Reducing Binge Eating to Prevent Weight Gain in Black Women

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Study Title: **Reducing Binge Eating to Prevent Weight Gain in Black Women**

UNC Principal Investigator (PI): Rachel Goode, PhD

UNC PI Department/Division: School of Social Work

Number of Sites: 1

Lead Site [If multi-site study]: UNC Department of Family Medicine

Lead Site Principal Investigator: Rachel Goode

Additional Site: N/A

UNC Co-Investigator(s) and Department/Division (as applicable): Laurel Sister; Department of Family Medicine, UNC-Chapel Hill

Sponsor(s) :

Name/Address: National Institutes of Health, National Institute of Diabetes, Digestive, and Kidney Diseases (NIDDK), P30DK56350

I HAVE READ AND APPROVE THIS VERSION OF THE PROTOCOL.

[electronic signature accepted]

Principal Investigator:  **Date:** **12/1/2018**

Summary of Changes from Previous Version [If applicable]:

Previous Version No.	Affected Section(s)	Summary of Revision(s)	Reason for Change(s)

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Statement of Compliance

This study will be conducted in accordance with the International Conference on Harmonisation guidelines for Good Clinical Practice (ICH E6) and the Code of Federal Regulations on the Protection of Human Subjects (45 CFR Part 46). The statistical analysis plans will be consistent with guidances such as the CONSORT Statement [1] or STROBE Statement [2], ICMJE recommendations [3], the 2016 and 2019 statements of the American Statistical Association [4,5], and recommendations in Nature [6,7].[1] All personnel involved in the conduct of this study have completed human subjects protection training.

[1] [1] www.consort-statement.org [2] www.strobe-statement.org [3] www.icmje.org [4] Wasserstein RL, et al. (2016), The ASA's Statement on p-Values, ***The American Statistician***, 70:2, 129-133 [5] Wasserstein RL, et al. (2019), Moving to a World Beyond p < 0.05, ***The American Statistician***, 73:sup1, 1-19 [6] Amrhein, et al. (2019) Scientists rise up against statistical significance, ***Nature*** 567, 305-307 [7] Editorial (2019) It's time to talk about ditching statistical significance: Looking beyond a much used and abused measure would make science harder, but better. ***Nature*** 567, 283-283.

Abbreviations and Definitions of Terms

[Spell out any acronyms, abbreviations, or non-standard terminology. Delete this text and any entries below that are not used in your protocol.]

Abbreviation/Acronym	Definition
AE	Adverse Event/Adverse Experience
CI	Confidence Interval
CIOMS	Council for International Organizations of Medical Sciences
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
CRO	Contract Research Organization
DCC	Data Coordinating Center
DSMB	Data and Safety Monitoring Board
eCRF	Electronic Case Report Form
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
IB	Investigator's Brochure
ICF	Informed Consent Form
ICMJE	International Committee of Medical Journal Editors
IDE	Investigational Device Exemption
IND	Investigational New Drug Application
IRB	Institutional Review Board
N	Number (typically refers to subjects)
NDA	New Drug Application
PHI	Protected Health Information
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event/Serious Adverse Experience
SD	Standard Deviation
SE	Standard Error
SOP	Standard Operating Procedures
STROBE	STrengthening Reporting of OBservational studies in Epidemiology
UP	Unanticipated Problem

1. Protocol Synopsis

Study Title	Reducing Binge Eating to Prevent Weight Gain in Black Women
Objectives	Primary: Examine the feasibility and acceptability of a 6-month AAT + NUTR (N=48) intervention. AA women (BMI ≥ 25 kg/m²) with weekly binge eating episodes will be randomized to the AAT+NUTR (n=24) or wait-list control (n=24). The study will examine recruitment, retention, barriers to completion, satisfaction, and adherence. Secondary: At 4 (end of treatment) and 6 months (follow-up), examine changes in (a) binge eating; (b) depressive symptoms; (c) dietary outcomes (e.g., overall energy intake, fat, fruit and vegetable intake); and (d) weight for participants in each group. Tertiary/Exploratory: Conduct key informant interviews (n=15-20) with UNC Department of Family Medicine staff and participants to determine acceptability of the AAT intervention in the primary care setting.
Target Population	**Key Inclusion Criteria** Individuals are eligible if they are non-Latino Black women, over 18 years of age, have a BMI ≥ 25kg/m², use a Bluetooth-enabled smartphone, report at least one binge eating episode weekly, and complete the screening. **Key Exclusion Criteria** Individuals will be excluded if they are currently pregnant, in substance use treatment, involved in a weight loss program, have a history of anorexia nervosa, engage in purging, are currently receiving psychological or pharmacological treatment for disordered eating or eating disorders, or are concurrent intravenous drug users or consume >4 alcoholic beverages/day.
Numbers of Participants	**Number to be recruited for screening** [some will not be eligible for enrollment] 200 **Number of eligible participants enrolled** [this is the target sample size for enrollment] 60
Clinical Phase	[I, II, III, or IV (if applicable)]
Intervention	Participants will participate in an 16-week combined Appetite Awareness Training (AAT) + Diabetes Prevention Program (NUTR) intervention. For the first 8 weeks, participants will attend 8 weekly AAT sessions and then transition to eight, weekly NUTR sessions. All sessions will be 60-90 minutes. The goal of AAT is to enable participants to be able to relearn their stomach's hunger signals and begin to obey and monitor functions of satiety. AAT has been successful in helping participants diagnosed with eating disorders reduce binge eating, overeating, and prevent weight gain. Sessions involve didactic training, review of self-monitoring of eating episodes, and homework assignments. NUTR includes group sessions that are based on the Diabetes Prevention Program curriculum, and include content on nutrition (e.g.,

	shopping, fruit and vegetable intake, eating away from home), physical activity, and goal setting.
Study Description	This study is a two-arm, randomized controlled trial to examine the feasibility and acceptability of 6 month AAT + NUTR compared to wait-list control. Patients will be recruited from the UNC Department of Family Medicine. AAT+NUTR participants will spend the first 2 months receiving treatment to reduce binge eating (AAT), and the next 2 months engaging in group-based nutrition counseling. Participants will then work independently for 2 months. Data from both intervention groups will be collected at 3 time points: baseline, before randomization (T1), at the end of month 4, post treatment (T2), and at the end of month 6, follow-up (T3). Descriptive analyses will first be performed overall, by treatment group, and time points to identify any data anomalies (e.g., missing data, outliers, non-normality) that may invalidate study findings. Remedial measures (e.g., single/multiple imputation of missing data, score/data transformation) will be applied as indicated based on the results of data screening.
Outcome Measures	[Measures that will used to assess the intervention (for feasibility, tolerability, efficacy, safety, comparability, pharmacokinetics/pharmacodynamics, etc.)] To assess the feasibility of recruiting adult, overweight/obese Black women to the proposed study, the percent of eligible overweight/obese black women who were enrolled and retained in the study will be examined and reasons for nonparticipation and attrition will be documented. Participants will also be asked to provide measurements for height/weight, blood pressure, binge eating, and complete several self-report measures.
Study Duration	2 years
Subject Participation Duration	30 hours
Estimated Time to Complete Enrollment	January 2019-July 2021
Statistical Analysis Plans	[Feasibility will also be determined by calculation of point and interval estimates (95% confidence intervals using sample size methods) of the feasibility parameters (proportion/percentages in terms of eligibility, participation, retention; means/medians for attendance at intervention sessions) and bivariate frequency distributions. Linear mixed effects modeling will be used to predict the association between treatment group assignment (AAT + NUTR or control), and binge eating, dietary intake, and weight scores at T2 and T3. Baseline scores will be used as

	covariates in these analyses. Standardized mean differences (e.g., Cohen's d with bias adjustment) will also be calculated as an effect size measure with 95% CI.

2. Introduction: Background and Scientific Rationale

2.1. Background Information

[Do not copy the background section from a grant application. This protocol should reflect only information relevant to the current study, which may be smaller in scope than a grant award. The Background section should include a brief discussion of: the health problem the study will address (knowledge gaps); the name/description of the study intervention; prior research (in vitro, preclinical in vivo, and clinical trials) and experience that provides context and scientific justification for conducting the study; and the importance of the study. Include references in support of claims; in-text citations should be numeric in ascending order to match the reference list.]

