Official Title: Improving Cardiovascular Risk Factors in Black Young Adults

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The purpose of this randomized controlled trial (RCT) is to demonstrate the efficacy of the investigator developed intervention targeting weight loss through healthy eating and increased physical activity in Black and Hispanic community college students.

2.2 Primary and Secondary Aims

The primary aim (Aim 1) of the Aspire to Better Health study is to test the efficacy of a smartphone app plus health coaching intervention targeting weight loss vs. an attention control condition utilizing a device which tracks sleep.

The secondary aim (Aim 2) is to examine mediating variables of the intervention delivery on percent weight loss at 6 and 12 months. The mediators include adherence to self-monitoring, levels of discrimination, and dietary and physical activity (PA) self-efficacy. Finally, the third aim (Aim 3) will explore potential moderators of percent weight loss at 6 and 12 months, including depressive symptoms, ideal body image, and motivation for behavior change.

2.3 Design

Participants will be randomized with equal allocation to a 12-month intervention that includes using a smartphone app and text messages from a health coach or to an attention-control condition. In total, 256 individuals will be enrolled and randomized with a target of 80% Non-Hispanic Black, 20% Hispanic Black with 50% male representation in each ethnic group. Participants will be enrolled from a community college in Columbus, OH. The intervention will be delivered via a smartphone and the health coach will send the text messages. This study employs an attention-control condition to keep control participants engaged in the study and have them return for data collection visits. Considering the limited number of studies describing recruitment and retention methods for this population, an attention-control condition rather than a standard control condition is warranted. The study was approved by the Institutional Review Board (IRB) at The Ohio State University (OSU).

2.4 Eligibility

Interested participants are instructed to complete an eligibility screening tool they receive via email, or complete a screening call with a trained research assistant to determine study eligibility. The project coordinator or assistant also screens for symptoms of disordered eating in all interested participants, using four behavioral questions from the Eating Attitude Test (EAT-26).[16] If an interested participant answers "yes" to one of four questions, they are not eligible to enroll in the study.

2.5 Inclusion and Exclusion Criteria

Table 1: Inclusion and Exclusion Criteria for the ASPIRE Study

Inclusion	Exclusion
• Age 17-25 • Enrolled in at least 1 CC class	• Currently pregnant or planning to become pregnant

• Identify as Black or Hispanic Black • BMI 25 or greater • Own a smartphone (iOS or Android) or compatible device • Ability to return for 12-month visit • Speak and read English	within 12 months • Current participation in another weight loss program or taking weight loss medications or medications known to increase weight • Lost ≥10% of body weight in past 6 months • Screens positive for symptoms of disordered eating • Diagnosed with type 1 diabetes

2.6 Sample Size and Randomization

A sample size of 256 participants (n=128 per each trial arm) will have sufficient power (80%) to detect an
average between-group difference with a moderate effect size of Cohen's $d = 0.4$. The mixed effect modeling for repeated outcome measures at 6 and 12 months was used for the power calculation using two-sided significance level of 0.05 assuming 1) first-order autoregressive covariance structure, 2) the within-structure correlation of 0.8, and 3) 20% attrition rate at 12-month follow-up. After completing the informed consent and baseline data collection, participants will be randomly assigned 1:1 to the intervention or the attention-control group. Stratified randomization by sex (female vs. male) and ethnicity (Non-Hispanic Black vs. Hispanic Black) will be used. For each sex-ethnicity stratum, randomization will occur in permuted blocks of varying block sizes. The advantage of permuted block randomization is that it will ensure balance in the number of participants in the two trial arms during the entire study period.

2.7 Consent

Informed consent will be obtained in a private session by a trained study team member (research coordinator/assistant). Potential participants will be assured that: 1) their participation is voluntary; 2) they are free to withdraw from the study at any time; and 3) if they decline to participate or withdraw

from the study, it will not affect their future care or participation in other activities. For participants under the age of 18, a parent or legal guardian must accompany them to their enrollment appointment. Once the participant is 18 years of age, they will repeat the consent process again at their next in-person visit and sign the relevant form.

2.8 Community Advisory Board

The study convenes a community advisory board (CAB) comprised of faculty, alumni, staff, and current students at CSCC. The CAB is comprised of a diverse group of individuals, most of whom identify as a racial or ethnic minority. The board is also made up of individuals who specialize in student needs, such as mental health counseling and student services. The CAB meets regularly to discuss recruitment standards and methods, intervention methods, current manuscripts and abstracts, as well as ethical standards, and dissemination of findings. The CAB contributes in a meaningful way to the ongoing study by partnering with the research team to contribute new ideas and to create process-related changes necessary for the deployment of a successful project.

