Title: The implementation of a community-health focused intervention using combined aerobic and resistance training protocols in a group setting.

NCT number (not available)

February, 23, 2023

Title: The Implementation Of A Community Health-focused Intervention Using Combined Aerobic and Resistance Training Protocols In A Group Setting

1. Research Design/Methods
   a. The purpose of this project is to provide an intervention focused on a combination of aerobic and resistance training exercise for adults residing in Somerset County, Maryland. Through a pre-determined, structured exercise program, participants will engage in physical activity sessions for 12 weeks. The program will be offered from January 9-March 31, 2022. This approach is appropriate as Somerset County has the highest physical inactivity level and poorest physical health amongst surrounding counties (CHNA, 2019). Currently, Somerset County residents only have access to fitness classes, offered twice a week, which take place in a classroom at Somerset Technical High School. The class is offered through Somerset County Recreation, Parks, and Tourism and interested participants pay a fee to join. However, this project offers participants pre and post assessments and monitored aerobic and resistance training sessions with a primary outcome of improving body weight, body composition and/or measures of fitness.

2. Subject Selection
   a. The subjects are adults, 18 years or older, residing in Somerset County. There is not an upper age limit to participate in the program. Funding for this project requires activities that address the poor health outcomes of adults in Somerset County, Maryland. Somerset County Health Department will assist in advertising for the project as the intervention is open to adults, 18 years of age or older, in Somerset County.
   b. Flyers will be posted around Somerset County. Somerset County Parks & Recreation will be contacted and sent a flyer. The flyer is attached.
   c. Subjects will be recruited from Somerset County, Maryland. This is a requirement for the funding that was received for the project. The PI will ask surrounding businesses and organizations permission to post the project flyer.
   d. Somerset County Health Department will assist in advertising for the project. Subjects are not being selected based on any specific characteristic(s). Any interested adult in Somerset County can participate. The project is limited to 15 individuals and therefore participation is on a first come-first serve basis.
   e. The project will be advertised through Somerset County Health Department and the surrounding businesses and organizations. All interested adults that reside in Somerset County are welcome to participate if space is still available.

3. Procedures
   a. Participants will be asked to participate in a health screening and preliminary fitness tests after the informed consent has been signed and returned. Participants will be asked to respond with a yes or no to the following questions as a preparticipation and/or health screening tool.

      1. Do you participate in regular exercise?
      2. Has a physician or other qualified health care provider ever diagnosed you with cardiac, peripheral vascular, cerebrovascular disease, or Type 1 or 2 diabetes?

3. Do you have any signs or symptoms suggestive of cardiovascular, renal, or metabolic disease including but not limited to: pain/discomfort in the chest, neck, jaw, or arms; shortness of breath at rest or with mild exertion; dizziness during exercise, ankle edema, palpitations (awareness of rapid beating of the heart) or tachycardia; or unusual fatigue or shortness of breath with usual activities?

The American College of Sports Medicine (ACSM) screening on a separate attachment will show how medical clearance is determined. Since the ACSM screening is limited in some regard, a Physical Activity Readiness Questionnaire Plus (PARQ+) will also be used as a precautionary measure prior to participation to gather additional information. The PARQ+ is located on a separate attachment. There is a line drawn through specific information related to a condition and/or medication because that information is not needed. The PARQ+ will be printed for the participants and the "please list" will be blacked out so that participants do not include this information. The information collected from the PARQ+ is only used to confirm whether or not the participant will need to obtain medical clearance prior to participation in any of the assessments and activities. The information is also used to determine proper exercise prescription for the intervention based on the participant's current state of health. The participant will be asked to sign the PARQ+ and return it to the PI. The information collected from this will be stored in a sealed envelope that will be kept in a locked cabinet in the PI's office. The PI is the only individual who has a key to the cabinet.

