Weight Loss and Exercise to Improve Rheumatoid Arthritis Cardiovascular Risk

NCT04356183

Version Date: 05/17/2022

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Consent to Participate in a Research Study

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CONCISE SUMMARY

The purpose of this study is to compare two approaches to managing rheumatoid arthritis (RA) on health outcomes including cardiovascular risk, disease activity, and patient reports of overall health. Participants 60-80 years of age will be randomized to one of two arms: 1) 16 weeks of a Counseling Health as Treatment (CHAT) program or 2) 16 weeks of a Supervised Weight loss and Exercise Training (SWET) program.

The impact of the CHAT and SWET interventions on self-reported outcomes will be assessed using questionnaires from the Patient Reported Outcomes Measurement Information System (PROMIS). Information collected from this study will assist us in designing larger RA interventions. Also, by determining which approach leads to the greatest improvements in RA-associated cardiovascular risk, disease activity and patient-reported global health, this work should provide immediate and long-lasting impacts on RA clinical care.

Participation in this study may last up to 25 weeks. People in this study will have five on-site study visits and an informed consent visit. Assessments will include the following:

- Blood tests
- Exercise tests on a treadmill
- Muscle strength and oxidative capacity (stress) tests
- Body fat measurements
- Health questionnaires
- 3-day food records
- Garmin activity monitor to measure daily step counts

Risks of blood tests are mild pain and/or bruising, infection, bleeding, clotting, and/or fainting.

Risks of exercise testing include fainting, falling, irregular heartbeat, wheezing and shortness of breath, and very rarely, heart attack or death (less than 1 in 10,000 cases).

If you want to learn more about this study, please continue reading below.

You are being asked to take part in this research study because you have Rheumatoid Arthritis (RA), which is a disease that affects the bones, joints, and muscles.

Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand.

Being in a research study is your choice, and we encourage you to talk with your family and friends before you decide to take part in this research study. If you do not sign this consent form, you will

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continue to receive care, but not as a part of this study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

Dr. Kim Huffman is the Principal Investigator leading the study. The study is funded by a grant from the National Institutes of Health (NIH), which will pay Duke University to perform this research. Portions of Dr. Kim Huffman's and her research team's salaries will be paid by this grant.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, Dr. Kim Huffman will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?
We are doing this study to compare two approaches to managing rheumatoid arthritis (RA) on health outcomes including cardiovascular risk, disease activity, and patient reports of overall health. Participants 60-80 yrs. of age will be randomized (like the flip of a coin) to one of two arms: 1) 16-weeks of a Counseling Health as Treatment (CHAT) program or 2) 16-weeks of a Supervised Weight loss and Exercise Training (SWET) program.

The impact of the CHAT and SWET interventions on self-reported outcomes will be assessed using questionnaires from the Patient Reported Outcomes Measurement Information System (PROMIS). Information collected from this study will assist us with designing larger RA interventions. Also, by determining which approach leads to the greatest improvements in RA-associated cardiovascular risk, disease activity, and patient-reported global health, this work should provide immediate and long-lasting impacts on RA clinical care.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 26 people will take part in this study at Duke.

WHAT IS INVOLVED IN THE STUDY?
If you agree to be in this study, you will be asked to sign and date this consent form.

If you have certain medical conditions and/or take certain medications, this study may not be a good fit for you. Study staff will review your medical history and current medications to confirm your eligibility.

People in this study will be asked to complete 5 on-site study visits and a consent visit that will take place either remotely via ZOOM or on-site at the Duke Center for Living campus.

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Schedule of Visits and Study Activities

Visit 1 – Consent (about 1.0 hour):
During this visit, you will review the consent form and discuss the study details with the research staff. If you choose to participate, you will be asked to sign and date the consent form. The consent visit will take place at the Duke Center for Living or remotely via a one-on-one virtual ZOOM meeting and will last approximately one hour.

After signing this consent form, the research staff will direct you to an online form. This form will allow you to fill out a brief medical history questionnaire and a current medication list. In addition, you will be asked to complete some online questionnaires (PROMIS questionnaires) about your overall health, pain, fatigue, physical function, sleep and ability to manage your disease.

Visit 2 – Baseline (~2.5 hours):
To prepare for this visit, you will need to fast for 12 hours (no eating, but you can drink water) before your visit. Please take any daily medications per your usual routine.

