Kennesaw State University
Consent Form

High Intensity Body-weight Circuit Training Feasibility and Efficacy for Improving Metabolic Profile, Body Composition, and Health-Related Fitness in Middle Aged Persons with Type 2 Diabetes

Researcher's Statement
You are being asked to take part in a research study. The information in this form will help you decide if you want to be in the study. Please ask the researcher(s) below if there is anything that is not clear or if you need more information.

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- This study will assess the effects of a program of brief but vigorous exercise training on markers of glucose control and fitness.
- Your involvement in the study is voluntary, and you may choose not to participate or to stop at any time without penalty or loss of benefits to which you are otherwise entitled.
- Your anticipated duration of participation in this study will be approximately 20-weeks.
- What to expect in participation in this study? (A total of 4 laboratory visits)
    - **Visit 1:** At the Kennesaw State University Exercise Physiology Lab (EPL), to obtain information regarding:
        - Cardiovascular markers: resting heart rate and blood pressure, and your heart rate variability, a marker of your involuntary nervous system activity, for a 10-minute period in a quiet dimly lit room.
        - your resting glucose regulation and lipid profile will be taken through finger sticks in a fasted condition. A two-hour glucose tolerance test will be taken along with lipid profile. During the two-hour glucose tolerance test.
        - Fitbit device orientation
    - **Visit 2:** Within two weeks of this visit you will be asked to arrive at the EPL in order obtain information regarding your;
        - body composition (height, weight, body fat percentage) by scale and DEXA Scan.

        - aerobic endurance assessment through a sub-maximal treadmill exercise test treadmill test which begins with a very slow and easy walk and progresses every three minutes in speed and grade. You will be asked to continue as long as you can, or until you achieve a heart rate that is approximately 85% of your age-predicted maximal heart rate at which time the speed and grade will be reduced to allow for you to cool down.
        - Leg strength which will require you to flex and extend your dominant leg as hard as you can while sitting on a machine that measures how much force you produce.
        - Arm and hand strength which involves you squeezing a device as hard as you can while it measures your force production
        - Intervention group orientation
    - You will be assigned to either 16 weeks of the high intensity bodyweight circuit (HIBC) or traditional exercise intervention(TEI) (See below for protocol details).
    - **Visits 3 & 4:** After 16 weeks of this training, you will be asked to visit to the EPL to repeat assessments that were described above so that we can determine whether the exercise training resulted in any improvements in glucose tolerance or health-related physical fitness.
- With any exercise intervention there are risks associated with participation. The reasonably foreseeable major risks or discomforts associated with this study are:
    - Overuse injury in joint or tendons (tendonitis)
    - Muscle strain
    - Shortness of breath
    - Fatigue
    - Short term low blood sugar
- The primary benefits to you and/or to others that may reasonably be expected from the research;
    - Participant benefits:
        - Learn about current blood sugar control status
        - Learn about current body fatness, aerobic and muscular fitness
        - May learn to sustain exercise following your involvement
    - Benefits to others
        - Society may benefit by learning about the influence of brief but vigorous exercise on glucose tolerance and physical fitness in people with type 2 diabetes.
    - Despite the previously mentioned potential benefits, you may not receive benefit from participation.

- Appropriate alternative procedures or courses of treatment are available outside of the participation of this study.

If you are interested in participating in the study, please read the additional information on the following pages, and feel free to ask questions at any point.

Study Procedures and Time Commitment

Eligibility Confirmation: Recruitment facilities/clinics will confirm you are between the ages of 40 and 65 years, have been diagnosed with type 2 diabetes at least one year, do not take insulin injections, glycosylated hemoglobin (A1C) is a minimum 6.0%.
You will not be eligible for this study if you have or experience the following: **history or active symptoms of myocardial infarct (heart attack), chest pain or angina, congestive heart failure, aortic stenosis or other heart valve disease, cardiac dysrhythmia, poorly controlled hypertension, poorly controlled asthma, actively symptomatic COPD**. If you have any of the following signs or symptoms you will not be eligible to participate in the study: **shortness of breath at rest or with mild exertion, dizziness or syncope, orthopnea or paroxysmal nocturnal dyspnea, ankle edema, palpitations or tachycardia, persistent claudication, known heart murmur indicative of heart disease, unusual fatigue or shortness of breath with usual activities** Once your eligibility is determined, you will be asked to obtain medical clearance and collect baseline measures (this will occur in visit 1) and ensure final eligibility.

