the healthiness of a participant's eating habits. Score ranges from 0 to 108, with higher scores associated with less healthy dietary intake.

This questionnaire will be performed at baseline and 16, 32, and 48 weeks post first group session. The data will be entered electronically by the patient through REDCap survey; however, paper copies of the questionnaire may be used if necessary.

Veggie Meter

The participant's fruit and vegetable intake will be measured by the participant's skin carotenoids. The Veggie Meter uses a pressure-mediated reflection spectroscopy device to measure these carotenoids. Study personnel will calibrate the Veggie Meter as needed, and then ask the participant to wash their hands with soap and water. The participant will then place their finger in the cradle of the meter, and will hold it there until the scan is complete.

The Veggie Meter procedure will be performed at baseline and 16, 32, and 48 weeks post first group session.

Weight and Height

The participant's weight will be measured using an electronic scale. Weight will be converted to kilograms to calculate participant BMI. The participant's height will be measured to the nearest centimeter to calculate participant BMI.

Weight will be performed at baseline and 16, 32, and 48 weeks post first group session. Height will be performed at baseline, and is optional to perform at 16, 32, and 48 weeks post first group session.

Hip Circumference

Hip circumference will be measured at the maximum width of the buttocks or gluteo-femoral fold. Two measurements will be recorded by study personnel. The mean of these measurements will be used for the waist-to-hip ratio.

Hip circumference will be measured at baseline and 16, 32, and 48 weeks post first group session.

Waist Circumference

Waist circumference will be measured at the midpoint between the upper iliac crest and lower costal margin in the midaxillary line. Study personnel will record two waist circumference measurements. The mean of these measurements will be used for the waist-to-hip ratio.

Waist circumference will be measured at baseline and 16, 32, and 48 weeks post first group session.

Il-6 and CRP

Specimens for the measurement of IL-6 and CRP will be collected using standard venipuncture.

The phlebotomy procedure to obtain the IL-6 and CRP measurements will be completed at baseline and 16, 32, and 48 weeks post first group session.

HgbA1C

HgbA1C will be assessed using a fingerstick procedure at baseline and 16, 32, and 48 weeks post first group session.

Blood Pressure

Blood pressure will be collected by an electronic sphygmomanometer after a five-minute rest in the sitting position. Study personnel will record three blood pressure measurements, and the average value will be used for analysis.

Blood pressure will be measured at baseline and 16, 32, and 48 weeks post first group session.

Contextualized Stress Scale

The participant's racial and gendered stress exposure will be measured using the Contextualized Stress Measure, which includes 69 items on a 5-point scale. The Contextualized Stress Measure is divided into six subscales, including race/racism, burden, personal history, workplace, coping and support, and stress states. Score ranges from 0 to 345, with higher scores associated with increased stress exposure.

This questionnaire will be performed at baseline and 16, 32, and 48 weeks post first group session. The data will be entered electronically by the patient through REDCap survey; however, paper copies of the questionnaire may be used if necessary.

Network Stress Scale

The participant's indirect and self-stress will be measured using the Network Stress Scale, which includes 10 items on a 4-point scale. The Network Stress scale assesses both exposure and appraisal of events that happened to both self and close family members and friends. Higher scores represent higher exposure and appraisal. Score ranges from 0, with 10 scores associated with a higher amount of indirect and self-stress.

This questionnaire will be performed during the pre-baseline period and 16, 32, and 48 weeks post first group session. The data will be entered electronically by the patient through REDCap survey; however, paper copies of the questionnaire may be used if necessary.

Mindful Eating Questionnaire

The participant's mindful eating will be measured using the Mindful Eating Questionnaire, which includes 28 items on a 4-point scale. Score ranges from 1 to 4, with higher scores associated with more mindful eating.

This questionnaire will be performed during the pre-baseline period and 16, 32, and 48 weeks post first group session. The data will be entered electronically by the patient through REDCap survey; however, paper copies of the questionnaire may be used if necessary.

Mindful Self-Care Scale

The participant's self-care will be measured using the Mindful Self-Care scale, which includes 42 items on a 5-point scale. The Mindful Self-Care scale assesses 6 domains of self-care: physical care, supportive relationships, mindful awareness, self-compassion and purpose, mindful relaxation, and supportive structure. Score ranges from 1 to 5, with higher scores higher associated with more self-care.

This questionnaire will be performed at performed at baseline and 16, 32, and 48 weeks post first group session. The data will be entered electronically by the patient through REDCap survey; however, paper copies of the questionnaire may be used if necessary.

Cognitive Emotion Regulation Questionnaire

The participant's cognitive emotion regulation strategies will be measured using the Cognitive Emotion Regulation questionnaire, which includes 20 items on a 5-point scale. The Cognitive Emotion Regulation Questionnaire assesses the sub-scales of self-blame, other-blame, rumination, catastrophizing, positive refocusing, planning, positive reappraisal, putting into perspective and acceptance. Scores for each sub-scale ranges from 2 to 10, with higher scores associated with an increased usage of a specific cognitive strategy.

This questionnaire will be performed at performed during the pre-baseline period and 16, 32, and 48 weeks post first group session. The data will be entered electronically by the patient through REDCap survey; however, paper copies of the questionnaire may be used if necessary.

PROMIS Self-Efficacy for Managing Emotions

The participant's management of emotions will be measured using the PROMIS Self-Efficacy for Managing Emotions, which includes 4 items on a 5-point scale. The PROMIS Self-Efficacy for Managing Emotions assesses the participant's confidence to manage and control symptoms stress, discouragement, disappointment, and negative feelings. Score ranges from 5 to 20, with higher scores associated with a higher confidence level in managing symptoms.

This questionnaire will be performed during the pre-baseline period and 16, 32, and 48 weeks post first group session. The data will be entered electronically by the patient through REDCap survey; however, paper copies of the questionnaire may be used if necessary.

PROMIS Emotional Distress-Depression Scale

The participant's depressive symptoms will be assessed using the PROMIS Emotional Distress- Depression Scale, which includes 4 items on a 5-point scale. The PROMIS Emotional Distress-Depression Scale assesses self-reported negative mood, views of self, social cognition, and decreased positive affect and engagement. Scores range from 5 to 20, with higher scores associated with a higher degree of depressive symptoms.

This questionnaire will be performed during the pre-baseline period and 16, 32, and 48 weeks post first group session. The data will be entered electronically by the patient through REDCap survey; however, paper copies of the questionnaire may be used if necessary.

Connor-Davidson Resilience Scale

The participant's resilience will be measured using the Connor-Davidson Resilience Scale, which includes 10 items on a 4-point scale. The Connor-Davidson Resilience Scale assesses ability to adapt to change, achievement of goals despite obstacles, and how participants handle strong feelings. Score ranges from 0 to 40, with higher scores associated with increased resiliency.

This questionnaire will be performed during the pre-baseline period and 16, 32, and 48 weeks post first group session. The data will be entered electronically by the patient through REDCap survey; however, paper copies of the questionnaire may be used if necessary.

Self-Efficacy for Exercise Scale

The participant's perceived self-efficacy for healthy exercise will be measured using the Self-Efficacy for Exercise Scale, which includes 9 items on a 11-point scale. Scores range from 0 to 90, with higher scores associated with higher self-efficacy for exercise.

This questionnaire will be performed at baseline and 16, 32, and 48 weeks post first group session. The data will be entered electronically by the patient through REDCap survey; however, paper copies of the questionnaire may be used if necessary.

Diet Self Efficacy Scale

The participant's perceived self-efficacy for healthy eating will be measured using the Diet Self-Efficacy scale, which includes 11 items on a 5-point scale. The Diet Self Efficacy Scale assesses high caloric food temptations, social and internal factors, and negative emotional events which impact eating behaviors. Scores range from 0 to 44, with higher perceived self-efficacy for healthy eating.

This questionnaire will be performed at baseline and 16, 32, and 48 weeks post first group session. The data will be entered electronically by the patient through REDCap survey; however, paper copies of the questionnaire may be used if necessary.

Five Facet Mindfulness Scale

The participant's level of mindfulness will be measured using the Five Facet Mindfulness Scale, which includes 39 items on a 5-point scale. The Five Facet Mindfulness Scale measures observing, the ability to verbally express one's experience, acting with awareness, nonjudging of inner experience, and non-reacting to one's inner experience. Score ranges from 1-5, with higher scores associated with a higher level of mindfulness.

This questionnaire will be performed at baseline and 16, 32, and 48 weeks post first group session. The data will be entered electronically by the patient through REDCap survey; however, paper copies of the questionnaire may be used if necessary.

Other Assessments

Cardiometabolic Risk Questionnaire

The cardiometabolic risk questionnaire will be performed during the screening period to assess for BMI, exercise frequency, family history, and cardiometabolic medical history.

The data will be entered electronically by the patient through REDCap survey; however, paper copies of the questionnaire may be used if necessary.

Physical Activity Readiness Questionnaire

The physical activity readiness questionnaire will be performed during the screening period to assess if the participant is able to exercise.

The data will be entered electronically by the patient through REDCap survey; however, paper copies of the questionnaire may be used if necessary.

