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A mHealth Intervention to Preserve and Promote Ideal Cardiovascular Health in College Students: Design and protocol of a cluster randomized controlled trial

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Abstract

Background: Cardiovascular disease (CVD) remains the leading cause of death globally. Seven health factors are associated with ideal cardiovascular health: being a non-smoker; not overweight; physically active; having a healthy diet; and normal blood pressure; fasting plasma glucose and cholesterol. Whereas approximately half of U.S. youth have ideal levels in at least 5 of the 7 components of cardiovascular health, this proportion falls to 16% by adulthood.

Objective: We will evaluate whether the NUYou cardiovascular mHealth intervention is more effective than an active comparator to promote cardiovascular health during the transition to young adulthood.

Methods: 302 incoming freshmen at a midwest university will be cluster randomized by dormitory into one of two mHealth intervention groups: 1) Cardiovascular Health (CVH), addressing behaviors related to CVD risk; or 2) Whole Health (WH), addressing behaviors unrelated to CVD. Both groups will receive smartphone applications, co-designed with students to help them manage time, interact with other participants via social media, and report health behaviors weekly. The CVH group will also have self-monitoring features to track their risk

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behaviors. Cardiovascular health will be assessed at the beginning of freshman year and the end of freshman and sophomore years. Linear mixed models will be used to compare groups on a composite of the seven cardiovascular-related health factors.

Significance: This is the first entirely technology-mediated multiple health behavior change intervention delivered to college students to promote cardiovascular health. Findings will inform the potential for primordial prevention in young adulthood.

Keywords

mHealth; health promotion; cardiovascular disease; college students; health behaviors

Introduction

Almost half of all Americans have at least one major risk factor for cardiovascular disease (CVD), (1) which affects approximately 83.6 million individuals in the US.(2) Unhealthy habits that predispose to CVD such as cigarette smoking, poor quality diet, physical inactivity, and obesity often manifest during emerging adulthood (defined as ages 18-25) and persist thereafter, reducing long-term cardiovascular health. (3–12) Because these risk factors are major preventable causes of CVD, the transition from adolescence to early adulthood may be an opportune time for interventions to preserve and promote cardiovascular health before poor lifestyle habits become entrenched. Since more than 40% of individuals between ages 17 and 22 attend college, (13) interventions targeting college students may offer an efficient and impactful way to reach the emerging adult population. Although many behavioral interventions have successfully modified CVD risk factors in older adults, (14–17) less research has targeted college students. Interventions for college students have primarily been overly burdensome and in-person, limiting uptake and scalability. (18–20) Delivering interventions remotely via mobile technologies may offer an alternative that is well-suited to college students.(21)

Research on internet and mobile health (mHealth) cardiovascular health interventions for college students is limited, although several mHealth interventions targeting single risk factors (e.g., smoking, unhealthy eating, and physical inactivity) have found positive impacts. (22–26) Null findings exist, particularly for the effects of internet-based interventions, yet even unsuccessful trials hint at conditions that may be necessary for intervention effectiveness.(27) For example, the use of intervention tailoring and provision of personalized feedback are features that may differentiate effective internet health promotion interventions (26) from ineffective ones. (28, 29)

Previous research on technology-supported health behavior change suggests that a mobile system that reinforces self-monitoring with personalized feedback and also integrates in-person social support can succeed in promoting healthy lifestyle change.(30, 31) Because in-person treatment is burdensome and expensive, recent trials have examined more scalable strategies that combine remote connected coaching (informed by data transmitted from a participant's app) with financial incentives to reinforce self-monitoring and behavior change. (32, 33) The combined use of technology to provide feedback and financial incentives to reward behavior change has both initiated and maintained large improvements in diet and

physical activity behaviors. (34, 35) A key challenge that remains, however, involves decreasing cost and increasing reach.