Binge eating Disorder (BED) is defined as recurrent binge eating while concurrently experiencing loss of control, marked distress, and with the absence of compensatory behaviors for weight loss. BED is the most common eating disorder among all racial and ethnic groups, affecting approximately 2.6% of the US population. Moreover, BED is associated with other co-morbid conditions, including that substance disorders and mood disorders.

While there are several effective behavioral treatments for BED (e.g., Cognitive Behavioral Therapy (CBT), Interpersonal Therapy) there are racial disparities in treatment access. African-Americans (AA) have some of the lowest rates of access to care, and less than 8% of AA women with BED seek treatment compared to 20% of White women. Furthermore, BED may be more severe among AA women who DO not access treatment; for example, AA women receiving treatment for BED demonstrate less pre-treatment binge eating compared to non-treatment seeking controls with BED. Therefore, it is imperative that investigators develop strategies for treatments that are accessible and effective for AA women.

One strategy may be to intervene with women who have not yet developed BED, but who may show signs of early risk factors (e.g., binge eating, rapid weight gain). A possible group for early intervention may be AA women, particularly since more than 30% of this population reports binge eating. Though treatment seeking specific to disordered eating is disparate among AA women, there is ample evidence to suggest their willingness to participate in nutrition counseling and weight stabilization, particularly when delivered in primary care. Early detection and intervention with this population may be a critical first step to the prevention of BED, and the increase in treatment access for disordered eating behaviors.

Because AA women who binge eat may be at risk for BED, we hypothesize that by participating in a combined AAT+ nutrition counseling (NUTR) intervention, participants would increase awareness of BED risk, reduce binge eating, and stabilize weight. We also hypothesize this intervention will help reduce known co-morbidities, including depressive symptoms.

2.2. Supporting Pilot / Unpublished Data

[Provide essential details of any as-of-yet unpublished data used to justify the proposed study, including any adverse event data.]

Currently, intervention research addressing binge eating behaviors among AA women is extremely scarce. I am working to fill this gap. My pilot APPETITE study (n=31) examined the feasibility of Appetite Awareness Training (AAT), a CBT-intervention for binge eating, in a community-based sample of AA women (BMI=25-40 kg/m²) with moderately severe binge eating behavior. In this pilot study, retention was high (88%), and binge eating was significantly reduced at 8 weeks.

2.3. Scientific Rationale

[Describe and justify the selected intervention (including dosage, timing, schedule, method of administration, validity of scales, as applicable) and study population.]

Currently, 55% of Black women are obese. Obesity is a serious health problem with numerous co-morbidities. Recent evidence has encouraged investigators to focus their efforts on weight gain prevention in Black women. Consuming a healthy, energy-balanced diet and engaging in physical activity are important for prevention of weight gain. Black women, however, may be vulnerable to certain eating behaviors that may pose barriers to weight management. One particular barrier is binge eating, which is associated with severe obesity. By reducing binge eating episodes in black women, weight gain may be prevented. Based on our analysis, we determined that a sample of 60, evenly allocated between treated and control groups, is sufficiently powered (.80) to identify large standardized mean differences in binge eating (d = .74) (Aim #2). The sample, however, is underpowered to determine differences in weight. Because this study is exploratory, we are prioritizing feasibility, and an exploration of differences, rather than determining efficacy.

3. Objectives

The overarching goal of this research to examine the feasibility and acceptability of a combined AAT and NUTR intervention (N=48) in the primary care setting. Participants will be recruited from the UNC Department of Family Medicine, and will be randomized to a group-based 16-week intervention (8 weeks AAT + 8 weeks NUTR) or wait-list control. Following the end of the intervention, I will conduct semi-structured interviews with participants and primary care providers to determine the acceptability of the program.

3.1. Specific Aim 1

Examine the feasibility and acceptability of a 6-month AAT + NUTR (N=48) intervention. AA women (BMI ≥ 25 kg/m²) with weekly binge eating episodes will be randomized to the AAT+NUTR (n=24) or wait-list control (n=24). The study will examine recruitment, retention, barriers to completion, satisfaction, and adherence.

3.2. Specific Aim 2

4. At 4 (end of treatment) and 6 months (follow-up), examine changes in (a) binge eating; (b) depressive symptoms; (c) dietary outcomes (e.g., overall energy intake, fat, fruit and vegetable intake); and (d) weight for participants in each group.

5. Study Design

The proposed study will use a randomized controlled clinical trial design. A sample of 60 black women who report at least weekly binge eating episodes will be randomized to 2 arms of a 6-month AAT + BWL intervention: AAT+BWL or a control group. AAT+BWL participants will receive an 8-week AAT program, and an 8-week BWL program, both using a group format. Assessments will be conducted at 0, 4, and 6 months. This study will be conducted at one site: UNC Department of Family Medicine.

The *goal of AAT is to enable participants to be able to relearn their stomach's hunger signals and begin to obey and monitor functions of satiety 11. AAT has been successful in helping participants diagnosed with Binge Eating Disorder (BED) and bulimia nervosa reduce binge eating, overeating, urges to eat in response to non-appetite stimuli, and prevent weight gain. 12-14 The AAT intervention includes eight 60-minute group sessions. All sessions involve didactic training, review of self-monitoring of eating episodes, interactive activities, and homework assignments to enable participants to practice learned skills. Participants will be provided a workbook, which will include session content, and self-monitoring forms.*

The curriculum for BWL (behavioral weight loss) will be based on the evidenced-based curriculum from the Diabetes Prevention Program, or Prevent T2. Eight weekly session will review core content including healthy eating, increasing physical activity, and caloric balance. An outline of session curriculum is attached to the protocol.

Physical measures will be taken by trained staff, who will be supervised by Dr. Rachel Goode, PI of this project. The following equipment will be used:

1. ***Height /Weight** will be measured on a digital scale and a wall-mounted stadiometer.*
2. ***Waist Circumference** will be measured twice with a Gullick II measuring tape.*
3. ***Blood pressure** assessment will be measured using an GE Dinamap Procare Auscultatory 400 Multi-Parameter Patient Monitor with the subject in a sitting position after at least a minute rest period.*

Questionnaires:

1. Eating Disorder Examination (EDE-Q*) is a self-reported questionnaire based on the Eating Disorder Examination.*

2. ***Beck Depression Inventory (BDI)24*** *is a 21-item questionnaire that measures symptoms and attitudes associated with depression.*

3. ***Weight Efficacy Life-Style Questionnaire (WEL) 25:*** *The WEL is a 20-item questionnaire that assesses participants' level of confidence in resisting eating in varied situations and in different emotional states, with*

higher scores indicating more confidence.