Demographics Questionnaire

The demographics questionnaire will be administered during the screening period to collect information regarding the participant's age, race, socioeconomic class, and other elements.

The data will be entered electronically by the patient through REDCap survey; however, paper copies of the questionnaire may be used if necessary.

Health History Questionnaire

The health history questionnaire will be administered during the screening period to obtain information about the participant's medical history and medication usage.

The data will be entered electronically by the patient through REDCap survey; however, paper copies of the questionnaire may be used if necessary.

University of Rhode Island Change Assessment Scale

The University of Rhode Island Change Assessment Scale assesses the participant's readiness for change. Scores range from +2 to +14.

This questionnaire will be performed during the first group session and at the half-day retreat. The data will be entered electronically by the patient through REDCap survey; however, paper copies of the questionnaire may be used if necessary.

Fitbit Measurements

Fitbit devices will be provided to each participant at the baseline visit. The participant will be instructed to wear the Fitbit consistently for the duration of the study.

A research staff member will create a email and password for each participant to connect the Fitbit device to the Fitabase platform.

Group Cohesion Questionnaire

The Group Cohesion Questionnaire assesses the participant's perception of group cohesion, which includes 12 items on a 7-point scale. Scores range from 12 to 84, with higher scores associated with less group cohesion.

This questionnaire will be performed at group sessions 2 and 7. The data will be entered electronically by the patient through REDCap survey; however, paper copies of the questionnaire may be used if necessary.

Credibility Scale

The credibility scale assesses the participant's expectation of benefit once the intervention has been explained to them. It includes 5 items on a 10-point scale. Scores range from 0 to 45, with higher scores associated with higher expectation on benefit.

This questionnaire will be performed at group sessions 2 and 7. The data will be entered electronically by the patient through REDCap survey; however, paper copies of the questionnaire may be used if necessary.

Buddy System Assessment

The buddy system assessment measures how often participants are communicating with their buddy, barriers to their participation in the buddy system, and other elements regarding the system.

This questionnaire will be performed at all group sessions, and at 16, 32, and 48 weeks post first group session. The data will be entered electronically by the patient through REDCap survey; however, paper copies of the questionnaire may be used if necessary.

Mindfulness Practice Assessment

The mindfulness practice survey assesses how often the participants are practicing mindfulness. This questionnaire will only be given to participants in the HARMONY group.

This questionnaire will be performed at all group sessions, and at 16, 32, and 48 weeks post first group session. The data will be entered electronically by the patient through REDCap survey; however, paper copies of the questionnaire may be used if necessary.

Nutritional Survey

The nutritional survey assess the participants knowledge of nutrition, and also asks about current eating habits.

This questionnaire will be performed prior to group session 1 and 8. The data will be entered electronically through REDCap survey; however, paper copies of the questionnaire may be used if necessary.

General Stress Assessment

The general stress assessment measures the participants overall stress levels. It is a one-question assessment, with answers ranging from 0 (no stress at all) to 3 (extreme stress).

If the participant selects answer choices 1, 2, or 3, they are eligible for the study.

Interview

All participants will have an interview conducted at the 16- and 48-week post first group session timepoint. The interview will ask about participant opinion regarding the interventions, and the HARMONY group participants will be also asked about mindfulness and superwoman schema.

8.2 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

8.2.1 DEFINITION OF ADVERSE EVENTS

This protocol uses the definition of adverse event from the OHRP Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events: “Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporarily associated with the subject’s participation in research, whether or not considered related to the subject’s participation in the research.”

8.2.2 DEFINITION OF SERIOUS ADVERSE EVENTS

This protocol uses the FDA’s definition of serious adverse event as defined in 21CFR312.32 (b):

An adverse event is considered serious if, in the view of either the investigator or sponsor, it results in any of the following outcomes:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolonging of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions; or
- A congenital anomaly/birth defect.

Important medical events that may not results in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgement, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

8.2.3 CLASSIFICATION OF AN ADVERSE EVENT

8.2.3.1 SEVERITY OF EVENT

For adverse events (AEs), the following guidelines will be used to describe severity.

- **Mild** – Events require minimal or no treatment and do not interfere with the participant's daily activities.
- **Moderate** – Events result in a low level of inconvenience or concerns. Moderate events may cause some interference with functioning.
- **Severe** – Events interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating. Of note, the term "severe" does not necessarily equate to "serious".

8.2.3.2 RELATIONSHIP TO STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

All adverse events (AEs) will have their relationship to study procedures, including the intervention, assessed by the study PIs based on temporal relationship and her clinical judgment. The degree of certainty about causality will be graded using the categories below.

- **Definitely Related** – There is clear evidence to suggest a causal relationship, and other possible contributing factors can be ruled out. The clinical event, including an abnormal laboratory test result, occurs in a plausible time relationship to study procedures administration and cannot be explained by concurrent disease or other drugs or chemicals. The response to withdrawal of the study procedures should be clinically plausible. The event must be pharmacologically or phenomenologically definitive.
- **Probably Related** – There is evidence to suggest a causal relationship, and the influence of other factors is unlikely. The clinical event, including an abnormal laboratory test result, occurs within a reasonable time after administration of the study procedures, is unlikely to be attributed to concurrent disease or other drugs or chemicals, and follows a clinically reasonable response on withdrawal.

- **Potentially Related** – There is some evidence to suggest a causal relationship (e.g., the event occurred within a reasonable time after administration of study procedures). However, other factors may have contributed to the event (e.g., the participant's clinical condition, other concomitant events). Although an AE may rate only as "possibly related" soon after discovery, it can be flagged as requiring more information and later be upgraded to "probably related" or "definitely related", as appropriate.
- **Unlikely to be related** – A clinical event, including an abnormal laboratory test result, whose temporal relationship to study procedures administration makes a causal relationship improbable (e.g., the event did not occur within a reasonable time after administration of the study procedures) and in which other drugs or chemicals or underlying disease provides plausible explanations (e.g., the participant's clinical condition, other concomitant treatments).
- **Not Related** – The AE is completely independent of study procedures administration, and/or evidence exists that the event is definitely related to another etiology. There must be an alternative, definitive etiology documented by the clinician.]

8.2.3.3 EXPECTEDNESS

The study PI will be responsible for determining whether an adverse event (AE) is expected or unexpected. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study procedures.

8.2.4 TIME PERIOD AND FREQUENCY FOR EVENT ASSESSMENT AND FOLLOW-UP

The occurrence of an adverse event (AE) or serious adverse event (SAE) may come to the attention of study personnel during study visits, group sessions or other interactions with a study participant, or upon review by a study monitor.

All AEs, not otherwise precluded per the protocol, will be captured on the appropriate case report form (CRF). Information to be collected includes event description, date of onset, PI's assessment of severity, relationship to study procedures (assessed only by those with the training and authority to make a diagnosis), and date of resolution/stabilization of the event. All AEs occurring while on study will be documented appropriately regardless of relationship. All AEs will be followed to adequate resolution.

Any medical or psychiatric condition that is present at the time that the participant is screened will be considered as baseline and not reported as an AE. However, if the study participant's condition deteriorates at any time during the study, it will be recorded as an AE.

Changes in the severity of an AE will be documented to allow an assessment of the duration of the event at each level of severity to be performed. Documentation of onset and duration of each episode will be maintained for AEs characterized as intermittent.

Study personnel will record events with start dates occurring any time after informed consent is obtained until the last day of study participation. At each study visit, study personnel will inquire about the occurrence of AE/SAEs since the last visit. Events will be followed for outcome information until resolution or stabilization.

8.2.5 ADVERSE EVENT REPORTING

Qualifying adverse events will be reported to the NIH funding institute.

8.2.6 SERIOUS ADVERSE EVENT REPORTING

The PIs will be responsible for conducting an evaluation of a serious adverse event. If the evaluation of the event determines that the event is related to the study, the study team shall report the results of such evaluation to the NIH and the reviewing Institutional Review Board (IRB) as soon as possible, but in no event later than 10 working days after the investigator first learns of the event.

8.3 UNANTICIPATED PROBLEMS

8.3.1 DEFINITION OF UNANTICIPATED PROBLEMS

This protocol uses the definition of Unanticipated Problems as defined by the Office for Human Research Protections (OHRP). OHRP considers unanticipated problems involving risks to participants or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the Institutional Review Board (IRB)-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;
- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.]

8.3.2 UNANTICIPATED PROBLEMS REPORTING

The investigator will report unanticipated problems (UPs) to the reviewing Institutional Review Board (IRB). The UP report will include the following information:

- A detailed description of the event, incident, experience, or outcome
- An explanation of the basis for determining that the event, incident, experience, or outcome represents an UP
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP

To satisfy the requirement for prompt reporting, UPs will be reported using the following timeline:

- UPs will be reported to the IRB a within 7 calendar days of the investigator becoming aware of the event

9 STATISTICAL CONSIDERATIONS

9.1 STATISTICAL HYPOTHESES

Primary Endpoints:

For each primary outcome (MVPA, dietary risk, and veggie meter), at each of 16, 32, and 48 weeks, the statistical hypotheses are:

H0: The change in the outcome does not differ between intervention and control groups.
HA: The change in the outcome does differ between intervention and control groups.