To address that challenge, we co-developed (with college students) a multicomponent, tailored, dynamic, and entirely technology-mediated mHealth intervention package to preserve and promote cardiovascular health among a college student population. (34, 35) Cardiovascular health will be operationalized by the American Heart Association's (AHA) Simple Seven metric, recently constructed as an evidence based measure of cardiovascular health.(4, 36, 37) By measuring health, as opposed to risk, we frame our goal as preserving cardiovascular health in this population rather than taking a more traditional risk reduction approach. Our trial will test the effectiveness of a mHealth intervention targeting cardiovascular-related health behaviors as compared to an active control mHealth intervention addressing other health behaviors on the primary outcome of cardiovascular health among students over the first 2 years of college. We hypothesize that those receiving the intervention for cardiovascular-related behaviors as versus different (control) behaviors will show greater preservation or improvement of cardiovascular health behaviors and biomarkers at the end of two years.

Methods

Study Design

The NUYou trial is a 24-month, prospective two-group paired cluster-randomized trial ([ClinicalTrials.gov #NCT02496728](https://clinicaltrials.gov/ct2/show/study/NCT02496728)). The study was approved by the University's Institutional Review Board. The trial has completed enrollment of 302 students as of the date of this publication.

Research with college students demonstrates that peers within a residence hall setting can influence each other's health behaviors. (28) The NUYou Study will leverage that social influence by randomizing residence halls to the treatment or control group so that all participants within the same residence hall receive the same intervention condition. This will create the opportunity for health behaviors to spread within a residence hall community and also decrease contamination between groups.

Dormitories will be randomized in matched pairs. We will use weighted Mahalanobis distance matching to identify pairs of dormitories that are similar with respect to number of residents, cost of living, and proportion of females. (38–41) Because number of residents was determined to be the covariate most associated with our outcomes, this variable will be weighted twice as much as the other variables in the distance metric. Each dorm within a pair will then be randomized to either: 1) the Cardiovascular Health intervention (CVH), a smartphone app targeting CV-related health behaviors (smoking, fruit/vegetable intake, physical activity, weight management); or 2) the Whole Health (WH) intervention, an app targeting health behaviors unrelated to CV health (hydration, sunscreen use, safe sex, and travel safety).

Participants

Eligible participants are incoming freshman students at an academically elite Midwestern university who own an iPhone or Android smartphone, are aged between 17 and 26 years, live on campus, are fluent in English, and are not pregnant or planning to become pregnant. Any participant determined to have an uncontrolled psychiatric or medical condition based on the PHQ screening questionnaire (42) or for whom physical activity could be considered risky, based on the Physical Activity Readiness Questionnaire, (43) will be excluded. Study candidates will be recruited using a comprehensive approach that includes brochures and postcards; emails; social media posts; TV; sidewalk chalk advertisements; school newspaper articles and advertisements; and flyers and banners posted on campus, at on-campus events and in dining halls. Advertisements direct potential participants to a website that presents full information about the study and a link to an online eligibility screener. Applicants who meet entry criteria and give informed consent will be enrolled in the study for two consecutive years.

Screening and Consent

Contact information and demographic data to assess study eligibility were collected via a secure online screening questionnaire. Candidates deemed eligible were sent a hyperlink to a YouTube video that explains study participation, followed by a link to an online consent form.

Self-report measures.—After providing consent, students will be redirected immediately to complete a 20-minute online baseline health questionnaire that measures the health behaviors comprising the primary outcome. The health questionnaire also determines whether participants have cardiovascular risk behaviors that should receive tailored intervention if the person is randomized to the CVH group (as described below). Next, participants will be scheduled for an in-person baseline health assessment conducted on campus by trained research assistants.

In-person health assessments.—To reduce contamination between intervention conditions, participants from the two groups will be scheduled on different days for their three in-person assessments (baseline, 1- and 2-year follow-up). Participants rotate through assessment and informational stations: 1) height, weight, expired carbon monoxide, 2) blood pressure, 3) cholesterol and glucose, and 4) introduction to the smartphone app and study condition (baseline only). The baseline assessment will last approximately 1 hour; follow-up assessments will use similar procedures but be briefer. Participants earn \$25 for attending each assessment.

