University of Wisconsin-Madison Consent to Participate in Research and Authorization to Use Protected Health Information for Research

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Study Title for Participants: RESIST Study

Formal Study Title: Resistance exercise to treat major depression via cerebrovascular mechanisms: confirming efficacy and informing precision medicine

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Key Information

The information in this section is to help you decide whether or not to be a part of this study. You can find more detailed information later on in this form.

Why are researchers doing this study?

Depression is common and affects a person's ability to function in many ways, including impairing sleep, appetite, energy, concentration, and more. Many people with depression do not get treatment and/or do not respond to current treatments, like medication or therapy. Resistance exercise training (RET), also known as strength training, may be helpful for managing symptoms of depression. Please note, however, that participation in the study is in no way a standard treatment for depression. Little is known about how effective RET is for improving depression or for who it helps the most. Therefore, the purpose of this study is to get a better understanding about how and if RET may be effective for treating Major Depressive Disorder.

We invite you to participate in this study because:

- You are between 18-65 years old
- You suffer depression
- You are EITHER not taking any mental health medications or seeking other mental health treatment (e.g., behavioral, psychological) OR are on a stable mental health medication and/or treatment regimen for the past 8 weeks, and encouraged to maintain that regimen for during the exercise intervention (16-weeks)
- You can safely begin an exercise program, based on a physical activity screening survey or approval from your primary care physician

You have a Smartphone and are willing to install study-related apps (like the MyWellness App used to provide warm up, cool down, and at home exercise instructions).

Due to the potential impact of certain conditions on study outcomes, potential participants will be excluded from participation if they:

- Are currently pregnant, nursing, or planning to become pregnant during the study
- Are currently diagnosed with Substance Use Disorder
- Are diagnosed with lifetime or current Psychosis, Mania, or Bipolar Disorder
- Have Class III+ or greater level of obesity (Body mass index ≥ 40)
- Have high active suicidal ideation
- Currently meet resistance exercise training (RET) recommendations of exercising 2 days per week for the last 8 weeks
- Suffered a recent (within 3 months) severe concussion, in which they lost consciousness
- Currently have cardiovascular disease, uncontrolled hypertension (blood pressure greater than 160/100 mmHg) or uncontrolled diabetes
- Exhibit behavioral disturbance (e.g., aggression, mild-moderate cognitive impairment) or relationships with study team members (i.e., clinical interviewers) that would significantly interfere with study participation, as assessed by clinical research personnel

If you have any questions about the inclusion and exclusion criteria for this study, please ask the study staff now. Research staff will make inclusion/exclusion decisions regarding your participation based on your responses to questions during this Intake Visit. You will be excluded from participation if you are deemed ineligible to participate based on your responses.

What will I need to do in this study?

The research team will ask you to complete an initial Intake Visit (today's visit), a Week 0 Assessment Visit, and then begin 16 weeks of resistance exercise training, exercising twice a week for one hour. There will also be a Week 8 Assessment Visit (midpoint), Week 16 Assessment Visit (post-intervention) and Week 26 and 52 Assessment Visits (follow-up visits). We expect that you will be in this research study for one year. This includes the 16-week intervention period and follow-up assessment visits completed at 6 months and 1 year.

Participation would include 2 resistance exercise sessions per week ('RET Sessions', ~1 hour each) for 16 weeks. During this time, you will complete ten different exercises on resistance exercise machines, such as chest press and leg press. You will be randomized to one of two groups that exercise at different intensities, a "High-Dose" (higher intensity similar to muscle strength-based training goals) or a "Low-Dose" (lower

intensity similar to muscle endurance-based training goals). In both groups, you will have an individualized workout and be guided on how to perform all exercises.

In addition, surrounding the intervention, you would complete 5 Assessment Visits that take ~2-3 hours, and you would complete questionnaires, a blood draw, mental health clinical interview, and brain blood flow measurements. You can find detailed information about the study procedures in the section called '*If I take part in the study, what will I do?'*

The group assignment you get will be chosen by chance; like flipping a coin. The groups will begin at different intensity levels, but both will progress in intensity throughout the intervention. You will have an equal chance of being in either group.

