Submission Type: Modification Date: 8-12-2025

IRB #: IRB-FY2025-184
Title: Novel Lifestyle Intervention to Improve Blood Pressure and Other Cardiovascular Disease Risk Factors in Adults with Hypertension and Overweight/Obesity
Creation Date: 7-2-2025
Status: Review Complete
Principal Investigator: Erika Zoellner

IRB Modification Request

Investigator/s are required to receive approval prior to implementing any changes. Changes to the study protocol may include:

- Changes in the research team
- Addition of a data collection site
- Changes in the instrument used or data collection procedures
- Changes to the target subject population or criteria for subject inclusion / exclusion

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*required

Please provide a summary of the modification(s) requested and a rationale for this request, if appropriate.

- Please make your changes in the appropriate sections to the left.
- Please **BOLD** the text that you have changed in each section so that the modifications can be readily located.
- Attach all necessary modified documents including updated consent forms, agency approval letters if adding a site, updated/additional testing instruments, and/or training certificates for new research team members.
- If you are making changes to the attachments, please remove the original/old attachment, and upload the new attachment with the changes **highlighted**.

Good Morning,

Very minor change - I have been asked by ORSP to switch the language in the protocol regarding "parking reimbursement with gift cards".

Instead of giving participants a $10 gift card at the end of each visit towards parking reimbursement we will change the language to a "$10 cash incentive" at the completion of each visit.

I have made this change throughout the protocol and in any documents that included messaging about compensation. We will re-consent and switch compensation to $10 cash incentive instead of gift cards for parking reimbursement once this modification is approved and we receive the check from ORSP.

Thanks,

Wesley

*required

Sections Requiring Modifications

Please check all sections in which modifications are made.

- [ ] 1 - Basic Information
- [ ] 2 - Research & Review
- [ ] 3 - Study Personnel
- [ ] 4 - Study Design & Methodology
- [ ] 5 - Subject Information
- [x] 6 - Subject Recruitment
- [ ] 7 - Study Procedures
- [x] 8 - Informed Consent
- [ ] 9 - Study Instruments
- [x] 10 - Risks & Benefits
- [ ] 11 - Protecting the Confidentiality of Subjects

Are there any other changes to the study that cannot be listed in the sections to the left?

For Legacy studies (studies submitted prior to the Cayuse implementation), any modifications with the exception of research personnel should be listed here.

Yes

✓ No

Additional Documents

Attach any additional documents (not listed in the sections to the left).

1- Basic Information

Preparing and Completing the Application

You do not have to finish the application in one sitting; the information will be saved and you may continue at a later time. As you complete the various sections of the application new sections relevant to the type of research being conducted will appear on the left-hand side; therefore, not all numbered sections may appear. You may go to another section using the menu on the left or the arrows at the bottom of each page. When adding attachments, each attachment button will allow you to add multiple documents and most common file types can be uploaded, including .pdf, .docx, and images.

Additional help information has been added throughout the form for guidance and clarity. That additional information can be found by clicking the question mark it the top-right corner of each section. You are strongly encouraged to use this feature! Once you have answered all required sections (indicated with a red asterisk), a green check mark will appear for that section (in the menu to the left). **After all required sections are marked as complete, the option to submit the application will appear at the bottom left underneath all of the sections.**

For more information about the TWU IRB submission process, IRB tracking, and Cayuse IRB Tasks, please refer to the TWU IRB Procedures, TWU IRB website, and Cayuse help features.

*required

TWU Campus

Note: If you are a student on a different campus than your faculty advisor, your faculty advisor's campus IRB will be the reviewing IRB.

- Dallas
- Denton
- ✓ Houston

*required

Is this activity research?

- ✓ Yes
- No
- Unsure

*required

Does this research involve human subjects?

- ✓ Yes
- No

2- Research & Review Type

*required

Type of Project

Select the type of project (Check all that apply).

- ✓ Thesis
- Professional paper
- ✓ Dissertation
- Class project
- ✓ Faculty research
- ✓ Pilot
- Other

*required

Study Review Category

Indicate the level of review for this study.

- Exempt
- Expedited
- ✓ Full

Drug, Devices, and Biologics

Will the study involve administering any of the following? Check all that apply.

- ✓ Drug/Supplements

Please describe

Daily Premier Protein Shake

Biologics

Devices

None of the above

Funding Source

Have you already received funding for this research project?

✓ Yes

List the funding agency/sponsor

TWU Foundation - Moore-Khourie Research Fund, TWU Research Enhancement Program (REP)

If you cannot find an agency/sponsor, please enter the sponsor name

No

*required

Study Dates

Provide an estimated start and end date for this study.

*required

Start Date

This is an estimated start date. You may NOT start your study until you receive IRB approval.

02/17/2025

*required

End Date

We will use the estimated end date you provide here as a basis for your expiration date.

12/01/2025

*required

Does this study involve working with more than one institution's IRB?

Yes

✓ No

3- Study Personnel Information

*required

What is the Principal Investigator's status at TWU?

Faculty

✓ Student

*required

Undergraduate Student

✓ Graduate Student

Staff

Other

Study Personnel

Note: If you cannot find a person in the people finder, please contact the IRB Office: irb@twu.edu.

*required

Principal Investigator

Provide the name of the Principal Investigator of this study.

Name: Erika Zoellner
Organization: Nutrition - Houston
Address:
Phone:
Email: ezoellner@twu.edu

*required

Primary Contact

Provide the name of the Primary Contact of this study.

Name: Erika Zoellner
Organization: Nutrition - Houston
Address:

Phone:
Email: ezoellner@twu.edu

*required

Faculty Advisor

Provide the name of your faculty advisor. This person must have a faculty appointment. Graduate Teaching Assistants may not supervise IRB protocols as the faculty advisor.
Name: Wesley Tucker
Organization: Nutrition - Houston
Address:
Phone:
Email: WTucker1@twu.edu

Co-Principal Investigator(s)

Provide the name(s) of Investigator(s) for this study.
Name: Wesley Tucker
Organization: Nutrition - Houston
Address:
Phone:
Email: WTucker1@twu.edu

Other TWU Research Team Members

Provide the name(s) of other TWU research team members for this study. Note: If you cannot find a person in the people finder, please contact the IRB Office.
Name: Mindy Patterson
Organization: Nutrition - Houston
Address: Texas Woman's University 6700 Fannin, Houston, TX 77030-2343
Phone:
Email: mpatterson14@twu.edu

Name: Derek Miketinas
Organization: Nutrition - Houston
Address: Texas Woman's University 304 Administration Drive, Denton, TX 76204-5619
Phone:
Email: dmiketinas@twu.edu

Name: Catherine Mbango
Organization: Nursing - Houston
Address: Texas Woman's University 6700 Fannin, Houston, TX 77030-2343
Phone:
Email: cmbango@twu.edu

Name: Zainabou Akum
Organization: Nutrition - Houston
Address:

Phone:
Email: zakum@twu.edu

Name: Wayne A. Brewer
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Address: Texas Woman's University 6700 Fannin, Houston, TX 77030-2343
Phone:
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Name: Smiti Mirmire
Organization: Nutrition - Houston
Address:
Phone:
Email: smirmire@twu.edu

Name: Gabrielle Lewis
Organization: Nutrition - Houston
Address:
Phone:
Email: glewis6@twu.edu

Human Subjects Training Certificates

If a research team member has not completed the CITI human subjects training but has a current NIH certificate (must be less than 3 years old), please attach it here.