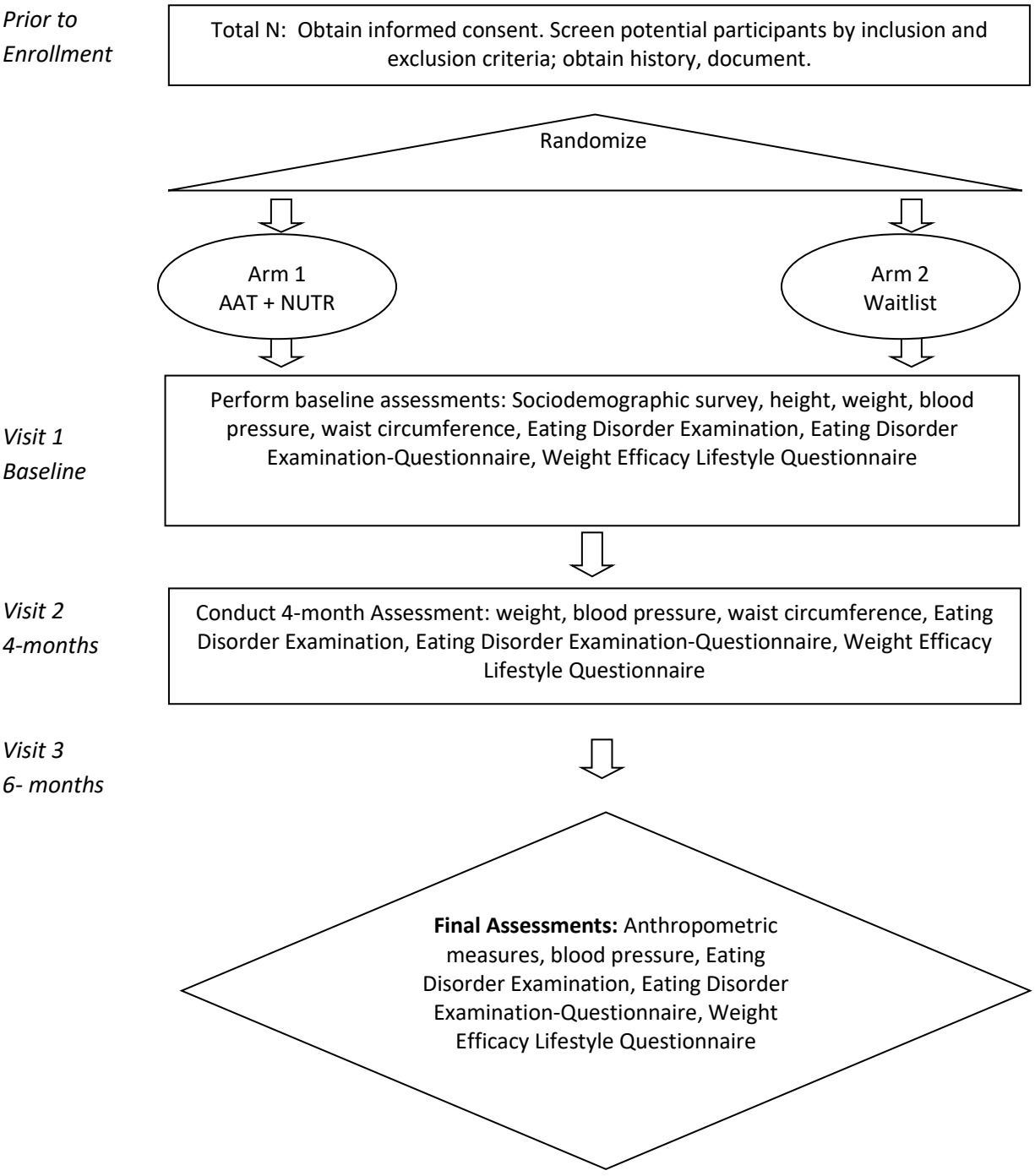
4. Eating Disorder Examination – Overeating Section (EDE) 20 *is a semi-structured interview to assess symptoms and DSM-IV diagnoses for Bulimia Nervosa, Anorexia Nervosa, and BED. Eating disorder symptoms are assessed on four subscales: restraint, eating concern, shape concern, and weight concern. The*

EDE has well-established validity, reliability, and has been used extensively as an established measure of disordered eating behavior.

5. Modified Sociodemographic Questionnaire *will be used to collect: age, marital status, education, neighborhood residence, employment status, household size, religious background, and income.*

Randomization will be performed by Microsoft Excel and the PI will be blinded to all randomization. A research assistant will be responsible for supervising randomization. Prior to randomization, potential participants will respond to flyers and will be screened to determine eligibility. If an individual is eligible, she will be given a date and time to meet with a research team member. Participants will be evaluated in person or by phone to determine the presence of at least one weekly binge eating episode using the overeating section of the Eating Disorder Examination. Participants will also complete anthropometric measurements, provide signed informed consent, and finish self-report measures. Once all baseline assessments are complete, participants will be randomized to the AAT + BWL intervention or control group. Participants will be assessed at 0, 4 months, and 6 months. Data on the AAT group will be collected at 3 time points: baseline, before randomization (T1); end of month 4, after the completion of intervention program (T2); and end of month 6, posttreatment follow up (T3). Data on the control group will be collected at: baseline (T1), 4 months (T2), and at the end of 6 months (T3).

Example #1 Flow diagram (e.g., randomized controlled trial). Customize to your study flow.]



5.1. Treatment Design

The proposed study will use a randomized clinical trial design. A sample of 48 Non-Latino, AA women (BMI ≥ 25 kg/m^2; *rationale*: *prior clinical and research experience suggests that AA women within this BMI range are most likely to identify their eating as problematic and engage in a clinical intervention*[26]) who report at least weekly binge eating episodes will be randomized to 2 arms of a 6-month intervention: ***AAT + NUTR*** or ***wait-list control***. AAT + NUTR participants (n=24) will first receive a weekly, group-based AAT program for the first two months, and then will begin NUTR and receive weekly, group sessions for the next 2 months. Wait-list control group (n=24) participants will receive an abbreviated AAT treatment at the end of 6 months. Following the intervention, UNC WMP providers (e.g., social workers, preventive medicine residents), and participants will be asked to participate in a 30-60 minute interview on the acceptability of the AAT +NUTR program, and to explore factors that will increase dissemination and uptake in the primary care setting.

5.2. Experimental / Observational Design

The proposed study will use a randomized clinical trial design. A sample of 60 black women who report at least weekly binge eating episodes will be randomized to 2 arms of a 6-month AAT + BWL intervention: AAT+BWL or a control group. AAT+BWL participants will receive an 8-week AAT program, and an 8-week BWL program, both using a group format. Assessments will be conducted at 0, 4, and 6 months.

5.3. Measurement Design

Table 1: Measures for Randomized Controlled Feasibility Trial

Measure	Description	Assessment Schedule		
		Baseline	4 months	6 months
Eating Disorder Examination – Overeating Section (EDE)[35]	A semi-structured interview to assess symptoms and DSM-V diagnoses for Bulimia Nervosa, Anorexia Nervosa, and BED.	X	X	X
Modified Sociodemographic Questionnaire	A questionnaire to collect age, marital status, education, neighborhood residence, employment status, household size, religious background, and income	X		
Height /Weight	Will be measured on a digital scale and a portable stadiometer.	X	X	X
Eating Disorder Examination-Questionnaire (EDE-Q) [36]	A 41-item scale to assess disordered eating behaviors and attitudes.	X	X	X
Dietary Intake (e.g., overall energy intake, fat, fruit and vegetable intake)	Two-24-hr dietary recall interviews (telephone-based) will be conducted on randomly selected days during a 2-week period.	X		X
Beck Depression Inventory[37]	A 21-item instrument used for measuring attitudes and symptoms of depression.	X	X	X

5.4. Outcome Measures

Primary Outcome(s):

Table 2: Feasibility Measures (Aim #1)[38]	
Question of Interest	**Feasibility Measures**
Can we recruit our target population?	# of screened and eligible participants, and proportion of eligible screens who enroll
Will participants do what they are asked to do?	Adherence to study protocol (e.g. session attendance, homework completion)
Are the assessments too burdensome?	Proportion of planned assessments completed; duration of assessment visits
Will participants stay in the study?	% of study retention and reasons for dropouts
Is AAT + NUTR acceptable to study participants?	Semi-structured telephone interviews (n=15-20) will be conducted to receive feedback on intervention and suggestions for improvement.

Secondary Outcome(s): Linear mixed effects modeling will be used to examine the association between treatment group assignment (AAT + BWL or wait-list control group coded as a (0,1)-indicator) and binge eating, eating self-efficacy, depressive symptoms, weight, blood pressure, and waist circumference scores at 2 and 6 months.

6. Study Participants

6.1. Number of Participants

Number to be recruited for screening: 160

Number of eligible participants enrolled: 60

Eligibility criteria includes Non-Latino Black women individuals over 18 years of age, have a BMI ≥ 25 kg/m², use a Bluetooth-enabled smartphone, and report at least one binge eating episode weekly. We will recruit participants in two ways: 1) We will request an IRB-waiver to allow Laurel Sisler, the director of the Weight Management Program and co-investigator on this study to a list of eligible participants (e.g., Non-Hispanic, AA & White women, BMI > 30 kg/m2) at UNC Family Medicine. The names will be randomly ordered, and women will be sent an introductory letter via email and/or postal mail describing the project and inviting them to contact the research team if no further contact is desired. If no such contact is received, the letter will be followed by a telephone call from the project coordinator, who will discuss all components of informed consent and participation. 2) Potential participants will respond to flyers, email announcements in community centers, doctor's offices, churches, and university listservs. Participants will also be approached in local community agencies by community center staff members and lay health counselors to request their consent to be approached by a member of the research team. IRB-approved flyers will be posted in the lobbies and recreation halls of the community facilities. Potential participants may self-refer to the study after reading the flyer.