What are some reasons I might – or might not – want to be in this study?

Possible reasons you might want to participate	Possible reasons you might not want to participate
• I will participate in a structured 16-week exercise training program using state-of-the-art equipment with highly trained staff to teach proper form and monitor my exercise • I will receive health education that includes personalized health data including muscle strength, physical activity summaries, and body composition. • I want to help researchers find out if RET could help me and other people with my condition. • I prefer to try RET instead of or in addition to other things I do to improve my mental health. • I am comfortable with the confidentiality measures in place, knowing that my personal information will not be disclosed.	• I want to decide which group I am assigned and don't want to leave it to chance. • I won't be able to dedicate the time to go to all the study visits. • I am not sure if I will be comfortable with the physical demands of the exercise training. • I may have concerns about the time commitment of exercising 2 times a week at the exercise facility for 16 weeks • I prefer to do other types of exercise, like walking, group fitness classes, or sports

Do I have to be in the study?

No, you do not have to be in this study. Taking part in research is voluntary. If you decide not to be in this study, your choice will not affect your healthcare or any services you receive. There will be no penalty to you. You will not lose medical care or any legal rights. You can ask all the questions you want before you decide.

Detailed Information

The following is more detailed information about this study. Please read carefully and notify the research team if you have any questions.

How is research different from health care?

When you take part in a research study, you are helping to answer a research question. Study tests and procedures are not for your health care. As noted previously, your participation in the study is in no way a standard treatment for depression.

Who can I talk to about this study?

If you have questions, concerns, or complaints, or think that participating in the research has hurt you, please talk to the research team. You can reach out to any of the following research personnel whenever necessary.

- Jacob Meyer, PhD - Principal Investigator: jdmeyer3@wisc.edu
- Jeni Lansing, PhD - Research Scientist: jlansing3@wisc.edu
- Taline Jouzi, MS - Research Specialist: jouzi@wisc.edu

Please note, email is generally not a secure way to communicate sensitive or health related information as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately or would prefer not to receive study communication by email, please contact Taline Jouzi, Research Specialist, at (608) 890-0154.

If you have concerns about your rights as a research participant or have complaints about the research study or study team, you can call the confidential research compliance line at 1-833-652-2506. UW Staff, not part of the study team, will work with you to address concerns and assist in resolving any complaints.

If I take part in the study, what will I do?

If you agree to participate, you will complete an initial Intake Visit (today's visit), a Week 0 Assessment Visit, and then begin 16 weeks of resistance exercise training, exercising twice a week for one hour. There will also be a Week 8 Assessment Visit (midpoint), Week 16 Assessment Visit (post-intervention) and Week 26 and 52 Assessment Visits (follow-up visits). See Appendix A for a visual of the study visits, Appendix B for an overview of the measures that occur during the Assessment Visits, and Appendix C for an overview of what you will do in the RET Sessions, each detailed below as well.

Intake Visit (2.5-3 hours)

The Intake Visit will be used to determine if you are eligible to participate or not. During this visit, after reading and signing the informed consent document (this document), we will measure your height, weight, heart rate and blood pressure.. Then, you will complete questionnaires. Following, you will then complete a mental health interview to check if you meet the inclusion criteria described above. The clinical interviewer has undergone extensive training in mental health assessment, who has been trained and is supervised by Dr. Simon Goldberg (licensed psychologist in the state of Wisconsin). Dr. Goldberg will not be present during the interview, but all mental health interviews will be video and audio-recorded for weekly supervision by Dr. Goldberg. After the clinical interview, if you are eligible to participate, you will be given an activity monitor that you will be asked to wear on your thigh for 7 days (24 hours/day) to assess your physical activity levels. We will ask you to keep a log of when you wear the monitor and your sleep time to use when processing the monitor data. After one week, you will return for a Week 0 Assessment Visit.

