The University of New Mexico Health Sciences Center

Consent and Authorization to Participate in a Research Study

Key Information for "The effect of perceived effort in resistance training on glycemic control and psychological responses in individuals living with type 2 diabetes mellitus: a Randomized-controlled, parallel-group, Clinical Trial" (version #05/22/2024)

You are invited to participate in a study about the effects of resistance exercise training with different degrees of effort on your glucose responses (what we call glycemic control) and on how you feel (what we call psychological responses).

WHAT IS THE PURPOSE, PROCEDURE, AND DURATION OF THE STUDY?

We hope to learn if when you do resistance exercise you need to push yourself hard to have benefits, or if you can do the exercise with less effort and still benefit. Your participation in this research will last about 18-24 weeks.

WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

If you agree to participate in this study, you will exercise under the supervision of health fitness professionals, using state-of-the-art equipment. You will also be given a copy of your glycemic and body composition results and these results will be explained to you. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE THE KEY REASONS YOU MIGHT NOT CHOOSE TO VOLUNTEER FOR THIS STUDY?

By participating, you might experience pain/discomfort/soreness and difficulty moving the exercised limbs, especially for exercises you are not used to do. You might also get injured performing the resistance exercises. There is also the risk of cardiovascular complications during exercise. Finally, there is a risk of discomfort and infection while using the continuous glucose monitoring device.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to participate, it should be because you want to. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

As an employee, if you decide not to take part in this study, your choice will not affect your employment status.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person responsible for this study is Roberto Ivan Mota Alvidrez of the University of New Mexico Health Sciences Center, Department of Pharmaceutical Sciences. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, his contact information is RMotaAlvidrez@salud.unm.edu, 505-415-8005.

If you have questions about your rights as a volunteer in this research, contact staff in the University of New Mexico Health Sciences (UNMHSC) Human Research Review Committee (HRRC) between the business hours of 8 AM and 5 PM, Mountain Standard Time (MST), Monday-Friday at 505-272-1129.

DETAILED CONSENT

Version 05/22/2024

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

- You do not qualify for this study if:
- You are under 18 or over 75 years old,
- You are unable to walk,
- You have a significant cognitive impairment,
- You have lower extremity amputation,
- You have renal failure,
- You have liver disease,
- You have uncontrolled hypertension,
- You have unstable cardiovascular disease,
- You have history of severe cardiovascular problems,
- You have decompensated heart failure,
- You have uncontrolled arrhythmias,
- You have severe pulmonary hypertension,
- You have severe and symptomatic aortic stenosis,
- You have acute myocarditis, endocarditis, or pericarditis,
- You have aortic dissection,
- You have Marfan syndrome,
- You have unrepaired aortic aneurysm,
- You have proliferative diabetic retinopathy,
- You have rapidly progressive terminal illness,
- You are unable to perform resistance exercise to due preexisting musculoskeletal conditions (e.g., joint pain, chronic injury or tendinopathy),
- You use metformin for less than 3 months,
- You have taken drugs known to increase the risk of tendon disorders (e.g., tendinopathy and tendon rupture), within the last 6 months. These drugs include, but maybe not limited to: fluoroquinolones, glucocorticoids, aromatase inhibitors, anabolic steroids, antiretrovirals, isotretinoin, cephalexin, rituximab, sitagliptin, cephalosporins, azithromycin, and sulfonamides,
- You are pregnant or trying to become pregnant during the study,
- You are a prisoner,
- You are a person who requires a legally authorized representative.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The research procedures will be conducted at the University of New Mexico in the Exercise Physiology Laboratory located in the Johnson Center (Room B143). You will need to come to this location twice a week over the next 18 to 24 weeks.

WHAT WILL YOU BE ASKED TO DO?

If you agree to participate in this study, you will go through the following situations:

1. (1) informed consent, (2) medical and exercise history, (3) medical evaluation and clearance, (4) pregnancy test (for women that can be pregnant only), (5) anthropometric characterization (estimated

duration ~60 min): In this visit, you will choose to sign this informed consent form after a study member explains all procedures, risks, and benefits. Then you will answer a medical and exercise questionnaire, and a medical doctor will evaluate you. If you are a woman who can get pregnant you will be asked to take a free pregnancy test (urine). If the test is positive, we suggest you schedule an appointment with your healthcare provider. After that, we will measure your body weight, height, waist circumference, and body composition.