Participants will be required to fast for 8 hours prior to the in-person health assessments for the purpose of measuring fasting glucose and cholesterol. Blood pressure will be measured using a portable BpTRU blood pressure monitor. Participants will have their arm circumference measured to determine the proper cuff size and will be seated and asked to rest quietly for 5 minutes. The BpTRU will automatically take 6 measurements and the average of the last 5 will be used. Height and weight will be assessed using calibrated portable scales and stadiometers. Glucose and cholesterol will be assessed via finger-stick

using a point of care testing unit (Cholestech LDX). Participants will self-report cigarette smoking status and expired carbon monoxide, a biomarker for short-term exposure to tobacco smoke, will be assessed via a Covita Pico + Monitor, where 8 ng/ml will be interpreted as evidence of recent smoking for analytic purposes.

Intervention Development

Formative work was undertaken to develop the intervention as described elsewhere. (44) Introductory meetings were held with key administrative leaders on the undergraduate campus. Focus groups (44) and charrettes (need-finding, design brainstorming events) were held with students, while other students in a computer science class undertook design of the app as a course project. This formative work shaped the selection of intervention and app features, the timing and setting of the assessments, and the recruitment and retention plan. Additional usability testing and in-depth interviews were undertaken to enhance recruitment and retention, as described in detail elsewhere. (45)

Intervention Components Common to Both Groups

The NUYou smartphone application.—Participants in both the CVFI and WFI intervention conditions will be required to download the custom-built NUYou app (Figure 1) onto their smartphone free of charge. The features available to the individual depends upon their assigned intervention condition, which specifies the risk behaviors to which they need to attend.

Devices.—Beginning in year 2 of the trial, all participants will be provided with one of two tracking devices. CVFI participants will be given a FitBit Zip to support physical activity tracking and WFI participants will be given a Flydracoach (i.e., a water bottle that recommends a daily hydration goal and displays data about the user's fluid consumption). WH will use the Hydracoach to support hydration tracking (see Figure 2).

Environmental cues.—Posters placed on dormitory bulletin boards will present information about healthy behaviors consistent with the intervention condition to which the dorm was randomized. Scales will be placed in common spaces of the CVH dorms to facilitate self-monitoring of weight.

“Closed” Facebook groups.—Participants will be asked to join either a CVH or a WH “closed” Facebook group that is not visible to the public. The rationale for including this intervention feature is to increase group cohesion, accountability, and peer support. Study staff are able to exercise full control over group membership and monitoring of posts. Participants will be asked and incentivized (as described below) to read content posted to the group by study staff and will be encouraged to support each other in attaining health and academic success. Posts by study staff will convey information and self-regulatory tips about the health behaviors targeted for the group's intervention condition. Facebook allows both individual and group interaction via chat, postings, and replies to other's comments and questions. Study staff will monitor all posts and comments several times a day inappropriate use such as, but not limited to: excessive foul language, illegal activity, risky activity, and bullying. Inappropriate posts will be deleted by study staff.

NUYou App Features Common to Both Intervention Conditions

Social media integration.—One page of the app will allow students to view all social media posts from their NUYou closed Facebook group. This feature provides students with a distraction-free way of viewing content pertinent to the intervention without going into the Facebook application.

Time manager.—During the formative work for this study, (44) students expressed a need to better manage their time. Hence, the university computer science students who took on design of the NUYou app as a class project, collaborated with research staff to design and program a time management feature for the app. This feature integrates with Google calendar (which syncs with the University's class schedule system) and allows students to enter, color code, edit, review, and delete events from the application or Google Calendar (Figure 3). When looking at calendar details, students will also be able to see available free time and select an option among several healthy behavior suggestions based on the behaviors targeted in their assigned intervention group.