An ACSM screening algorithm and the PARQ+ will be used to determine if a participant needs medical clearance prior to participation in the preliminary fitness tests which is completed a week before the program begins. The preliminary fitness tests will include the curl up, the pushup, bench press, vertical jump, and the Rockport 1-mile or 1.5 mile walk test. The purpose of the fitness test is to acquire baseline data about physical fitness levels before implementation of the intervention. The preliminary fitness test will not be used to determine if an individual can or cannot participate. Participants will complete a Bio-electrical Impendence Analysis (BIA), body weight, and waist circumference measurements before and after the study. The BIA will be used to determine percent body fat, skeletal muscle, and body mass index. The PI will program the BIA device. The participant will be asked to step on a scale and hold the handle of the BIA device. The participant will be asked to hold the BIA device for up to 5 seconds until the device completes the scan. The weight of the BIA device is approximately 12 ounces. BIA devices are available for the public and may be purchased by the public. To measure the participant's waist circumference, a tape measure will be placed around the participant's waist on the outside of their shirt. The participant will be asked to identify where their belly button is and the participant will wrap the tape measure around their waist. One inch below the participant's belly button is where the participant will be asked to place the tape measure. The BIA and waist circumference measurements will be conducted in the exercise science lab located in the Department of Kinesiology in Hytche Athletic Complex on UMES campus.

These data collected from participants will be recorded and stored on a password protected university-owned laptop. The participant's middle name will be used as an

identifier until post assessments are complete. Post assessments are completed at the end of the program and will include all of the preliminary assessments.

Participants will progress from once to twice a week on non-consecutive days after 2 weeks of participating in the study. This will help participants adapt to the new movement and become familiar with an increase in physical activity. Participants have the option of whether to continue with the study for 12 weeks. Participants will report to Hytche Athletic Complex for a 60-minute combined aerobic and resistance group training session facilitated by the PI. The session will include pre-exercise stretching, an (aerobic) warm-up, weight training, (aerobic) recovery, and a period of post-exercise stretching. The warm-up and recovery will include 10 minutes of steady-state aerobic activity on the indoor or outdoor track. During these periods, walking, jogging, or cardio machines may be used at participant discretion. Static and/or dynamic stretching of each major muscle group will be taught and implemented. The resistance/weight training session will include 8-10 different exercises that target major muscle groups (legs, chest, and back). The time and intensity will progress from one set of 10-15 reps per exercise to three sets of 8-10 reps per exercise. The intensity follows the American College of Sports Medicine guidelines for exercise testing and prescription and will progress from low to moderate intensity (ACSM, 2021). Abdominal and low-back exercises will also be incorporated throughout the weight training portion to promote muscular balance. Participants can ask for an alternative method and/or not to participate in one or all of the exercises after they are demonstrated and explained.

b. The BIA, bodyweight, waist circumference, pushup, curl-up, bench press, and the vertical jump test will take place in the exercise science lab of the Department of Kinesiology in Hytche Athletic Complex on the UMES campus. Males will complete pushups on their toes without their knees being down while women will complete pushups in the modified version with their knees down. An Airex cushion will be placed under both males and females as a precautionary measure if they are unable to complete a pushup. Participants will be given an exercise mat to complete their curl-up on the floor. For the bench press, the participant will lie on a bench that includes a barbell and free-weight plates, if applicable. The PI will spot all participants behind the bench with hands ready to catch the barbell. For the vertical jump test, participants will stand on a mat and jump straight up in the air to hit and/or move the rung. This will be performed on a mat to allow for a softer landing. The vertec is a piece of equipment used to measure leg power which is the result of leg strength. The vertec includes several mobile rungs. A standing reach height is measured first and then a jump height is measured. The reach height is measured by the participants extending their arms overhead in the air and walking past the vertec to move the rungs with their fingers. The jump height is measured by the rung that the participant hits/touches when he/she jumps straight up. The participant will jump three separate times with rest in between each. The participant is able to control when he/she wants to stop and therefore, the participant does not have to jump all three times. The PI will demonstrate all assessments and allow participants to ask questions throughout. The aerobic and resistance training activities that are a part of the intervention session will take place in the dance studio in Hytche Athletic Complex. The dance studio will have all equipment related to the session in the room. Some of the

aerobic and flexibility activities will take place in the main arena in Hytche Athletic Complex on the track.