2. Familiarization period (can last from 2 to 8 weeks, 2 visits per week, ~45 min each). You will start being familiarized with the study by doing resistance exercises and answering the psychological questionnaires. A research team member will show you how to perform the seven resistance exercises (hex bar squat (or the belt squat), seated chest press, leg press, lat pulldown, leg extension, shoulder press, leg curl), to guarantee you are performing them in the correct, safe form. During the familiarization period, the weight you lift will be slowly increased, following your own pace. After the exercises, you will answer some scales so we know how you felt about the session. You can skip any question that makes you uncomfortable at any time.

3. Strength tests (estimated duration ~60 min): In this visit, you will have your strength tested in all seven exercises. After a warm-up, the weight in each of the exercises will be adjusted so you can perform up to 10 repetitions. Rest time between exercises will be 120 sec (2 minutes). Based on that, we can know what weight to use in the exercise sessions below.

4. Measurement of glucose and physical activity (estimated duration ~30 min). In this visit, you will come to the lab only to be instrumented with the glucose monitoring device (to measure your blood sugar levels), and an accelerometer (which is a sensor that measures your movement). You will also receive the meals you are to ingest. You must let the researchers know if you have any food allergies or sensitivities before this visit. Inserting a glucose monitoring device sensor isn't painful, but there is a small needle in the sensor and the feeling is described as a slight pinching sensation as the sensor slides under the skin, after which the sensor is comfortable and easy to wear. A small area (~6 cm^2, ~1 $in.^2$) of the back of your upper arm skin will be shaved, and cleaned with alcohol, before applying the sensor. To measure your physical activity levels, you will wear an accelerometer on your wrist. It is a tiny, waterproof unit that weighs very little (11 grams, ½ ounce) and looks like a watch. There is no inconvenience in wearing it. Because what and how much you ingest can interfere with your glucose results, we will provide a total of 12 meals for you to ingest during each experimental condition.

5. Resistance training (estimated duration ~50 min each): Over the next 16 weeks, 2 days per week, you will visit the lab 32 times to do the resistance training. We will flip a coin to see which of the 2 groups you are assigned to: the high-effort group, or the low-effort group. If you are assigned to the high-effort group, you will exercise every day pushing yourself hard, within your limits. If you are assigned to the low-effort group, you will do the same protocol, but exercising will feel easier.

6. After you finish the resistance training protocol, you will repeat the measurement of glucose and physical activity, as described above.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

(1) Pain/discomfort/soreness and difficulty moving the exercised limbs (common). The risk of experiencing pain/discomfort/soreness and limited range of motion (difficulty moving the exercised body part) from resistance exercise exists, especially for exercises you are not used to, and more likely during the initial phase (first 2-3 weeks) of the study. These risks will be minimized by having you perform

many familiarization sessions, during which the weight you lift will be carefully increased, based on how much you can handle, and by allowing a few days between sessions to allow your recovery.

(2) Injury performing resistance exercise (occasional). There is a risk of injury performing resistance exercise, but to minimize this risk, you will be thoroughly instructed on lifting form, and you will perform several familiarization sessions during which the weight you lift will be carefully increased, based on how much you can handle, constant feedback on lifting technique will be provided, and all sessions will be supervised by a study member.

(3) Tendon injury and rupture (occasional). People living with diabetes have a higher chance of having tendon abnormalities that can, in worse cases, lead to tendon rupture, and this could be aggravated by exercise. Also, some medications can increase this risk. To minimize the risk of tendon injury or rupture, a medical doctor member of the research team will evaluate you before you begin participation and if any abnormalities are detected, will you be excluded from the study. Also, you will be asked about the medications you took in the last 6 months so the doctor can evaluate if any of them are associated with increased tendon issues, and if they are, will you be excluded from the study. Finally, to minimize the risk of developing tendon issues during participation, a thorough familiarization period will be conducted (as described above) to allow proper tendon adaptation.