During this visit, you will undergo the following assessments:

- ***Brief medical history, including list of medications, and PROMIS questionnaires:*** If you were unable to access or finish your online medical history, list of medications, and/or PROMIS questionnaires, we will ask you to finish these forms during this visit.
- ***Anthropometric measurements:*** We will measure your height and weight to calculate your Body Mass Index (BMI).
- ***Physical exam:*** The study physician will give you a brief physical exam.
- ***Physician RA joint assessment:*** The study doctor will do a 28-joint examination to assess RA disease activity and your overall health.
- ***Vitals and blood draw:*** We will measure your resting blood pressure and heart rate. A study nurse will draw up to 150 mL (~10½ tablespoons) of blood to evaluate inflammation, immune cell function, and cardiovascular risk. We will isolate cells from your blood and measure the types of blood cells present and the function of these cells.
- ***Muscle stress (or muscle oxidative capacity):*** We will test how well your forearm and calf muscles use oxygen using a process called Near-Infrared Spectroscopy (NIRS). You will first have a small device the size of a deck of cards placed on your calf muscle and held in place by an elastic bandage. This will cause no discomfort. You will then have a blood pressure cuff placed over your thigh slightly above your kneecap. The investigator will turn the blood pressure cuff on and off multiple times. While this process is similar to getting your blood pressure checked at your physician's office, the pressure cuff system used for this test inflates and deflates much faster than a normal blood pressure cuff. You may experience mild discomfort as a result. Finally, you will be asked to move your foot down like you are pressing on a gas pedal while the investigator resists your movement repeatedly for 10 to 15 seconds. You may experience some tingling and fatigue in your leg during the test, and following the test for the next 1-2 hours. You will then have a similar test performed for your arm.
- ***Skeletal muscle biomechanical measurement:*** We will measure the condition of your skeletal muscle using a small, non-invasive device called a MyotonPro®. You will be asked to relax as much as possible while lying flat on an examination table. The investigator will mark your skin

for target locations of measurements on both sides of your body, on your upper and lower arms and legs. Then, a small probe will be placed on the skin overlying your muscle followed by a brief and light impulse, which can barely be felt. This is similar to the pressure of your finger pressing into your skin. This will be repeated 3 times at each location.

- ***3-day food record:*** To assess your current eating habits, you will be provided a 3-day food log along with instructions for completion.

Visit 3 – Baseline (~3.0 hours):
During this visit, you will undergo the following assessments:

- ***Body composition:*** Body composition assessments include waist circumference and BODPOD® testing. Your waist circumference will be obtained using a tape measure. Your percent body fat will be determined using the BODPOD® method. This test consists of measuring your body weight on an electronic scale and determining your overall volume by sitting inside a BODPOD® chamber. From these two measurements, percent body fat is calculated. You will be asked to wear spandex clothing and a swim cap, provided by the study staff, to reduce the amount of air trapped within your clothing and hair in order to obtain the most accurate measurements.
- ***Strength tests:*** We will measure the strength of your hand grip and thigh muscles. For the grip test, you will squeeze a device that measures the strength of the muscles in your hands, wrist and forearms. We will use a special exercise machine to measure the strength of your thigh muscles. You will be seated in a leg extension machine and will be asked to extend your knee as hard as you can after a five-minute warm-up period. Your one repetition maximum will be determined as the maximum of three to six trials with 1- to 3-minute rests between each trial.
- ***Pulmonary function test (PFT):*** We will measure how well your lungs function using a non-invasive test that will require you to breathe in and out of a hand-held tube. We will instruct you to use maximal effort to blow out and breathe in room air. The breathing maneuvers will be repeated several times to make sure the results are accurate.
- ***Cardiopulmonary exercise test (CPET):*** You will be asked to exercise on a treadmill to maximal effort while wearing nose clips and a mouthpiece in your mouth so we can measure your expired air in order to evaluate your breathing and oxygen consumption. For safety purposes, your electrocardiogram (ECG), blood pressure and perceived exertion will be monitored throughout this test by trained personnel. On-site medical supervision will be provided during testing should an emergency arise.
- ***Nutrition data:*** We will collect your completed 3-day food records.