Week 0 Assessment Visit (2 hours)

Assessment Visits will occur at the Medical Sciences Center. Prior to the Week 0 and all Assessment Visits, we will ask that you follow some lifestyle considerations that may influence blood flow function. These include avoid taking aspirin or non-steroidal anti-inflammatory drugs (NSAIDS) for 48 hours; abstain from alcohol, exercise and dietary supplements for 24 hours prior; are 4 hours fasted; and do not consume caffeine the day of testing. Please DO continue to take your prescribed medications. We will also ask you about the date of your last menstrual cycle, as this is also important to note regarding blood flow function. Finally, we will also ask that you wear loose fitting, comfortable clothing and tennis shoes (or similar) for each study visit to complete body composition analyses, strength assessments and resistance exercises.

To start this visit, a trained phlebotomist will collect approximately 4 teaspoons of blood (i.e., 2 tubes). These samples will be drawn via venipuncture, and are collected to examine how blood biomarkers relate to depression and may change with RET. You will then complete questionnaires, a grip strength assessment, height, weight, and a body composition analysis (described below).

You will then complete blood flow assessments. We will do this while you lie on your back after 10 minutes of quiet rest in a dimly lit room. All the blood flow assessments are non-invasive (e.g., no needles, no blood). We will always measure your blood pressure first using the standard physician’s office arm cuff, followed by simultaneous measurement of your neck blood flow, brain blood flow, blood pressure waveforms, heart rate variability, blood pressure variability, and exhaled carbon dioxide (i.e., these measures will take place at the same time in order to be more efficient). Although these

measures are being conducted at the same time, only the probes at your temples measuring brain blood flow will remain on you for the entire testing period. These test will give us information about how the arteries in your brain regulate blood flow. Each of the assessments are detailed below too. After the blood flow tests are complete, you will be done with your Week 0 Assessment Visit, and you will begin Resistance Exercise Training sessions within one week.

Resistance Exercise Training (RET Sessions; ~1 hour each)

During the intervention period, you will complete RET sessions two times per week for 16 weeks. All exercises will be performed using state-of-the-art resistance exercise machines, and all RET sessions will be fully supervised by a research staff member, available for questions and help at any time. All RET sessions will occur in the Bakke Recreation & Wellness Center.

The first two weeks of training will be spent one-on-one with a RET Session Lead who will teach you about the exercise machines, proper exercise form, and lead you in strength testing on each machine, which will be used to develop your personalized exercise plan. We will also provide you with resistance exercise bands and teach you how to complete a workout at home if needed, such as for holidays or when traveling. You will also have the opportunity to get additional assessments related to fitness, like body composition and balance, if you'd like.

All RET sessions will take ~1 hour. You will begin each session with a 5-minute warmup. The warmup will include an aerobic activity (like walking on a treadmill or cycling on a stationary bike) and stretching. During the rest of the session, you will complete a full body workout. Specifically, you will perform 3 sets of 8-12 repetitions on 9 different exercise machines, including leg press, leg curl, leg extension, chest press, low row, vertical traction (or lat pulldown), shoulder press, arm curl, arm extension, and one body weight abdominal exercise (e.g., crunches). The workload of your RET sessions will be tailored based on your group assignment and your personal strength tests. Again, you will be randomized to one of two groups that exercise at different intensities, a "High-Dose" (higher intensity similar to muscle strength-based training goals) or a "Low-Dose" (lower intensity similar to muscle endurance-based training goals). Each group will begin at different intensity levels, but both will use the same machines and progress in intensity throughout the intervention. Like the warmup, you will end each workout with a 5-minute cooldown. Additionally, once a week, you will be asked to take a few surveys.

Week 8, 16, 26, and 52 Assessment Visits (~2.5 hours each)

You will return to the Medical Sciences Center for Assessment Visits at the end of week 8, 16, 26 (~6 months), and 52 (~1 year) weeks that will last about 2 hours. You will be asked to re-wear the activity monitor for one week after each Assessment Visit.

Assessment Visits will be identical to what was completed during the Intake Visit and Week 0 Assessment Visit. Each will include a blood draw, mental health interview, questionnaires, grip strength, height, weight, and a body composition analysis, followed by blood flow tests.