4. Risks & Anticipated Benefit Analysis
   a. Risks associated with participation in this study will include low to moderate cardiovascular and/or muscular fatigue, also known as delayed onset muscular soreness (DOMS), associated with a new mode of activity/bodily movements that may or may not be a part of the participant's normal routine. Aerobic and resistance training will result in an increase in heart rate which may be uncomfortable for participants. Additionally, resistance training may cause an increase in heart rate and blood pressure as a result of low to moderate exertion. Cardiovascular and/or muscular fatigue and DOMS are normal for adults to experience at the start of physical activity. It is also normal for DOMS to occur with adults who have a history of being physically active. Risks associated with a vertical jump include knee discomfort. To minimize knee discomfort, the participant will complete the assessment on an exercise mat which will soften the impact when landing. The participant is also permitted to complete one jump or no jumps at all, if applicable.

      BIA is free of radiation and there are no known associated risks with this. The participant, however, may experience emotional discomfort from his/her body weight, body fat, and/or waist being measured. The PI will provide encouragement to the participant and remind them of the purpose of the research study. The PI will also ask the participant if he/she would rather not know their individual measurements. Lastly, the participant will be reminded that he/she may withdrawal from the research study at any time.

   b. To minimize cardiovascular and muscular fatigue (DOMS) associated with a new mode of activity/bodily movements, participants can withdraw from the activity and/or exercise session at any time. Also, weeks one and two of the study will only use the participant's body weight to allow for a gradual adaptation of new activity/bodily movements. Participants will also be introduced to the new movement before it is introduced as a part of the program. To minimize discomfort associated with an increase in heart rate, participants will be reminded that they can take rest as needed and that they may also withdraw from the session and/or study whenever they choose. To minimize the effect that resistance training can have on blood pressure, the National Strength and Conditioning Association (NSCA) recommends aerobic, steady-state activity, such as walking proceed resistance training sessions. A 10-minute recovery period is a part of the 60-minute training session. During this time participants will walk or ride a non-weight bearing cardio machine.

      Apparently healthy participants and/or those participants cleared by a physician to participate, still may be terminated by the principal investigator if participants' ratings of perceived exertion with an activity is too high. The Borg Rating of Perceived Exertion Scale is a scale used to monitor intensity during exercise. This scale has since been updated to the revised category ratio scale, CR10. The scale originally went from 6 to 20 with 6 being no exertion at all and 20 being maximal exertion. The revised/updated scale goes from 0 to 10. The scales correlate with exercise heart rates. Three revised CR10

color-coded posters will be hung around the dance studio. Participants will be asked to rate themselves throughout each 60-minute session. A detailed description of the scales is included with the IRB materials that are attached.

c. The participants will be the direct beneficiaries of this study. Currently, there are limited to no opportunities for community residents to be physically active. Somerset County has the highest physical inactivity and physical health levels among surrounding counties. Expected benefits include improved weight maintenance, body composition, and health-related physical fitness. Participants can also expect to learn proper form and technique with flexibility, calisthenics, and resistance training exercises. Participants will also gain an understanding of how they can maintain physical activity levels despite the conclusion of the intervention. This study will contribute to existing research on health-focused community-health intervention programs in rural areas.
d. Since the study is open to Somerset County community residents, the benefits will be distributed fairly. Participants will engage in the same program and receive the same services. It must be noted that participants may receive different levels of benefits based on individual motivation, consistency, and initial starting point in regards to physical activity. Children are not included in this study because children require a different training regime due to physical and neurological limitations associated with participation in a training session. Additionally, it is not appropriate for pregnant women to participate in this program. It would be difficult to assess changes in body composition and components of physical fitness as pregnant women undergo physiological changes that are relevant to being pregnant. For example, pregnant women may have a higher resting heart rate, lower aerobic capacity and/or exercise tolerance, and higher body fat levels. The purpose of this program contradicts some of the changes expected to take place with pregnant women and therefore the risks associated with their participation outweigh the potential benefits.