➢ ***Pre- and post-CPET blood draw:*** You will have the option to donate additional blood during this visit for a total of up to 100 mL (~6½ tablespoons). Your participation in this sub-study will allow scientists to learn more about the mechanisms of exercise effect on RA inflammation and immune function. If you agree to participate, the study nurse will collect a blood sample prior to beginning your exercise test and will collect subsequent blood samples immediately after (within 5 minutes) and 30 minutes post-exercise.

_____ (initials) **Yes, I agree** to have an additional blood draw pre- and post-CPET for both the baseline and end-of-study visits. I understand that this portion of the study is completely optional and will not influence my study eligibility or randomization status.

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_____ (initials) **No, I do not agree** to have an additional blood draw pre- and post-CPET for both the baseline and end-of-study visits. I understand that this portion of the study is completely optional and will not influence my study eligibility or randomization status.

Visit 4 – Familiarization (~1.5 hours):
At this visit, the following will take place:

- Randomization assignment
- Distribution of activity monitor, exercise resistance bands, digital body scale, and tablet
- Familiarization with intervention arm

You will be randomly assigned (like the flip of a coin) to receive either a counseling health as treatment (CHAT) program or a supervised weight loss and exercise training (SWET) program. Each of the interventions will last 16 weeks and is described below:

CHAT: This intervention is standard of care for treatment of RA. During a meeting with an exercise physiologist, you will receive recommendations for physical activity to improve overall health. Resistance training recommendations will be two sessions per week, each separated by at least 48 hours. Instructions for 8-10 upper and lower body resistance exercises using exercise bands will be reviewed. Exercise bands and written summaries will be provided. You will be given a Garmin activity monitor to wear, a scale and an exercise journal to record physical activity. Study staff will connect with you once a month to ensure you don't have any questions or concerns.

SWET: This is an experimental treatment for RA. At your initial consult, an exercise physiologist will meet with you to discuss your goals as described below:

Aerobic Training: During your initial consultation, you will meet one-on-one with an exercise physiologist to receive an individualized exercise prescription, which will include a specified target heart rate range to attain during exercise and both a weekly step count and weekly active-minutes goals. Part of your exercise prescription will include required attendance at a ZOOM virtual aerobics class once a week. This class will be led by a study staff member and will allow for remote supervision. This supervised training will be approximately 60 minutes long, consisting of a warm up and cool down period and moderate aerobic moves that can be done without the need for any exercise equipment. Each class will end with a stretching session. During these exercise training sessions, you will monitor your heart rates with a wrist worn device and with staff assistance, modify as needed aerobic moves to maintain heart rates within the prescribed range. A pre-recording of the exercise moves will be available on our study YouTube page for you to view at any time. In addition to the aerobics workout videos, other aerobic exercises you can perform are: walking, running, and dancing to name a few. If walking is uncomfortable, other similar activities can be substituted with approval from study staff. You will be asked to upload your step count and active minutes preferably daily. As needed, weekly calls from staff will be used to discuss problems with devices (i.e., data uploading) or exercise (i.e., general barriers, difficulty maintaining heart rates in the target range).

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Resistance Training: You will be prescribed two weekly resistance training sessions, with each resistance session separated by at least 48 hours. A familiarization session with an exercise physiologist will introduce you to the resistance exercise training format, exercise bands, targeted muscle groups, and proper technique. For each of the 10-11 exercises, a ramp period (~4 weeks) will include a structured training progression from 1 to 3 sets of 8-15 repetitions per exercise. The initial intensity (exercise band resistance and number of repetitions per exercise) will be determined by the exercise physiologist during the initial familiarization session with you. The amount of resistance lifted and/or repetitions will be slowly increased such that progression occurs while minimizing musculoskeletal soreness and/or injuries. Part of your exercise prescription will include required attendance at a ZOOM virtual resistance class once a week. This class will be led by a study staff member and will allow for remote supervision. This supervised training will be approximately 60 minutes long, consisting of a warm up and cool down period and 8-11 resistance exercise movements. Each class will end with a stretching session.

Weight loss program: You will meet one-on-one with a registered dietitian to receive an individualized dietary prescription. Your diet will be designed just for you to allow a weight loss of 7% of your starting body weight. Your weight loss will be achieved through participation in a weight loss program for a period of 16 weeks. This program will be delivered remotely and will begin with a couple one-on-one counseling sessions with a dietitian during which you will be given an individualized diet plan calculated to help you lose 1-2 pounds each week. After this, you will attend on-going group nutrition classes once per week. You will be asked to record your food intake daily in the My Fitness Pal app. You may choose to download this app onto your personal smart phone or the electronic tablet that we will give you. You will also be given a scale to help you to track your progress. Weekly attendance at the group nutrition sessions, including reporting weight and daily diet intake, is required as a participant in this study.