Behavioral queries.—Once per week, participants will be asked to use the NUYou application (Figure 4) to self-report whether they have met ideal criteria for each of the four behaviors targeted by their intervention condition. CVH participants will be asked about minutes of physical activity, average daily servings of fruits and vegetables, cigarette smoking, and average pounds over normal weight. WH participants will be asked about safe travel, safe sex, hydration and practicing sun safety. Participants will also be asked to rate their level of stress and happiness on a 5 point scale ranging from *not at all* to *very*, a feature requested by students. For every month a student answers all questions each week, they will receive an item displaying the University's logo (e.g., bag, lanyard, coffee mug).

NUYou App Features Specific to the CVH Group

The CVH app will contain four possible self-monitoring and progress modules specific to the four targeted CV-related health behaviors. Each module will provide feedback about behavioral accomplishment relative to goals, allow for self-monitoring of behaviors on a daily basis and graphically represent progress toward goals over time. These behavior-specific modules will only become accessible when a participant is found to exhibit a level of risk behavior that is classified as "poor" or "intermediate" CVH as defined by the American Heart Association Strategic Planning Task Force and Statistics Committee ((37) see Table 1). Behavioral risk classifications will be made: 1) at the baseline assessment; 2) during the intervention when the participant's response to weekly behavior queries indicates poor/immediate levels of a targeted health behavior for 3 consecutive weeks. Thus, if an individual shows lower than ideal levels of physical activity and fruit and vegetable consumption, two colored bars representing the week's accumulated total minutes of physical activity and total number of fruit and vegetable servings will be displayed at the bottom of the app screen (Figure 1). If an individual for whom a targeted behavior has been classified as at risk endorses ideal levels of a behavior for three consecutive weeks, the participant will be given the option to turn off the self-monitoring module for that behavior. This system will be personalized and dynamic, in that it only makes visible needed information and tools, and provides a choice of whether to continue receiving support in

their newly acquired positive behavior or to turn off the added support. As a result, all CVH participants will attend to at least one behavior, but could be burdened by attending to up to all four.

Daily fruit and vegetable self-monitoring.—The fruit and vegetable module (Figure 5) will be visible and accessible to participants who do not eat 5 servings of fruits and vegetables per day. This module will allow participants to either quickly indicate how many servings they consumed so far that day, or to go to another screen to refer to categories and serving size guides to determine servings of each type of fruit or vegetable consumed. Participants will be provided with a historical graph presenting their progress relative to goal over time.

Daily physical activity monitoring.—The physical activity module (Figure 6) will be visible and accessible to participants who do not achieve 150 minutes of moderate to vigorous physical activity (MVPA) weekly. The opening screen will display the number of minutes that the smartphone accelerometer or connected FitBit captured and categorized as MVPA. The participant can then choose to accept what is displayed as recorded by FitBit or to modify the total number of minutes reported as accumulated that day. Participants will also see historical data presenting the amount of MVPA achieved over time.

Daily weight management monitoring.—Participants who are classified as having overweight or obesity (body mass index (BMI) of 25 or higher) will have access to the weight loss module (Figure 7), which will encourage them to track all dietary consumption and weight daily. Calorie goals will be displayed, based either upon weight as measured at baseline or upon the first entered weight classified as overweight during the course of the study. Participants will see visual feedback about their caloric consumption relative to their goal as well as a breakdown of macronutrients consumed. Also, they will receive visual feedback on how close their current weight is to their goal weight range. Goal weights will be set to the lowest amount of weight loss between either a loss that would return the individual to a normal BMI range or a range set to display 7% weight loss at the lower bound and 10% at the upper bound relative to the initial weight. Participants with a range will be encouraged to focus on the lower bound first and as the study progresses and 7% is achieved, shift focus to the upper bound. The app will display visual feedback about the participant's will historical weight over time.

