TEXAS WOMAN'S UNIVERSITY (TWU)

CONSENT TO PARTICIPATE IN RESEARCH

Novel Lifestyle Intervention to Improve Blood Pressure and Other Cardiovascular Disease Risk Factors in Adults with Hypertension and Overweight/Obesity

STUDY INVESTIGATORS:

Principal Investigator (PI): Erika Zoellner, MS RDN; EZoellner@twu.edu; 281-731-6809
Co-PI: Wesley Tucker, PhD RDN; WTucker1@twu.edu; 919-744-0532

Summary and Key Information about the Study

You are being asked to participate in a research study conducted by faculty at Texas Woman's University (TWU) in Houston. The purpose of this research is to determine whether a 4-week diet and exercise intervention can improve blood pressure, heart health, and sleep. You have been invited to participate in this study because you are an adult, have high blood pressure (also called hypertension), overweight or obese, and do not currently exercise regularly (sedentary/inactive). As a participant you will be asked to come to TWU-Houston for a total of 15 study visits over the next 5 or 6 weeks.

At the first study visit we will give you a portable blood pressure monitor and wrist-worn physical activity/sleep monitor (Fitbit) to wear for the next 7 days. One week later, you will return to TWU-Houston with these monitors and we will conduct baseline testing, where you will have your blood drawn and we will also measure your blood pressure, body composition (amount of fat, muscle, and bone in your body), blood vessel function, and exercise capacity. In addition, we will have you complete a number of different surveys including dietary assessment, quality of life, and sleep quality. Thereafter you will attend 4 weeks of supervised exercise training at TWU-Houston. You will also be provided with diet education from a Registered Dietitian Nutritionist for a heart-healthy diet called the MIND diet. We will provide financial assistance (in the form of gift cards) to purchase foods that are part of this diet plus give you extra virgin olive oil, mixed nuts, and protein supplements for the duration of the study. After the 4-week intervention, you will return to TWU-Houston for a final testing visit so we can complete the same measures taken before you started the intervention. The total time commitment for this study is 15 hours. We will pay you $100 in gift cards and $450 in cash for completing this research study. The gift cards include $100 to purchase food as part of the study diet. For the cash incentive, you will receive $10 in cash at the completion of each study visit and then a $300 lump sum cash incentive upon full study completion. You will have a code assigned to you to protect your confidentiality. The greatest risks of this study include potential loss of confidentiality, radiation exposure from the body composition test, pain, bruising, and/or infection from the blood draw, sleep disruption from wearing monitors, loss of data to a third party, and small risk of adverse cardiovascular events during exercise. We will discuss these risks and study procedures in detail below.

Your participation in this study is voluntary. If you are interested in learning more about this study, please review this consent form and take your time deciding whether you want to participate. Please ask the researcher any questions you may have about the study.

Description of Procedures

As a participant in this study, you will be asked to come to the TWU-Houston Campus (located in the Texas Medical Center) on 15 separate occasions.

This consists of 1 initial screening visit, 2 testing visits (before and after the intervention) and 12 supervised exercise training sessions over the course of 4 weeks. The procedures and protocols for these visits are discussed in detail in the two sections below.

Initial Screening and Consent Visit

At this initial screening and consent visit (today's visit), we will do additional screening including a health history questionnaire, assessment of height and weight to ensure you meet the inclusion criteria for body mass index (BMI), and measurement of seated resting blood pressure to ensure it is safe for you to participate in exercise. If you pass this screening, we will explain the study in detail, complete informed written consent and enroll you in the study. At the end of this initial screening visit, we will give you a portable blood pressure monitor and wrist-worn physical activity/sleep monitor (Fitbit) to wear for the next 7 days. This initial screening and consent visit will take about 1 hour to complete.

Portable Blood Pressure Monitor: An ambulatory blood pressure monitor is a small, electronic portable monitor that you wear around your waist – like a belt. This little monitor has a small hose that connects to a blood pressure cuff, which is worn on your upper (non-dominant) arm. The monitor is programmed to inflate the blood pressure cuff on your arm and take a blood pressure reading every 30 minutes during the day and night. This type of blood pressure measurement is similar to blood pressure measurements done in a doctor's office. However, it allows us to assess your blood pressure in a more natural setting (home and work) and provides average blood pressure during the day and at night.

Before sending you home with the portable monitor, we will give you very detailed instructions and a demonstration on blood pressure assessment including how to wear the cuff, posture and arm placement during measurements, how to deflate the cuff manually, and troubleshooting. You will also complete and sign a patient care agreement form stating that you will adhere to our instructions and return the blood pressure unit to us. This patient care agreement form includes your name, cell phone number, and current address. When the blood pressure unit is returned to us, we connect it to a password-protected computer and download your blood pressure, heart rate, and time of measurement data – all data is non-identifiable. You must return the blood pressure unit to us upon study completion. This training/demonstration takes ~15 minutes.