As a part of each Assessment Visit (either in a separate session or combined with the above assessments), you will also complete strength testing in the Bakke Recreation & Wellness Center (~30 minutes). During this time, you will again have the opportunity for assessments related to fitness, if you choose.

If I take part in the study, what are the tests that will be done?

Questionnaires:
You will be asked to complete several questionnaires about your health (including sensitive medical history information), physical activity, how you are feeling and other psychological factors. Most questionnaires will be completed electronically, and all questionnaires will only be associated with a unique study ID number. You will be able to skip any questions that you do not feel comfortable responding to.

Body composition assessment:
We will estimate your body composition using bioelectrical impedance, which estimates the composition of various tissues in the body (muscle vs fat) by determining the tissue's resistance to an electrical current. For this assessment, you will be asked to remove your shoes, socks, accessories, and all metal (e.g., watches, jewelry). You will also be asked if you have any implanted devices, such as a pacemaker. If you do, you will not complete this analysis and instead continue with the rest of the study visit. Otherwise, to complete the analysis, you will stand on a platform barefoot (i.e., no socks/shoes) and hold onto the device's handles for ~60 seconds while a safe, painless electrical current flows through your body. We will also measure your height and resting heart rate and blood pressure using a standard stadiometer and automated blood pressure monitor.

Mental Health Interview
You will meet with a clinical interviewer (trained and supervised by Dr. Simon Goldberg, a licensed psychologist in the state of Wisconsin) to complete a mental health interview. A mental health interview is a face-to-face conversation between a mental health professional and a person in which the professional ask questions and gathers information about a person's behavior, attitudes, current situation, personality, and life history. This interview will be used to determine if you meet eligibility criteria (e.g., currently have Major Depressive Disorder) and to assess mental health symptoms throughout the study. As part of this assessment, we will collect video/audio recordings of you during the interview for training and supervision purposes. The recordings will not be used for purposes outside of the study or in any papers or publications.

Blood flow tests:
All blood flow tests will occur at the end of the Assessment Visit (i.e., after questionnaires and the mental health interview), and will include the following:

<u>Heart rate, blood pressure, oxygen saturation and breathing frequency monitoring</u>. Your heart rate will be measured using an electrocardiogram (ECG) machine and small adhesive patches which will be placed on your chest and abdominal areas. The patches will send signals to a computer, which will monitor your heartbeat. Blood pressure will be monitored by a cuff wrapped around your finger and around your upper arm. This device is only used for research purposes. Your oxygen saturation will be measured with a clip

on your finger. Your breathing frequency will be measured by a nasal cannula that will rest in your nostrils.

Blood vessel stiffness measurements. Arterial tonometry will be used to study the stiffness of your blood vessels. A small, pen-like device that measures and records blood vessel pressure will be placed on the skin over arteries in your wrist, arm, neck and upper thigh.

Trans-cranial Doppler ultrasound. Trans-cranial Doppler is a noninvasive imaging method used to view blood vessels and measure how fast blood is flowing through them. We will apply some gel to the probe and then place the probe over your temple on the side of your head, near your ear. The Doppler probe will be secured with a headband to hold it in place throughout the visit.

Ultrasound. The blood vessels in your neck will be imaged using an ultrasound machine. The investigator handling the ultrasound will put some gel on the probe before applying the probe to your neck to measure blood flow in the vessels. We will perform ultrasound imaging of the blood vessels in your neck while you are lying at rest.

Carbon dioxide (CO_2) breathing test. You will be lying on a bed, in a comfortable position. When completing the carbon dioxide breathing using the pre-mixed compressed gas tanks, normal air, oxygen, and carbon dioxide will be delivered through the mask. First, you will breathe normal air quietly at rest for up to 5 minutes. You will then be switched to different ratios of oxygen/carbon dioxide and asked to make a full inhale followed by relaxed normal breathing. Each level will be 21% oxygen and either 4% or 6% CO_2. You will breathe each level for up to 5 minutes each. You will be asked to breathe in a consistent, relaxed manner. These trials may be repeated for reproducibility or if they end early for any reason except your discomfort.