Daily smoking self-monitoring.—Participants who self-report smoking cigarettes at baseline or who acquire smoking behavior during the trial will be given access to the smoking module. Participants will be asked to choose a goal regarding changing their smoking behavior (“not now,” “reduce,” or “quit”) and will be given tailored information according to their chosen option. Participants will see feedback about their progress at all times and will have the option to press a button to receive a tip about how to reduce a craving. In the “not now” and “reduce” options, participants will be asked to record number of cigarettes smoked per day (Figure 8). In the quit option, participants will be able to report a smoking lapse at any time. In both the “reduce” and “quit” options, participants will see how much money they have saved and how much time they have added to their lives by

reducing or quitting. Any time that a participant in the quit program does not endorse being smoke-free at least once out of 7 days, the program will revert back to the “not now” program and encouraged to set a new reduce or quit goal.

Just-in-time messaging.—During the development of the smartphone app, (44) many students stated that a recommendation system would be helpful if it provided assistance that was relevant, actionable, and personalized. To accommodate that preference, the CVH intervention was designed so that the app delivered messages during a time when they would be most likely to be acted upon. CVH participants will receive up to four messages a day: one for each risk behavior they monitor through the app. Messages will not be sent when a participant is known to be unavailable (e.g., time manager indicates the student is in class) or unreceptive (e.g., when a previous message was sent within the prior two hours). A deferred message about the targeted behavior will be sent once an available time occurs. Message tailoring will be guided by an algorithm that reflects: self-monitoring performance, goal attainment, availability, and location. A push notification will allow participants to read part of the message. The remainder of the full message can be accessed by opening the app (i.e., enabling the research team to track message receipt). Messages can then be dismissed by hitting a “like” or “dislike” button (i.e., providing feedback about message acceptability).

Primary and Secondary Study Outcomes

This primary outcome of the NUYou trial is a composite cardiovascular health score. (46) The cardiovascular health score includes the following risk factors, referred to by the American Heart Association as the “Simple Seven”: diet quality, physical activity, smoking, BMI, blood glucose, cholesterol, and blood pressure. Secondary outcomes of the trial are changes in behavioral (eating, physical activity, and smoking) and biomedical factors (fasting cholesterol and glucose, weight and blood pressure) as assessed at three time points as described below.

Primary outcome measures.—Table 1 presents information regarding the scoring of the seven factors comprising the cardiovascular health score outcome. The composite score as described by others (4, 37) is derived by assigning a value of 0 for each factor assessed as “at risk,” a value of 1 for each factor assessed to be at an intermediate level, and a value of 2 for ideal level (Table 1), and then summing the individual scores. This will provide us with a composite cardiovascular health score ranging from 0 (maximum risk) to 14 (minimum risk) for each participant at each time point. (36) Change over time in cardiovascular health score will have a potential range, from −14 to +14. Positive change in cardiovascular health score over time is therefore indicative of an increase in overall healthy factors and reduction of cardiovascular risk, and negative change over time is reflective of a participant becoming less healthy through acquisition of risk-related factors.

Weight, blood pressure, fasting glucose, and cholesterol are collected during in-person health assessments at the beginning of participants’ freshman year, the start of their sophomore year (1-year follow-up) and beginning of their junior year (2-year follow-up). On the same three occasions, the three cardiovascular health behaviors will be assessed using the following measures:

Diet: The Rapid Eating and Activity Assessment for Patients.: This 31-item questionnaire (47) measures a variety of healthy eating behaviors with respect to intake of fruits, vegetables, soft drinks, and sodium, as well as food preparation habits. The five dietary components and their scoring criteria are as follows: 1) fruit and vegetable score: rarely/never eat less than 2-3 servings of fruit a day = 1 and rarely/never eat less than 3-4 servings of vegetables/potatoes a day = 1; 2) whole grain score: rarely/never eat less than 3 servings of whole grain a day = 2; 3) soda score: rarely/never drink 16 ounces or more of non-diet soda, fruit drink/punch, or Kool-Aid a day = 2; 4) salt score: rarely/never eat high-sodium processed foods like canned soup or pasta, frozen/packaged meals, or chips = 1 and rarely/never add salt to foods during cooking or at the table = 1; and 5) processed meats score: rarely/never eat regular processed meats instead of low-fat processed meat = 2. If a participant reports with a frequency of *sometimes* or *usually/often* for any of these items, they will receive a score of 0 for that item. A total score of 8-10 indicates that 4-5 components are in ideal range and will be converted to a cardiovascular health score of 2 (as per Table 1), a total score of 4-7 indicates that 2-3 components are in ideal range and will be converted to a cardiovascular health score of 1, and a total score of less than 3 indicates that 0-1 component is in ideal range and will be converted to a cardiovascular health score of 0. This questionnaire has been demonstrated to have good test-retest reliability ($r=0.86$) and is correlated with other measures of eating behaviors such as the Healthy Eating Index ($r=0.49$). (47)

Physical Activity: The International Physical Activity Questionnaire.: This 27-item questionnaire (30) asks participants to estimate how much time they spent engaged in various types of MVPA during the past 7 days. In a study administering this questionnaire to diverse samples across several countries, (48) the measure demonstrated acceptable psychometric properties (e.g., pooled repeatability coefficient of $p=0.81$; pooled criterion validity correlation of $p=0.33$).

Smoking: Opiate Treatment Index (OTI) and Covita Pico + Monitor.: A monitor reading of 8 ng/ml will be converted to a cardiovascular health score of 0 as it would indicate a participant to be a current smoker. The tobacco items from the OTI (49) will then be used to measure quantity and frequency of tobacco use for the purposes of calculating intermediate and ideal cardiovascular health scores as per Table 1. Specifically, participants will be asked whether they have ever smoked cigarettes, whether they currently smoke cigarettes, and how many days ago that they last used tobacco.

Secondary behavioral outcomes.—We will examine each of the four targeted CV behaviors individually (i.e., diet, physical activity, smoking, weight) in secondary analyses. As shown in Table 1, full presence of a risk behavior (poor) will be assigned a score of 0, ideal-level absence of assessed risk will receive a value of 2, and presence of a risk behavior assessed as being at an intermediary level will receive a score of 1.

Data Analysis Plan

For the primary analysis of intervention effectiveness, we will test for group and time-related differences on cardiovascular health composite scores using all time points (baseline, 12

months, and 24-months), via linear mixed models for longitudinal data, controlling for clustering within dorm pairs, via a three-level linear mixed model for longitudinal data. (50, 51) This class of model does not assume that subjects are measured at all time points and therefore provides valid inferences in the presence of missing data under the assumption that the data are missing at random. (52) In these analyses, we will treat the effect of time using baseline as the reference cell and will compare 12- and 24-months to baseline. Besides time, the main independent variable is intervention group (i.e., CVH, WH), and we will test for the group by time interactions (i.e., group differences in the 12- and 24-month changes relative to baseline). We will fit additional models to test for heterogeneous treatment effects across dorm pairs by including a random treatment effect term at the pair level. Further, we will explore the effect on our inferences of departures from the missing at random assumption through the use of pattern mixture models. (50)

Because results of the linear mixed model—particularly the standard errors for the fixed effects (group, time, group by time)—depend on the variance-covariance structure, we will examine several possible structures including unstructured and auto-correlated error structures (e.g., CS, AR(1), Toeplitz). We will choose the most reasonable structure using likelihood ratio tests for nested models and Akaike Information Criterion for non-nested models. This will ensure that the standard errors, and thus the p-values, for the fixed effects are reasonable.