5. Privacy/Confidentiality
   a. Confidentiality of subjects' identification and information collected will be maintained on a password-protected laptop loaned by the principal investigator by UMES. The laptop is kept in locked office. The principal investigator is the only individual who will have access to the computer. The middle name of the subject will be used for assessing before and after intervention changes. The participant's middle name will be used to generate a pseudonym. The key/code for the pseudonym will be kept on the same file that data is being stored on. The principal investigator is the only individual who will see individual test results. The participant may be given their own results after completion of the assessments for personal use. The principal investigator will not share individual test results with anyone other than with the participant. Before and after test results will be used for research purposes to determine effectiveness of the intervention however, the middle names of the participants will be removed from the data/file since it will no longer be needed. The key/code will be deleted.

   b. Information collected from the participants will not be shared with other participants. The principal investigator is the only individual who will have access to the information collected. If participants would like to know the information being collected from

him/herself, this information will be shared with the participant. Information collected from each participant will be done on an individual basis in the exercise science lab. The exercise science lab is located in the Department of Kinesiology in Hytche Athletic Complex on UMES campus. The PI will put the data into an excel spreadsheet. The PI will ask each participant if he/she would like a copy. Each individual session for the collection of measurements and assessments will be by appointment only. The information collected from the participants will be stored on a password protected laptop that only the principal investigator has access to. The participant's middle name will be used to identify their pseudonym until the conclusion of the intervention. Once the intervention ends, the participant's middle name and pseudonym will be deleted from the key/file and numbers will replace the names.

6. Informed Consent
   a. See attachment.
   b. Interested participants may call, email, or access the google form through the link provided by the principal investigator on the invitation to participate. Once the participant expresses interest by providing their contact information, an individual appointment will be scheduled to explain the study and the procedures. The informed consent, ACSM screening algorithm, PARQ+, and supplemental informed consents, if applicable, will be explained to the participant. The participant will be given time to ask questions. If the participant is still interested in participating, he/she will be asked to sign the documents. At these individual meetings, each participant will be provided a copy of the informed consent for him/her to keep.

   c. The readability report for the informed consent was over 12^{th} grade with an age of 19 to 20 years old.
7. Research Plan for Collection, Storage, and Analysis of Data
   a. Data will be collected using a tape measure and a bioelectrical impedance analysis (BIA) device. Participants will be asked to complete a fitness test which includes a bench press, vertical jump, pushup, curl up, and either a 1-mile walk or 1.5 run/walk test. Data collected is what the participant completes through counting or by using a stopwatch. Participants can choose not to complete some or all of the fitness test. The PI is responsible for supervising all sessions. The PI is certified through both national certifying organizations, the National Strength and Conditioning Association and the American College of Sports Medicine, for exercise program design, implementation, and safety. The PI is required to maintain three certifications through pre-approved continuing education through the certifying organization as well as maintaining a current Cardiopulmonary Resuscitation (CPR) and Automated External Defibrillator (AED) certification. Additionally, there is a licensed athletic trainer working in Hytche Athletic Complex.

   b. Data will be stored in an excel spreadsheet on a password-protected laptop loaned to the principal investigator from the university. The PI is the only individual who has access to the laptop.

c. Data will be analyzed for the mean and standard deviation of pre and post individual assessment data as a result of the intervention sessions. ANOVA with significance set at $p<0.05$ will be used to determine the significance of the change in body weight, composition, waist circumference, and measures of fitness that may or may not have occurred. The mean and standard deviation of scores, pre and post, will be calculated and reported.

d. The PI is the only individual who will have access to the data. Participants may request a copy of personal measurements/assessments prior to the conclusion of the study as pseudonyms may be replaced with numbers.
e. The data will be kept for three years at the conclusion of the study.
f. After the three-year period, the file will be deleted from the computer and the deleted folder will be emptied.