3. Program Implementation

3.1 Components of Intervention

Intervention components include the following: 1) access to a smartphone app called Lose It! 2) Health Coach counseling session, 3) Health coach text messages, 4) Fitbit Inspire 2 accelerometer.

3.2 Smartphone Application (Lose It!)

The Lose It! app is a free program, commercially available on both Android and iOS devices. The application is capable of monitoring energy intake, body measurements, and weight loss goals personalized to the participant. The Lose it!! application has previously been examined for behavioral theory content in five distinct categories: knowledge, cognitive strategies, behavior strategies, emotion-focused strategies, and therapeutic interventions. Further, it was ranked number one overall for behavioral theory score and persuasive technology score, and has been successfully employed in a similar study with a racially diverse group of young adults[17]. Participants can self-monitor their energy intake by scanning barcodes on food labels or using the large, international database of foods/drinks available on the app.[18] Participants will be given a manual for use of the app.

The smartphone app is associated with a program called Ascend, which provides health coaches access to real-time data from each of their participants, including food intake, calories consumed, macronutrient and micronutrient intake, and physical activity performed. The health coaches use these data to send text messages to participants. All user data are stored on a system with a user identifier and placed in a separate data store. The data stores are hosted in a secure data system with industry standard approaches to access control. Data transfer between participant devices (phone and computer) takes place over an authenticated HTTPS channel. Only the health coach and research staff have access to all participant data.

3.3 Health Coach

Health and wellness coaches have been recruited from the Health and Wellness Innovation in Healthcare Program at OSU and are responsible for delivering intervention components. They are selected as health coaches by the Director of Health Coaches (Investigator B.B.) and then interviewed to ensure fit for the

study. In addition to having a healthcare background (ie. registered nurse, patient care nursing assistant, etc.) coaches received training from the principal investigator (PI) and Director of Health Coaches and are continuously monitored throughout the study with in-person meetings with the study PI.

The director of health coaches attends approximately 20% of all baseline coaching sessions to ensure intervention fidelity. The project coordinator and the study PI monitor text messages sent from the health coaches to participants to ensure duplicate messages are not sent and that health coaches are following text message guidelines.

3.4 Counseling Session with Health Coach

Participants in the intervention group are seen for a one-time, 45-minute counseling session at baseline. Due to COVID-19, these meetings will take place via Zoom and all are conducted in English. The counseling will focus on (1) adhering to good nutrition practices, (2) PA guidelines, (3) motivators and outcome expectations for weight loss, (4) goal-setting for diet and PA. Each participant works with their health coach to identify appropriate and individualized goals for energy consumption and physical activity.

3.5 Content of Text Messages from Health Coach

The health and wellness coaches are responsible for electronically monitoring the daily progress of the participant and interact with the participant through push-only text messaging (no response from participant). Health coaches will send one text message per day to each participant. Text messages will not be repeated from the health coach. A database of text messages was created and tested in our previous study and will be used as message stems for the current study. The database contains over 3,000 basic text messages (stems), derived from Social Cognitive Theory, organized by content and mechanism to increase self-efficacy (Table 2). The health and wellness coach will select an area of focus (sodium content, calories, etc.) based on the participant's daily electronic log and select a text message stem and then will personalize that stem based on their client's specific goals or progress for that day. Health coaches also have the ability to create new messages based on the participant's current progress and needs. In addition, due to the ongoing Covid-19 pandemic, health coaches send text messages related to mental wellness and stress management.

Table 2: Example Text Message Stems

Self-Efficacy Enhancing Mechanism	Content Area	Example Stem
Social Modeling	Physical Activity Motivation	Find a friend that needs or wants to exercise and ask them to take a walk or jog with you today

Verbal Persuasion	Breakfast Consumption	Did you know that people who skip breakfast tend to snack more during the day?
Self-Regulation/Mastery	Cultural Foods	Not finding your homemade family meals on the app? Create your own recipe in Lose it! To help you keep track!
Improving Physical/Emotional State	Body Image Ideals	Find YOUR ideal and work towards it!

3.6 Fitbit

A Fitbit Inspire 2 device will be given to each participant in the intervention group and they will be asked to wear it daily for the duration of the study (12 months). The Fitbit Inspire 2 syncs automatically with the Lose it! App and will update the participant's PA log in real-time. It will also update the participant's daily energy intake needs based on energy expenditure. Health coaches use this adjustment and the real-time PA data for personalization of text messages. Lost or malfunctioning Fitbits are replaced by the study team at no cost to the participant.