At this visit, you will be given a Garmin activity monitor, a set of resistance bands, a smart digital scale, and an electronic tablet. The tablet will be used to access the Garmin Connect and Pattern Health apps to facilitate your study intervention. The Garmin Connect app is a tool for tracking, analyzing and sharing health and fitness activities recorded with your paired Garmin activity monitor. At this visit, the study team will provide you with access to a unique study account that you will use to “Create Your Account” in the Garmin Connect app. The Garmin activity monitor will capture your measurements related to your daily activities such as step counts, heart rate and sleep. You will wear the activity monitor daily throughout the remainder of the study. Study staff will have online access to your activity data through the Garmin Connect platform. If you are randomized to the SWET group, you will be asked to interact with the Pattern Health app to monitor and track your study activities. At this visit, study staff will provide you with a unique study email so you can access your Garmin account, set up your Pattern Health account, and My Fitness Pal account. If you are randomized to the CHAT group, study staff will provide you with a unique study email so you can access your Garmin account and set up your Pattern Health account.

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Visit 5 – Post-Intervention (~2.5 hours):
- Repeat Visit 2 Assessments

Visit 6 – Post-Intervention (~3.0 hours):
- Repeat Visit 3 Assessments
- Collect exercise journal from CHAT group only
- Complete exit survey (online or in-person)

  Exit Survey: You will be asked to complete an exit survey regarding your experiences with the program.

HOW LONG WILL I BE IN THIS STUDY?
Your participation in the study may last up to 25 weeks, which includes the baseline testing prior to randomization, followed by the 16-week intervention and post-intervention assessments.

You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

In addition, you have the option to volunteer to be in future follow-up studies. If you agree, a member of the study team will contact you for this potential future research if funding becomes available. You can still participate in the current study if you do not consent to be contacted for potential follow-up research studies in the future.

_____(initials) **Yes, I agree** to be contacted by the study team if funding becomes available for future follow-up studies. I understand that this is completely optional and does not impact my study eligibility or randomization status for the current study.

_____(initials) **No, I do not agree** to be contacted by the study team if funding becomes available for future follow-up studies. I understand that this is completely optional and does not impact my study eligibility or randomization status for the current study.

WHAT ARE THE RISKS OF THE STUDY?
- **Blood draws:** There is a risk of local pain, soreness, bleeding, bruising and swelling, as well as light-headedness, dizziness and rarely, fainting and/or a local infection.
- **BODPOD:** This test may not be comfortable for anyone who has felt claustrophobic (uncomfortable in small places) but is generally well tolerated.
- **Pulmonary function test:** This is a non-invasive procedure. Dizziness during the breathing maneuvers, feeling short of breath, coughing, asthma attack brought on by deep inhalation are possible side effects.
- **Cardiopulmonary exercise test:** The risks of the cardiopulmonary exercise test include but are not limited to: fainting, falling, irregular heartbeat, wheezing and shortness of breath, and very

rarely, heart attack or death (less than 1 in 10,000 cases). Participants will be given careful instruction prior to, and during, exercise testing to determine when it is appropriate for them to stop exercising. The exercise test will be performed under the supervision of medical staff who are equipped to deal with emergencies.

- **NIRS:** This is a non-invasive procedure. Site deformation to the skin, redness or bruising may occur momentarily while the cuff is inflated during the assessment.
- **Exercise training:** Participation in an exercise program may result in muscle, bone and/or joint soreness, discomfort and/or injury. There is also the risk of falling.

In addition to the risks listed above, you may experience a previously unknown risk or side effect.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

We cannot and do not guarantee that you will receive any benefit from taking part in this study. Your willingness to take part may, however, increase knowledge regarding the treatment of RA. Several likely benefits include the following:

If you agree to take part in this study, there may be direct medical benefit to you. You will have physical examinations and laboratory tests provided to you at no cost. The study doctor will share with you any findings on these tests that indicate a potential problem. If you are randomized to SWET, you will receive exercise physiologist-supervised exercise training and ongoing, dietician delivered feedback about diet and weight loss. If you are randomized to CHAT, you will receive one on one counseling about proper diet and exercise recommendations. Upon study completion, CHAT graduates will have the opportunity to join the weekly group nutrition classes in addition to gaining access to the study YouTube exercise channel link; therefore, CHAT graduates will receive the same educational materials as the SWET group upon finishing the study. These benefits are well-recognized as contributing to overall improved health. We hope that in the future the information learned from this study will benefit other people with your condition.