Other Non-TWU Research Team Members

Provide the name(s) and email address(es) of other Non-TWU research team members for this study.
Sean Savitz, MD - Sean.I.Savitz@uth.tmc.edu

Seema Aggarwal - Seema.S.Aggarwal@uth.tmc.edu

Please attach a human subjects training certificate for each non-TWU research team member listed.

Note: If the Non-TWU research team member has not completed the CITI human subjects training but has a current NIH certificate (must be less than 3 years old), please attach it here.
Aggarwal_CITI Training.pdf

Savitz_CITI Training.pdf

Other Research Personnel

Provide the name(s) of any other research personnel who will have access to study data (e.g., transcriber of recorded interviews, transcription agencies, phlebotomist, translator, survey analyst, etc.), but will not be included as part of the research team.

Kennedy Onuoha - Phlebotomist

Kelly Akum - Phlebotomist

Attach signed confidentiality agreement form for each person listed.

Kelly Akum_Confidentiality Agreement.pdf

Kennedy Onuoha_irb-confidentiality-agreement for Tucker-Zoellner Study.pdf

*required

Conflict of Interest

Do you or any research team member(s) participating in this study have a financial interest related to this research project?

Yes

✓ No

4- Study Purpose & Research Questions/Hypotheses/Objectives

*required

Is this study a clinical trial?

- [x] Yes
- [ ] No

*required

Type of Clinical Trial

Select the type of clinical trial below. Check all that apply.

- [ ] Randomized
- [x] Non-Randomized
- [ ] Placebo
- [ ] Blinded
- [ ] Other

*required

Clinical Trial Phase(s)

Select the phase of the clinical trial. Check all that apply for this study.

- [x] Pilot Study
- [ ] Phase I
- [ ] Phase II
- [ ] Phase III
- [ ] Phase IV

N/A

*required

Study Purpose

Describe the purpose of the study and/or the rationale for conducting this study.

Background/Rationale:

Hypertension (HTN) is one of the strongest risk factors for cardiovascular disease (CVD), and nearly half of all U.S. adults currently experience HTN (~47%, 122.4 million). Treatment of HTN typically involves a combination of pharmacotherapy and lifestyle modifications to control BP. However, despite the effectiveness of pharmacotherapy to treat HTN, incidence remains high due to poor adherence to medications, presence of resistant HTN and poor lifestyle habits. In 2015, a hybrid diet of the Mediterranean and DASH diet, termed the Mediterranean-DASH Intervention for Neurodegenerative Delay (MIND) diet was introduced. The MIND diet was developed after research findings from the Mediterranean and DASH diets suggested a positive correlation between specific foods and improved cognitive function. However, recent epidemiological data also suggests that high adherence to the MIND Diet eating pattern is associated with a 24% lower prevalence of HTN and lower systolic blood pressure as compared to low adherence to the diet. These preliminary data support the need for further clinical trials to investigate the feasibility and efficacy of the MIND diet to treat HTN.

To date, no study has examined the feasibility and efficacy of using the MIND diet to specifically treat HTN. Furthermore, given the additional benefit provided by exercise on BP reduction in patients with HTN, a lifestyle intervention that incorporates both the MIND diet and exercise training in patients with HTN is warranted.

Purpose/Objective of this study:

The overall objective is to assess the feasibility and efficacy of a 4-week novel diet and exercise intervention to improve blood pressure (BP), other cardiovascular disease (CVD) risk factors, and sleep in adults with hypertension and overweight/obesity.

*required

Research Questions/Hypotheses/Objectives

Provide the research question(s), study hypotheses and/or study objectives.

Specific Aims & Hypotheses

1. To determine the feasibility of a 4-week novel lifestyle intervention consisting of a modified-MIND diet and high-intensity interval training (HIIT) in adults with hypertension and overweight/obesity.

Hypothesis: Adherence to 4-week lifestyle intervention will be high; with ≥ 75% supervised exercise training visits completed and ≥ 75% dietary compliance. We also hypothesize that study attrition will be low; with ≥ 75% of enrolled participants completing our pilot study.

2. To evaluate the effectiveness of a 4-week novel lifestyle intervention consisting of a modified-MIND diet and high-intensity interval
training (HIIT) to lower blood pressure in adults with hypertension and overweight/ obesity.

Hypothesis: This 4-week lifestyle intervention will significantly lower blood pressure in adults with hypertension and overweight/obesity.

3. To evaluate the effectiveness of a 4-week novel lifestyle consisting of a modified-MIND diet and high-intensity interval training (HIIT)
to improve exercise capacity, other cardiovascular disease risk factors, and sleep duration and quality in adults with hypertension and
overweight/obesity.

Hypothesis: This 4-week lifestyle intervention will significantly improve maximal oxygen uptake (VO2max), quality of life, vascular function, blood inflammatory markers, insulin sensitivity, visceral fat, and sleep duration and quality in adults with hypertension and overweight/obesity.

5- Subject Information

*required

Subject Enrollment

Provide a description of the subjects in this study.

Up to 12 adults with hypertension and overweight/obesity will be recruited, prescreened, and enrolled in the study with the overall goal of at least 9 participants fully completing the intervention.

*required

Approximate Number of Subjects to be Enrolled

Please enter the estimated total number of subjects to be enrolled in this study.

12

*required

Vulnerable Populations

Select below any population(s) that you will specifically recruit for this study. Check all that apply. If no vulnerable populations will be recruited, check "None of the Above."

- Pregnant women
- Fetuses
- Minors
- Prisoners
- Individuals with Impaired Decision-Making Capacity
- Other
- ✓ None of the Above

*required

Age (or age range)

Provide the age or age range of study subjects.

18 to 74 years

*required

Provide a rationale for the inclusion/exclusion based on age.

We are interested in investigating the efficacy of this intervention for blood pressure and CVD risk factor improvement (prevention) in young, middle-aged, and early older adults.

~~As such, we have excluded older adults (65 years and older). We have done this to limit the established role that aging plays on blood pressure.~~

*required

Sex of Study Subjects

Select the sex of the subjects that will be enrolled in this study.

- Female
- Male
- ✓ Both

*required

Ethnicity of Subjects

Will subjects be included/excluded based on ethnicity?