Strength assessments:
Grip Strength: Grip strength will be collected for a simple, quick, overall estimate of strength, assessed using a hand dynamometer. For this assessment, you will squeeze the device as hard as possible. There will be three separate trials completed on each hand.

Estimated One-Repetition Maximum Strength (1-RM): During the first two weeks of training and as part of Assessment Visits, we will do strength testing on all machines to program your workout and assess strength changes. For these tests, on each resistance exercise machine, you will push or pull as hard as you can 3 times with proper form. The exercise machines will use how hard you push or pull to estimate the maximum amount of weight you could move exactly one time (or what is called a 1-repitiation max).

Fitness Assessment: Fitness assessments are optional and available for you to track indicators related to fitness across the exercise intervention. This assessment will

involve 3 different tests. The first is a body composition test, like what is described above. For this test, you will stand still on metal plates while holding onto two bars for a total of 5 minutes. The second test assesses mobility, and you will complete a series of different motions, like moving your neck side to side, moving your shoulders in circles, and reaching toward your toes. The third test assesses balance, and you will stand on one leg for 20 seconds. During each test, the machine (called the Checkup) will scan your body and provide information on how well you did on each test. Your reports will be available to you in your MyWellness App.

What protected health information is used in this study?

Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth or medical record number. To do this study, we will use the following kinds of PHI: contact information for scheduling purposes (e.g., name, email, phone), results of tests or procedures done as part of the study, and things you tell the researchers about your health.

What happens if I say yes, but I change my mind later?

You can leave the research study at any time. If you choose to leave the study, your choice will not affect your healthcare or any services you receive. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights. If you decide to leave the research study, please contact the investigator so that the investigator can remove you from the study.

If you stop being in the research, already collected data may not be removed from the study database. You may be asked whether the investigator can collect data from your routine medical care. If you agree this data will be handled the same as research data.

Your authorization for researchers to use your protected health information (PHI) does not have an end date. However, information that could identify you (like your name) will be destroyed at study closure. However:

- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.
- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.
- If you take back your authorization, you will not be able to take part in the research study.
- To take back your authorization, please contact Taline Jouzi, Research Specialist, at (608) 890-0154. The research team will need to acquire a written note (email or by mail) that you take back your authorization, and the Research Specialist will work with you to do so.

Will being in this study help me in any way?

As part of the study, you will receive personal health information and education about that information. This will include personalized health data, including physical activity summaries (e.g., average number of times you step per day, how much you sit per day), body composition results (e.g., amount of muscle mass you have), and muscle strength information.

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Participation in this study may result in physical and mental health benefits.

We hope that the study will benefit you and society by helping us learn more about how we can use behavioral treatments, like exercise, for improving symptoms of depression and other mental health conditions.

What are the study risks?

There are some risks and/or discomforts you may experience during participation in this research study. Each risk is detailed below, along with a description of how the research team will attempt to minimize their occurrence.

Risk Type	Description	Mitigation Strategies
Physical Risks of Exercise	Discomfort during or after exercise or strength assessments, such as delayed onset muscle soreness, musculoskeletal injury, shortness of breath, dizziness, fatigue, or in extremely rare cases, a heart rhythm abnormality or heart attack	Proper exercise instruction, individualized exercise prescription, close supervision during exercise, warm-up/cool-down provided, and staff first aid, CPR, & AED trained. For at home exercise sessions (if needed), we will provide thorough in-person instructions and videos for you to reference when completing them independently.
Bood draws	Fainting or dizziness, bruising, bleeding, infection, nerve or vein damage	Trained phlebotomists, sterile equipment, presence of two research staff members
Body Composition Assessment	Electrical current used to conduct assessment could interfere with and cause the malfunction of electrical medical implant, and it should not be used on subject with pacemakers or other medical implants.	Trained assessment administrators; explicit questions about if you have a pace maker or implanted device; not completing this assessment if contraindicated
Fitness Assessment	For the body composition test, electrical currents could interfere with and cause malfunction of electrical implants. For the balance test,	Fitness assessments are always optional; explicit questions will be asked about a pace maker or implanted device; trained research