Physical Activity/Sleep Monitor (Fitbit): You will be asked to wear a Fitbit Inspire 3 device on your non-dominant wrist, which will continuously collect data on your physical activity levels, sleep patterns, and heart rate. The Fitbit device should be worn every day and night for the duration of the study period. You can remove the device for part of each day as needed and when you feel comfortable doing so.

At your first study visit, you will be provided with a Fitbit Inspire 3 device, and we will have you download the Fitbit app to your smartphone and then 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. All you have do is regularly (once per day) open the Fitbit app on your phone and "sync it" and the data will be available for your viewing and automatically available to our research team as well. You must return the Fitbit Inspire 3 device to us upon study completion. This initial training/demonstration takes ~10 minutes.

One week after your initial screening visit, you will return to TWU-Houston with the portable blood pressure monitor and Fitbit, and we will conduct baseline testing.

Baseline and Post-Intervention Testing Visits

At the baseline testing visit, we will confirm that you have met the minimum wear time and physical activity requirements to continue participation in the study. We require a minimum of 70% of portable blood pressure recordings over a 24-hour period and an average daily step count of < 7,500 steps per day during the initial week of monitoring.

Both testing visits (before and after the intervention) will be fasting visits (no food for ≥ 8 hours prior to the visit). However, water is permitted during this time. We will perform several tests that measure your blood pressure, blood vessel function, height and weight, body composition, and blood biomarkers (in that order). In addition, we will assess your maximal aerobic exercise capacity on a stationary exercise bike. After completion of the maximal exercise test, we will provide you with lunch and ask you to complete several different surveys to assess your current quality of life and sleep quality, and dietary intake (in that order). The name of each of these tests and a quick description of each of these tests is provided below:

Resting Blood Pressure: You will sit and rest in a chair for 5 minutes, and then we will place a cuff on your non-dominant arm and rest this arm comfortably on the table in front of you. The blood pressure cuff will inflate and relax in order to measure your blood pressure. This will be repeated twice. This test takes ~10 minutes.

Blood Vessel Response: You will lie down on a bed, and we will take pictures of the major vessel in your arm using an ultrasound camera, similar to ultrasound tests done to examine babies prior to birth. We will first take a picture of your arm blood vessel at rest. Then we will place a blood pressure cuff on your forearm and inflate it for 5 minutes. After 5 minutes, we will rapidly deflate the blood pressure cuff and take pictures of the same major vessel in your arm for the next 3 minutes. This test allows us to assess the responsiveness of your blood vessels to widen in response to a stimulus (measure of blood vessel function). The test takes ~25 minutes.

Height and Weight: You will stand on a dual-function stadiometer and scale, and we will measure your height and weight. This test takes ~2 minutes.

Body Composition Test: Your body composition (how much fat, muscle, and bone is in your body) will be measured with dual energy X-ray absorptiometry (DEXA). You will be required to wear loose fitting clothing for the scan. If you do not arrive in this attire, scrubs will be provided. You will be asked to remove all metal and jewelry before the scan, as well as any footwear.

You will then be instructed to lie down on a padded table with your arms at your sides, and your feet will be secured with a strap or tape to hold them in place during the scan. You will be instructed to not move and breathe normally during the scan. After the scan, which takes about 6 minutes, you will be instructed to change back into your clothing [if necessary], and put any footwear, metal, or jewelry back on. During this time, analyses will be performed on the image by our research team.

Fasting Blood Draw: For this testing, we will place a small needle in the vein in your arm and collect a fasting blood sample. We will draw approximately 10 ml (2 tsp) of blood to measure glucose, insulin, and biomarkers of inflammation. All blood draws will be performed by a trained phlebotomist. All blood will be kept in containers in a freezer located in the lab until we analyze them. We will label the containers in a way that only we will be able to identify them. This test takes 5 minutes.

Maximal Exercise Test: For this test, you will be wearing a mask attached to a hose that collects the air you breathe out. You will also wear a heart rate monitor that consists of an elastic strap that wraps around your chest to measure your heart rate. These devices will measure your breathing and heart rate. You will sit quietly on the stationary exercise bike for 2 minutes and then you will be asked to pedal at a speed of your choice at a light resistance for 5 minutes for the warm-up phase. After the warm-up phase the resistance will gradually increase and the resistance will get harder until you cannot continue. We will encourage you to push yourself as hard as you feel comfortable in order to obtain an accurate measurement. After a 10-minute rest period you will perform an “all-out” bout of exercise at the same resistance you ended at on the previous test. The whole test will take 45 minutes.

Quality of Life Questionnaire: You will fill out a questionnaire that will ask several questions about your overall health-related quality of life. This takes 10 minutes.

Sleep Quality Questionnaire: You will fill out a questionnaire that will ask several questions about your sleep quality during the last month. This takes 10 minutes.