- Yes
- ✓ No

Additional/ Other Inclusion Criteria

List any other inclusion criteria to be considered for participation in the study. Provide a rationale for all inclusion criteria listed.

Inclusion criteria include:

- Age 18 to 74 years old (Rationale: This is the best age range to target for BP reduction for primary prevention)
- Overweight or class I/II obesity (body mass index [BMI] = 25 - 39.9 kg/m2) (Rationale: Overweight or obesity is prevalent in over 60% of patients with hypertension in the US so translation is high here)
- Clinically diagnosed hypertension (by Physician or Nurse Practitioner) with or without current use of hypertensive medication (Rationale: To have the highest application and translation of these study findings to patients with hypertension we wanted to include patients with both treated (on medications) and untreated (not on medications) hypertension - we appreciate this could be a potential limitation and will include "medication use" as as covariate in our final data analysis).
- Sedentary or physically inactive as defined as < 7,500 steps per day with physical activity monitor (Fitbit) (Rationale: We want to see the effects of this exercise intervention on individuals who are currently sedentary or inactive, not those who are already meeting the current ACSM guidelines for physical activity).
- Ambulatory (Rationale: In order to participate in exercise testing and exercise training the patients must be ambulatory)
- Able to read and speak English (Rationale: All participants must be able to read, speak, and understand English to participate in the study, as this is a requirement to follow diet and exercise instructions)
- Willingness to share medical record indicating diagnosis of HTN and current medication use

Additional/Other Exclusion Criteria

List any other exclusion criteria to be considered for participation. Provide a rationale for all exclusion criteria listed.

Exclusion criteria include:

- Current smoker (Rationale: May confound improvements in BP and other CVD risk factors and exercise tolerance)
- Severe/Class III obesity (BMI greater than or equal to 40 kg/m2) (Rationale: Severe/Class III obesity is associated with ambulatory issues that will limit participation in exercise testing and training)
- Height > 6 foot 6 inches (78 inches) (Rationale: Individuals taller than 6 foot 6 inches fall outside the region of interest (table) for DEXA images)
- Blood pressure ≥ 160/100 mm Hg (Contraindication to exercise testing and training)
- History of diagnosed cardiovascular diseases including myocardial infarction, atrial fibrillation, stroke, coronary artery disease, peripheral artery disease, or heart failure

- History of cancer, liver disease, kidney disease
- Diagnosis of type 1 or type 2 diabetes, or current use of insulin or metformin
- Diagnosed moderate or severe obstructive sleep apnea, use of CPAP, insomnia or history of any other sleep disorder (Rationale: The presence of major sleep disorders may mitigate intervention efficacy)
- Night shift and/or rotating shift worker (current or in the past 2 years) (Rationale: Night shift workers have known metabolic disturbances and their work schedule makes it difficult to participate in study testing and exercise training)
- Current use of sleep medications or sleep aids
- Excessive alcohol consumption defined as 8 or more alcoholic drinks per week in women and 15 or more alcoholic drinks per week in men (Rationale: Excessive alcohol intake may mitigate intervention efficacy)
- Any injury, joint issue, or medical condition that prevents participation in exercise testing and training
- A "yes" response to any questions on the Physical Activity Readiness Questionnaire (PAR-Q) (excluding Question 6 on use of BP medications)
- Pregnancy, breastfeeding
- Food allergy or lactose intolerance
- History of gastric bypass or other weight loss surgery
- Current use of dietary supplements or drugs for weight loss (including Ozempic and Mounjaro)
- Weight stable for the last 2 months (< 5 pounds body weight change)
- Current participation in exercise training (2 or more days per week of structured aerobic and resistance exercise training at a gym or at home)
- Current participation in a special diet to facilitate weight loss (Ketogenic Diet, Atkins, Paleo, Intermittent Fasting, etc.)
- Prior hospitalization for COVID-19 (Rationale: This is an added safety precaution to ensure patient safety as the long-term effects of COVID-19 hospitalization on exercise tolerance and CVD risk are unknown)
- Any medications or supplements that may alter study outcomes as determined by study PI during screening

6- Subject Recruitment

*required

Subject Recruitment

*Will this study **ONLY** utilize secondary data (is this a retrospective study)?*

Yes

✓ No

*required

Recruitment Process

Describe subject recruitment process in detail. Include information on how potential participants will receive information about the study.

Adults with hypertension and overweight/obesity will be recruited using research flyers (**see Study Flyer below**) that will be posted on the TWU Houston campus and in doctor's offices in the Texas Medical Center, shared by TWU listservs, and shared by social media (Facebook and Twitter) and word of mouth. **We will also purchase META ads to advertise on Facebook and provide a link to our study website (PDF of study website on Department of Nutrition Website provided).** Interested participants will contact the study PI (Erika Zoellner) or Co-PI (Dr. Tucker) who will respond to them by phone using the "**Phone Conversation Recruitment Script for Novel Lifestyle Study**" document included in this IRB application **or send them a Qualtrics pre-screening survey to assess their eligibility for the study.** This will include specific inclusion and exclusion criteria for the study. If the individual is interested in participating in this research study, an initial pre-screening visit will be scheduled over the Phone or using zoom with either the study PI (Erika Zoellner) or Co-PI (Dr. Tucker). If they are eligible to participate, an initial study visit at TWU will be scheduled. Private rooms are available for the PI to do pre-screening and obtain informed written consent.

Recruitment Documents/Materials

Attach all study recruitment materials you will use in this section. This includes (but is not limited to) flyers, email/phone/verbal scripts, social media posts, letters, advertisements, etc.

Example of MIND Diet and Exercise Study Website for Recruitment.pdf

Participant Follow-Up Email Script with Qualtrics Pre-Screening Survey.docx

Phone Conversation Recruitment Script for Novel Lifestyle Study_CLEAN COPY.docx

Phone Conversation Recruitment Script for Novel Lifestyle Study_REDLINE COPY.docx

TWU MIND Diet & Exercise Study Flyer_CLEAN COPY.docx

TWU MIND Diet & Exercise Study Flyer_REDLINE COPY.docx

Updated Tucker & Zoellner_Qualtrics Pre-Screener Survey.pdf

*required

Eligibility Screening/Testing

Will the study utilize screening/eligibility questionnaires, tests, forms to be completed by or administered to the subject?

✓ Yes

Please explain the process for screening subjects.

Pre-Screening

Prior to informed written consent and enrollment in the study, all interested participants will either**complete an online Qualtrics Pre-screening survey** or a virtual screening over the phone or via Zoom which includes:

- Inclusion/Exclusion Criteria Checklist: All inclusion and exclusion criteria are included in the **online Qualtrics pre-screening survey** and in a checklist as an attachment below (used for phone screenings).