Specifically, it is expected that AAW participating in an 8-session culturally relevant mindfulness intervention plus an exercise and nutrition education CM risk-reduction intervention will have greater sustained improvement in exercise and healthy eating behaviors at 16, 32, and 48 weeks post first intervention session, compared to AAW in an attention-control exercise and nutrition education CM risk-reduction intervention without mindfulness.

Secondary Endpoints:
For each secondary outcome (CM risk biomarker), at each of 16, 32, and 48 weeks, the statistical hypotheses are:

H0: The change in the outcome does not differ between intervention and control groups.

HA: The change in the outcome does differ between intervention and control groups.

It is hypothesized that AAW participating in an 8-session culturally relevant mindfulness intervention plus an exercise and nutrition education CM risk-reduction intervention will have greater reduction in CM risk biomarkers at 16, 32, and 48 weeks post first intervention session, compared to AAW in an attention-control exercise and nutrition education CM risk-reduction intervention without mindfulness.

Tertiary Endpoints:

Tertiary outcomes are self-reported mindfulness, stress management, positive reappraisal, self-regulation, and self-efficacy mediate effects of the intervention on exercise and nutrition.

For each tertiary outcome, at each of 16, 32, and 48 weeks, the statistical hypotheses are:

H0: The change in the outcome does not differ between intervention and control groups.
HA: The change in the outcome does differ between intervention and control groups.

9.2 SAMPLE SIZE DETERMINATION

200 participants will be enrolled (100 each in HARMONY and NEEW). Conservatively, based on prior research, comparisons of complete data on 80 participants per group are assumed, and also assume 20% attrition. Power calculations were performed with POWERLIB20 SAS/IML modules that incorporate methods to calculate power for the general linear multivariate model, which includes repeated measures data structures. Based on pilot study data, power analysis focuses on a group of representative variables addressed in the primary and secondary endpoints for CM risk factors. For primary and secondary endpoints, power is based on a separate multivariate model for these outcomes, incorporating measures from all timepoints. It is hypothesized that through improvements in self-management, women in HARMONY (experimental group) will show greater sustained improvements in exercise and healthy eating behaviors (primary endpoint) and greater reduction of CM risk biomarkers (secondary endpoint). Each hypothesis will be considered by specifying both a between-group contrast (HARMONY vs. NEEW) and the appropriate within-group contrast (three post-baseline timepoints versus baseline). This facilitates testing the null hypothesis that both groups have the same difference in population means for the change from baseline at a specific post-baseline time point against the alternative that the between-group difference of the change from baseline significantly differs from 0.

The primary endpoint at 48 weeks post first group session is tested at a significance level of 0.05; the other two timepoints will be tested using a Bonferroni correction of a two-sided 0.025 (=0.05/2) significance level. A compound symmetry correlation structure is assumed across all timepoints in our calculations. Based on pilot data, correlation parameters are 0.35 for BMI, 0.11 for WHR and -0.45 for A1C. With 80 participants per group (total of 160), statistical power is 85% to detect an effect size of 0.56 for BMI and exceeds 95% to detect an effect size of 0.45 for A1C and 0.59 for waist-hip ratio at each post-baseline time point.[76,94] In tertiary endpoints, it is hypothesized that mediation of the intervention effect on the primary outcomes (exercise and healthy eating) by the tertiary outcomes (improvements in self-reported mindfulness, stress management, positive reappraisal, self-regulation, and self-efficacy).[In simulations of power for mediation tests, Fritz and Mackinnon[95] found that when effect sizes (standardized regression coefficients) relating the intervention to the mediator and the mediator to the outcome are all ≥ 0.26 (small- medium, according to Cohen's [1988] definition)[96], the sample size (n=160)

is adequate for at least 80% power. If either effect size is much smaller (simulations used 0.14), the study will be underpowered.

9.3 POPULATIONS FOR ANALYSES

Intent-to-treat analyses will be used and all participant's data will be analyzed according to their random group assignment.

9.4 STATISTICAL ANALYSES

9.4.1 GENERAL APPROACH

All statistical tests, except for the exceptions noted here, will be conducted at an alpha level of 0.05.

Exceptions: The 16-week and 32-week tests of intervention effect on the primary and secondary outcomes will be conducted using a Bonferroni-corrected alpha level of 0.025.

For every primary endpoint, a linear mixed model will be built for the outcome at all three follow-up timepoints (16, 32, and 48 weeks) with the following fixed effects: intercept, value of the endpoint at baseline, timepoint (three parameters total, with baseline as the referent), intervention (control as the referent), and intervention by timepoint interaction (three parameters total, allows for a different intervention effect at each timepoint). The test of the outcome at 48 weeks will be a test of the coefficient for the intervention effect at 48 weeks.

A random intercept will be included to account for within-participant correlation. For the primary outcome, modeled at the three follow-up visits, the within-subject covariance matrix will be chosen based in the lowest AIC among unstructured, compound symmetric, and first-order autoregressive. To improve model fit, transformation of non-normal (i.e., highly skewed) endpoints will be considered. If imbalance is detected among the randomized groups on one or more variables associated with the outcome (identified in section 9.4.4), these variables will also be included in the model.

The fixed-effects can be interpreted like multiple regression parameters and provide basis for population regression lines. The random- effects component allows variation among participants. This plan accounts for within-subject correlations between measurements from the same individual across time.

9.4.2 ANALYSIS OF THE PRIMARY ENDPOINT(S)

The primary endpoints of MVPA, dietary risk, and veggie meter will be assessed using the linear model described in 9.4.1. A test of the appropriate interaction parameter at a significance level of 0·05 will serve as the test of the intervention's effect on each primary outcome.

9.4.3 ANALYSIS OF THE SECONDARY ENDPOINT(S)

The secondary endpoints (BMI, % Body Fat, WHR, BP, and cytokines), dietary risk, and veggie meter will be assessed using the linear model described in 9.4.1. A test of the appropriate interaction parameter at a significance level of 0·05 will serve as the test the intervention's effect on each primary outcome.

The tertiary endpoints (mindfulness, stress management, positive reappraisal, self-regulation, and self-efficacy dietary risk, and veggie meter will be assessed using the linear model described in 9.4.1. A test of the appropriate interaction parameter at a significance level of 0·05 will serve as the test the intervention's effect on each primary outcome

9.4.4 BASELINE DESCRIPTIVE STATISTICS

Descriptive statistics will be presented for study demographics and endpoints, by intervention group, in the following manner:

For continuous variables, means with standard deviations and range for variables with approximately normal distributions; median with IQR and range for variables that are not close to normally distributed.

For categorical variables, sample size and percents will be presented for each category.

Baseline comparison of participants randomized to HARMONY vs. NEEW will be conducted using t-tests (for approximately normal variables), Wilcoxon rank sum (for variables that are not approximately normal), and chi-square tests (for categorical or dichotomous variables; categories will be collapsed and/or Fisher's Exact test will be used if the cell counts do not support the chi-square test). These tests will each use an alpha level of 0.05.

For each primary and secondary endpoint, we will use linear mixed models to assess whether HARMONY, compared to NEEW, will yield greater improvement on each outcome measure from baseline to post-baseline timepoints.

9.4.5 PLANNED INTERIM ANALYSES

N/A

9.4.6 SUB-GROUP ANALYSES

N/A

9.4.7 TABULATION OF INDIVIDUAL PARTICIPANT DATA

For data sharing purposes, individual participant data will be listed by measure and timepoint.

9.4.8 EXPLORATORY ANALYSES

Other timepoints: The intervention effect will be examined on the 16- and 32-week primary and secondary outcomes. Using the models described in 9.4.1, the intervention effect will be estimated at 16-

and 32-weeks using the appropriate interaction parameters. These tests will be conducted at an alpha level of 0.025; this alpha level was selected using a Bonferroni correction because each outcome has two tests.

Mediation: mediation of the intervention effect on the primary outcomes will be tested by each of the tertiary outcomes over 48 weeks. To account for temporal precedence, these analyses will use values for mediators measured at 32 weeks and primary outcome measured at the end of 48 weeks. Mediation will first be assessed using each of the three potential mediators one at a time and then in combination, to assess the possibility of multiple mediation.

The indirect effect of the intervention will be estimated via the mediator(s), along with a 95% bias-corrected bootstrapped confidence interval. This effect will be interpreted to the extent that it is in a direction consistent with the mediation hypothesis. It is important to estimate and test for mediation even if there is no evidence of an overall intervention effect. It is possible that the test of mediated effect has more statistical power, and mediation can be found in the absence of an overall effect.

10 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

10.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

10.1.1 INFORMED CONSENT PROCESS

10.1.1.1 CONSENT/ASSENT AND OTHER INFORMATIONAL DOCUMENTS PROVIDED TO PARTICIPANTS

Verbal consent will be obtained from the participant prior to any study procedures.