Health Care Provider's Authorization to Participate: You will be asked to acquire an "authorization to participate" from your overseeing physician. The purpose for this is to ensure that you will be able to safely engage in the exercise involved in this study. This will be completed by your overseeing physician and he or she will fax the completed forms back to us. Note that we will not be able to enroll you into the study until we receive your physician's authorization for you to participate.

Training Group Assignment: Because participants will be admitted to the study on a rolling basis, The method of randomization to be utilized in this study is called the "covariate adaptive randomization" technique, which is akin to flipping a coin. Because there is an interest in controlling for sex and race/ethnicity, participants will then be categorized into either "male" or "female" as well as "white" or "non-white." Since it is desired to have an equal number of participants in each treatment group, allowing the researcher to implement a level of control in maintaining balance as participants are admitted.

Lab Sessions: Lab sessions will be conducted in the exercise physiology laboratory (EPL) in Prillaman Hall at Kennesaw State University. During your lab visits you will undergo several assessments of fitness and glucose tolerance as described below:

Visit 1 & 3 *- Body Composition, Resting Cardiac Autonomic Activity, Aerobic and Muscular Fitness:* Following consent and physicians' approval, you will be asked to arrive at the Kennesaw State University Exercise between 8:00 am and 10:00 am in a fasted condition *(no medication unless physician approved), no food or beverage except water 12 hours* and no structured or vigorous exercise for at least 24 hours prior to this assessment. *Note: Fasted conditions may lead to lightheadedness or dizziness. Please notify the PI or co-I in the event this occurs.*

We will measure your height, weight, and waist circumference. You will then undergo a DEXA scan which will provide information about your body fatness and fat distribution patterns. We will then measure your resting heart rate and blood pressure, and your heart rate variability, a marker of your involuntary nervous system activity, for a 10-minute period in a quiet dimly lit room. Following this you will be asked to complete a brief questionnaire about your enjoyment of exercise.

Background on DEXA: A dual-energy x-ray absorptiometry (also known as DEXA) scanner utilizes two low-dose x-ray beams of different levels to estimate body composition and bone density. DEXA is considered the most accurate and reliable method of assessing body composition.

In order to assess aerobic fitness, you will perform a treadmill test which begins with a very slow and easy walk, and progresses every three minutes in speed and grade. You will be asked to continue as long as you can, or until you achieve a heart rate that is approximately 85% of your age-predicted maximal heart rate at which time the speed and grade will be reduced to allow for you to cool down. You will then undergo an assessment of leg strength which will require you to flex and extend your dominant leg as hard as you can while sitting on a machine that measures how much force you produce. Finally, your arm and hand strength will be measured via an assessment of grip strength, which involves you squeezing a device as hard as you can while it measures your force production.

Visit 2 & 4 *- Resting Metabolism, Glucose Tolerance, Device & Protocol Orientation:* Within 2 weeks of visit 1 & 3, you will be asked to return to the EPL for standard care labs which will be comprised of: hemoglobin A1c (HbA1c), fasted glucose, insulin, oral glucose tolerance test (OGTT), lipid profile: total cholesterol, HDL-cholesterol, LDL-cholesterol, and triglycerides. All markers will be assessed through finger stick procedures.

Device and Intervention Orientation: Upon completing the lab sessions, you will be given an activity tracker. At this time, you will learn how to operate, sync the data to a secured online platform that will store activity data (e.g., steps, distance, activity minutes, calories, and heart rate), and communicate with the research team. These data will be used to account for any non-exercise physical activity changes that may or may not occur during the intervention periods an exercise training program. Participants will lastly be provided detailed instruction for their assigned intervention. For the High-intensity Bodyweight Circuit (HIBC) group, you will be provided a take home TRX system and instructed on the movement standards. Prior to departure, HIBC participants will demonstrate ability and comfort performing the designated movements. Total expected laboratory time is 3.5 hours.