Initial pre-screening will take place **using the online Qualtrics Pre-screening survey** or over the phone or via Zoom with the study study PI (Erika Zoellner) or Co-PI (Dr. Tucker). These pre-screening questions will be repeated in-person in a private room in the 10th floor research suite at the TWU-Houston campus to confirm. In order to limit the number of screen fails that occur in person, we have included the major inclusion criteria in the study flyer and will conduct initial study pre-screening over the phone or Zoom to save the participants and researchers time.

Attach any screening/eligibility testing documents. (If uploading a survey/questionnaire link, please also upload a pdf version for IRB records.)

Physical Activity Readiness Questionnaire_Non-Identifiable Version.pdf

Inclusion and Exclusion Criteria Checklist for Novel Lifestyle Study_CLEAN COPY.docx

Inclusion and Exclusion Criteria Checklist for Novel Lifestyle Study_REDLINE COPY.docx

Participant Follow-Up Email Script with Qualtrics Pre-Screening Survey.docx

Updated Tucker & Zoellner_Qualtrics Pre-Screener Survey.pdf

No

*required

Will the subjects be told about the intent of the study prior to participating?

✓ Yes

No

7- Study Procedures

*required

Research Procedures

Describe the research procedures in detail. (See the question mark on the right side for information that should be included here.)

Study Design

Participants who meet the inclusion/exclusion criteria for participation (as determined by Qualtrics pre-screening survey or pre-screening phone or Zoom call) will be asked to attend an in-person screening and consent visit at TWU – Houston. During the in-person screening visit, participants will complete a questionnaire regarding demographic and medical history, as well as the PAR-Q. Participants will also be asked to provide a copy of their medical records confirming the diagnosis of hypertension with or without current medication use. In addition, we will measure height, weight, and seated resting BP, to ensure that they meet the inclusion criteria for BMI and BP, respectively. If they pass screening, participants will undergo written informed consent to be enrolled in the study. At the end of this screening and consent visit, each participant will be provided with a physical activity/sleep monitor (Fitbit) to wear for 7 days. This is to ensure participants meet the criteria for sedentary or inactive – defined as < 7,500 steps per day. In addition, this Fitbit monitor also objectively measures sleep duration and quality (further details below). Finally, each participant will also be provided with an Ambulatory Blood Pressure Monitor to wear for the next 2 days.

Approximately one week later, participants will return to our research lab at TWU Houston to undergo baseline testing. At this time, the research team will retrieve the ambulatory blood pressure monitor and Fitbit monitor from the participant to ensure compliance and eligibility, respectively. **We require a minimum of 70% of ambulatory blood pressure monitor recordings over a 24-hour period and an average daily step count of < 7,500 steps per day during the initial week of monitoring to qualify for the study.**All testing visits will be completed early in the morning following an overnight fast – water is permitted. Participants will be instructed not to consume any caffeine or alcohol, take any dietary supplements, or conduct vigorous exercise 24 hours prior to this visit. Thereafter, participants will undergo numerous physiological testing including seated resting BP, assessment of vascular function, anthropometry, venous blood draw, and maximal exercise testing to measure maximal oxygen uptake (VO2max). In addition, we will have participants complete surveys on quality of life and sleep quality, and current dietary intake. Following the completion of baseline testing, all participants will undergo a 4-week lifestyle intervention consisting of the MIND diet and supervised exercise training – HIIT. All study outcomes will be reassessed 48 to 96 h after the intervention is completed. All outcome assessments and exercise training will take place in the 10th floor research wing at TWU – Houston. **The return of ambulatory blood pressure monitors is required after baseline and post-intervention testing. The Fitbit monitors must be returned to the study team immediately upon study completion at the final testing visit.**

Procedures & Methodology

Private rooms are available for the PI to obtain informed written consent and collect other health-related data (medical history questionnaire and list of medications). All exercise testing and training for this study will take place in the Cardio Lab (Room 10131) located on the 10th floor research wing at TWU – Houston. The following assessments will be performed at baseline and post-intervention (in this order):

Ambulatory Blood Pressure Monitoring: Each participant will be given an Ambulatory Blood Pressure

Monitor (ABPM) (Oscar 2 ABP, Sun Tech Medical, Morrisville, NC) to wear for 48 h prior to and then again for 48 h during the final week of the lifestyle intervention. ABPM is a non-invasive, fully automated technique where BP is measured and recorded frequently over an extended period of time – typically 24 h. The major advantages of ABPM include the collection of multiple BP measurements to provide more comprehensive information on BP (mean 24-h BP readings) and ability to measure both daytime and nocturnal BP in a more natural setting. Over the last few decades, multiple studies have shown that BP measured by ABPM has a stronger association with clinical CVD outcomes compared with standard office-based BP measurements. For this study, each ABPM will be programmed to record BP measurements every 30 min during waking hours and sleep. We will NOT use an app for this device, we will initialize (set-up) the device by entering the participant's non-identifiable study ID onto the device. The ABPM only records blood pressure, heart rate, and time of each measurement. When the ABPM is returned to us we connect it to the PC via a USB and download the blood pressure, heart rate, and time of measurement data from the device. Each participant will receive a verbal explanation and demonstration regarding the process of ABPM and written instructions regarding frequency of inflations and deflations, how to deflate manually, and how to keep the monitor attached at night. Participants will also be provided with an activity diary to complete while wearing the ABPM, which includes hours of sleep, time at work, time at leisure activities, and periods of driving. Times used to define daytime and nighttime will be determined by using self-report (activity diary sleep times) and actigraphy (Fitbit). This will allow us to define the mean 24-h BP, daytime BP, and nocturnal BP. ABPM readings will be considered acceptable for data analysis purposes if ≥ 70% of planned readings are acquired. All ABPM devices must be returned to the study team immediately following completion of baseline and post-intervention testing.

Physical Activity and Sleep: Habitual physical activity levels and sleep will be measured using a wrist-worn, physical activity and sleep monitor (Fitbit Inspire 3, Fitbit LLC, San Francisco, CA) for the duration of the study. The Fitbit Inspire 3 device uses motion sensors (Actigraphy) and heart rate to measure total steps and minutes of light, moderate, and vigorous physical activity. These measurement tools also allow it to measure total time in bed, total sleep time (sleep duration), and wake time after sleep onset. It also uses a proprietary sleep staging algorithm to derive sleep stage durations including light, deep, and rapid eye movement (REM) sleep. Prior studies indicate that Fitbit is a reliable alternative to polysomnography (the gold standard) for collecting objective sleep data.