WHAT ALTERNATIVES ARE THERE TO PARTICIPATION IN THIS STUDY?

If you do not want to take part in the study, you have the choice to undergo standard treatment for RA. If you decide not to take part in this study, your decision will have no effect on the quality of medical care you receive.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. People involved in this research may view your personal information, including those who are working on, funding, and/or regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include the

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Duke University Health System Institutional Review Board, the sponsor and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

As part of this study, you will be asked to have certain tests and/or procedures performed. Results of tests and studies done solely for this research study and not as part of your regular care will not be included in your medical record.

If you are not a Duke patient, and you decide to participate, Dr. Kim Huffman will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

The sponsor of this study may further disclose your information. If shared by the sponsor, the information is no longer covered by federal privacy regulations.

If this information is shared with outside reviewers for audit purposes, it may be further shared by them and may not be covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private.

If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
2) you have consented to the disclosure, including for your medical treatment; or
3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you

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want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

Data Privacy/Security Risks of Mobile Apps:

The data collected via the Garmin wristband activity monitor and the My Fitness Pal app will be stored on your tablet or personal device and uploaded to the respective servers of each app. Data will also be stored on the Garmin activity monitor itself. The study team will create a unique study-specific Duke email (e.g., SWEAT01@dmpi.duke.edu) and an assigned unique default password for each participant. Passwords will be assigned in accordance with applicable Duke Health password security policy requirements. This email address and password will be used solely for account creation and will not be used for communication. No personal information will be used in the study-specific email or password. You will access the mobile applications used in this study using the unique email address and password issued to you by the study team. We will provide you the study account information and log-in information so you can activate the apps on your study tablet or phone. During the study, the study team will have access to your study-specific email and password as well as the information maintained in the Garmin Connect, Pattern Health, and My Fitness Pal accounts in order to monitor your data collected. For security purposes this information, including the unique default password should not be used for any other account. At the end of the study we will stop collecting your activity data and you will be provided instructions on how to log out of all study accounts. The study team will also provide directions on how you may set up your own personal Garmin Connect account and connect your activity monitor.

Information collected by mobile applications or 'apps' is subject to their terms of use, and end user license agreements. You are encouraged to review the Garmin Connect Terms of Use and End User License Agreement, the Pattern Health Terms and Conditions, and the My Fitness Pal Terms and Conditions of Use prior to using the mobile applications. By logging into your study accounts, you are agreeing to abide by these guidelines. Many apps make claims that they are very secure, compliant with federal privacy regulations, and used and tested by other academic centers. However, any mobile app that is downloaded carries potential security risks, and Duke cannot guarantee that these mobile apps are free of risk. Some apps may be able to perform hidden functions or may have security flaws that allow unauthorized access to information. We are unable to fully tell you what information these mobile apps are able to access or change on your device (phone/tablet) or what information from your device may be stored outside of Duke. During the study, you are encouraged to limit personal identifiers you enter into these mobile applications (particularly your name, date of birth, address, place of employment, and other details that could allow someone to identify you) only to that information that you wish to voluntarily share with others. These apps may send/receive information with other mobile apps, including social networking apps or websites (for example, Facebook). If you give permission for this, the terms of use for those apps/websites apply and you should read them carefully. For the purposes of this study, the data managed in the Garmin Connect platform is transmitted to the Pattern Health Technologies' secure platform for use and analysis by the Duke study team.

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Duke is providing a tablet for you to use throughout the duration of the study. You will own the tablet and keep it at the end of the study. The tablet is considered your personal property and Duke will not configure or manage any aspect of this device. It is recommended that you run a current operating system (OS) on your device, review the privacy/security settings often, and restrict any unnecessary access. These applications may run in the background of your device. Mobile apps may have unanticipated impact on the operations of your device (e.g., battery drainage). If you do not have an unlimited data/text plan, you may incur additional charges. At the conclusion of the study, we will provide you instructions on how to remove the mobile apps from your device.