(4) Cardiovascular risk (chest pain, heart attack, etc.) performing resistance exercise (rare). Resistance exercise is safe for the cardiovascular system, and adverse cardiovascular events have not been documented. However, to minimize the risk of a cardiovascular event, you will be evaluated by a medical doctor and will be instructed on lifting techniques to avoid any issues. In the highly unlikely case that a cardiovascular event does happen, the study members are certified in cardiorespiratory resuscitation (CPR) and the Exercise Physiology Laboratory is equipped with emergency medical equipment.

(5) Risk wearing the Continuous Glucose Monitor (CGM) device (rare). Wearing the CGM device is safe. The risk of infection will be minimized by thoroughly cleaning the application area before applying the device to your skin. In case of any discomfort related to the CGM device, please contact Dr. Roberto Mota Alvidrez or Dr. Gabriel Palley immediately.

(6) Risk of low blood sugar (rare). The risk of low blood sugar levels during exercise exists. To minimize this risk, we will ask you to carry a small snack (candy bar, fruit juice, white bread, etc.) to treat low blood sugar levels, in case it occurs. Also, the study team will be watching for signs of low blood sugar levels (paleness, shakiness, headache, excessive sweating, uncommon fatigue, irritability, etc), and we will ask you constantly to tell us how you are feeling.

(7) Risk of being assigned to a group that does not improve as much as the other. Because in this study you will be assigned to one group or the other by chance (flipping a coin), there is a chance that the group to which you are assigned does not improve as much as the other.

There is always a chance that any medical treatment can harm you. The research treatments/procedures in this study are no different. In addition to the risks described in this consent, you may experience a previously unknown risk or side effect.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

We do not know if you will get any benefit from participating in this study. But, you will exercise under the supervision of a certified fitness professional, who is a member of the study team, using state-of-the-art equipment. Also, you will be given a copy of your glycemic and body composition results and these

results will be explained to you. If you participate in this study, the information learned may help others with your condition.

WHAT WILL IT COST YOU TO PARTICIPATE?

There are no costs to you. Costs will be paid by Dr. Roberto Ivan Mota Alvidrez. There might be some possible very minimal cost of getting to the study site but we will provide free parking or pay for parking fees.

You and/or your insurance company, Medicare or Medicaid, will be responsible for the costs of all care and treatment that you would normally receive for any conditions you may have. These are costs that are considered medically necessary and will be part of the care you receive even if you do not participate in this study.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

When we share the results of the study, we will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave information, or what the information is. All computer and paper records will be stored in locked cabinets and password-protected storage devices. Please be aware, that while we make every effort to safeguard your data, we can never guarantee the confidentiality of the data while still en route to the server.

You should know there are some circumstances in which we may have to show your information to other people because of any regulatory agency's requests. For example, the law may require us to share your information with the following agencies for the following reasons:

- The law requires us to share your information with authorities if you report information about a child being abused
- If you pose a danger to yourself or someone else.
- A court or agency, if you have a reportable disease or condition.
- Authorities, if you report information about a child being abused, if you pose a danger to yourself or someone else.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently from anyone else if you decide to leave the study. If you choose to leave the study early, and request that your data is not used, your request will be honored, and your data will be destroyed. The investigators conducting the study may need to remove you from the study. This may occur for several reasons. You may be removed from the study if you are not able to follow the directions, and they find that your participation in the study is more risky than beneficial to you.

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You can participate in this study if you are involved in another research study. It is important to let the investigator and your doctor know if you are in another study. You should discuss this with the investigator and your doctor before you agree to participate in another research study while you are in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call Dr. Gabriel Palley at 505-440-2026, or Dr. Mota Alvidrez at 505-415-8005, immediately. The medical team, led by Dr. Palley, will determine what type of treatment, if any, is best for you at that time.

- If it is an emergency, you should call 911 immediately.

You need to understand that the University of New Mexico does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while in this study. Also, the University of New Mexico will not pay for any wages you may lose if you are harmed by this study.

WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?

You can receive up to $250.00 (merchandise cards) [$100 for completing the familiarization period and strength tests, $100.00 for completing the training period, and $50.00 for completing all visits]. If you decide not to participate in the study after starting, or if we have to remove you from the study, you will be compensated relative to the number of visits you had.