We will use Fitbit's free, web-based application programming interface (API) to tailor the Fitbit to the specific needs of this study. Fitbit API allows us to created deidentified participant accounts using unique codes that are specific to the study – for example "Study Participant 001". These de-identified Fitbit accounts are also linked to unique, study-generated gmail accounts such StudyParticipant001@gmail.com and not a personal email account. This effectively removes any personal information (email, name, DOB, phone number) directly linked to the data collected during the study with Fitbit. At the first study visit, our team will show each participant how to download the Fitbit app to their mobile device/smartphone and then have them use the deidentified Fitbit account and study-generated Gmail account information provided to them to set up their account. Once their deidentified Fitbit account is setup we will send them a "push" to approve us to access the data, which is automatically downloaded to their app every time they open the app and "sync" it. We will only collect physical activity, heart rate, and sleep data from the Fitbit device for this study. Physical activity data includes steps taken and moderate-to-vigorous intensity physical activity minutes per day. Sleep data includes sleep duration and sleep quality indices (light, deep, REM, non-REM sleep). We only collect Fitbit data that directly impacts study outcomes. Once paticipant data is accessed we will download it as an Excel file for storage on a password-protected computer for later analysis.

Anthropometrics and Blood Pressure: Height and weight will be measured in duplicate and averaged using a dual-function stadiometer and weighing scale (Health-O-Meter Professional 500KL, Pelstar LLC, McCook, IL) for calculation of body mass index (BMI) in kg/m2. Resting seated blood pressure will be take

in triplicate and averaged, with a 2-min break in between each measurement (Spot Vital Signs 4200B, Welch Allyn, Skaneateles, NY, USA). This takes 10 minutes to complete.

Body Composition Assessment: Body composition will be assessed using whole body Dual-energy X-ray Absorptiometry (DXA) (Horizon W, Hologic® Marlborough, MA, USA). A whole-body DXA scan provides high-resolution body composition assessment that includes percent body fat, total lean mass, bone density, limb comparison for muscle imbalance detection, and visceral fat determination. The participant will be instructed to wear clothing sans metal, and to remove any jewelry, dental appliances, eyeglasses, coins, etc. prior to being scanned. The participant will be instructed to lie supine on the DXA table. The researcher will ensure adequate positioning of the participant and ask them to remain still during the 7-minute whole-body scan. All study personnel included on this protocol have been certified to operate the DXA and have current radiation safety training. If a second scan is necessary due to movement or inadequate results, a Second Consent will be obtained. A maximum of two scans can be performed on a subject on any given day. Any printed results will be kept in a locked cabinet located in Room 7017 (Dr. Tucker's office). This test takes about 15 minutes.

Assessment of Vascular Function with Brachial Artery Flow-Mediated Dilation (FMD): This is a **non-invasive** assessment of the ability of the brachial (upper arm) artery to dilate in response to an increase in blood flow, and is assessed using ultrasound. Brachial artery FMD measures nitric oxide-mediated endothelial function and correlates strongly with coronary artery endothelial function. This procedure is performed while the subject is lying supine on a padded ultrasound table. All measurements are made on the non-dominant arm. A blood pressure cuff is positioned on the subject's forearm. After recording baseline ultrasound measures on the upper arm, the blood pressure cuff is inflated to 250mmHg for 5 minutes. The cuff is then deflated rapidly and brachial artery blood flow and arterial diameter are measured continuously for 5 minutes using the ultrasound probe. These procedures conform to the published guidelines of the International Brachial Artery Reactivity Task Force. The brachial artery FMD assessment is an extremely safe test with no reported adverse events in the published literature has been recommended for use in children, adults, and clinical populations. The PI (Dr. Tucker) has experience with and has published using this technique. This test usually takes 25 minutes.

Assessment of Blood CVD Biomarkers: Participants will be instructed to arrive to the testing site (room 10128, TWU-Houston) having fasted for ≥8 hours other than water. A trained phlebotomist will collect up to 10 ml of fasting blood into appropriately labeled vacutainers and store it for pickup and analysis by LabCorp. Blood will be analyzed for glucose, insulin, lipids, and inflammatory markers. All blood draws will be performed by a trained phlebotomist. This test usually takes 5 minutes.

Maximal Exercise Testing: Maximal oxygen uptake (VO2max) will be assessed during an incremental ramp rest on an electronically-braked cycle ergometer (Corival, Lode, Gronigen, Netherlands) using a Parvo Medics TrueOne 2400 (Parvo Medics, Sandy, UT) computerized metabolic measurement system. Ventilation and gas exchange will be continuously measured via indirect calorimetry. Heart rate will be continuously measured using a Polar heart rate monitor (Polar Electro Inc., Lake Success, NY). After 2 min of rest, participants will conduct a 5-min warm up at 50 W (men) and 25 W (women). Following the warm-up, wattage (W) will increase in a ramp fashion by 20 W/min (men) and 15 W/min (women) until each participant reaches volitional exhaustion despite strong verbal encouragement. Following the 10-min cool-down phase, each participant will perform a verification phase test. The verification phase test consists of cycling at a constant power output equivalent to 100% of maximum power achieved on the incremental ramp test. VO2max will be defined as the average of the 2 highest consecutive 15-sec averages achieved for VO2 during either the ramp or verification phase. Maximal heart rate (HRmax) will be defined as the highest HR achieved during either the ramp or the verification phase. This test usually takes 45 minutes.

Quality of Life: Health-related quality of life will be measured with the 36-item Short-Form Health Survey (SF-36) (Brazier et al., 1992; Lyons, Perry, & Littlepage, 1994). In brief, scores on the physical and mental component subscales of the SF-36 range from 0 to 100, with higher scores indicating better health status; the minimal clinically important difference is 2 points. Participants will complete the SF-36 survey in a quiet, private room in the 10th floor research suite. This takes 10 minutes to complete.

Subjective Sleep Quality: Subjective sleep quality during the last 30 days will be assessed with the validated Pittsburgh Sleep Quality Index (PSQI). The PSQI is a widely used self-report questionnaire that measures overall sleep quality (global PSQI score) and sleep components along several different domains during the last 30 days. This includes subjective sleep quality, sleep latency, sleep duration, sleep efficiency, sleep disturbances, use of sleep medication, and daytime dysfunction. This takes 10 minutes to complete.

Dietary Assessments and Dietary Adherence: Dietary intake before and after the intervention will be assessed using the Automated Self-Administered 24-h (ASA24) Dietary Assessment Tool, version 2020, developed by the National Cancer Institute, Bethesda, MD. This tool will be administered 100% online and only de-identified information will be collected (e.g., participant ID only). The ASA24 prompts participants to record everything consumed in the previous 24 hours from midnight to midnight using detailed probes and has been validated against interviewer-administered 24-h recalls, food records, and actual intakes (Kirkpatrick et al., 2014; Park et al., 2018; Thompson et al., 2015). This assessment takes about 25 minutes to complete.

Dietary adherence is always a concern in nutrition studies. To maximize dietary adherence, participants will meet with a dietitian at the beginning of the study and then every 2 weeks thereafter to assess adherence to the prescribed diet using the **validated 16-item Mediterranean Eating Pattern for Americans (MEPA) Questionnaire**. This tool measures adherence to the dietary patterns and serving sizes recommended in the Mediterranean Diet and has been adapted for use in Americans (Cerwinske et al. 2017). This assessment takes about 15 minutes to complete.