3.7 Fitabase

This study utilizes the Fitabase program. Fitabase LLC offers a robust data management platform designed to remotely collect wearable device data. Using Fitabase with wearable devices enables access to daily and intraday data for a variety of tracked types of data including steps, intensity, calories, heart rate

and sleep. This study employs Fitabase to aggregate the active minutes data. Fitbit determines active minutes using a metabolic equivalents measurement ratio (rate of energy expended during an activity: rate of energy expended during rest) that factors in a participant's body mass and heart rate. Fitabase then charts and aggregates this data into categories of light, moderate, and intense minutes. These data are collected for a period of seven days in accordance with their baseline visit, and their 6- and 12-month visits.

Fitabase is a fully hosted, cloud-based software solution that implements robust industry standards to maintain secure databases and keep data private. Fitabase stores information provided to it by the Fitbit Application Programming Interface (API). Data is stored and indexed in the Fitabase SQL Server database in day total, hour, and minute-by-minute intervals. The account for this study is password protected and only the research staff have access to the credentials.

3.8 Attention Control Condition

Participants in the attention-control condition will also receive a Fitbit Inspire 2 device to track their sleep daily for 12 months. The Fitbit app offers sleep quality tracking and enables users to track pertinent sleep statistics. Participants will passively track their sleep daily and can also actively enter items about their day to help understand their sleep habits.

Participants will be asked to wear the Fitbit Inspire 2 on their non-dominant wrist for 7 days continuously for baseline, 6-month, and 12-month data collection. Their data will be automatically downloaded for use by the research team through the Fitabase platform.. At the final 12-month visit, the attention-control group will download and receive a training session on the Lose it! App, as well as keep their Fitbit.

3.9 Systems of Support

Project staff are provided cell phones to enable accessible and timely communication with participants in regarding technological issues, scheduling, and other emergency circumstances. Acknowledging the various social determinants of health that CC students of color experience, project staff have designed an ecosystem of support in collaboration with the community college to enable access to mental and physical health, financial, educational, and housing services if requested by the student. If students screen positively for suicidal ideation on the administered PHQ-9, they are immediately connected to services and study staff follow up with participants until they participate in their first appointment. Additionally, project staff are trained in Mental Health First Aid to equip them with the tools and skills to manage a mental health crisis in a young adult, e.g. recognizing signs and symptoms, how to listen non-judgmentally and give reassurance, and how to refer someone to appropriate services.

4. Measurements

The study team will collect outcome measure data (Tables 3 and 4) from all participants at in-person or Zoom visits at baseline (prior to randomization), 6- and 12-months. The project coordinator and research assistant are not blinded to the treatment condition. At the conclusion of the 12-month visit, participants complete a quality assessment survey to detail their satisfaction with or suggestions for the program.

Table 3: Main Outcome Measures

Outcome	Time Measured	Definition	Measurement Procedure	Measurement Tool

Weight	Baseline, 6 and 12 months	Body weight (kilograms)	Wears light clothing, no shoes; 2 measurements taken and averaged	Tanita BS-549 Ironman Scale
Percent Weight Loss	6 and 12 months	Comparison of current weight to baseline weight, then convert to % of baseline weight	Same as above	Same as above
Weight Loss Maintenance	12 months	Sustained weight loss of 5- 10% of baseline body weight OR maintenance of % weight lost at 6-months	Same as above	Same as above
Height	Baseline	Length of individual (meters)	Same as above	Seca 213 portable stadiometer
Body Mass Index	Baseline, 6 and 12 months	Weight to height ratio	Height and weight of participant	Quetelet index (kg/m2)
Physical Activity	Baseline, 6 and 12 months	Active minutes per day	Wear Fitbit on non-dominant wrist continually except for shower, bath, swimming Staff calculate average active minutes/day over 7 days at each time	Fitbit Inspire 2 • High correlation with steps recorded by the Actigraph and the Yamax pedometer. • Reliable and valid device for measuring activity

			point Data collected remotely over Fitbit's open application programming interface	levels (minutes) in young adults.
Diet	Baseline, 6 and 12 months	Compliance with dietary guidelines for Americans	Participant completed Food Frequency Questionnaire (FFQ) at each time point, FFQ analyzed offsite, returned to researchers. Researchers compute Healthy Eating Index (HEI) score	2014 Full-length Block FFQ is converted HEI Score • Reliable and valid in a population >18 years of age, with the FFQ very close to standardized interviewer administered 24-hour food recalls

Table 4: Proposed Mediators and Moderators

Mediator/Moderator Name	Measure Tool and Procedure	Definition	Reliability/Validity
Adherence to Self-Monitoring (mediator)	Health coach tracks through Ascend app using diet entry of 50% or more of caloric intake	Entering at least 50% of caloric goal on at least 80% of days (or 24 days/month)	This method has been used successfully in previous studies.[19]
Dietary Self Efficacy (mediator)	Dieting Self-Efficacy Scale (DIET-SE)	Examines three factors of a person's belief in their ability to eat in a certain way: (1) high caloric foods, (2) social and internal factors, and (3) negative emotional events.	Internal consistency between 0.82-0.87 in college students. The test-retest reliability of the scales is 0.83 for a 2-3 week interval.[20]