In addition to our primary analysis, we will also examine each of the four targeted CVH factors (diet, physical activity, weight, smoking) across time in a similar way in secondary analyses. As these are multivariate ordinal outcomes with values ranging from 0-2, we will use a multivariate ordinal logistic mixed model to jointly examine changes due to time, group, and group by time for the four targeted behaviors following the approach detailed in Liu and Hedeker. (53) In doing this, we will follow the same modeling approach as detailed above for the composite cardiovascular health score using baseline as the referent time point. Again, our primary interest was on the tests of the group by time interaction, overall and for each of the four behaviors.

Sample Size and Power

In a cluster-randomized trial, the group level intraclass correlation (ICC) is needed to determine adequate sample size due to its inverse relationship with power. Based on a prior study of college students living in dorms, (54) we based our sample size on an assumption of an ICC of 0.01, attrition of 10% across 24 months, and an alpha of .05. Powering the study at 0.8 and using the formula from Thompson et al, (55) 300 participants will provide adequate power to detect an effect size of 0.36. Different ICCs will result in different detectable effect sizes. For example, if we instead assume an ICC of 0, we would be able to detect an effect size as small as 0.34 and assuming an ICC of 0.02, we could detect an effect size of 0.38.

Discussion

CVD continues to impose significant cost and mortality burdens in the US. (56) Key indicators of cardiovascular health include not smoking, being physically active, eating a

good quality diet, and healthy BMI, cholesterol, glucose, and blood pressure. (46) Heart disease is the fifth leading cause of death in the 18-25 age group, accounting for 3.2 per 100,000 deaths in the US. (57) Although 50% of US children have ideal levels of 5 out of the 7 key indicators, that proportion plummets to 16% in the young adult population, signaling a critical time of risk for loss of cardiovascular health and a timely window for healthy lifestyle promotion. (58)

Paffenberger and colleagues were the first to note a connection between poor health in the college years and later fatal coronary heart disease. (59) In fact, some evidence suggests that maintenance of a healthy lifestyle in this period of young adulthood can protect against CVD and may even result in reversal of subclinical atherosclerosis. (60, 61) There have been multiple calls to assess, track, and intervene on CVH during the college years. (62–64) Despite the potential to stave off CVD via health promotion efforts during young adulthood, there is a paucity of research on how to intervene to support the multiple cardiovascular-related health behaviors in young adults. (65)

By intervening early in adulthood, we aim to provide an opportunity for primordial prevention, avoiding development of cardiovascular risk factors. (66) One challenge of primordial prevention strategies is motivating individuals to attend to health behaviors before problems occur, when maintaining positive health behaviors could be easier than reversing unhealthy behaviors that have become habitual. Some approaches such as seminars, (19, 20, 67) appear promising, although not all have been successful. One effective, albeit burdensome, intervention delivered via seminars not only reduced college students' risk factors, but also maintained changes in weight, alcohol consumption, and triglycerides for two years. (16) In an effort to reduce burden and increase scalability, the NUYou study will evaluate the effectiveness of a fully automated, low-cost, entirely technology-mediated intervention that intervenes during the young adult years to support maintenance of cardiovascular health behaviors. Use of mobile technology will make it feasible to monitor individuals regularly to identify when health behaviors begin to slip and to intervene when new risk behaviors become apparent. MHealth technology offers the advantage of being able to reach a large number of individuals at relatively low cost. The NUYou intervention is unique in that it will be mostly automated and delivered remotely, yet it is designed to be personalized and tailored to the individual's needs and context. While this method does mean that participants could be burdened more or less depending on the number of risk behaviors in which they engage, the intervention is always tailored, titrating up and down to meet the needs of the participant. The scalable and dynamic nature of the NUYou intervention creates the potential to support primordial prevention across an entire population at lifespan period of heightened health vulnerability.