Written consent will be obtained from the participant at their baseline visit. Consent forms describing in detail the study intervention, study procedures, and risks will be given to the participant at that visit and written documentation of informed consent will be completed prior to starting further study procedures.

10.1.1.2 CONSENT PROCEDURES AND DOCUMENTATION

Verbal consent from the participant will be obtained via telephone during the telephone screening visit. The telephone consent form describes the study intervention, procedures, and risks. Documentation of

verbal consent will be kept by the study team in the participant's file. Verbal consent will be obtained from the participant prior to sending their pre-baseline period questionnaires.

Written consent will then be obtained from the participant at the beginning of their baseline visit, prior to conducting any further study procedures.

For both verbal and written consent, the consent discussion will be led by study personnel delegated to conduct the consent process. Study personnel will explain the consent form to the subject, and the study subject will have the opportunity to ask any questions they may have regarding the consent before signing. The consent process will be documented in the participant's study file.

For written consent, a copy of the consent will be given to the patient for their records.

10.1.2 STUDY DISCONTINUATION AND CLOSURE

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. If the study is prematurely terminated or suspended, the Principal Investigator (PI) will promptly inform study participants, the Institutional Review Board (IRB), and the NIH and will provide the reason(s) for the termination or suspension. Study participants will be contacted, as applicable, and be informed of changes to study visit schedule.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Demonstration of efficacy that would warrant stopping
- Insufficient compliance to protocol requirements
- Data that are not sufficiently complete and/or evaluable
- Determination that the primary endpoint has been met
- Determination of futility

The study may resume once concerns about safety, protocol compliance, and data quality are addressed, and satisfy the funding agency, IRB, or other relevant regulatory or oversight bodies.

10.1.3 CONFIDENTIALITY AND PRIVACY

Participant confidentiality and privacy is strictly held in trust by the study staff, the safety and oversight monitor(s), and the funding agency. This confidentiality is extended to the data being collected as part of this study. Data that could be used to identify a specific study participant will be held in strict confidence within the research team. No personally identifiable information from the study will be released to any unauthorized third party without prior written approval of the sponsor/funding agency.

All research activities will be conducted in as private a setting as possible. However, due to the nature of the online group intervention, participants may talk about personal experiences in a group setting. Participants will be instructed to not reveal private information about other group members to others. In addition, participants will be asked to attend group sessions in a private area.

The study monitor, other authorized representatives of the sponsor or funding agency, representatives of the Institutional Review Board (IRB), or regulatory agencies may inspect all documents and records required to be maintained by the investigator, including but not limited to, study records for the participants in this study. The study site will permit access to such records.

The study participant's contact information will be securely stored at each clinical site for internal use during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by the reviewing IRB, Institutional policies, or sponsor/funding agency requirements.

Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be and stored at UNC Chapel Hill. Individual participants and their research data will be identified by a unique study identification number. The study data entry and study management systems used by clinical sites and by research staff will be secured and password protected. At the end of the study, all study databases will be de-identified and archived at UNC Chapel Hill.

Measures Taken to Ensure Confidentiality of Data Shared per the NIH Data Sharing Policies
It is NIH policy that the results and accomplishments of the activities that it funds should be made available to the public (see *https://grants.nih.gov/policy/sharing.htm*). The PI will ensure all mechanisms used to share data will include proper plans and safeguards for the protection of privacy, confidentiality, and security for data dissemination and reuse (e.g., all data will be thoroughly de-identified and will not be traceable to a specific study participant). Plans for archiving and long-term preservation of the data will be implemented, as appropriate.

Certificate of Confidentiality
To further protect the privacy of study participants, the Secretary, Health and Human Services (HHS), has issued a Certificate of Confidentiality (CoC) to all researchers engaged in biomedical, behavioral, clinical or other human subjects research funded wholly or in part by the federal government. Recipients of NIH funding for human subjects research are required to protect identifiable research information from forced disclosure per the terms of the NIH Policy (see *https://humansubjects.nih.gov/coc/index*). As set forth in 45 CFR Part 75.303(a) and NIHGPS Chapter 8.3, recipients conducting NIH-supported research covered by this Policy are required to establish and maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the award is managed in compliance with Federal statutes, regulations, and the terms and conditions of award. It is the NIH policy that investigators and others who have access to research records will not disclose identifying information except when the participant consents or in certain instances when federal, state, or local law or regulation requires disclosure. NIH expects investigators to inform research participants of the protections and the limits to protections provided by a Certificate issued by this Policy.

10.1.4 FUTURE USE OF STORED SPECIMENS AND DATA

Data collected for this study will be analyzed and stored at UNC Chapel Hill. After the study is completed, the de-identified, archived data will be stored for use by other researchers including those outside of the study to comply with NIH guidelines for sharing of study data. This data sharing will ensure that confidential information is not disclosed, data are released in a form that does not endanger national security or compromise law enforcement activities, and that proprietary data are not released inadvertently.

With the participant's approval and as approved by local Institutional Review Boards (IRBs), de-identified biological samples will be stored at UNC Chapel Hill. These samples could be used to research the increased risk of cardiometabolic conditions in African American and Black women and to improve treatment.

During the conduct of the study, an individual participant can choose to withdraw consent to have biological specimens stored for future research. However, withdrawal of consent with regard to biosample storage may not be possible after the study is completed.

When the study is completed, access to study data and/or samples will be provided through UNC Chapel Hill.

10.1.5 KEY ROLES AND STUDY GOVERNANCE

Principal Investigator	**Safety Officer**
Dr. Cheryl Giscombe, Dr. Susan Gaylord	
UNC Chapel Hill	
4103 Carrington Hall, CB 7460 Chapel Hill NC, 27599	
919-843-9491	
Cheryl.Giscombe@unc.edu, gaylords@med.unc.edu	

10.1.6 SAFETY OVERSIGHT

Oversight for this study will be provided by the MPIs with delegation of responsibilities to designated study personnel. The Safety Officer will review the all reports of adverse events quarterly and when

necessary, make recommendations to the MPIs concerning continuation, termination or modification of any study protocol/ procedure based on observed beneficial or adverse effects.

10.1.7 DATA HANDLING AND RECORD KEEPING

10.1.7.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

Data collection will be the responsibility of the study staff under the supervision of the MPIs. The investigator will be responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

All source documents will be completed in a neat, legible manner to ensure accurate interpretation of data.

Any hardcopies of the study visit worksheets will be provided for use as source document worksheets for recording data for each participant consented/enrolled in the study. Data recorded in the electronic case report form (eCRF) derived from source documents will be consistent with the data recorded on the source documents. In many cases, the data will be entered directly into the eCRF, in those cases, the eCRF will be considered source.

Data (including adverse events (AEs), concomitant medications, and expected adverse reactions data) will be entered into REDCap. The data system includes password protection and quality features to identify data that appear inconsistent, incomplete, or inaccurate. Clinical data will be entered directly from the source documents.

10.1.7.2 STUDY RECORDS RETENTION

Study documents will be retained for a minimum of 3 years from the date of NIH Federal Financial Report submission. These documents should be retained for a longer period, however, if required by local regulations. No records will be destroyed without the written consent of the funding agency, if applicable. It is the responsibility of the funding agency to inform the investigator when these documents no longer need to be retained.

10.1.8 PROTOCOL DEVIATIONS

This protocol defines a protocol deviation as any noncompliance with the clinical trial protocol, or International Council on Harmonisation Good Clinical Practice (ICH GCP) requirements. The noncompliance may be either on the part of the participant, the MPIs, or the study site staff. As a result of deviations, corrective actions will be developed by the site and implemented promptly.

These practices are consistent with ICH GCP:

- Section 4.5 Compliance with Protocol, subsections 4.5.1, 4.5.2, and 4.5.3
- Section 5.1 Quality Assurance and Quality Control, subsection 5.1.1
- Section 5.20 Noncompliance, subsections 5.20.1, and 5.20.2.

It will be the responsibility of the MPIs to use continuous vigilance to identify and report applicable deviations. All deviations will be addressed in study source documents, reported to NIH Program Official and IRB if deemed necessary by their policies. The site investigator will be responsible for knowing and adhering to the reviewing IRB and NIH requirements.

10.1.9 PUBLICATION AND DATA SHARING POLICY

This study will be conducted in accordance with the following publication and data sharing policies and regulations:

National Institutes of Health (NIH) Public Access Policy, which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication.

This study will comply with the NIH Data Sharing Policy and Policy on the Dissemination of NIH-Funded Clinical Trial Information and the Clinical Trials Registration and Results Information Submission rule. As such, this trial will be registered at ClinicalTrials.gov, and results information from this trial will be submitted to ClinicalTrials.gov. In addition, every attempt will be made to publish results in peer-reviewed journals. Data from this study may be requested from other researchers after the completion of the primary endpoint by contacting UNC Chapel Hill. Considerations for ensuring confidentiality of these shared data are described in Section 10.1.3.

In addition, this study will comply with the NIH Genomic Data Sharing Policy, which applies to all NIH-funded research that generates large-scale human or non-human genomic data, as well as the use of these data for subsequent research. Large-scale data include genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data.