Physical Activity Self-Efficacy (mediator)	Self-Efficacy for Exercise scale (14 questions)	Making time for exercise and sticking to exercise.	In a population of adults, the internal consistency was 0.90 and a test-retest correlation was 0.67.[21]
Discrimination (mediator)	Experiences of Discrimination (EOD) measure	9 item questionnaire measuring exposure to racial discrimination	Confirmatory factor analysis of 0.74 and test/re-test coefficient of 0.70 and validity of r=0.79 in a population of African American and Latino adults.[22]
Depressive Symptoms (moderator)	CDE Patient Health Questionnaire for adults (PHQ-9)	10 questions that assess depressive symptoms. Questions are scored on a 0-3 scale. Total scores range from 0 (no depression) to 27 (severe depression).	Reliable and valid in a diverse group of adults over 18, with a Cronbach alpha reported at 0.89 and 0.86 in two studies and a test-retest score of 0.84.[23]
Ideal Body Image (moderator)	Contour Drawing Rating Scale	Contour drawing of graduated sizes, with 9 images for males and 9 images for females.[24] Participants will circle the figure that represents their ideal body image.	Test-retest reliability was confirmed in college students with a reliability rating of 0.78 and validity was confirmed in college students with 95% accuracy in correct ordering of images.[24]
Motivation (moderator)	Treatment Self-Regulation Questionnaire (TSRQ)	15 questions to assess diet and 15 questions to assess exercise. The TSRQ measures three	The TSRQ for diet and exercise was proven reliable in a racially/ethnically diverse group of males and females, aged 18+ years,

		types of motivation: (1) controlled, (2) autonomous, and (3) amotivation.	with Cronbach alphas >0.73.[25]
Emotional Support (moderator)	NIH PROMIS tool for emotional support (16 questions)	Assesses perceived feelings of being cared for and valued as a person and having confidant relationships	Questionnaire has been validated in adult populations.[26]

6. Statistical Analysis

Aim 1: Descriptive statistics will be used to check the distribution of the data, identify outliers, and describe the sample characteristics. Bivariate statistics will be used to comparebaseline characteristics between the two trial arms. We will use mixed-effects linear regression modeling for repeated measures to 1) estimate the fixed effects of intervention, time, and their interactions, 2) drive contrast estimates for between-group differences in % weight loss at 6 months and 12 months, 3) adjust for covariates (e.g., any imbalance in baseline characteristics) and within-subject dependency from repeated measures.[27] All tests will be performed using Intent-to-Treat (ITT) analysis.
Aim 2: We denote X = Independent variable, Y= Outcome measures, and M = Potential mediator. Mediation will be tested through first showing that X (e.g. intervention) is associated with both M (e.g., dietary self-efficacy) and Y (e.g., % weight change) using mixed-effects regression models as described above. Then, we will sequentially model the effect of X on Y, without and with adjusting for potential mediators. At last, we will use mediation path analysis to simultaneously regress (a) Y on M and X, and (b) M on X.. Estimates for the mediation effect will be derived using delta method or bootstrapping method if lack of normality is evident.[28] Adequacy fit of the path model is indicated by a non-significant $\chi 2$ statistic, Comparative Fit Index (CFI) and Tucker-Levis Index (TLI) ≥ 0.9, and a root mean square error approximation (RMSEA) ≤ 0.08.
Aim 3: Similarly, we specify X = independent variable (e.g., intervention), Y = outcome variables (e.g., % weight change), and W = potential moderator (e.g., depressive symptoms). We will then test the significance of the moderating effect by including the interaction term of X and W in the mixed-effects regression models. A significant interaction between X and W suggest that the effect of X on Y changes at different levels of W.
Missing data: We will carefully examine the pattern of missing data and conduct appropriate multiple imputation if data are missing at random. If missing not at random is indicated, pattern mixture modeling will be used instead. Sensitivity analysis will be used to evaluate the robustness of study findings under different methods.

7. Data Management

REDCap data collection projects rely on a study-specific data dictionary defined in an iterative self-documenting process. REDCap supports electronic signatures by positively identifying the user through a unique username and password combination. The provisioning of accounts for system authentication is

integrated with the OSU Wexner Medical Center (OSUWMC) LDAP authentication service for studies containing protected health information (PHI) and is secured behind the OSUWMC firewall.