If you earn $600 or more by participating in research at UNM, it is potentially reportable for tax purposes.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

A member of the study team will tell you if they learn new information that could change your mind about staying in the study. They will ask you to sign a new informed consent form if this new information is provided to you after you have joined the study.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESEARCH TESTS?

Generally, tests/surveys done for research purposes are not meant to provide health information/diagnoses and cannot be used to make decisions about medical care. Because the investigators will not have access to information that identifies you, the research findings will not be provided to you.

There is a slight possibility that during a research project, an investigator could discover something that could affect the health of you or your family. If this occurs, the finding will be reviewed by Dr. Roberto Ivan Mota Alvidrez.

You can be given feedback about the results of your tests/surveys done for this research.
Do you permit Dr. Roberto Ivan Mota Alvidrez to contact you with information about research results or incidental findings that are determined to be important to you/your family's health? Incidental findings are unforeseen findings discovered during the research that may affect your or your family's health.

☐Yes ☐No Initials _____

A description of this study will be available on ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

You may also remove your consent to be contacted with information about research results or incidental findings by sending a written request to Dr. Roberto Ivan Mota Alvidrez.

Do you give permission to be contacted about future studies?

☐Yes ☐No Initials _____

WHAT ELSE DO YOU NEED TO KNOW?

If you decide to participate in this study, you will be one of about 80 people to do so.

FUTURE USE OF YOUR SAMPLE AND INFORMATION-PROTECTED HEALTH INFORMATION OR SPECIMEN(S).

Identifiable information such as your name, or date of birth may be removed from the information or samples collected in this study. After removal, the information or samples will not be used for future research or shared with other researchers without your additional informed consent.

HIPAA AUTHORIZATION FOR THE USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION (PHI).

As part of this study, we will be collecting health information about you and sharing it with others. This information is "protected" because it is identifiable or "linked" to you.

Protected Health Information (PHI)

By signing this Consent Document, as described in this consent form, you are allowing the investigators and other authorized personnel to use your protected health information for this study. This information includes a questionnaire, sample analysis results, metadata, metrics, and medical history.

Right to Withdraw Your Authorization

Your authorization for the use and disclosure of your health information for this study shall not expire unless you cancel this authorization. This is because the information used and created during the study may be analyzed for many years and it is not possible to know when this will be complete. Your health information will be used or disclosed as long as it is needed for this study. However, you may withdraw your authorization at any time provided you notify the UNM investigators in writing. To do this, please send a letter notifying them of your withdrawal to:

Dr. Roberto Ivan Mota Alvidrez, MD, MS, FAHA
2703 Frontier Ave NE, Albuquerque, NM 87106
College of Pharmacy, University of New Mexico, Research Incubator Building (RIB), Office: RIB room 299, Lab: RIB room 250
1 University of New Mexico

Please be aware that the research team will not be required to destroy or retrieve any of your health information that has already been used or shared before the date that your withdrawal is received.

If you become pregnant anytime during the study, you must inform the study doctor or research coordinator.

The researchers agree to only share your health information with the people listed in this document. Should your health information be released to anyone who is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information would still be regulated by applicable federal and state laws.

You may not be allowed to participate in the research study if you do not sign this form. If you decide not to sign this form it will not affect your:

- Current or future healthcare at the University of New Mexico;
- Current or future payments to the University of New Mexico;
- Ability to enroll in any health plans (if applicable); or
- Eligibility for benefits (if applicable).

After signing the form, you can change your mind and NOT let the researcher(s) collect or release your health information (revoke the Authorization). If you revoke the authorization:

- You will send a written letter to Dr. Roberto Ivan Mota Alvidrez to inform him of your decision.
- Researchers may use and release the health information already collected for their research study.

The use and sharing of your information have no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of New Mexico Health Sciences Privacy Officer between the business hours of 8 am and 5 pm Mountain Pacific Time, Monday-Friday at (505) 272-1493.

INFORMED CONSENT SIGNATURE PAGE

You are participating. This consent includes the following:

- Key Information Page
- Detailed Consent

You will receive a copy of this consent form after it has been signed.

_____ _____

Signature of research subject **Date**

_____

Printed name of the research subject

_____ _____

Printed name of [authorized] person obtaining informed consent/HIPAA Authorization

Date

_____

Signature of [authorized] person obtaining informed consent/HIPAA Authorization