10.1.10 CONFLICT OF INTEREST POLICY

The University of North Carolina at Chapel Hill's Policy on Conflicts of Interest and Commitment includes a rebuttable presumption that an investigator may not conduct human subjects' research that is related to a financial interest of the investigator (or immediate family) except in compelling circumstances. Compelling circumstances are those facts that convince the reviewer that a covered individual who has a financial interest should be permitted to conduct human subjects' research, taking into account the following factors:

- The nature of the research,
- The nature and magnitude of the financial interest
- How closely the financial interest is related to the research
- The extent to which the interest may be affected by the research
- The degree of risk to the human subjects involved that is inherent in the research protocol
- The extent to which the investigator is uniquely qualified to perform a research study with important public benefit
- The extent to which the interest is amenable to effective oversight and management.

The applicable UNC-Chapel Hill COI Chair and/or Committee takes into these criteria into account when reviewing any disclosed conflict of interest in the context of the human study.

The COI Chair or Committee considers the following factors into their review:

- How the research is supported or financed,
- The nature and extent of the conflict,
- The role and responsibilities of the conflicted individual in the design, conduct, and reporting of the research, and
- The ability of the conflicted individual to influence the outcome of the research.

The IRB has final authority to determine whether the research, the COI, and the related management plan, if any, allow the research to be approved.

10.2 ADDITIONAL CONSIDERATIONS

NA

10.3 ABBREVIATIONS AND SPECIAL TERMS

AE	Adverse Event
ANCOVA	Analysis of Covariance
AAW	African American Women
CFR	Code of Federal Regulations
CLIA	Clinical Laboratory Improvement Amendments
CM	Cardiometabolic
CMP	Clinical Monitoring Plan
COC	Certificate of Confidentiality
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
DCC	Data Coordinating Center
DHHS	Department of Health and Human Services
DSMB	Data Safety Monitoring Board
DRE	Disease-Related Event
EC	Ethics Committee
eCRF	Electronic Case Report Forms
FDA	Food and Drug Administration

FFR	Federal Financial Report
GCP	Good Clinical Practice
GWAS	Genome-Wide Association Studies
HIPAA	Health Insurance Portability and Accountability Act
ICH	International Council on Harmonisation
ICMJE	International Committee of Medical Journal Editors
IRB	Institutional Review Board
ISM	Independent Safety Monitor
ITT	Intention-To-Treat
LSMEANS	Least-squares Means
MedDRA	Medical Dictionary for Regulatory Activities
MOP	Manual of Procedures
NCT	National Clinical Trial
NIH	National Institutes of Health
NIH IC	NIH Institute or Center
OHRP	Office for Human Research Protections
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SMC	Safety Monitoring Committee
SOA	Schedule of Activities
SOP	Standard Operating Procedure
SWS	Superwoman Schema
UP	Unanticipated Problem
US	United States

10.4 PROTOCOL AMENDMENT HISTORY.

Version	Date	Description of Change	Brief Rationale

11 REFERENCES

1. Heart Disease and Stroke Statistics—2016 Update Dariush Mozaffarian, Emelia J. Benjamin, Alan S. Go, Donna K. Arnett, Michael J. Blaha, Mary Cushman, Sandeep R. Das, Sarah de Ferranti, Jean-Pierre Després, Heather J. Fullerton, Virginia J. Howard, Mark D. Huffman, Carmen R. Isasi, Monik C. Jiménez, Suzanne E. Judd, Brett M. Kissela, Judith H. Lichtman, Lynda D. Lisabeth, Simin Liu, Rachel H. Mackey, David J. Magid, Darren K. McGuire, Emile R. Mohler, Claudia S. Moy, Paul Muntner, Michael E. Mussolino, Khurram Nasir, Robert W. Neumar, Graham Nichol, Latha Palaniappan, Dilip K. Pandey, Mathew J. Reeves, Carlos J. Rodriguez, Wayne Rosamond, Paul D. Sorlie, Joel Stein, Amytis Towfighi, Tanya N. Turan, Salim S. Virani, Daniel Woo, Robert W. Yeh and Melanie B. Turner. Circulation. 2015;CIR.0000000000000350, originally published December 16, 2015 https://doi.org/10.1161/CIR.0000000000000350

2.CDC 2016. Health, United States, 2017, With Chartbook on Long-term Trends in Health. Retrieved from https://www.cdc.gov/nchs/data/hus/hus16.pdf

3. Armstrong S, Wong CA, Perrin E, Page S, Sibley L, Skinner A. Association of Physical Activity With Income, Race/Ethnicity, and Sex Among Adolescents and Young Adults in the United States: Findings From the National Health and Nutrition Examination Survey, 2007-2016. JAMA Pediatr. 2018;172(8):732–740. doi:10.1001/jamapediatrics.2018.1273

4. Schiller JS, Lucas JW, Ward BW, Peregoy JA. Summary health statistics for U.S. adults: National Health Interview Survey, 2010. Vital Health Stat 10. 2012 Jan;(252):1-207. PubMed PMID: 22834228.

5. National Center for Health Statistics. Health, United States, in Health, United States, 2015: With Special Feature on Racial and Ethnic Health Disparities. 2016, National Center for Health Statistics (US): Hyattsville, MD.

6. Stress and Health Disparities Working Group at the American Psychological Association (Brondolo, E., Byer, K.,Kaplan, J., Liu, C., Prather, A., Thomas, K., & Woods-Giscombe, C. (2017). Stress and Health Disparities: Contexts, Mechanisms and Interventions among Racial/Ethnic Minority and Low Socioeconomic Status Populations. An Official Report of the American Psychological Association: Washington: DC. Retrieved from http://www.apa.org/pi/health- disparities/resources/stress-report.aspx PMCID: N/A

8.Woods-Giscombe CL, Lobel M. Race and gender matter: a multidimensional approach to conceptualizing and measuring stress in African American women. Cultur Divers Ethnic Minor Psychol. 2008 Jul;14(3):173-82. doi: 10.1037/1099-9809.14.3.173. PubMed PMID: 18624581; PubMed Central PMCID: PMC2553624.

9. Woods-Giscombé CL, Lobel M, Zimmer C, Wiley Cené C, Corbie-Smith G. Whose stress is making me sick? Network-stress and emotional distress in African-American women. Issues Ment Health Nurs. 2015;36(9):710-7. doi: 10.3109/01612840.2015.1011759. PubMed PMID: 26440874. PMCID In Progress

10. Woods-Giscombé CL. Superwoman schema: African American women's views on stress, strength, and health. Qual Health Res. 2010 May;20(5):668-83. doi: 10.1177/1049732310361892. PubMed PMID: 20154298; PubMed Central PMCID: PMC3072704.

11. Romero, R. E. (2000). The icon of the strong Black woman: The paradox of strength. In L. C. Jackson & B. Greene (Eds.), Psychotherapy with African American women: Innovations in psychodynamic perspectives and practice (pp. 225-238). New York: Guilford Press.

12. Woods-Giscombé, C. L., Lobel, M., & Zimmer, C. Obesity in African American women: Using structural equation modeling to examine the contribution of multidimensionally-defined stress, superwoman schema – emotional suppression, and the use of food to cope [Abstract]. Ann.Behav. Med. 2012 April: 43(Suppl 1): 1. S50-S50. doi:10.1007/s12160-012-9354-9 PMCID Not Applicable

13. Black AR, Woods-Giscombé C. Applying the Stress and 'Strength' Hypothesis to Black women's breast cancer screening delays. Stress Health. 2012 Dec;28(5):389-96. doi: 10.1002/smi.2464. PubMed PMID: 23129558; PubMed Central PMCID: PMC3696631.

14. Carthron D, Bailey DE Jr, Anderson R. Adaptive Challenges Rising from the Life Context of African-American Caregiving Grandmothers with Diabetes: A Pilot Study. Healthcare (Basel). 2015 Sep 1;3(3):710-725. PubMed PMID: 27064619; PubMed Central PMCID: PMC4824619. Mullings,L. (2006). Resistance and resilience: The Sojourner Syndrome and the social context of reproduction in Central Harlem. In A. J. Schulz & L. Mullings (Eds.), Gender, race, class, and health (pp. 345-370). San Francisco: Jossey-Bass.

15. Beauboeuf-Lafontant, T. Strong and large Black women? Exploring relationships between deviant womanhood and weight. Gender & Society 2003 Feb: 17(1), 111-121.DOI: 10.1177/0891243202238981

16. Beauboeuf-Lafontant, T. You have to show strength: An exploration of gender, race, and depression. Gender & Society, 2007 Feb: 21(1), 28-51. DOI: 10.1177/0891243206294108

17. Beauboeuf-Lafontant, T. (2009). Behind the mask of the strong Black woman: Voice and the embodiment of a costly performance. Philadelphia: Temple University Press.