	there are risks of falling or injury to the knee while trying to balance on once leg.	staff will be beside you during each assessment
Discomfort wearing activity monitor	You may experience skin discomfort or irritation from the tape used to adhere the activity monitor to your leg.	Instructions for switching legs if irritation is encountered, shaving your leg where the tape adheres, changing the tape less frequently
Psychological Risks	Psychological or emotional stress from discussing mental health in interview or answering questions in surveys	Supervised clinical interviews with substantial training, safety plan creation, mental health resources always available
Social Risks	Stigmatization, harm to reputation, or embarrassment if disclosed to others	Strategic study name, individual assessments, assessments in closed rooms, advertised as hosting another study
Discomfort from brain blood flow assessments	When you are breathing the increased levels of CO2, you may notice a slight increase in heart rate and breathing frequency (like what you might experience after walking up a flight of stairs); flushed skin or minor disorientation; possible headache	All gases administered during the study will closely be monitored throughout each assessment.
Mobile Charges	Taking part in this research study may lead to added costs to you, such as mobile charges for phone calls or texts made with the study team.	We attempt to minimize this risk by notifying you now that you are responsible for all mobile charges related to communications made with the study team.

Digit Health Technology is required for study participation and may relate to risks described above. Specifically, you'll need 1) a Smartphone for communication with the study team and to install an app, and 2) wear an activPAL activity tracker to measure your sitting and activity patterns.

The Technogym MyWellness App will be used to provide instructions for your exercise warm-up, exercise workouts (in person and at home), exercise cool-down, and to receive reports related to fitness assessments. We will help you install and set up the app during your first week of exercise sessions. You may receive weekly automated messages within the app, but all information used to install the app will not be linked to you. The app used in this study is similar to other freely available fitness apps you may already use, and your welcome to continuing using other fitness apps while in the study. Information on this app will be shared with the research team in a cloud. This helps the research team track information about the exercises you complete during the

intervention, like weight, number of sets, and number of reps completed. The research team will store the data until the study is completed and then it will be destroyed, but you are welcome to delete the app anytime after the 16-week intervention period. Steps the research team has completed to promote confidentiality are: having the University of Wisconsin-Madison's Office of Cyber Security complete a formal Risk Assessment, only allowing access to senior research personnel using secure passwords, accessing data on secure devices. To promote your privacy, we also encourage you to use secure passwords and locked devices.

In addition, we will ask you to wear an activPAL accelerometer. This is a research grade fitness tracker. Again, we will set up the device and provide clear instructions with how you will use it. This device measures your leg position, if you're moving, and how quickly you are moving. After you wear the monitor for one week, the research team will download the data from the device to get data regarding your sitting time, walking time, and exercise time (like average steps per day). This data will be erased from the device and stored on a HIPPA-compliant restricted research drive, only accessible to senior research personnel.

Who has access to the information collected for the research?

We have strict rules to protect your personal information and protected health information (PHI). We will limit the use and disclosure of your personal information, including research study and medical records, as described in this consent form.

However, we cannot promise complete confidentiality. We will share information with individuals or organizations identified in this consent form. Federal or state laws may also permit or require us to show information to university or government officials responsible for carrying out or monitoring this study. This includes University of Wisconsin and its representatives and affiliates, including those responsible for ensuring compliance, such as the Human Research Protection Program, the Food and Drug Administration (FDA), and the Department of Health and Human Services.

The study is protected by a Certificate of Confidentiality from the National Institutes of Health. This means we will not share any information that would identify you as a participant in the study, even if the police or courts ask to look at the data we have collected.

We may have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts).

Authorizing the research team to use your PHI means that we can release it to the people or groups listed in this form for the purposes described in this form. Once we share your identifiable health information outside UW-Madison, the HIPAA Privacy Rule may no longer protect it. However, we try to make sure that everyone who sees your health information keeps it confidential.

We will share information collected for this study with researchers or organizations outside UW-Madison, including the University of Minnesota and Iowa State University.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This Web site will not include information that can identify you. At most, the Web site will include a summary of the study results. You can search this Web site at any time.