This study has several potential limitations. First, we acknowledge that enrolling the sample from a single university will limit generalizability. The results from this study at an academically elite institution may not replicate in other types or sizes of higher education institutions. However, since this is, to our knowledge, the first study of its kind, we found it important to heavily engage a specific student body to co-create and refine the intervention components. (44) We also recognize that the participant burden level could have a moderating effect on behavior change and the outcome of interest such that participants that

only have to attend to one behavior fare better than those who attend to several. It is possible there is an ideal level of burden to achieve the highest level of health improvement and future work should examine this question. Results from this trial will inform further development and potential for larger multi-site trials. Also, the study follow-up period will be limited to 24 months. Finally, vaping was not measured due to lack of affordable biological verification and initial lack of strong empirical evidence demonstrating similar cardiovascular risk as compared to combustible cigarette smoking. Now that more recent research has revealed a heightened risk associated with vaping, (Verhaegen & Gaal, 2019) future research should address this shortcoming and plan to measure and intervene on vaping in this population as vaping becomes more popular. Although limitations will prevent conclusions about this smartphone based intervention's ability to prevent future cardiovascular events, it should be feasible to evaluate change to health behaviors that are proximal outcomes on the pathway to more distal cardiovascular events.

Intensive lifestyle treatments known to improve cardiovascular health behaviors in adults are costly and unlikely to show uptake by college students who are short on time, money, and motivation to address behaviors whose adverse consequences are in a distant future. (44) The NUYou intervention aligns with current best practice recommendations for mHealth interventions that suggest the use of multimodal communication, tailored messaging, goal setting, and self-monitoring. (68) This cardiovascular health intervention is, to our knowledge, the first remotely delivered, multiple health behavior intervention for college students. We hypothesize that this scalable mHealth intervention will prevent the acquisition of poor cardiovascular health habits in a college student population, as compared to a control group receiving mHealth intervention for other health behaviors. Developing and testing potential interventions during this vulnerable time in the lifespan is a needed next step toward the primordial prevention of cardiovascular disease.

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Figure 1:
NUYou App Homepage

Verizon 10:32 AM 83%

HOW MUCH WATER HAVE YOU DRANK TODAY?

- 24 +
OUNCES

4 oz 8 oz 12 oz 20 oz

HOW STRESSED OUT WERE YOU?

Somewhat
STRESSED

HOW HAPPY HAVE YOU BEEN?

Somewhat
HAPPY

SKIP ALL DONE!

Figure 2:
Hydration Tracking for WH Group

Figure 3:
NUYou AppTime Manager

Figure 4:
Weekly Behavior Quenes

Figure 5:
Fruit and Vegetable Module

Figure 6:
Physical Activity Module

Figure 7:
Weight Module

Figure 8:
Smoking Module

Table 1.**Simple Seven Levels and Scoring to Measure Cardiovascular Health**

Health Metric	Level	Definition
Smoking	Ideal	Never or quit >12 months
	Intermediate	Former 12 months
	Poor	Current
BMI	Ideal	<25 kg/m ²
	Intermediate	25-29.99 kg/m ²
	Poor	≥30 kg/m ²
Physical Activity	Ideal	≥150 min/week moderate + vigorous
	Intermediate	1-149 min/week moderate, 1-74 min/week vigorous, or 1-149 min/week moderate + vigorous
	Poor	None
Diet Score	Ideal	4-5 components
	Intermediate	2-3 components
	Poor	0-1 components
Total Cholesterol	Ideal	<200 mg/dl, without medication
	Intermediate	200-239 mg/dl or treated to <200 mg/dl
	Poor	≥240 mg/dl
Blood Pressure	Ideal	<120/<80 mm Hg, without medication
	Intermediate	SBP 120-139 or DBP 80-89 mm Hg or treated to <120/<80 mm Hg
	Poor	SBP ≥140 or DBP ≥90 mm Hg
Fasting Serum Glucose	Ideal	<100 mg/dl, without medication
	Intermediate	100-125 mg/dl or treated to <100 mg/dl
	Poor	≥126 mg/dl