18. Nuru-Jeter, A., Chae, D.H., David H., Price, M., Telesford, J., Mendoza-Denton, R., & Woods-Giscombé, C. Anticipatory racism threat and Superwoman Schema: Elucidating the relationship between racial discrimination and chronic inflammation [Abstract]. Circulation, 2013. September. SS-A09550-AH. doi. 10.1161/CIR.0b013e3182aa075e PMCID Not Applicable

19. Giscombé, C. L., Black, A. R., Nuru-Jeter, A., Steed, T., Tillman-Meakins, P. (2012, December). Stress and the Superwoman: An innovative agenda for African American women's health disparities research, practice, and policy. Paper presented at the 2012 Summit on the Science of Eliminating Health Disparities: Building a Healthier Society, Integrating Science, Policy, and Practice. National Harbor, Maryland.

20. Woods-Giscombe CL, Allen AM, Black AR, Steed TC, Li Y, Lackey C. The Giscombe Superwoman Schema Questionnaire: Psychometric Properties and Associations with Mental Health and Health Behaviors in African American Women. Issues Ment Health Nurs. 2019 Aug;40(8):672-681. doi: 10.1080/01612840.2019.1584654. Epub 2019 May 13. PubMed PMID: 31081707. PMCID: In Progress

21. Imaeyen Ibanga [Senior Producer] (March 2018). Is The 'Strong Black Woman' Stereotype Hurting Black Women [Video file]. Al Jazeera Plus, Because Facts. Retrieved from https://www.facebook.com/becausefacts/videos/209508169795897/and *https://www.youtube.com/watch?v=OIYSzI8fX9o*

22. Nigg, Claudio R.; Borrelli, Belinda; Maddock, Jay; Dishman, Rod K.; Applied Psychology: An International Review, Vol 57(4), Oct, 2008 pp. 544-560. Publisher: Blackwell Publishing.

23. Chrousos GP, Gold PW. A healthy body in a healthy mind--and vice versa--the damaging power of "uncontrollable" stress. J Clin Endocrinol Metab. 1998 Jun;83(6):1842-5. PubMed PMID: 9626106.

24. Szanton, S. L., Gill, J. M., & Allen, J. K. (2005). Allostatic load: a mechanism of socioeconomic health disparities?. Biological research for nursing, 7(1), 7-15.

25. McEwen BS, Stellar E. Stress and the individual. Mechanisms leading to disease. Arch Intern Med. 1993 Sep 27;153(18):2093-101. Review. PubMed PMID: 8379800.

26. Geronimus AT. Understanding and eliminating racial inequalities in women's health in the United States: the role of the weathering conceptual framework. J Am Med Womens Assoc. 2001 Fall;56(4):133-6, 149-50. PubMed PMID: 11759779.

27. Mezuk B, Abdou CM, Hudson D, Kershaw KN, Rafferty JA, Lee H, Jackson JS. "White Box" Epidemiology and the Social Neuroscience of Health Behaviors: The Environmental Affordances Model. Soc Ment Health. 2013 Jul 1;3(2). doi: 10.1177/2156869313480892. PubMed PMID: 24224131; PubMed Central PMCID: PMC3820104.

28. Ng DM, Jeffery RW. Relationships between perceived stress and health behaviors in a sample of working adults. Health Psychol. 2003 Nov;22(6):638-42. PubMed PMID: 14640862.

29. Payne N, Jones F, Harris P. The impact of working life on health behavior: the effect of job strain on the cognitive predictors of exercise. J Occup Health Psychol. 2002 Oct;7(4):342-53. PubMed PMID: 12396067.

30. Steptoe A, Wardle J, Pollard TM, Canaan L, Davies GJ. Stress, social support and health-related behavior: a study of smoking, alcohol consumption and physical exercise. J Psychosom Res. 1996 Aug;41(2):171-80. PubMed PMID: 8887830.

31. Joseph RP, Keller C, Affuso O, Ainsworth BE. Designing Culturally Relevant Physical Activity Programs for African-American Women: A Framework for Intervention Development. J Racial Ethn Health Disparities. 2017 Jun;4(3):397-409. doi: 10.1007/s40615-016-0240-1. Epub 2016 May 13. PubMed PMID: 27178447; PubMed Central PMCID: PMC5107357.

32. Kabat-Zinn J. Coming to our senses: Healing ourselves and the world through mindfulness. New York, NY: Hyperion; 2005.

33. Garland E, Gaylord S, Park J. The role of mindfulness in positive reappraisal. Explore (NY). 2009 Jan-Feb;5(1):37-44. doi: 10.1016/j.explore.2008.10.001. Review. PubMed PMID: 19114262; PubMed Central PMCID: PMC2719560.

34. Garland EL, Farb NA, Goldin P, Fredrickson BL. Mindfulness Broadens Awareness and Builds Eudaimonic Meaning: A Process Model of Mindful Positive Emotion Regulation. Psychol Inq. 2015 Oct 1;26(4):293-314. Epub 2015 Nov 24. PubMed PMID: 27087765; PubMed Central PMCID: PMC4826727.

35. Garland EL, Farb NA, Goldin PR, Fredrickson BL. The Mindfulness-to-Meaning Theory: Extensions, Applications, and Challenges at the Attention–Appraisal–Emotion Interface. Psychol Inq. 2015;26: 377–387. doi: 10.1080/1047840X.2015.1092493

36. Garland EL, Kiken LG, Faurot K, Palsson O, Gaylord SA. Upward Spirals of Mindfulness and Reappraisal: Testing the Mindfulness-to-Meaning Theory with Autoregressive Latent Trajectory Modeling. Cogn Ther Res. 2016; 1–12. doi: 10.1007/s10608-016-9768-y

37. Garland EL, Hanley AW, Goldin PR, Gross JJ. Testing the mindfulness-to-meaning theory: Evidence for mindful positive emotion regulation from a reanalysis of longitudinal data. PLoS One. 2017 Dec 6;12(12):e0187727. doi: 10.1371/journal.pone.0187727. eCollection 2017. PubMed PMID: 29211754; PubMed Central PMCID: PMC5718463.

38. SWS Instrument Development Manuscript (under review – will update reference).

39. Abbott RA, Whear R, Rodgers LR, Bethel A, Thompson Coon J, Kuyken W, Stein K, Dickens C. Effectiveness of mindfulness-based stress reduction and mindfulness based cognitive therapy in vascular disease: A systematic review and meta-analysis of randomised controlled trials. J Psychosom Res. 2014 May;76(5):341-51. doi: 10.1016/j.jpsychores.2014.02.012. Review. PubMed PMID: 24745774.

40. Khoury B, Sharma M, Rush SE, Fournier C. Mindfulness-based stress reduction for healthy individuals: A meta-analysis. J Psychosom Res. 2015 Jun;78(6):519-28. doi: 10.1016/j.jpsychores.2015.03.009. Review. PubMed PMID: 25818837.

41. Sharma M, Rush SE. Mindfulness-based stress reduction as a stress management intervention for healthy individuals: a systematic review. J Evid Based Complementary Altern Med. 2014 Oct;19(4):271-86. doi: 10.1177/2156587214543143. Review. PubMed PMID: 25053754.

42. Keyworth C, Knopp J, Roughley K, Dickens C, Bold S, Coventry P. A mixed-methods pilot study of the acceptability and effectiveness of a brief meditation and mindfulness intervention for people with diabetes and coronary heart disease. Behav Med. 2014;40(2):53-64. doi: 10.1080/08964289.2013.834865. PubMed PMID: 24754440; PubMed Central PMCID: PMC4017270.

43. Rosenzweig S, Reibel DK, Greeson JM, Edman JS, Jasser SA, McMearty KD, Goldstein BJ. Mindfulness-based stress reduction is associated with improved glycemic control in type 2 diabetes mellitus: a pilot study. Altern Ther Health Med. 2007 Sep-Oct;13(5):36-8. PubMed PMID: 17900040.

44. Hartmann M, Kopf S, Kircher C, Faude-Lang V, Djuric Z, Augstein F, Friederich HC, Kieser M, Bierhaus A, Humpert PM, Herzog W, Nawroth PP. Sustained effects of a mindfulness-based stress-reduction intervention in type 2 diabetic patients: design and first results of a randomized controlled trial (the Heidelberger Diabetes and Stress-study). Diabetes Care. 2012 May;35(5):945-7. doi: 10.2337/dc11-1343. PubMed PMID: 22338101; PubMed Central PMCID: PMC3329807.

45. Gregg JA, Callaghan GM, Hayes SC, Glenn-Lawson JL. Improving diabetes self-management through acceptance, mindfulness, and values: a randomized controlled trial. J Consult Clin Psychol. 2007 Apr;75(2):336-43. PubMed PMID: 17469891.

46. van Son J, Nyklícek I, Pop VJ, Blonk MC, Erdtsieck RJ, Spooren PF, Toorians AW, Pouwer F. The effects of a mindfulness-based intervention on emotional distress, quality of life, and HbA(1c) in outpatients with diabetes (DiaMind): a randomized controlled trial. Diabetes Care. 2013 Apr;36(4):823-30. doi: 10.2337/dc12-1477. PubMed PMID: 23193218; PubMed Central PMCID: PMC3609486.