6.2. Eligibility

Inclusion Criteria: In order to be eligible to participate in this study, an individual must meet **all** of the following criteria:

- Non-Latino Black women
- Over 18 years of age,
- Have a BMI ≥ 25 kg/m²
- Use a Bluetooth-enabled smartphone
- Report at least one binge eating episode weekly

Exclusion Criteria: Any individual who meets one or more of the following criteria will be excluded from participation:

- Individuals who are currently pregnant,
- In substance use treatment,
- Currently receiving psychological or pharmacological treatment for disordered eating or eating disorders,
- Children (under the age of majority for their location),
- Nonviable neonates or neonates of uncertain viability,
- Prisoners, other involuntarily detained or incarcerated (this includes parolees help in treatment centers as a condition of their parole),
- Decisionally impaired individuals,
- Children who are wards of the State (Foster children),
- Non-English-speaking individuals,
- People, including children, who are likely to be involved in abusive relationships, either as perpetrator or victim

6.3. Strategies for Recruitment and Retention

Recruitment Strategy:

Using an IRB-approved waiver, a list of eligible participants (e.g., Non-Hispanic, AA women, BMI ≥ 25 kg/m^2) at UNC Family Medicine will be generated from examining the electronic health record. We will then send an introductory letter via postal mail to all eligible participants. This letter will describe the study, and then provide information on opting out. Study staff will contact those who do not opt out and conduct an eligibility screen. If an individual is eligible, they will be given a date and time to meet with a research team member. Participants will be evaluated in person to determine the presence of at least one weekly binge eating episode using the overeating section of the Eating Disorder Examination. Participants will also complete height/weight measurements, provide signed informed consent, and finish self-report measures (See Table 1). Once all baseline assessments are complete, participants will be randomized to the AAT + NUTR intervention or wait-list control.

Retention Strategy:

Participants will receive $25 for completing the assessment at 0, 4, and 6 months, for a total of $75.00. Participants will be provided the incentive after participating in each assessment. If a participant withdraws prior to the completion of a particular assessment, the participant will only have access to incentives based on what assessments were previously completed. Because we wanted to prevent

coercion, we have purposely kept study incentives at a reasonable cost, and only at a level to offset the burden of participating in the study.

6.4. Consent Process

If participants are eligible for the study, the applicant will be given a date and time to meet with the PI and will be provided an email link to access the self-report measures associated with this study. At appointment, participants will provide signed informed consent, finish self-report measures, and be evaluated in person to determine the presence of at least one weekly binge eating episode using the overeating section of the Eating Disorder Examination. Participants will also have their height, weight, blood pressure, and waist circumference measured at this time. Baseline appointment will take place in a private room at the UNC Department of Family Medicine. If all inclusion criteria are met, participants will be randomly assigned to one of the two treatment conditions. There will be a brief waiting period between the initial consent discussion and obtaining consent for this study. In addition, consent will be obtained by research assistants affiliated with this study, other than the study PI.

7. Study Intervention

[An interventional study may involve a drug, device, biologic agent, or a medical, surgical, dental, radiological, nutritional, neurological, or behavioral intervention. The study may use an experimental design (e.g. a randomized trial) or it may use an observational design (e.g., a single-arm study or study in which the physician and patient choose from among available treatment regimens). **Complete only the sections below that are relevant to your study; enter N/A otherwise.**]

7.1. Intervention – Test Article (if applicable)

Description:

The Appetite Awareness Treatment (AAT) intervention includes eight 60-minute group sessions. All sessions involve didactic training, review of self-monitoring of eating episodes, interactive activities, and homework assignments to enable participants to practice learned skills. Participants will be provided a workbook, which will include session content, and self-monitoring forms.

The Behavioral Weight Loss (BWL) intervention us based on the curriculum for the Diabetes Prevention Program, and offers training in healthy eating, increasing physical activity, and achieving caloric balance.

Acquisition: [State how test article will be acquired, e.g., from manufacturer, IND/IDE Sponsor, UNC Investigational Drug Services, or internal, e.g., device developed by a UNC faculty or laboratory.]

N/A

Formulation/Packaging/Labeling:

N/A

Storage and Stability:

N/A

Preparation and Administration:

N/A

Modification:

N/A

Accountability: [

N/A

7.2. Assignment Procedures

[If applicable to the study design, specify complete details of the plan for assigning enrolled participants to the treatment regimens.]

Matching and Stratification: (if applicable) [If applicable, specify exactly how matching and/or stratification of subjects will be accomplished]

N/A

Randomization, Concealment, and Blinding:

Randomization will be performed by Microsoft Excel and the PI will be blinded to all randomization. A research assistant will be responsible for supervising randomization.

Masking (Blinding):

Randomization will be performed by Microsoft Excel and the PI will be blinded to all randomization.

7.3. Intervention – Procedural (if applicable)

Description:

The training manual for this intervention is based on the Appetite Awareness Training Workbook by Linda Craighead.

Training on Procedural Intervention:

MSW-trained social work clinicians will be responsible for conducting both interventions, and will have weekly supervision with the PI (Dr. Goode). Due to their training in the social determinants of health and in providing behavioral health interventions, social workers with graduate training are well-equipped to apply a person-in-environment perspective, and treat the biopsychosocial factors that influence the health and eating behaviors of study participants. Moreover, using social workers may reduce burden in a busy, primary care setting, and increase treatment access and uptake.

7.4. Concomitant Therapy (if applicable)

[Describe what is prohibited, what is recommended and/or allowed, and what information about this topic will be collected as part of the study.]

N/A

7.5. Rescue Medications and Procedures (if applicable)

[Describe rescue procedures or medications that are permissible or required for adverse events.]

N/A

7.6. Compliance Checks

[Discuss measures and procedures to assess participant compliance.]

N/A

7.7. Withdrawal / Discontinuation of Enrolled Participants

Participants may be withdrawn if participant develops a condition that is an exclusion criterion (e.g. participants who become pregnant will be asked to withdraw from the study).

7.8. Voluntary Withdrawal (Drop-Out) of Enrolled Participants

Participants may voluntarily withdraw participation at any time, for any reason, with no penalty or loss of rights. If a participant withdraws prior to the completion of a particular assessment, the participant will only have access to incentives based on what assessments were previously completed.

8. Study Procedures and Schedule

[Information presented in this section should be consistent with the Synopsis (MPD Section 1) and the Table of Events (example below)

8.1. Table of Events

Table 1: Measures for Randomized Controlled Feasibility Trial				
Measure	**Description**	**Assessment Schedule**		
		Baseline	**4 months**	**6 months**
Eating Disorder Examination – Overeating Section (EDE)[35]	A semi-structured interview to assess symptoms and DSM-V diagnoses for Bulimia Nervosa, Anorexia Nervosa, and BED.	X	X	X
Modified Sociodemographic Questionnaire	A questionnaire to collect age, marital status, education, neighborhood residence, employment status, household size, religious background, and income	X		
Height /Weight	Will be measured on a digital scale and a portable stadiometer.	X	X	X
Eating Disorder Examination-Questionnaire (EDE-Q) [36]	A 41-item scale to assess disordered eating behaviors and attitudes.	X	X	X
Dietary Intake (e.g., overall energy intake, fat, fruit and vegetable intake)	Two-24-hr dietary recall interviews (telephone-based) will be conducted on randomly selected days during a 2-week period.	X		X
Beck Depression Inventory[37]	A 21-item instrument used for measuring attitudes and symptoms of depression.	X	X	X

[In the following sections 7.2 – 7.8, fully describe:

- All contact with subjects (study visits, telephone/electronic contact)
- Permissible time windows for study procedures, lab tests, etc. While a treatment visit may have a small window (such as ± 1 day), a 6-month follow-up call may have larger window (such as ± 1 week)
- Clearly distinguish activities and procedures that participants will complete in the course of clinical care from those that participants will complete solely for research purposes]

Table 3. Timeline of Research Activities								
Study Activities	**Year 01**				**Year 02**			
	Q1	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**
Aim 1: Feasibility Study								
Start-up								
Recruitment								
Conduct of feasibility study								
Data Analysis								
Presentations and publications								
Aim 2: Acceptability Interviews								
Semi-structured interviews and analysis								
Presentations and publications								
Prepare and submit R-series grant								

8.2. Pre-Screening / Screening (Day -X to Day Y)

During recruitment, participants will not be directly contacted identified from privately held sources without the participant's permission. Methods that are the "least intrusive" will be used, and participants will be encouraged to contact the research team if they are interested in receiving more information about the study. Participants will self-refer to the study, and provided the link to participate in the survey. Participants will be contacted by email or telephone to after determining preliminary eligibility via a Qualtrics web survey. Recruitment will be managed by study investigators and research assistants. Potential participants will respond to notices by calling number on flyer or filling out the screening link, and will be screened to determine eligibility. If an individual is eligible, she will be given a date and time to meet with a research team member.