Will information from this study go in my medical record?

None of the information we collect for this study will go on your medical record. The researchers are not required to release health information to you if it is not part of your medical record.

Will my information and samples be used in other research or shared with others?

With appropriate confidentiality protection, we might use information and samples that we collect during this study for other research or share it with other researchers without additional consent from you.

Because health information from this research study can be useful for many different kinds of research, organizations like the National Institutes of Health (NIH) have created large databases that collect health information from research studies. We will put health information from this study in a federal database or in other public scientific resources to make the information broadly available. We cannot predict how this information will be used in the future. Because it can be used for many kinds of research, your health information may be used for research that you disagree with or would not choose to be involved in.

We will share the data from this study in a database that collects information from research studies and is publicly available on a website. Anyone can use the data for any purpose in the future. This is called “open access.” We will remove any personal information that could directly identify you (like name, birthdate, address, phone number), and replace it with a code number. We will share this code number, dates information was collected, your age, your sex, and your responses to questionnaires in the study. In using the coded number, we believe there is a low risk that study data could be used to re-identify you. However, it’s possible that data that cannot be used to identify you today could be used to identify you in the future. It is also possible that you will participate in more than one study that sends data to the database. The database and other researchers can connect your data from different studies by matching the code number on your data from each study.

Will I receive the results of research tests?

Most tests done as part of a research study are only for research and have no clear meaning for health care. In this study, you will not be informed of any test results or

unexpected findings. However, we will provide you with activity, strength, and body composition reports.

The questionnaires you will complete in this study may show that you are experiencing symptoms of emotional distress such as depression, suicidal thoughts, and/or anxiety. If the questionnaires show that you are experiencing symptoms of depression, anxiety, or suicidal thought, please utilize the mental health resources provided by the research team.

Can I be removed from the research without my agreement?

The person in charge of the research study can remove you from the research study without your approval. Possible reasons for removal include:

- You do not follow the study rules or no longer meet the requirements to be in the study
- The research team determines you need a higher level of professional mental health treatment (e.g., severe suicidality or imminent threat to others or yourself)
- The study is stopped by the researchers

What else do I need to know?

What happens if I am injured because of this study?

If you are injured because of this study, medical care is available to you through UW Health, your local provider, or emergency services, as it is to all sick or injured people.

- If it is an emergency, call 911 right away or go to the emergency room.
- For non-emergency medical problems, please contact the study team to report your sickness or injury by phone at 608-890-0154 to document the event, and follow up with your regular healthcare provider.

Here are some things you need to know if you get sick or are injured because of this research:

- If sickness or injury requires medical care, the costs for the care will be billed to you or your insurance, just like any other medical costs.
- Your health insurance company may or may not pay for this care.
- No other compensation (such as lost wages or damages) is usually available.
- UW-Madison and UW Health do not have a program to pay you if you get sick or are injured because of this study.
- By signing this consent form and taking part in this study, you are not giving up any legal rights you may have. You keep your legal rights to seek payment for care required because of a sickness or injury resulting from this study.
- In emergency situations, your personal information (like your name, contact information) may be shared with emergency services (like EMS), building safety officers, or others if needed to provide help or document the event.

Will I receive anything for participating?

If you agree to take part in this research study, we will pay you for your time and effort after each Assessment Visit you attend, up to $250 provided in compensation (i.e., $50 for Week 0 and Week 8 Assessment Visits, $100 for Week 16 Assessment Visit, $25 for Week 26 and 52 Assessment Visits).). Additionally, you can decide if you would like to be reimbursed or not for travel to study visits. If you choose to be reimbursed for travel, you may receive reimbursement for every mile beyond 5 miles and up to 15 miles for trips to and from the RET Sessions you attend at the Bakke Recreation Center. Please note, your information will be shared with a third party platform specifically for payment reasons.

In addition, you will receive incentives throughout the intervention for reaching intervention milestones (e.g., completing strength testing, attending 8 RET sessions). These may include: a study tee-shirt, water bottle, hat, bag, workout towel, lanyard, and/or pin. Everyone will also receive their own set of resistance exercise bands to use during the intervention for at-home workouts when necessary and to keep after the intervention period ends.