47. Walsh E, Eisenlohr-Moul T, Baer R. Brief mindfulness training reduces salivary IL-6 and TNF-α in young women with depressive symptomatology. J Consult Clin Psychol. 2016 Oct;84(10):887-97. doi: 10.1037/ccp0000122. PubMed PMID: 27281371; PubMed Central PMCID: PMC5037002.

48. Rogers JM, Ferrari M, Mosely K, Lang CP, Brennan L. Mindfulness-based interventions for adults who are overweight or obese: a meta-analysis of physical and psychological health outcomes. Obes Rev. 2017 Jan;18(1):51-67. doi: 10.1111/obr.12461. Epub 2016 Nov 11. Review. PubMed PMID: 27862826.

49. Ruffault A, Bernier M, Juge N, Fournier JF. Mindfulness may moderate the relationship between intrinsic motivation and physical activity: a crosssectional study. Mindfulness. 2016;7(2):445–52.

50. Chatzisarantis NL, Hagger MS. Mindfulness and the intention-behavior relationship within the theory of planned behavior. Pers Soc Psychol Bull. 2007 May;33(5):663-76. Epub 2007 Apr 17. PubMed PMID: 17440208

51. Woods-Giscombe CL, Gaylord SA. The Cultural Relevance of Mindfulness Meditation as a Health Intervention for African Americans: Implications for Reducing Stress-Related Health Disparities. J Holist Nurs. 2014 Sep;32(3):147-60. doi: 10.1177/0898010113519010. PubMed PMID: 24442592; PubMed Central PMCID: PMC4102670.

52. Woods-Giscombe CL, Gaylord SA, Li Y, et al. A Mixed-Methods, Randomized Clinical Trial to Examine Feasibility of a Mindfulness-Based Stress Management and Diabetes Risk Reduction Intervention for African Americans with Prediabetes. Evid Based Complement Alternat Med. 2019;2019:3962623. Published 2019 Aug 14. doi:10.1155/2019/3962623. PMCID: PMC6710811

53. Dutton MA, Bermudez D, Matas A, Majid H, Myers NL. Mindfulness-Based Stress Reduction for Low-Income, Predominantly African American Women With PTSD and a History of Intimate Partner Violence. Cogn Behav Pract. 2013;20(1):23–32. doi:10.1016/j.cbpra.2011.08.003

54. Burnett-Zeigler IE, Satyshur MD, Hong S, Yang A, T Moskowitz J, Wisner KL. Mindfulness based stress reduction adapted for depressed disadvantaged women in an urban Federally Qualified Health Center.

Complement Ther Clin Pract. 2016 Nov;25:59-67. doi: 10.1016/j.ctcp.2016.08.007. Epub 2016 Aug 13. PubMed PMID: 27863611

55. Watson-Singleton NN, Black AR, Spivey BN. Recommendations for a culturally- responsive mindfulness-based intervention for African Americans. Complement Ther Clin Pract. 2019 Feb;34:132-138. doi: 10.1016/j.ctcp.2018.11.013. Epub 2018 Nov 27.

56. K. Witkiewitz, B.L. Greenfield, S. BowenMindfulness-based relapse prevention with racial and ethnic minority women Addict. Behav., 38 (12) (2013), pp. 2821-2824
https://doi.org/10.1016/j.addbeh.2013.08.018

57. D. Abercrombie, A. Zamora, A. KornLessons learned providing a Mindfulness-based Stress Reduction Program for low-income multiethnic womenwith abnormal pap smears. Holist. Nurs. Pract., 21 (1) (2007), pp. 26-34. *https://doi.org/10.1016/j.apnu.2007.12.004*.

58. Cox TL, Krukowski R, Love SJ, Eddings K, DiCarlo M, Chang JY, Prewitt TE, West DS. Stress management-augmented behavioral weight loss intervention for African American women: a pilot, randomized controlled trial. Health Educ Behav. 2013 Feb;40(1):78-87. doi: 10.1177/1090198112439411. PubMed PMID: 22505570. 2

59. Chung S, Zhu S, Friedmann E, Kelleher C, Kozlovsky A, Macfarlane KW, Tkaczuk KH, Ryan AS, Griffith KA. Weight loss with mindful eating in African American women following treatment for breast cancer: a longitudinal study. Support Care Cancer. 2016 Apr;24(4):1875-81. doi: 10.1007/s00520-015-2984-2. Epub 2015 Oct 13. PubMed PMID: 26463645; PubMed Central PMCID: PMC4909150.

60. West DS, Elaine Prewitt T, Bursac Z, Felix HC. Weight loss of black, white, and Hispanic men and women in the Diabetes Prevention Program. Obesity (Silver Spring) 2008 Jun;16(6):1413–1420.

61. Samuel-Hodge CD, Johnson CM, Braxton DF, Lackey M. Effectiveness of Diabetes Prevention Program translations among African Americans. Obes Rev. 2014 Oct;15(Suppl 4):107–124.

62. Knowler WC, Barrett-Connor E, Fowler SE, Hamman RF, Lachin JM, Walker EA, Nathan DM; Diabetes Prevention Program Research Group.. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. N Engl J Med. 2002 Feb 7;346(6):393-403. PubMed PMID: 11832527; PubMed Central PMCID: PMC1370926.

63. Hollis JF, Gullion CM, Stevens VJ, Brantley PJ, Appel LJ, Ard JD, Champagne CM, Dalcin A, Erlinger TP, Funk K, Laferriere D, Lin PH, Loria CM, Samuel-Hodge C, Vollmer WM, Svetkey LP; Weight Loss Maintenance Trial Research Group.. Weight loss during the intensive intervention phase of the weight-loss maintenance trial. Am J Prev Med. 2008 Aug;35(2):118-26. doi: 10.1016/j.amepre.2008.04.013. PubMed PMID: 18617080; PubMed Central PMCID: PMC2515566.

64. Carson TL, Jackson BE, Nolan TS, Williams A, Baskin ML. Lower depression scores associated with greater weight loss among rural black women in a behavioral weight loss program. Translational Behavioral Medicine. 2017;7(2):320-329. doi:10.1007/s13142-016-0452-2.

65. Palmer JR, Boggs DA, Krishnan S, Hu FB, Singer M, Rosenberg L. Sugar-sweetened beverages and incidence of type 2 diabetes mellitus in African American women. Arch Intern Med. 2008 Jul 28;168(14):1487-92. doi: 10.1001/archinte.168.14.1487. PubMed PMID: 18663160; PubMed Central PMCID: PMC2708080.

66. Fitzgibbon ML, Tussing-Humphreys LM, Porter JS, Martin IK, Odoms-Young A, Sharp LK. Weight loss and African-American women: a systematic review of the behavioural weight loss intervention literature. Obes Rev. 2012 Mar;13(3):193-213. doi: 10.1111/j.1467-789X.2011.00945.x. Review. PubMed PMID: 22074195; PubMed Central PMCID: PMC3288708.

67. Franklin NC, Arena R. Personalized Weight Management Interventions for Cardiovascular Risk Reduction: A Viable Option for African-American Women. Prog Cardiovasc Dis. 2016 May- Jun;58(6):595-604. doi: 10.1016/j.pcad.2016.02.003. Review. PubMed PMID: 26908050.

68. Jenkins F, Jenkins C, Gregoski MJ, Magwood GS. Interventions Promoting Physical Activity in African American Women: An Integrative Review. J Cardiovasc Nurs. 2017 Jan/Feb;32(1):22-29. PubMed PMID: 26544170; PubMed Central PMCID: PMC4860177.

69. Kong A, Tussing-Humphreys LM, Odoms-Young AM, Stolley MR, Fitzgibbon ML. Systematic review of behavioural interventions with culturally adapted strategies to improve diet and weight outcomes in African American women. Obes Rev. 2014 Oct;15 Suppl 4:62-92. doi: 10.1111/obr.12203. Review. PubMed PMID: 25196407; PubMed Central PMCID: PMC4159728.

70. Lancaster KJ, Carter-Edwards L, Grilo S, Shen C, Schoenthaler AM. Obesity interventions in African American faith-based organizations: a systematic review. Obes Rev. 2014 Oct;15 Suppl 4:159-76. doi: 10.1111/obr.12207. Review. PubMed PMID: 25196412.

71. Timmons SM. Review and evaluation of faith-based weight management interventions that target African American women. J Relig Health. 2015 Apr;54(2):798-809. Review. PubMed PMID: 25015128.

72. Walker RE, Gordon M. The Use of Lifestyle and Behavioral Modification Approaches in Obesity Interventions for Black Women: A Literature Review. Health Educ Behav. 2014 Jun;41(3):242-58. doi: 10.1177/1090198113492768. Review. PubMed PMID: 23821434.

73. Kumanyika SK, Espeland MA, Bahnson JL, Bottom JB, Charleston JB, Folmar S, Wilson AC, Whelton PK; TONE Cooperative Research Group.. Ethnic comparison of weight loss in the Trial of Nonpharmacologic Interventions in the Elderly. Obes Res. 2002 Feb;10(2):96-106. PubMed PMID: 11836455.