8.3. Enrollment / Baseline (Day 0)

If participants are eligible for the study, the applicant will be given a date and time to meet with the PI and will be provided an email link to access the self-report measures associated with this study. At appointment, participants will provide signed informed consent, finish self-report measures, and be evaluated in person to determine the presence of at least one weekly binge eating episode using the overeating section of the Eating Disorder Examination. Participants will also have their height, weight, blood pressure, and waist circumference measured at this time. Baseline appointment will take place in a private room at the UNC Department of Family Medicine. If all inclusion criteria are met, participants will be randomly assigned to one of the two treatment conditions.

8.4. Study Visits (Numbered as V1, V2, etc., Day X ± Y)

Participants will attend 8 weekly AAT sessions and then transition to eight, weekly NUTR sessions. All sessions will be 60-90 minutes.

V1: Data on AAT group and control group collected at baseline, before randomization (T1)

V2: Data on AAT group and control group collected at end of month 4, after completion of intervention program (T2)

V3: Data on AAT group and control group collected data end of month 6, posttreatment follow-up (T3)

Data collected includes height, weight, blood pressure, and waist circumference.

8.5. Phone Contact (Day Day X ± Y)

[Describe information/data to be collected, e.g., activities of daily living, symptom rating.]

<Insert text>

8.6. Final Visit (Day Day X ± Y)

[List all interventions/evaluations/procedures in the sequence they will occur, e.g., record adverse events as reported by subject or observed by investigator, record subject's compliance with intervention, provide final instruction to subject.]

<Insert text>
Data collected at end of month 4, after the completion of intervention program, includes: height, weight, blood pressure, and waist circumference. Participants will also be asked to complete the Eating Disorder Examination, Eating Disorder Examination-Questionnaire, Weight Efficacy Lifestyle Questionnaire, and the Beck Depression Inventory.

8.7. Follow-Up Contact (Day Day X ± Y)

[Describe information/data to be collected, e.g., adverse events, disease progression/recurrence.]

<Insert text>
Data collected at end of month 6, posttreatment follow up, includes: height, weight, blood pressure, and waist circumference. Participants will also be asked to complete the Eating Disorder Examination, Eating Disorder Examination-Questionnaire, Weight Efficacy Lifestyle Questionnaire, and the Beck Depression Inventory.

8.8. Premature Discontinuation

[If a subject withdraws or the investigator discontinues subject participation, specify evaluations that should be performed and data that should be collected. Indicate if you plan to collect medical record data for the duration of the study for follow-up purposes, even if the study intervention is discontinued.]

<If a participant withdraws or study participation is discontinued by the principal investigator, participants will be asked to complete the Eating Disorder Examination-Questionnaire Survey.

8.9. Collection and Management of Tissue Specimens

Sample Preparation: [As applicable, describe measures to prevent sample loss and degradation, cooling and freezing procedures, sample labeling, etc.]

Record Keeping and Monitoring: [As applicable, describe procedures for maintaining sample accountability and traceability and for ensuring regulatory compliance.]

Sample Storage and Security: [As applicable, describe the location, facility, and storage method/equipment; sample chain of custody; the remote monitoring and maintenance procedures; data security system, encryption, and access restrictions for study personnel.

9. Study Measurements and Evaluations

9.1. Outcome Measures for Evaluation of Feasibility / Tolerability

To assess the feasibility of recruiting adult, AA women to the proposed study, the percent of eligible women who were enrolled and retained in the study will be examined and reasons for nonparticipation and attrition will be documented. Feasibility will also be determined by calculation of point and interval estimates (95% confidence intervals using sample size methods) of the feasibility parameters (proportion/percentages in terms of eligibility, participation, retention; means/medians for attendance at intervention sessions) and bivariate frequency distributions.

Table 2: Feasibility Measures (Aim #1)[38]

Question of Interest	Feasibility Measures
Can we recruit our target population?	# of screened and eligible participants, and proportion of eligible screens who enroll
Will participants do what they are asked to do?	Adherence to study protocol (e.g. session attendance, homework completion)
Are the assessments too burdensome?	Proportion of planned assessments completed; duration of assessment visits
Will participants stay in the study?	% of study retention and reasons for dropouts
Is AAT + NUTR acceptable to study participants?	Semi-structured telephone interviews (n=15-20) will be conducted to receive feedback on intervention and suggestions for improvement.

9.2. Outcome Measures for Evaluation of Efficacy

Linear mixed effects modeling will be used to examine the association between treatment group assignment (AAT + BWL or wait-list control group coded as a (0,1)-indicator) and binge eating, eating self-efficacy, depressive symptoms, weight, blood pressure, and waist circumference scores at 2 and 6 months. Baseline scores will be used as covariates in these analyses with interactions between treatment group assignments with baseline values of outcome scores. Standardized mean differences (e.g., Cohen's d with bias adjustment) will also be calculated as an effect size measure with 95% CI. Standardized residuals will be examined to assure no assumptions are violated.

9.3. Outcome Measures for Evaluation of Safety

[e.g., rate of hospitalization, rate of safety events, rate of drop-outs due to adverse events]

N/A

9.4. Other Outcomes in the Causal Pathway

N/A

9.5. Baseline Characteristics of the Participants

Non-Latino Black women, over 18 years of age, have a BMI ≥ 25kg/m², and report at least one binge eating episode weekly.

9.6. Variables Representing Treatment

N/A

10. Statistical Analysis Plans

10.1.Strategies that Apply to all the Specific Aims

To help ensure replicability of the research, the analysis plans will be reviewed and finalized prior to collection of data (a priori). For each specific aim, the analysis plans specify detailed steps for obtaining estimates of population parameters (e.g., treatment effects) and for making inferences.

Sensitivity analyses will be performed to assess the robustness of the major results as indicated by their sensitivity to reasonable perturbations of the choices of the methods and assumptions used. Any question about the optimal choice of methods and assumptions are best handled by relegating competing approaches to roles in the domain of sensitivity analyses. Results of the sensitivity analyses will be used to guide our level of trust in the main results. Best practices for dealing with incomplete data will depend on the documented causes of missing, censored, and coarsened values. The reasons for missing data values, drop-out, and protocol departures will have been documented in/with the database.

All hypothesis tests yielding p-values that are deemed to be not statistically significant will be reported as being inconclusive. The proposed statistical analysis strategy acknowledges that no p-value can reveal the plausibility, presence, truth, or importance of an association or effect--which is consistent with the statements of the American Statistical Association [4,5], the recommendations in Nature [6,7], and guidances, such as the CONSORT Statement [1], STROBE Statement [2], and ICMJE guidance [3].[2]]

10.2.Description of the Study Cohort

Descriptive analyses will first be performed overall, by treatment group, and time points to identify any data anomalies (e.g., missing data, outliers, non-normality) that may invalidate study findings. Remedial measures (e.g., single/multiple imputation of missing data, score/data transformation) will be applied as indicated based on the results of data screening.