Permission to communicate about the study by email, telephone, and text messaging

We are requesting your phone number and email address so we can send you reminders of your study visits, communicate about schedule changes, and provide you links to surveys or at-home workouts when necessary. These are generally not secure ways to communicate about your health as there are many ways for unauthorized users to access them. You should avoid sending sensitive, detailed personal information by email or text message. Email and text messages should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact Taline Jouzi, Research Specialist, +1(608)-890-0154. You will need to provide either your phone or email address to participate in this study.

How many people will be in this study?

We expect about 200 people will be in this research study.

Who is funding/supporting this study?

This research is being funded by the National Institute of Mental Health (NIMH), a sub-agency of the National Institutes of Health (NIH).

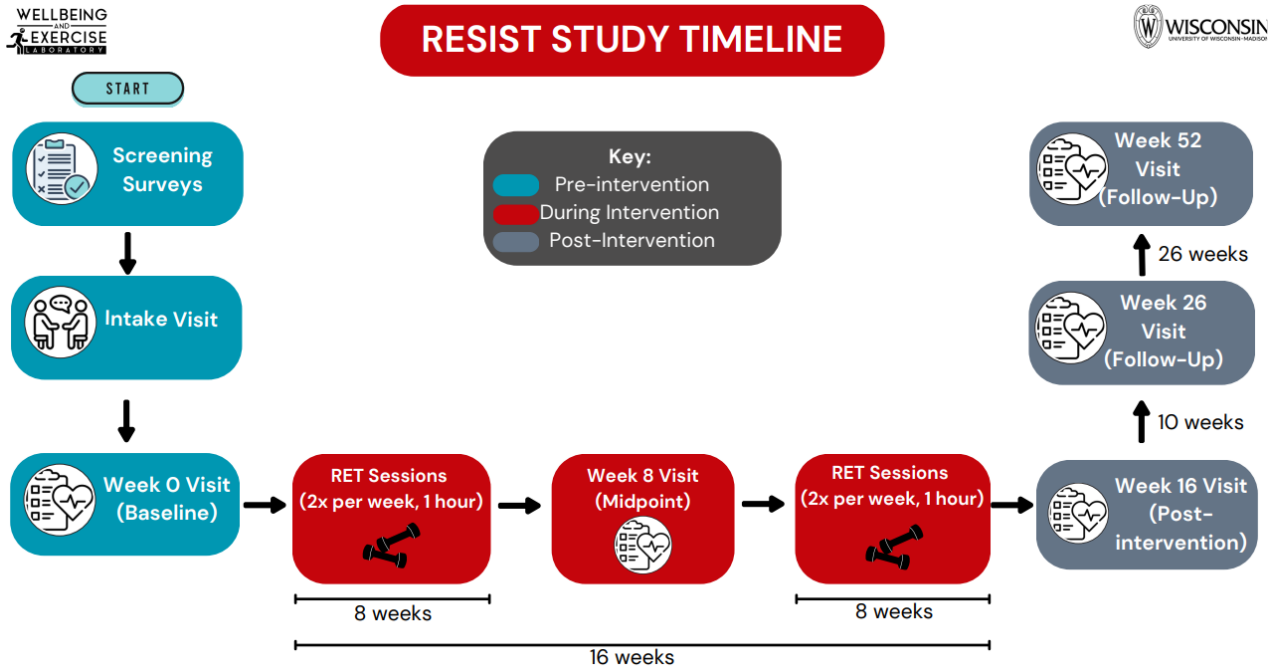
Agreement to participate in the research study

You do not have to sign this form. If you refuse to sign, however, you cannot take part in this research study. If you sign the line below, it means that:

- You have read this consent and authorization form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You want to be in this study.
- You give authorization for your protected health information to be used and shared as described in this form.

Signature of participant	Date
Printed name of participant	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

Appendix A - Visual of the Study Visits



Appendix B - Overview of Assessment Visits