8. Conflict of Interest
   a. Potential conflict of interest includes receiving a grant from Somerset County Health Department (SCHD) for the development and implementation of a health intervention program for adults in Somerset County. This research effort and collection of data is not a condition of the funding received. This project may be carried out without intentions of a publication and/or presentation however, it has the potential to contribute to a body of knowledge on community health interventions and how they may be implemented. Additionally, results obtained from this project will be useful in applying for additional funding opportunities that will benefit the surrounding community. A narrative will be shared with SCHD at the completion of the project however, no raw data will be shared. The narrative will include results from the data analysis. The funding covers the equipment that will be needed, supplies for the participants, and salary. Equipment will include items such as the most accurate BIA home device, medicine/physio balls, exercise mats, stretching bands, and dumbbells. Supplies will include items such as hand towels, water, sanitizing wipes, and post-session snacks. Salary will be given to the PI for development and implementation of the intervention. This conflict will not affect the level of risk to the study participants and will be disclosed in the informed consent. Additionally, disclosure of this conflict of interest will be included in publications and/or presentations of the study results.

9. HIPPA Compliance
   a. This research includes the collection of protected health information. The participant's anthropometrics (body weight and waist circumference) and body composition (BIA) will be recorded at the beginning and again at the conclusion of the 12 weeks. The PI, however, will not be contacting health care providers for any reason. Participants are allowed to receive a copy of personal measurements and/or assessments to give to their physician if it is requested prior to the conclusion of the study. Pseudonyms will be replaced with numbers therefore it will be impossible to determine a specific individual's results at the conclusion of the study. The health screening will be an interview with the potential subject. The interview includes three questions to determine if medical clearance is needed prior to participation as a precautionary measure. The answers to

these questions will not be shared with anyone. The questions for the ACSM preparticipation screening include:

1. Do you participate in regular exercise?
2. Has a physician or other qualified health care provider ever diagnosed you with cardiac, peripheral vascular, cerebrovascular disease, or Type 1 or 2 diabetes?
3. Do you have any signs or symptoms suggestive of cardiovascular, renal, or metabolic disease including but not limited to: pain/discomfort in the chest, neck, jaw, or arms; shortness of breath at rest or with mild exertion; dizziness during exercise, ankle edema, palpitations (awareness of rapid beating of the heart) or tachycardia; or unusual fatigue or shortness of breath with usual activities?

The ACSM screening on a separate attachment will show how medical clearance is determined. Since the ACSM screening is limited in some regard, a Physical Activity Readiness Questionnaire Plus (PARQ+) will also be used as a precautionary measure prior to participation to gather additional information. The PARQ+ is located on a separate attachment. There is a line drawn through specific information related to a condition and/or medication because that information is not needed. The PARQ+ will be printed for the participants and the "please list" will be blacked out so that participants do not include this information. The information collected from the PARQ+ is only used to confirm whether or not the participant will need to obtain medical clearance prior to participation in any of the assessments and activities. The information is also used to determine proper exercise prescription for the intervention based on the participant's current state of health. The participant will be asked to sign the document. The information collected from this will be stored in a sealed envelope that will be kept in a locked cabinet in the PI's office. The PI is the only individual who has a key to the cabinet.

b. The responses from the interview will be used to determine if medical clearance is necessary to participate in the study as a precautionary measure.

References

American College of Sports Medicine. (2021). *ACSM's guidelines for exercise testing and prescription, eleventh edition.* Philadelphia: Wolters Kluwer.

Centers for Disease Control and Prevention. (2021, October 20). *Radiation and Your Health*. U.S. Department of Health and Human Services. Retrieved October 13, 2022 from cdc.gov/nceh/radiation/dexa-scan.html

Community Health Needs Assessment 2019. (2018). Peninsula Regional Medical Center and Wicomico and Somerset County Health Department. https://somersethealth.org/wp-content/uploads/2017/03/commuity-heath-needs-assessment-2019.pdf

Informed Consent

Title: The Implementation Of A Community Health-focused Intervention Using Combined Aerobic and Resistance Training Protocols In A Group Setting

Statement of Age of Subject
I state that I am over 18 years of age, in good physical and mental health, and wish to participate in the research study being conducted by [redacted] in the Department of Kinesiology.