[2] [1] www.consort-statement.org; [2] www.strobe-statement.org; [3] www.icmje.org; [4] Wasserstein RL, et al. (2016), The ASA's Statement on p-Values, ***The American Statistician***, 70:2, 129-133. [5] Wasserstein RL, et al. (2019), Moving to a World Beyond p < 0.05, ***The American Statistician***, 73:sup1, 1-19. [6] Amrhein, et al. (2019) Scientists rise up against statistical significance, ***Nature*** 567, 305-307. [7] Editorial (2019) It's time to talk about ditching statistical significance: Looking beyond a much used and abused measure would make science harder, but better. ***Nature*** 567, 283-283.

10.3.Aim-Specific Plans

Plans for Aim 1: [e.g., to evaluate Efficacy, characterize and compare two treatment regimens]

To evaluate the feasibility and acceptability of 6-month AAT + NUTR, we will examine several feasibility outcomes. To assess the feasibility of recruiting adult, AA women to the proposed study, the percent of eligible women who were enrolled and retained in the study will be examined and reasons for nonparticipation and attrition will be documented. Feasibility will also be determined by calculation of point and interval estimates (95% confidence intervals using sample size methods) of the feasibility parameters (proportion/percentages in terms of eligibility, participation, retention; means/medians for attendance at intervention sessions) and bivariate frequency distributions.

Plans for Aim 2: [e.g., to evaluate Safety, characterize and compare two treatment regimens]

At 4 and 6 months, compare changes in (a) binge eating, eating self-efficacy, and depressive symptoms and (b) weight for participants in the AAT vs. control group. Linear mixed effects modeling will be used to examine the association between treatment group assignment (AAT + BWL or wait-list control group coded as a (0,1)-indicator) and binge eating, eating self-efficacy, depressive symptoms, weight, blood pressure, and waist circumference scores at 2 and 6 months. Baseline scores will be used as covariates in these analyses with interactions between treatment group assignments with baseline values of outcome scores. Standardized mean differences (e.g., Cohen's d with bias adjustment) will also be calculated as an effect size measure with 95% CI. Standardized residuals will be examined to assure no assumptions are violated.

Plans for Aim 3: N/A

Plans for Aim 4: N/A

10.4.Planned Interim Analyses (If Applicable)

N/A

10.5.Plans for Coping with Withdrawals and Loss-To-Follow-Up

Enrolled participants who discontinue/are withdrawn will not be replaced. The initial target number of enrolled participants is large enough to cope with loss of participants' data due to discontinuation, withdrawal, or insufficiently complete data (missing values).

10.6. Sample Size Rationale

Because this is a feasibility study, we are not prioritizing powering the sample to determine the efficacy of the AAT intervention. However, we ran conservative tests for statistical power incorporating parameters from our preliminary study using G*Power. Based on our analysis, we determined that a sample of 60, evenly allocated between treated and control groups, is sufficiently powered (.80) to identify large standardized mean differences in binge eating (d = .74) (Aim #2). The sample, however, is underpowered to determine differences in weight. Because this study is exploratory, we are prioritizing feasibility, and an exploration of differences, rather than determining efficacy. This is a pilot study, If this pilot study is successful, we will conduct a larger study with a greater sample of participants and test the AAT intervention for a longer duration.

11. Safety Monitoring and Management

11.1.Risk / Benefit Assessment

Potential Risks:

The major risks are likely to be fatigue, distress from revealing personal information and possibly during the intervention trial if the participant is not feeling like she is making progress. If participants complain about fatigue or distress, they will be given an opportunity to complete the questionnaire later.

Potential Benefits: [State anticipated direct benefit(s) for individual subjects, if any, or to society]

Participants may benefit from the tools learned within the intervention, and healthy non-eating coping skills. Study participants will also have the opportunity to receive support from sharing of their experiences and may receive further insight regarding tools to manage their binge eating behaviors and gain awareness for future weight loss attempts. They may also experience pride in knowing that they are contributing to a study that may make a significant contribution to the field in the future.

11.2.Assessment of Safety

To minimize emotional distress, if participants cite this concern, they will be provided the option to a) pause

and regroup; and/or b) finish the survey at a later time. If the previous is not sufficient, and participants report experiencing significant distress, participants will be provided the number to Hopeline (https://www.hopeline-nc.org; 919-231-4525), a North Carolina crisis line and to the local emergency room.

Participants who experience significant distress will also be asked permission to provide their contact

information to the PI (Dr. Goode). Dr. Goode, who is a licensed clinical social worker, will contact those

participants on the next day. Dr. Goode will also be updated immediately on all participants who experience

significant distress.

Depression – Beck Depression Inventory
Using the total score (from all added scores on the BDI), the following interpretation applies:

Total Score	Range of Depression
0 – 13	Minimal
14 – 19	Mild
20 – 28	Moderate
29 – 63	Severe

Potential participants who on initial assessment (or is there a screening assessment) have a BDI-II score of 29 or greater ("severe" depression) are excluded from the study (please see below).

If a participant's total score is 20 or greater, this will be reported to the Principal Investigator (PI) or Project Director (PD) who will discuss their results, inquire about current status and treatment, will **provide information on community resources for the treatment of depression, and document the conversation and actions taken.**

For question #9 "Suicidal Thoughts or Wishes": If a participant chooses response option 1, 2 or 3, this will be reported to the PI or PD who will discuss the results, inquire about current status and treatment and document the conversation and actions taken (providing a detailed note of the discussion that will be maintained using the participant's ID number). The participant will also be referred to their PCP, given a list of mental health providers in the community, and urged to seek treatment if they are not already receiving treatment.

I**f a participant endorses suicidality or imminent fear of self-harm**, the PD will contact and inform the PI (who is a licensed mental health professional), and also make telephone contact with the local suicide crisis network while in the presence of the participant; if a significant other is with the participant, that individual will be provided with instructions to accompany the person to the nearest Emergency Room. In either of these situations, the individual will be asked for permission to contact and inform their PCP of their condition.

11.3.Unanticipated Problems, Adverse Events, Serious Adverse Events

Unanticipated Problems: An unanticipated problem is any incident, experience or outcome that meets all three OHRP criteria (1) unexpected (in severity, specificity, frequency, or nature), (2) related or possibly related to the research, and (3) suggests the research places subjects or others at greater risk than previously known or recognized.

Adverse Event (AE) Definitions: An adverse event is one that occurs during the course of a research protocol that either causes physical or psychological harm, or increases the risk of physical or psychological harm, or results in a loss of privacy and/or confidentiality to a research participant or others (such as family members).

Serious Adverse Events (SAE) Definition: A serious adverse event means any event temporally associated with the subject's participation in research that meets any of the following criteria: results in death; is life threatening (places the subject at immediate risk of death from the event it occurred); requires inpatient hospitalization or prolongation of existing hospitalization; results in a persistent or significant disability/incapacity; results in a congenital anomaly/birth defect; or any other adverse event that, based upon appropriate medical judgement, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the outcomes listed .

Reporting and Documentation Procedures:
Data and safety monitoring will be conducted during meetings with the PI and research assistants during which recruitment, data acquisition, management and any adverse events arising from the study will be reviewed. Any unanticipated and adverse events will be reported immediately to the IRB, a serious event will be reported to the IRB and funding agency.

Participant Notification of New Information: All participants will be aware of new safety information within 7 days of the event preceding the development of new information.

11.4.Safety Monitoring

Data and safety monitoring will be conducted during meetings with the PI and research assistants during which recruitment, data acquisition, management and any adverse events arising from the study will be reviewed. Any unanticipated and adverse events will be reported immediately to the IRB, a serious event will be reported to the IRB and funding agency.

11.5.Study Suspension / Early Termination of the Study

Given that this is such a minimal risk intervention, we do not expect that serious AEs will occur and require stopping the trial. Though extremely unlikely, difficulties with compliance and/or attrition would be far more likely to result in trial stoppage. However, as previously noted, we, along with our safety officer, will closely monitor any injury rates and notify the UNC Chapel Hill IRB and the UNC NORC if a larger than expected SAE rate is observed.