Novel Lifestyle Intervention Protocols

Supervised Exercise Training: All subjects will complete 4 weeks of supervised exercise training in the Cardio Lab (Room 10131) at TWU – Houston. The supervised exercise training sessions will take place on 3 days per week and consist of high-intensity aerobic interval training (HIIT) on a cycle ergometer. Each HIIT session will be 30 minutes and consist of a 5-min warm-up at 50-60% HRmax followed by ten 1-min vigorous intervals at 90-95% HRmax separated by 1-min periods of active recovery at a low-intensity (30 to 50W), with a 5-min cool-down at 50-60% of HRmax. Heart rate will be continuously measured with Polar HR monitors and recorded to ensure adherence to prescribed exercise intensities. To ensure patient safety and appropriate aerobic endurance progression, high-intensity intervals will be set at 80 to 85% HRmax during week 1 and gradually increased up to 90 to 95% HRmax by week 3 of the study. A summary table of the supervised exercise training protocol is also included as an attachment for easy viewing. Participants will be advised to maintain their usual physical activity outside of the exercise sessions and this will be confirmed with a wrist-worn physical activity monitor for the duration of the study.

Dietary Intervention: Participants will meet with a registered dietitian (Study PI or Co-PI) and receive diet education on how to adopt and adhere to a MIND diet. The MIND (Mediterranean-DASH Intervention for Neurodegenerative Delay) diet has emerged as a promising intervention, yielding favorable improvements in BP and other CVD markers. The MIND diet shares similarities with both the Mediterranean and DASH diets by prioritizing natural, plant-based foods while restricting the intake of animal products and foods high in saturated fat. However, it distinguishes itself through its unique emphasis on the inclusion of

berries and green leafy vegetables. For adoption of the MIND diet, participants will be instructed to consume fatty fish at least twice per week (6-10 oz.), 5 servings of berries weekly (2 ½ cups), 5 servings of nuts weekly (5 oz.), one serving of leafy greens daily (1 cup raw, ½ cup cooked), and at least 2 tablespoons of extra virgin olive oil daily (used in cooking or dressings). In addition, they will be instructed to limit red and processed meats to no more than 1 serving per week (3-5 oz.), fast or fried foods (including potato chips) no more than once per week, and sweets no more than 3 times per week. The research team will provide participants with a stipend ($25 gift card each week) for grocery shopping, a daily 30g whey protein supplement, 48 oz of extra-virgin olive oil, and packaged mixed nuts to help with compliance. To track dietary compliance, participants will be provided with a dietary tracker, which includes the foods to incorporate and limit, and instructed to complete and return the tracker each week.

Statistics

All data will be analyzed using IBM SPSS software (Version 25, IBM, Armonk, NY). Data will be explored for departures from normality with the Shapiro-Wilk test. Paired T-tests will be used to assess changes (pre-post) in main outcome measures following the intervention within-group. In the event that data are observed to violate parametric assumptions, group comparisons will be made with Wilcoxon signed-rank tests where appropriate. All statistical tests will be two-sided with a critical alpha level of 0.05 indicating statistical significance.

*required

Is video recording a part of this study?

Yes

✓ No

*required

Is audio recording a part of the study?

Yes

✓ No

*required

Is internet/email a part of the study?

✓ Yes

*required

Describe how the internet and/or email will be used.

We will use the internet for recruitment via distribution of the flyer via email and social media. Also, we will use Qualtrics or Zoom for participant screening.

No

*required

Non-TWU Study Site

Will the subjects be affiliated with a specific non-TWU agency, institution, or organization?

Yes

✓ No

*required

Location/Setting of the Study

Where will the study take place? Describe the physical and privacy aspects of this location.

All exercise testing and training for this study will take place in the 10th floor research suite at TWU-Houston. Private rooms are available for the PI to obtain informed written consent and collect other health-related data (medical history questionnaire and list of medications).

*required

Time Commitment

What is the time commitment for the subjects? Include the number of sessions/visits, maximum time commitment per session, and the maximum total time commitment.

Each subject will come to the TWU Houston Campus for a total of 15 study visits. The initial screening and consent visit will take 1 hour to complete. The baseline and post-intervention testing visits will each take

~2.5 hours. The exercise training visits (12 total) will each take ~45 minutes (9 hours total for exercise training during study). **Total maximum study time commitment is 15 hours, which does not include travel to and from TWU.**

*required

Subject Data, Specimens, and Records

Does this project involve the collection or use of materials (data or specimens) recorded in a manner that could identify the individuals who provided the materials, either directly or through identifiers linked to these individuals?

- ✓ Yes
- No

8- Informed Consent Process

*required

Questions about the Study

Subjects should be provided the opportunity to ask the researchers questions about the study at any time before, during and after the completion of the study. Describe how subjects can contact you if they have questions about the study.

Subjects are free to ask the researchers any questions regarding the study at any time. At the initial screening and consent visit we will explain the study to the subject in detail and ask them if they have any questions. Once we have answered all of their questions we will undergo the informed consent process. Subjects will be given a copy of their signed and dated consent form to keep. The contact information (both email and phone number) for all research personnel are included at the top of the first page of the consent form. The contact information for the study PI and Co-PI are also included on the study flyer. If the subjects have any further questions they can contact the study PI (Erika Zoellner) or Co-PI (Dr. Tucker) - details for both are listed below:

Erika Zoellner, MS RDN LD
Study Principal Investigator
Doctoral Candidate
Department of Nutrition
Texas Woman's University
Email: Ezoellner@twu.edu
Cell: 281-731-6809

Wesley Tucker, PhD RDN
Study Co-Principal Investigator
Department of Nutrition and Food Sciences
Texas Woman’s University
Email: WTucker1@twu.edu
Phone: 713-794-2379
Cell: 919-744-0532

*required

Does this study use handwritten or digitally signed informed consent?

This is intended for studies where handwritten or digitally documented signatures are obtained on a consent form.

✓ Yes

*required

Signed Informed Consent

Describe in detail the process for obtaining written/documented informed consent.

During the initial study visit, written informed consent will be obtained from all eligible participants prior to participating in the study. The study purpose, procedures, time commitment, risk/benefits, and compensation will all be covered in detail and we will ask the patient if they have any questions prior to them providing written informed consent about voluntary participation in our research study. Subjects will be given a copy of their signed and dated consent form to keep. The consent process will occur in a quiet, private room in the 10th floor research suite during the baseline study visit.

*required

Signed Consent Form Storage

Describe where you will securely store signed consent forms (must be in a secure location). Explain how long the consent forms will be kept (must be maintained for a minimum of three years from the study close date). Describe how you will destroy the signed consent forms after this period. Note that copies of signed consent forms must be submitted to the IRB when you submit your study close request.