High-intensity Bodyweight Circuit (HIBC) Group-
Upon completing the lab sessions, you will begin the exercise training program. In order to ensure proper technique and promote social distancing, the first two weeks of the intervention will be monitored online live via a virtual viewing platform (e.g., ZOOM, FaceTime, Skype…). Subsequent workouts will be self-report each week and submitted to the participant designated file online a secure data capture platform

This program will involve a light, 5-minute warm-up walk around the house/yard/or safe location, and four simple movements that utilize your bodyweight as resistance. The exercises include squats, modified push-ups, modified rows, and abdominal curl-ups. You will be provided instructions on how to correctly and safely perform the exercises. It will be important to perform the exercises correctly in order that you achieve the greatest fitness benefit, as well as ensuring that you do not injure yourself while exercising. The exercise sessions will involve you simply repeating a series of repetitions of each movement in sequence and completing as many sequences as you can in good form in the time allotted for the exercise (initially, 5 minutes).

You will be asked to complete three sessions per week at home, after three weeks of training, you will be asked to add a fourth session each week. Initially, the HIBC sessions will be five minutes long, and the duration of the sessions will increase by one minute each week as tolerated beginning in week four, peaking at 10-minutes per session (warm up not included in this timing) as early as the eighth week of training. Session durations are capped at 10-minutes.

After you've completed the circuit portion of the exercise session, you will perform a light 5-minute cool-down walk around the house/yard/or safe location.

Aerobic Training Group-
Upon completing the baseline measures in the required lab sessions, you will begin the exercise training program that will be monitored via online file submission and activity tracker confirmation. Each week, you will send an exercise log to your assigned lab ID numbered (e.g., T001) folder to the online secure data capture platform. This information will include date, start time, and end time. The timing provided by the logs will be used to track your activity, which will be confirmed with the activity tracker. The aerobic protocol will initially consist of three sessions per week of 40 minutes of continuous physical activity and increase to a fourth weekly session following the third week. This will consist of walking exercise at a moderate intensity of 40-60% heart rate reserve (([maximal heart rate – resting heart rate] x 0.4-0.6) + resting heart rate). Participants will continue this protocol for 16-weeks.

After 16 weeks of this training, you will be asked to schedule your visits to the EPL to repeat assessments that were described above so that we can determine whether the exercise training resulted in any improvements in glucose tolerance or health-related physical fitness.

Risks and discomforts
Finger Sticks: Some people find the finger stick to be painful. There is also a slight risk of infection which will be minimized by using sterile equipment and standard sterilization procedures, such as wiping the fingertips with alcohol wipes.
Exercise: All exercise brings the risk of shortness of breath, abnormal heart rhythms, abnormal blood pressure, dizziness, stroke, heart attack, and even death. Treadmill exercise can also result in muscle strains and pulls, sprained ankles, and joint, hip, or back pain. Muscular fitness testing can result in strained or pulled muscles, joint discomfort, and muscle fatigue and soreness. These risks will be minimized by monitoring your exercise sessions and by ensuring that you understand how to proceed when you are fatigued. In addition, people administering the assessments are experienced physiologists and are trained in CPR including use of automated external defibrillators.
DEXA Scan: During the DEXA scan, you will be exposed to a small amount of radiation. The radiation level is lower than natural background exposure each day and are considerably less than radiation exposure experienced during a flight from NY to LA or a chest x-ray. This radiation exposure is not medically necessary and is to be used for research purposes only. To minimize your risk, the Department of ESSM adheres to the ALAR A (As Low as Reasonably Achievable) philosophy ascribed by the International Society for Clinical Densitometry (ISCD).

DEXA For Female Participants: Though the radiation exposure from a DEXA scan is miniscule, out of an abundance of caution, we do not wish to expose a pregnant woman to radiation. In addition, pregnancy complicates the interpretation of body composition estimates, which makes pregnant women unsuitable as research subjects for this study. For these reasons, we will not perform DEXA scans on women who think they may be pregnant. In addition to signing a statement of consent to participate in this research study at the end of the document, females of child-bearing potential must certify that, to the best of their knowledge, they are not pregnant. Females of child-bearing potential are to be provided a free urine-based pregnancy test to be used to inform their decision to consent to participate in this study. This test can be completed in a private restroom before the DEXA scan. Please be aware that a pregnancy test may not detect pregnancy even when you may be pregnant (false-negative result). DEXA operators are not authorized to help you diagnose or interpret pregnancy test results. If you have any reason to suspect that you might be pregnant, you should not submit to DEXA scan. The research investigator will be happy to reschedule the DEXA scan after you confirm that you are not pregnant.