We are not asking you to make any health decisions based on the use of these mobile apps. You should discuss health decisions directly with your healthcare provider.

As with all technology, we ask you to wait to use the device until you are in a safe environment, use good judgment and follow prevailing laws. Do not perform study-related activities while you are driving.

Because e-mail and text does not provide a completely secure and confidential means of communication, please do not use email or text if you wish to keep your communication private. Instead, call 919-668-1182 to speak with the study coordinator directly.

Data Privacy/Security Risks of Group Sessions:

Part of the intervention will include exercise or nutrition sessions using the ZOOM virtual platform. These sessions may involve several participants, accompanying family members and/or other support persons participating in the same physical or virtual visit room at the same time. Your participation in the group session is required in order to participate in the study. If you choose to participate, you volunteer to share certain protected health information (PHI), but you determine how much information to share in the group session.

Because group sessions often involve participants disclosing private medical and social information, we ask all participants in the group visit—including the participant, and any accompanying family members or support persons—to agree to respect the privacy of all participants and keep their information confidential. However, Duke Health cannot make any guarantees about the confidentiality of the information you share in the group session and there is a risk that other participants may share your information with others.

By signing this informed consent confidentiality agreement, you acknowledge that you are voluntarily participating in the group session and assume the responsibility for keeping all information confidential.

WHAT ARE THE COSTS TO YOU?

There will be no additional costs to you as a result of being in this study. However, routine medical care (care you would have received whether or not you were in the study) will be charged to you or your insurance company. The tests performed in this research study are not part of routine care, and people who are not part of the study do not usually have them performed. Please ask Dr. Huffman or a

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member of the study team if you would like to know more about which tests and studies are being done solely for research purposes.

WHAT ABOUT COMPENSATION?
You will be paid a total of $200 for completion of the entire study. You will be paid $50 upon completion of both baseline visits and $150 for completion of the intervention and both exit visits. The physical activity monitoring device, set of resistance bands, tablet, and Bluetooth enabled digital scale are yours to keep ($300 value). No compensation will be provided for completing the consent process. Compensation will be provided by Duke ClinCard, which is a reloadable debit card. To provide you with compensation we will be required to collect your social security number. If you do not wish to provide your social security number, you may still participate in the research. However, you will not be compensated if you decline to provide your social security number.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate medical care is available at Duke University Medical Center if you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Huffman at 919-668-1644 during regular business hours and at 919-308-4236 after hours and on weekends and holidays.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you decide to withdraw, we would like to schedule an exit interview with a member of our study team or have you complete an exit survey. The information collected will assist us with the development of future study designs and how to make them work for everyone. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Huffman in writing and let her know that you are withdrawing from the study. Her mailing address is:

Kim M. Huffman, MD
Division of Rheumatology and Immunology
Duke Molecular Physiology Institute
Duke University School of Medicine
300 North Duke Street/Room: 51-202/Durham, NC 27701

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We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without your consent. If this occurs, you will be notified and your study doctor will discuss other options with you.

A description of this clinical trial will be available on https://clinicaltrials.gov/ as required by U.S. Law.

This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

We will store samples for additional analyses that can be performed once the study is complete. These will include additional measures of blood cell function, inflammation, and metabolism. No genetic DNA testing will be performed on these samples.

These samples will only be identified by your study identification number and will be stored as long as this study IRB application remains open or a sample repository protocol will be opened for continued storage of these samples. No additional participation from you will be required for any such future research. You will not be informed of any such future research. If you consent to allow storage of your samples for future research, you may withdraw your consent at any time in writing to your study doctor. You can still participate in this clinical trial if you do not consent to have your samples stored for future research.

_____(initials) **Yes, I agree** that my blood samples taken for this study can be used for future research and that these samples can be retained as long as this study IRB application remains open or a sample repository protocol will be opened for continued storage of these samples.

_____(initials) **No, I do not agree** that my blood samples taken for this study can be used for future research and that these samples can be retained as long as this study IRB application remains open or a sample repository protocol will be opened for continued storage of these samples.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Huffman at 919-668-1644 during regular business hours and at 919-308-4236 after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

Duke University Health System

Consent to Participate in a Research Study

Weight Loss and Exercise To Improve Rheumatoid Arthritis Cardiovascular Risk

STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time

_____
Printed Name of Subject

_____	_____	_____
Signature of Person Obtaining Consent	Date	Time