The signed consent forms will be stored in a locked filing cabinet in the Co-PI's office (Dr. Tucker), room 7017 on the TWU-Houston Campus. These signed consent forms will be destroyed 3 years after study closure by shredding the hard copies.

*required

Consent Form(s)

Attach the study consent form(s).

Consent for a Second Horizon DXA Scan CLEAN COPY.docx

TWU Novel Lifestyle Intervention Study Informed Consent Document_CLEAN COPY.docx

TWU Novel Lifestyle Intervention Study Informed Consent Document_REDLINE COPY.docx

No

9- Study Instruments

*required

Study Instruments

Will any data collection instruments (e.g., data collection forms, surveys, questionnaires, interviews, focus group discussion, etc.) be used in the study?

✓ Yes

*required

Please attach all data collection instruments here.

NOTE: If you upload a survey link, the IRB will also need a PDF of the survey for IRB records. (This is necessary for the IRB to have on file once you close the survey.)

Blood Pressure and Anthropometry Data Collection Sheet.docx

Demographics and Health History Questionnaire.docx

Mediterranean Eating Pattern for Americans (MEPA) Questionnaire.pdf

Physical Activity Readiness Questionnaire_Non-Identifiable Version.pdf

Pittsburgh Sleep Quality Index (PSQI).pdf

SF 36 Quality of Life Questionnaire.pdf

VO2max Testing Sheet.docx

Exercise Training Data Collection Sheet.docx

Supervised Exercise Training Protocol for Novel Lifestyle Study.docx

MIND Dietary Intervention Education and Adherence Tracking Sheet.pdf

ABPM Patient Diary.pdf

ABPM Protocol.docx

MIND Study_Oscar 2 ABPM Device Patient Care Agreement Form.docx

MIND_ABPM_HowToWear_For Patients.pdf

Initial Testing Visit Screening and Data Collection Form_CLEAN COPY.docx

Initial Testing Visit Screening and Data Collection Form_REDLINE COPY.docx

No

*required

Will these instruments record any information that can identify the subjects?

✓ Yes

*required

Please justify why the instruments need to record identifiable information.

The form "MIND Study_Oscar 2 ABPM Device Patient Care Agreement Form" requests that the participant share their name and contact details (phone number and physical address) with us. The College of Health Sciences and Institute of Women's Health requested that we have participants complete this form as a deterrent for theft - these ambulatory blood pressure monitors cost ~$3,000 each. We will keep this completed form in the same binder as other identifiable information (signed consent form and any copies of medical records) in locked cabinet in Dr. Tucker's office. It will always be separate from non-identifiable participant data.

No

10- Risks & Benefits

*required

Potential Risks and the Steps to Minimize the Risks

*required

List all the potential risks to the human subjects involved in this research. All risks must be identified and listed on the consent form (if applicable).

Please ONLY list the risks here. Descriptions and steps to minimize will be requested below.

Study risks include:

- Risk of an adverse cardiovascular event during exercise testing and exercise training
- Risk of increased muscular soreness and injury during exercise training
- Exposure to very low levels of radiation during body composition testing using the dual energy X-ray absorptiometry (DEXA)
- Discomfort, minor pain, bruising, swelling, anxiety, infection, light-headedness, or fainting during the blood draw
- Risk of sleep disruption due to wearing the ambulatory blood pressure monitor
- Risk of coercion
- Loss of participant time
- Loss of data to a third party
- Loss of participant confidentiality

As such we have outlined the strategies we will utilize to minimize each of these risks in the section below.

*required

Describe how each risk will be minimized.

Make sure all steps listed here match the steps listed in the consent form.

Potential Risks

Potential physical risks to participants in this study will be minimized by using only trained research personnel in testing procedures. If you do not feel comfortable with testing procedures, the test will not be completed at that time.

In the instance that information indicates immediate action is needed, emergency personnel will be contacted. You may ask questions at any time during the study protocol.

The risks of drawing blood from your arm include pain or discomfort, possible bruising and swelling, rarely an infection, and lightheadedness from the procedure. To reduce these risks only a trained phlebotomist will draw your blood. Only ~2 teaspoons of blood will be collected. Your arm will be cleaned with alcohol before the collection. Drinking water the morning of the blood draw is

encouraged to minimize the risk of bruising and improve blood flow. Only non-latex gloves will be used to minimize the risk of latex allergy.

Body composition will be measured using dual energy X-ray absorptiometry (DEXA). Very low levels of radiation are used, as such the researcher will obtain verbal acknowledgement from you stating that you are certain that you are not pregnant, nor planning to get pregnant. You will lie on a padded table for approximately 6 minutes while your body is scanned. A whole-body scan produces less than one-tenth of the radiation dose of a standard chest X-ray and less than one day's exposure to natural radiation. To minimize the risk of radiation exposure, only one DEXA scan will be performed. If a second DEXA scan is needed, you will provide additional consent. No more than two scans will be performed on one day.

You may experience disruptions in sleep while wearing the portal blood pressure monitor. To minimize this risk, we will provide troubleshooting tips to help avoid major sleep disturbances during your initial education session at the end of the baseline testing visit. In addition, you will only be required to wear the blood pressure monitor for 2 days at the beginning, and then again for 2 days at the end of the study.

You may experience increased shortness of breath, muscle tiredness, lightheadedness, and/or dizziness during exercise. There is a very minor risk of a heart attack or cardiac arrest happening during exercise. However, we will take all necessary precautions to further reduce your risk. All exercise testing and training will be supervised by a certified exercise training specialist and all research staff are CPR-certified. Your heart rate and blood pressure will be measured before, during, and after each training session for additional precautions. If we notice an irregular heart rate or blood pressure response during exercise, we will stop the training session immediately.

During exercise training there is a risk of muscle soreness and injury. To minimize this risk, we will start off low and slow. This means we will start at a lower intensity for the cycle exercise, before gradually increasing the intensity as you get used to the exercise and build up your aerobic and muscular endurance.

Loss of time is another risk. The study will take roughly 15 hours to complete. The risk of loss of time will be reduced by having the equipment ready for use, phlebotomist and researcher readily available for data collection, and all forms and study items will be available before you arrive. This time does not include your travel to TWU.

Loss of data to a third party. As part of this study, you will be asked to wear a Fitbit device, and we will use a Fitbit app on your smartphone to collect data. To avoid the potential loss of sensitive personal data (names, personal emails, date of birth, etc.) while using the Fitbit app, we will provide you with deidentified Fitbit and Gmail account information that is unique only to this research study. You will use this information to setup your Fitbit account on the Fitbit app and then a member of research study team will send you a "push notification" to allow us to access your Fitbit data during the study. We will only collect deidentified data on your physical activity levels, sleep patterns, and heart rate. When we download your deidentified study data from your Fitbit it will be stored on a password-protected computer at all times.