Dietary Assessments: You will complete two different dietary assessments. The first is a 24-hour dietary recall done using the Automated Self-Administered 24-h Dietary Assessment Tool – a web-based tool that asks you to record everything consumed in the previous 24 hours on an iPad. The second dietary assessment is a 16-question survey completed with pen/paper about your current diet and how it aligns/adheres to the Mediterranean Diet. These assessments will take ~40 minutes to complete.

After the completion of all this testing, we will provide you with further instructions about the exercise and diet intervention (details below). This initial baseline testing visit will take about 2 ½ hours to complete. These measurements will be repeated after the 4-week diet and exercise intervention. The follow-up testing visit will take about 2 ½ hours to complete.

Exercise and Diet Intervention

You will receive 4 weeks of supervised exercise training and a dietary intervention. The exercise training portion of the intervention requires you to attend supervised exercise training at TWU-Houston 3 days per week. Each exercise training session will be 30 minutes long and will consist of a 5-minute warmup (light pedaling), 20 minutes of high-intensity interval training (HIIT) (repeated sprints with periods of light pedaling for recovery), and then a 5-minute cool down (light pedaling). We will start at a lower intensity during the first week so you can gradually get used to the exercise. Over time we will increase the exercise intensity as your body adapts. A certified exercise training specialist will supervise all exercise training sessions. In addition to the exercise training, you will also receive a 4-week dietary intervention. The dietary intervention is aimed at improving blood pressure, heart health, and sleep. The Mediterranean-DASH Intervention for Neurodegenerative Delay (MIND) diet is a hybrid of the Mediterranean and DASH diets that emphasize foods that improve overall heart and brain health.

At the end of the baseline testing visit, you will receive diet education from a Registered Dietitian Nutritionist on what foods to eat as part of the MIND diet. This diet includes plenty of fruits and vegetables – in particular berries and dark green leafy vegetables, whole grains, fatty fish, avocadoes, nuts, and low-fat dairy. In addition, extra virgin olive oil is the primary fat source in this diet and is believed to be the main reason for improved health benefits. Because of the importance of extra virgin olive oil for health benefits, we ask that you consume 2 tablespoons of extra virgin olive oil each day during the study - this can be drunk, added to salads or vegetables, or used during cooking. In addition, we ask that you consume 10 small bags of mixed nuts each week (100 calorie packs) for the duration of the study as a snack. We will provide you with enough extra virgin olive oil (~48 fluid oz) and mixed nuts (40 small bags) to meet these weekly requirements for the duration of study.

To support increased protein needs with exercise training, we ask that you also drink 1 protein shake each day during the study. Protein shakes will be given to you free of charge. Finally, to make it easier for you to eat foods that are a part of the MIND Diet, we will give you a $25 gift card each week to purchase green leafy vegetables, berries, fatty fish, avocadoes, and low-fat dairy. You may have up to 1 alcoholic drink per day (5 oz of wine, 12 oz of beer) during the study. You will meet with the Registered Dietitian Nutritionist at the beginning of the study and then every 2 weeks to assess how closely you are following the MIND diet using a 16-question validated survey. This takes about 15 minutes to complete and allows the dietitian to make adjustments to your diet.

The total time commitment for this study is ~15 hours. We will pay you $100 in gift cards and $450 in cash for completing this research study. The gift cards include $100 to purchase food as part of the study diet. For the cash incentive, you will receive $10 in cash at the completion of each study visit and then a $300 lump sum cash incentive upon full study completion.

In addition, you will receive 4 weeks of free supervised exercise training and foods/supplements.

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 our 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/answer/14816019?hl=en

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 _____.

The researchers will try to prevent any problem that could happen because of this research. You should let the researchers know at once if there is a problem and they will try to help you. However, TWU does not provide medical services or financial assistance for injuries that might happen because you are taking part in this research.

Participation and Benefits

Your involvement in this study is completely voluntary and you may withdraw from the study at any time. We will pay you $100 in gift cards and $450 in cash for completing this research study. The gift cards include $100 to purchase food as part of the study diet. For the cash incentive, you will receive $10 in cash at the completion of each study visit and then a $300 lump sum cash incentive upon full study completion. In addition, you will receive 4 weeks of free supervised exercise training and free foods/supplements as outlined above. If you opt to withdraw from the study prior to study completion, you will only receive cash compensation and gift cards to purchase food up to the week you decide to drop out of study. If you would like to know the results of this study, we will email them to you. * If yes, provide email at the end of the consent form.

Questions Regarding the Study

You will be given a copy of this signed and dated consent form to keep. If you have any questions about the research study, you should ask the researchers; their contact information is at the top of this form. If you have questions about your rights as a participant in this research or the way this study has been conducted, you may contact the TWU Office of Research and Sponsored Programs at 940-898-3378 or via e-mail at irb@twu.edu.

_____ _____

Signature of Participant Date

_____ _____

Signature of Research Team Member Date

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

Email Address: _____