12. Supporting Documentation and Operational Considerations

12.1.Regulatory, Ethical, and Study Oversight Considerations

The following subsections should include a description of the regulatory and ethical considerations, and context for the conduct of the trial. Of note, the guiding ethical principles being followed by this study are included in the **Statement of Compliance** at the beginning of this protocol. For NIH Intramural Research Program studies only: A statement referencing compliance with NIH Human Research

Protections Program policies and procedures is adequate for **Subsection 10.1.1, Informed Consent Process.**

12.1.1. Informed Consent Process

12.1.1.1. Consent/Assent and Other Informational Documents Provided to Participants

In obtaining and documenting informed consent, the investigator must comply with applicable regulatory requirements (e.g., 45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56) and should adhere to ICH GCP. Prior to the beginning of the trial, the investigator should have the IRB's written approval for the protocol and the written informed consent form(s) and any other written information to be provided to the participants.

This section should demonstrate that the consent form contains all required regulatory elements. List all consent and/or assent documents and materials submitted with this protocol. Include consent and/or assent forms, printed or web-based materials, phone scripts and any other related material.

If needed, describe special documents or materials (e.g., Braille, another language, audio recording)

Example text provided as a guide, customize as needed:

[Consent forms describing in detail the study intervention, study procedures, and risks are given to the participant and written documentation of informed consent is required prior to starting intervention/administering study intervention. The following consent materials are submitted with this protocol <insert list>.]

<Insert text>

12.1.1.2. Consent Procedures and Documentation

Informed consent is a process that is initiated prior to the individual's agreeing to participate in the study and continues throughout the individual's study participation. Consent forms will be Institutional Review Board (IRB)-approved and the participant will be asked to read and review the document. The investigator will explain the research study to the participant and answer any questions that may arise. A verbal explanation will be provided in terms suited to the participant's comprehension of the purposes, procedures, and potential risks of the study and of their rights as research participants. Participants will have the opportunity to carefully review the written consent form and ask questions prior to signing. The participants should have the opportunity to discuss the study with their family or surrogates or think about it prior to agreeing to participate. The participant will sign the informed consent document prior to any procedures being done specifically for the study. Participants must be informed that participation is voluntary and that they may withdraw from the study at any time, without prejudice. A copy of the informed consent document will be given to the participants for their records. The informed consent process will be conducted and documented in the source document (including the

date), and the form signed, before the participant undergoes any study-specific procedures. The rights and welfare of the participants will be protected by emphasizing to them that the quality of their medical care will not be adversely affected if they decline to participate in this study.

12.2.Study Discontinuation and Closure

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to study participants, investigator, funding agency, and UNC-Chapel Hill. If the study is prematurely terminated or suspended, the Principal Investigator (PI) will promptly inform study participants, the Institutional Review Board (IRB), and sponsor 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

Study may resume once concerns about safety, protocol compliance, and data quality are addressed, and satisfy the sponsor, IRB and/or NIH.

<Insert text>

12.3.Confidentiality and Privacy

Confidentiality of information will be maintained and assured by use of a unique numerical code that will be used for managing data. Only trained and certified staff will obtain data according to detailed research protocols. All research staff is required to have human subjects training. All gathered data will be used only for research purposes.

A master list of participant names and code numbers will be kept in a locked file maintained by the PI. Study results will be reported in the aggregate. The PI will monitor all data management and security procedures and report any adverse events to the IRB as soon as they occur. In addition, all of the samples and the databases will contain anonymous information only, each sample/entry associated with only a unique code. In addition, every precaution will be taken to minimize exposure of the data to persons outside of this project by using passwords for all computer files and keeping all hard copies of data within locked files. All results generated from this project will be reported in aggregate only. To decrease the likelihood of a breach of confidentiality, questionnaire data will be assigned a code number and stored in a locked file cabinet. This file will be separate from the file with the participants' identifying information.

Certificate of Confidentiality (if applicable)

To further protect the privacy of study participants, a Certificate of Confidentiality will be issued by the National Institutes of Health (NIH). This certificate protects identifiable research information from forced disclosure. It allows the investigator and others who have access to research records to refuse to disclose identifying information on research participation in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. By protecting researchers and institutions from being compelled to disclose information that would identify research participants, Certificates of Confidentiality help achieve the research objectives and promote participation in studies by helping assure confidentiality and privacy to participants.

12.4.Future Use of Stored Specimens and Data

Once the study has ended, data will be kept for at least 7 years to keep with federal regulations, and to ensure there is no reasonable probability left to defend against allegations of scientific misconduct . If, after the seven years have passed, and it is deemed appropriate, paper records containing identifiable data will be shredded and recycled. Records stored on the computer will be erased with commercial erasing applications designed to move all data from the storage device.

12.5.Key Roles and Study Governance

Provide the name and contact information of the Principal Investigator and the Medical Monitor.

Principal Investigator	**Medical Monitor**
Rachel Goode, PhD, MPH, Principal Investigator	Deborah Tate, PhD
University of North Carolina at Chapel Hill, School of Social Work	Department of Health Behavior and Nutrition
Address: 325 Pittsboro Street; Chapel Hill, NC 27599	Address: CB #7440 Chapel Hill, NC
Phone Number: 919-962-6429	Phone Number: 919-966-7546
rwgoode@email.unc.edu	dtate@unc.edu

12.6.Safety Oversight

12.7.Clinical Monitoring

Clinical site monitoring is conducted to ensure that the rights and well-being of trial participants are protected, that the reported trial data are accurate, complete, and verifiable, and that the conduct of the trial is in compliance with the currently approved protocol/amendment(s), with International Conference on Harmonisation Good Clinical Practice (ICH GCP), and with applicable regulatory requirement(s).

The intervention and evaluation protocols pose minimal risk to participants. Because of this low risk status, the data safety monitoring plan (DSMP) for this trial focuses on close monitoring by the principal investigator (PI) as safety officer, along with prompt reporting of excessive adverse events and any serious adverse events that are possibly related to the intervention to the NIH and to the IRB at the University of North Carolina at Chapel Hill.

Our project director will oversee the creation of several additional safety reports that will be shared regularly with the PI/safety officer. The frequency of data review for this study differs according to the type of data and can be summarized in the following table:

Data type	**Frequency of Review**
Subject accrual (adherence to protocol regarding demographics, inclusion/exclusion)	Monthly during the 3-month recruitment period
Adverse event rates (injuries)	As they occur
Intervention Engagement	Quarterly
Stopping rules report regarding statistical power implications of drop outs and missing data	Annually

The safety officer for this trial will be Rachel W. Goode, PhD, MPH. Dr. Goode has been PI on several obesity treatment clinical trials and has a high degree of understanding about the types of injuries potentially experienced when individuals engage in weight management interventions. As principal investigator and safety officer for this study, Dr. Goode will review the reports sent by the project director (at the frequency outlined above) to determine whether there is any corrective action, trigger of an ad hoc review, or stopping rule violation that should be communicated to the study investigator, the UNC-Chapel Hill IRB, UNC NORC, and the NIH IC. In addition, Dr. Goode will consult with senior consultants on this pilot/feasibility study, Dr. Deborah Tate and Dr. Anna Bardone-Cone.

12.8.Quality Assurance and Quality Control

The principal investigator will guide the creation of all study protocol, and have involvement with trainings and supervision of study staff. Quality control will be conducted in all phases of the project. Intervention sessions will be supervised by the principal investigator. All staff will be trained on the

intervention and will be required to attend weekly supervision to assure integrity to the intervention protocol. Quality assurance and control concerns will be addressed by the principal investigator.

12.9.Data Handling and Record Keeping

Each participating site will maintain appropriate medical and research records for this trial, in compliance with ICH GCP and regulatory and institutional requirements for the protection of confidentiality of participants. As part of participating in a NIH-sponsored or NIH-affiliated study, each site will permit authorized representatives of the NIH, sponsor, and regulatory agencies to examine (and when permitted by applicable law, to copy) clinical records for the purposes of quality assurance reviews, audits, and evaluation of the study safety, progress, and data validity. Describe in this section who will have access to records.

12.9.1. Data Collection and Management Responsibilities

Study data will be collected and managed using REDCap electronic data capture tools hosted at the University of North Carolina at Chapel Hill. REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.

12.9.2. Study Records Retention

Once the study has ended, data will be kept for at least 7 years to keep with federal regulations, and to ensure there is no reasonable probability left to defend against allegations of scientific misconduct . If, after the seven years have passed, and it is deemed appropriate, paper records containing identifiable data will be shredded and recycled. Records stored on the computer will be erased with commercial erasing applications designed to move all data from the storage device.