You understand that your Fitbit data will be stored securely and will only be used for research purposes as outlined in this consent form. In order to use the provided Fitbit device, you will have to create a deidentified account (using unique information provided by our research team) on the Fitbit website and agree with Fitbit's Privacy Policy and Terms of Service, which are separate from this research consent form. Fitbit's Privacy Policy describes how Fitbit collects, uses, shares, and

protects your data. By agreeing to Fitbit's Privacy Policy and Terms of Service, you give Fitbit the right to use Fitbit information so they can provide, improve, and develop their services. In addition, it is important to read Fitbit's Terms of Service because it includes information about your legal rights when using Fitbit's products that may differ from your rights as a participant in this study. You can always exercise your right to access your personal information and to understand how Fitbit collects, uses, and discloses the information to other third parties by logging into your Fitbit account and using your account settings.

Fitbit's Privacy Policy and Terms of Service can be accessed here:
https://support.google.com/product-documentation/a...

Another risk in this study is loss of confidentiality. Confidentiality will be protected to the extent that is allowed by law. You will receive a code which will be used on all records and samples (blood samples, data collection sheets, portable blood pressure data, Fitbit data). Only a password-protected spreadsheet will link your name with your code. The signed informed consent form, portable blood pressure monitor patient care agreement form, and any medical records with your name and/or contact information (phone number and physical address) will be locked in a cabinet in the researcher's office. Only approved researchers will have access to the informed consent, any medical records, and password-protected spreadsheets.

The results of the study may be reported in scientific journals but your name or any other identifying information will not be included. There is a potential risk of loss of confidentiality in all email, downloading, electronic meetings, and internet transactions.

The researchers will remove all of your personal or identifiable information (e.g., your name, date of birth) from all study information. After all identifiable information is removed, your personal information collected for this study may be used for future research or be given to another researcher for future research without additional informed consent.

If you would like to participate in the current study but not allow your de-identified data to be used for future research, please initial here _____.

*required

Benefits/Remuneration

What will the subject receive for participating in the study?

(i.e., financial remuneration, free services, access to information, and access to an intervention) If there are none, state below that there are no direct benefits to the subject.

Direct Benefits to Subjects

Participants may benefit from this research by learning more about their blood pressure, body composition, aerobic exercise capacity, and/or sleep. Furthermore, by participating in this lifestyle

intervention, adults with hypertension and overweight/obesity who are at-risk for CVD may learn diet and exercise strategies for primary prevention of CVD.

Subject Compensation:

Participant incentive will be $100 in gift cards + $450 cash incentive for full study completion. Each participant will receive a $25 gift card at the beginning of each week to purchase foods that are part of the MIND Diet ($25 each week for 4 weeks = $100 total in gift cards to purchase foods). In addition, we will provide a $10 cash incentive at the completion of each study visit (15 study visits x $10 = $150 cash) and then a $300 lump sum cash incentive upon full study completion. If a subject opts to withdraw from the study prior to study completion, they will only receive cash compensation and food up until the study visit and week they decided to opt out. In addition, each subject receives ~$70 in free food and nutrition supplements, and 4 weeks of free supervised exercise training.
~~Subject incentive will be $250 in gift cards +~~ **$300** ~~in cash and study time commitment is 15 hours. The subject incentive includes a $25 gift card at the beginning of each week to purchase foods that are part of the MIND Diet ($25 each week for 4 weeks = $100 in gift cards to purchase foods). In addition, we will give them a $10 gift card at the end of each study visit as compensation for parking (15 study visits X $10 = $150). Finally if the participant completes all testing visits and finishes the study they will receive~~ **$300** ~~in cash to encourage study completion.~~

What are the generalizable benefits of this study? *(i.e., contribution to knowledge in a particular field)*

Scientific contribution to knowledge of treatment options to improve blood pressure, CVD risk factors, exercise capacity, and sleep in hypertensive adults with overweight/obesity.

*required

Study Results

Will you provide results of the study to the subjects after the completion of the study?

✓ Yes

*required

Explain how *(e.g., mail, email, posting online, etc.)* you will provide the results of the study to the subjects.

We will email the results of the study to subjects who would like to know them. This is an opt-in/opt-out option at the end of the consent form that appears as:

*If you would like to know the results of this study tell us where you want them to be sent:

Email Address: _____

No

11- Protecting the Confidentiality of Subjects

*required

Identifiable Private Information to be Collected

List all documents, consent forms, recordings, electronic data, health records, biospecimens, etc., that contain identifiable private information to be collected in this study.

Identifiable information will include the signed consent forms, any medical records to show diagnosis of hypertension and current medication use, and ambulatory blood pressure monitor patient care agreement forms. All of this identifiable participant information will be stored in a locked filing cabinet in the Co-PI's office (Dr. Tucker), room 7017 on the TWU-Houston Campus. A medical record and current medication use is required for the diagnosis of hypertension. As such, the patient will share a physical copy of their medical record with us (only pertinent to diagnosis of hypertension and medication use) and we store it along with their signed consent form. In addition, the College of Health Sciences has requested that we have each participant fill out and sign an ambulatory blood pressure monitor patient care agreement form that states that the participant will follow instructions on how to use the monitor and return it to us. These monitors cost $3,000 each and this additional measure of requesting name, cell number, and physical address is seen as an additional deterrent to device theft. Completed ambulatory blood pressure monitor patient care agreement forms will be stored in the same folder as other identifiable data (the signed consent forms and medical records).

*required

Storage Location and Protection of Identifiable Private Information

Where will the identifiable private information or data be stored? Describe the security measures you will take to protect the stored data.
(e.g., in a locked file cabinet with limited access, or a password protected computer.)

All identifiable participant information will be stored in a locked filing cabinet in the Co-PI's office (Dr. Tucker), room 7017 on the TWU-Houston Campus. All other collection procedures will utilize a subject ID. The identifiable information (consent forms, medical records, ambulatory blood pressure monitor patient care forms) will be stored in a separate folder and apart from all other non-identifiable data folders. The subject codebook will be on a password-protected computer in the Co-PI's office (Dr. Tucker).

*required

Electronic Transmission of Identifiable Private Information

Will the identifiable private information be transmitted electronically? (This includes, but is not limited to downloading, emailing, transferring from cloud storage to computer/hard drive/flash drive, and/or video conferencing .)

Yes

✓ No

*required

Identifiable Private Information Destruction Timeline

Will the documents containing Identifiable Private Information be destroyed?

✓ Yes

*required

Timeline for the Destruction

Provide a time frame for when the documents containing identifiable private information will be destroyed. (e.g., 5 years after the completion of the study.)

3 years after completion of the study

*required

Method(s) of Destruction

Identify specific ways that the documents containing identifiable private information will be destroyed at the end of this period of time.

The signed consent forms, medical records, and ambulatory blood pressure monitor patient care forms will be removed from locked filing cabinets and shredded. Digital data corresponding to the subject codebook will be erased from all servers.

No