74. Resnicow K, Baranowski T, Ahluwalia JS, Braithwaite RL. Cultural sensitivity in public health: defined and demystified. Ethn Dis. 1999 Winter;9(1):10-21. Review. PubMed PMID: 10355471.

75. United States Department of Health and Human Services. (2018). Improving patient adherence to treatment and prevention regimens to promote health (PA-18-722). Retrieved from *https://grants.nih.gov/grants/guide/pa-files/PA-18-722.html*

76. Woods-Giscombe CL, Black AR. Mind-Body Interventions to Reduce Risk for Health Disparities Related to Stress and Strength Among African American Women: The Potential of Mindfulness- Based Stress Reduction, Loving-Kindness, and the NTU Therapeutic Framework. Complement Health Pract Rev. 2010 Dec 14;15(3):115-131. PubMed PMID: 21479157; PubMed Central PMCID: PMC3071547.

77. Woods-Giscombe, C. L., Gaylord, S. A., Li, Y., Bangdiwala, S. I., Buse, J., Mann, F. D., Lynch, C., Phillips, P. E., Smith, S., Leniek, K., Young, L., A., Al-Barwani, S., Yoo, J., & Faurot, K. (2016). Mindfulness-based diabetes risk reduction for African Americans with pre-diabetes: A pilot, sequential mixed-methods RCT. Annals of Behavioral Medicine, 50, S240. PubMed Central PMID:26956014 DOI:10.1007/s12160-015-9766-4 PMCID:26956014

78. Franz MJ, VanWormer JJ, Crain AL, Boucher JL, Histon T, Caplan W, Bowman JD, Pronk NP. Weight-loss outcomes: a systematic review and meta-analysis of weight-loss clinical trials with a minimum 1-year follow-up. J Am Diet Assoc. 2007 Oct;107(10):1755-67. Review. PubMed PMID: 17904936.

79. Sciamanna CN, Kiernan M, Rolls BJ, Boan J, Stuckey H, Kephart D, Miller CK, Jensen G, Hartmann TJ, Loken E, Hwang KO, Williams RJ, Clark MA, Schubart JR, Nezu AM, Lehman E, Dellasega C. Practices associated with weight loss versus weight-loss maintenance results of a national survey. Am J Prev Med. 2011 Aug;41(2):159-66. doi: 10.1016/j.amepre.2011.04.009. PubMed PMID: 21767723.

80. Shallcross AJ, Spruill TM. The Protective Role of Mindfulness in the Relationship Between Perceived Discrimination and Depression. Mindfulness (N Y). 2018 Aug;9(4):1100-1109. doi: 10.1007/s12671-017-0845-4. Epub 2017 Nov 4. PubMed PMID: 30128053; PubMed Central PMCID: PMC6097525.

81. Brown-Iannuzzi JL, Adair KC, Payne BK, Richman LS, Fredrickson BL. Discrimination hurts, but mindfulness may help: Trait mindfulness moderates the relationship between perceived discrimination and depressive symptoms. Pers Individ Dif. 2014 Jan;56. doi: 10.1016/j.paid.2013.09.015. PubMed PMID: 24347755; PubMed Central PMCID: PMC3862075

82. Garland EL, Hanley AW, Goldin PR, Gross JJ. Testing the mindfulness-to-meaning theory: Evidence for mindful positive emotion regulation from a reanalysis of longitudinal data. PLoS One. 2017 Dec 6;12(12):e0187727. doi: 10.1371/journal.pone.0187727. eCollection 2017. PubMed PMID: 29211754; PubMed Central PMCID: PMC5718463.

83. Witt DR, Lindquist R, Treat-Jacobson D, Boucher JL, Konety SH, Savik K. Motivational interviewing to reduce cardiovascular risk in African American and Latina women. West J Nurs Res. 2013 Nov;35(10):1266-79. PubMed PMID: 23797099

84. Forsberg L, Källmén H, Hermansson U, Berman AH, Helgason AR. Coding counsellor behaviour in motivational interviewing sessions: inter-rater reliability for the Swedish Motivational Interviewing Treatment Integrity Code (MITI). Cogn Behav Ther. 2007;36(3):162-9. PubMed PMID: 17852172.

85. Rollnick S, Miller WR, Butler CC. Motivational Interviewing in Health Care: Helping Patients Change Behavior. 1st edition. New York, NY, USA: Guilford Press; 2007.

86. Miller ST, Oates VJ, Brooks MA, Shintani A, Gebretsadik T, Jenkins DM. Preliminary efficacy of group medical nutrition therapy and motivational interviewing among obese African American women with type 2 diabetes: a pilot study. J Obes. 2014;2014:345941. doi: 10.1155/2014/345941. PubMed PMID: 25243082; PubMed Central PMCID: PMC4163289.

87. Hölzel BK, Lazar SW, Gard T, Schuman-Olivier Z, Vago DR, Ott U. How Does Mindfulness Meditation Work? Proposing Mechanisms of Action From a Conceptual and Neural Perspective. Perspect Psychol Sci. 2011 Nov;6(6):537-59. doi: 10.1177/1745691611419671. PubMed PMID: 2616837

88. Fulwiler C, Brewer JA, Sinnott S, Loucks EB. Mindfulness-Based Interventions for Weight Loss and CVD Risk Management. Curr Cardiovasc Risk Rep. 2015 Oct;9(10). pii: 46. doi: 10.1007/s12170-015-0474-1. Epub 2015 Aug 29. PubMed PMID: 28405260; PubMed Central PMCID: PMC5386400.

89. Schneider J, Malinowski P, Watson PM, Lattimore P. The role of mindfulness in physical activity: a systematic review. Obes Rev. 2018 Nov 23. doi: 10.1111/obr.12795. [Epub ahead of print] Review. PubMed PMID: 30468299.

90. Spadaro KC, Davis KK, Sereika SM, Gibbs BB, Jakicic JM, Cohen SM. Effect of mindfulness meditation on short-term weight loss and eating behaviors in overweight and obese adults: A randomized controlled trial. J Complement Integr Med. 2017 Dec 5;15(2). pii: /j/jcim.2018.15.issue- 2/jcim-2016-0048/jcim-2016-0048.xml. doi: 10.1515/jcim-2016-0048. PubMed PMID: 29211681

91. Mason AE, Epel ES, Aschbacher K, Lustig RH, Acree M, Kristeller J, Cohn M, Dallman M, Moran PJ, Bacchetti P, Laraia B, Hecht FM, Daubenmier J. Reduced reward-driven eating accounts for the impact of a mindfulness-based diet and exercise intervention on weight loss: Data from the SHINE randomized controlled trial. Appetite. 2016 May 1;100:86-93. doi: 10.1016/j.appet.2016.02.009. Epub 2016 Feb 8. PubMed PMID: 26867697; PubMed Central PMCID: PMC4799744.

92. Surgeon General's Perspectives: quiet heroes, deafening impacts. Public Health Rep. 2014 Nov-Dec;129(6):470-1. PubMed PMID: 25364044; PubMed Central PMCID: PMC4187286.

93. Kim MM, Elliott-Bynum S. Healing With CAARE: An Oasis of Care in the Changing Landscape of Translational Science. N C Med J. 2015 Jul-Aug;76(3):185-9. doi: 10.18043/ncm.76.3.185. PubMed PMID: 26510227.

94. Jilcott SB, Laraia BA, Evenson KR, Lowenstein LM, Ammerman AS. A guide for developing intervention tools addressing environmental factors to improve diet and physical activity. Health Promot Pract. 2007 Apr;8(2):192-204. PubMed PMID: 17384406

95. Johnson JL, Muller KE, Slaughter JC, Gurka MJ, Gribbin MJ, and Simpson SL. POWERLIB: SAS/IML Software for Computing Power in Multivariate Linear Models. Journal of Statistical Software. 2009;30(5):1-27.

96. Fritz M. S., MacKinnon D. P. Required sample size to detect the mediated effect. Psychological Science. 2007;18:233–239. doi:10.1111/j.1467-9280.2007.01882.x. MacKinnon D. P., Fritz M. S., Williams J.,

Lockwood C. M. Distribution of the product confidence limits for the indirect effect: Program PRODCLIN. Behavior Research Methods. 2007a;39:384–389. doi:10.3758/BF03193007.

97. U.S. Census Bureau (2018). American Community Survey 1-year estimates. Retrieved from Census Reporter Profile page for Raleigh-Durham-Chapel Hill, NC CSA Retreived from *https://censusreporter.org/profiles/33000US450-raleigh-durham-chapel-hill-nc-csa/*

98. Diggins A, Woods-Giscombe C, Waters S. The association of perceived stress, contextualized stress, and emotional eating with body mass index in college-aged Black women. Eat Behav. 2015 Dec;19:188-92. doi: 10.1016/j.eatbeh.2015.09.006. PubMed PMID: 26496005. PMCID: N/A

99. Barksdale, Debra J.; Woods-Giscombé, Cheryl; Logan, Jeongok G.; Stress, Cortisol, and Nighttime Blood Pressure Dipping in Nonhypertensive Black American Women. Biological Research for Nursing. PMCID Not Applicable