12.10. Protocol Deviations

A protocol deviation is any noncompliance with the clinical trial protocol. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions are to be developed by the site and implemented promptly. The site investigator will use continuous vigilance to identify and report deviations in a timely manner. The site investigator is responsible for knowing and adhering to the reviewing IRB requirements.

12.11. Publication and Data Sharing Policy

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 x years after the completion of the primary endpoint by contacting <specify person or awardee institution, or name of data repository>.

12.12. Conflict of Interest Policy

The independence of this study from any actual or perceived influence, such as by the pharmaceutical industry, is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial. The study leadership in conjunction with the NIDDK has established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest

13. Additional Considerations

This section should include a description of any additional considerations not currently covered in this protocol template, such as particular institutional or IRB-related requirements.

N/A

14. References

1. Brownley KA, Berkman ND, Sedway JA, Lohr KN, Bulik CM. Binge eating disorder treatment: a systematic review of randomized controlled trials. Int J Eat Disord. 2007;40(4):337-348.

2. Grilo CM, Masheb RM, Wilson GT, Gueorguieva R, White MA. Cognitive-behavioral therapy, behavioral weight loss, and sequential treatment for obese patients with binge-eating disorder: a randomized controlled trial. J Consult Clin Psychol. 2011;79(5):675-685.

3. Marques L, Alegria M, Becker AE, et al. Comparative prevalence, correlates of impairment, and service utilization for eating disorders across US ethnic groups: Implications for reducing ethnic disparities in health care access for eating disorders. Int J Eat Disord. 2011;44(5):412-420.

4. Pike KM, Dohm FA, Striegel-Moore RH, Wilfley DE, Fairburn CG. A comparison of black and white women with binge eating disorder. Am J Psychiatry. 2001;158(9):1455-1460.

5. Tanofsky-Kraff M, Bulik CM, Marcus MD, et al. Binge eating disorder: the next generation of research. Int J Eat Disord. 2013;46(3):193-207.

6. Striegel-Moore RH, Dohm FA, Kraemer HC, et al. Eating disorders in white and black women. Am J Psychiatry. 2003;160(7):1326-1331.

7. Bennett GG, Foley P, Levine E, et al. Behavioral treatment for weight gain prevention among black women in primary care practice: a randomized clinical trial. JAMA Intern Med. 2013;173(19):1770-1777.

8. Davis Martin P, Rhode PC, Dutton GR, Redmann SM, Ryan DH, Brantley PJ. A primary care weight management intervention for low-income African-American women. Obesity (Silver Spring, Md). 2006;14(8):1412-1420.

9. Ivezaj V, Kalebjian R, Grilo CM, Barnes RD. Comparing weight gain in the year prior to treatment for overweight and obese patients with and without binge eating disorder in primary care. J Psychosom Res. 2014;77(2):151-154.

10. Franko DL, Thompson-Brenner H, Thompson DR, et al. Racial/ethnic differences in adults in randomized clinical trials of binge eating disorder. J Consult Clin Psychol. 2012;80(2):186-195.

11. Mama SK, Schembre SM, O'Connor DP, Kaplan CD, Bode S, Lee RE. Effectiveness of lifestyle interventions to reduce binge eating symptoms in African American and Hispanic women. Appetite. 2015;95:269-274.

12. Goode RW, Kalarchian MA, Craighead L, et al. The feasibility of a binge eating intervention in Black women with obesity. Eat Behav. 2018;29:83-90.

13. Lydecker JA, Grilo CM. Different yet similar: Examining race and ethnicity in treatment-seeking adults with binge eating disorder. J Consult Clin Psychol. 2016;84(1):88-94.

14. Jarosz PA, Dobal MT, Wilson FL, Schram CA. Disordered eating and food cravings among urban obese African American women. Eat Behav. 2007;8(3):374-381.

15. Johnston DW, Lee WS. Explaining the female black-white obesity gap: a decomposition analysis of proximal causes. Demography. 2011;48(4):1429-1450.

16. Lovejoy M. Distrubances in the Social Body: Differences in Body Image and Eating Problems among African-American and White Women. Gender & Society. 2001;15(2):239-261.

17. Willig AL, Richardson BS, Agne A, Cherrington A. Intuitive eating practices among African-American women living with type 2 diabetes: a qualitative study. Journal of the Academy of Nutrition and Dietetics. 2014;114(6):889-896.

18. Dressler H, Smith C. Health and eating behavior differs between lean/normal and overweight/obese low-income women living in food-insecure environments. American journal of health promotion : AJHP. 2013;27(6):358-365.

19. Goode RW, Kalarchian MA, Craighead L, et al. Perceptions and experiences of appetite awareness training among African-American women who binge eat. Eat Weight Disord. 2018.

20. Udo T, White MA, Lydecker JL, et al. Biopsychosocial Correlates of Binge Eating Disorder in Caucasian and African American Women with Obesity in Primary Care Settings. Eur Eat Disord Rev. 2016;24(3):181-186.

21. American Psychiatric Association. Feeding and Eating Disorders. In:2013.

22. Hudson JI, Hiripi E, Pope HG, Jr., Kessler RC. The prevalence and correlates of eating disorders in the National Comorbidity Survey Replication. Biol Psychiatry. 2007;61(3):348-358.

23. Taylor JY, Caldwell CH, Baser RE, Faison N, Jackson JS. Prevalence of eating disorders among Blacks in the National Survey of American Life. Int J Eat Disord. 2007;40 Suppl:S10-14.

24. Kessler RC, Berglund PA, Chiu WT, et al. The prevalence and correlates of binge eating disorder in the World Health Organization World Mental Health Surveys. Biol Psychiatry. 2013;73(9):904-914.

25. Scott TN, Gil-Rivas V, Cachelin FM. The need for cultural adaptations to health interventions for African American women: A qualitative analysis. Cultur Divers Ethnic Minor Psychol. 2018.

26. Grilo CM, Lozano C, Masheb RM. Ethnicity and sampling bias in binge eating disorder: Black women who seek treatment have different characteristics than those who do not. Int J Eat Disord. 2005;38(3):257-262.

27. Mazzeo SE, Saunders R, Mitchell KS. Binge eating among African American and Caucasian bariatric surgery candidates. Eat Behav. 2005;6(3):189-196.

28. Bennett GG, Warner ET, Glasgow RE, et al. Obesity treatment for socioeconomically disadvantaged patients in primary care practice. Arch Intern Med. 2012;172(7):565-574.

29. Diabetes Prevention Program Research G. The Diabetes Prevention Program (DPP): description of lifestyle intervention. Diabetes Care. 2002;25(12):2165-2171.

30. Zerden L, Lombardi B, Fraser M, Jones A, Garcia-Rizo Y. Social work: Integral to interprofessional education and integrated practice. Journal of Interprfoessional Education & Practice. 2017;10:67-75.

31. Creswell J. Qualitative Inquiry & Research Design. Third ed. Thousand Oaks, CA: Sage Publications; 2013.

32. Strauss A, Corbin J. Basics of Qualitative Research: techniques and procedures for developing grounded theory. 2nd ed. Thousand Oaks, CA: SAGE; 1998.

33. Fitzgibbon ML, Stolley MR, Schiffer L, Sharp LK, Singh V, Dyer A. Obesity reduction black intervention trial (ORBIT): 18-month results. Obesity (Silver Spring, Md). 2010;18(12):2317-2325.

34. 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;13(3):193-213.

35. Fairburn CG, Cooper Z. The Eating Disorder Examination (12th ed). In: Fairburn CG, Wilson GT, eds. Binge eating: Nautre, assessment, and treatment. New York: Guilford Press; 1993:333-360.

36. Fairburn CG, Beglin SJ. Assessment of eating disorders: interview or self-report questionnaire? Int J Eat Disord. 1994;16(4):363-370.

37. Beck AT, Ward CH, Mendelson M, Mock J, Erbaugh J. An inventory for measuring depression. Arch Gen Psychiatry. 1961;4:561-571.

38. National Center for Complementary and Integrative Health. Pilot Studies: Common Uses and Misuses. 2017; https://nccih.nih.gov/grants/whatnccihfunds/pilot_studies. Accessed June 9, 2018.

15. List of Appendices

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