I was given the opportunity to complete a simple urine test for pregnancy (please check one): ___ Yes ___ No

_____ Please initial here to confirm that you are not pregnant

Benefits

You may benefit from learning about your current blood sugar control status, your resting metabolic rate, and your levels of body fatness, aerobic, and muscular fitness. The DEXA scan provides an accurate estimate of body composition and can also be used to measure bone density. Department of Exercise Science and Sport Medicine (ESSM) DEXA operators are not authorized to provide any clinical diagnosis from the information provided by the scan, but you are welcome to share the results with a qualified medical professional. You may also benefit from learning to perform bodyweight exercises correctly, as this may allow you to sustain an exercise program that requires relatively little time after your involvement in this study is completed.

Society may benefit by learning about the influence of brief but vigorous exercise on glucose tolerance and physical fitness in people with type 2 diabetes. The prevalence of this condition is continuing to increase in the United States, and people with type 2 diabetes may be able to benefit from knowing whether clinical markers of glucose tolerance and control can be improved with just a few minutes of exercise each week.

Confidentiality of records

Only the PI and Co-I of the study will have access to the information/specimens collected includes information that identifies participants directly (e.g., name, e-mail address), while the PI, Co-I, and approved members of the research team will have access that indirectly identifies participant (codes). Any electronic information will be held in a password protected computer, with a password protected file. Any physical record will be stored in a locked room, and locked drawer.

Three years following the completion of data collection, any record that directly identifies you as a participant will be deleted or destroyed (i.e., shredded). We do not plan to share this information with anyone who is not connected to this research study.

The IRB Office at the Kennesaw State University responsible for regulatory and research oversight may access the records. Researchers will not release identifiable results of the study to anyone other than the PI and Co-I without your written consent unless required by law.
Identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative.

Research Injuries
In the event that any research-related activities result in an injury, the sole responsibility of the researchers will be to arrange for your transportation to an appropriate health care facility. If you think that you have suffered a research-related injury, you should seek immediate medical attention and then contact Brian Kliszczewicz right away at 315-415-6609. Medical expenses will be your responsibility or that of your third-party payer (insurance). However, you cannot be prevented from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research.

Incentives
You will be paid $100 for participating in this study. Additional incentives, include a fitbit activity tracker and an at home suspension training system that you will be permitted to keep (TEI group will receive one upon completion). The approximate retail value of this equipment is $200.

Withdrawal
You can stop being in this research study ("withdraw") at any time before, during, or after the treatment begins, but you will not be provided information (e.g., body composition, blood cholesterol, and glucose control) that will be collected in this research study after you withdraw. Deciding to withdraw will otherwise not affect your relationship with the investigator or Kennesaw State University. You will not lose any benefits to which you are entitled.

You may be taken off the study if you don't follow instructions of the investigator or the research team. If you miss more than a cumulative eight sessions over the course of the intervention, then you will be removed from the study.

If the research team gets any new information during this research study that may affect whether you would want to continue being in the study you will be informed promptly.

If you withdraw or are removed from the study, you will be permitted to keep the fitbit activity tracker as well as the home suspension equipment (both intervention groups). The $100 gift card will only be received upon the completion of the final measurements.

HIPAA Authorization
You have rights regarding the privacy of your medical information collected before and during this research. This medical information, called "protected health information" (PHI), typically may include, depending upon the nature of this research, demographic information (like your address and birth date), the results of physical exams, blood tests, x-rays and other diagnostic and medical procedures, as well as your medical history.

By signing this consent form, you are allowing your PHI to be shared with the researchers. The research team includes the investigators listed on this consent form and other personnel involved in this specific study at Kennesaw State University. Your PHI will be used only for the purposes described in this consent form. Your PHI may be shared, as necessary, with the Institutional Review Board (IRB) and with any person or agency required by law. The results of clinical tests and therapy performed as part of this research may be included in your medical record.

Signing this consent form, authorizes us to use your PHI for the duration of this research study. You may cancel this authorization at any time by contacting the principal investigator in writing. However, the PHI which is included in the research data obtained to date may still be used. If you cancel this authorization, you will no longer be able to participate in this research.

Participant rights

If you have any questions or concerns regarding your rights as a research participant in this study, you may contact the Institutional Review Board (IRB) Chairperson at (470) 578-2268 or irb@kennesaw.edu.

If you agree to participate in this research study, please sign below:

_____	_____	_____
Name of Researcher	Signature	Date
_____	_____	_____
Name of Participant	Signature	Date

Please keep one copy and return the signed copy to the researcher.