Purpose
The purpose of this project is to provide a 12-week intervention focused on a combination of aerobic and resistance training exercise for adults residing in Somerset County, Maryland.

Procedures
To participate in this study, you will need to read and sign this document. After the signing of this document, you will be asked to complete a Physical Activity Readiness Questionnaire Plus (PAR-Q+). An American College of Sports Medicine (ACSM) screening algorithm will be used to determine if medical clearance is needed prior to participation in this study. If medical clearance is needed to participate, you will be asked to visit your primary care physician for clearance to participate.

You will also be asked to complete preliminary fitness tests which will include the curl up, the pushup, bench press, vertical jump, and the Rockport 1-mile or 1.5 mile walk test. Physical assessments will include body weight, waist circumference, and body composition testing. These assessments will be completed again at the conclusion of the intervention. The data collected from these assessments will be analyzed without any identifying information.

You will be a part of a 12-week intervention which will include a variety of flexibility, aerobic, and resistance training activities. Each session will last for 60 minutes, and the PI will oversee the entire session.

Confidentiality
The principal investigator is the only individual who will see and be able to access individual data that is collected from the assessments. The data will be kept on a password-protected laptop assigned to the PI by the university. This information will not be shared with anyone other than with the participant themselves, if asked. Results from this study may also be used for scientific purposes however, all pseudonyms used will be removed at the conclusion of the intervention and therefore the PI will not be able to disclose any information to program participants.

A description of the clinical trial will be available http://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.

_____ (Printed name, date) **_____(Signature)**

Risks
Participation in this study may involve cardiovascular and/or muscular fatigue and delayed onset muscular soreness at the onset. Participation in aerobic and resistance training will result in an increase in heart rate and blood pressure which may be uncomfortable for you. The increase in heart rate and blood pressure is the result of low to moderate exertion. The results from the initial assessments may cause emotional discomfort due to increased awareness of your current physical state. A vertical jump, which is a part of the assessments may cause knee pain and/or discomfort. To minimize pain and/or discomfort that may be associated with a vertical jump, you would complete the jump on a cushioned exercise mat. You may also choose not to jump at all. Bioelectrical Impedance Analysis (BIA) is free of radiation and will be used to determine body composition and body mass index. There are no known associated risks with BIA.

Freedom to Withdraw & Ask Questions
I understand that I can ask questions at any time during my participation and that I can withdraw from the study at any time without penalty. I also understand that I can take rest as needed and it will not affect my participation in the study.

Benefits
Expected benefits are individualized and may include improved weight maintenance, body composition, and/or health-related physical fitness levels with consistency. You may receive a copy of pre and post assessment results for personal use. You can also expect to learn proper form and technique with flexibility, calisthenics, and resistance training exercises. You may also expect to gain knowledge about how to continue being physically active despite the conclusion of the intervention. This study will also contribute to existing research on health-focused community-health intervention programs in rural areas.

Conflict of Interest
A potential conflict of interest includes the PI receiving a grant from Somerset County Health Department for the development and implementation of a health intervention program for adults in Somerset County. This research effort and collection of data is not a condition of the funding received. The funding covers the equipment, supplies, and salary.

Where Medical Care is Available
In the event of injury resulting from participation in this study, I understand that immediate medical treatment is available nearby at Tidal Health. However, I understand that the University of Maryland Eastern Shore does not provide any medical or hospitalization insurance coverage for participants in the research study nor will the University of Maryland Eastern Shore provide any compensation for any injury sustained as a result of participation in this research study except as required by law.

Conclusion
You are making a decision whether or not you will participate in this study. If you give consent, you are agreeing to participate based on your reading and understanding of this form.

_____ (Printed name, date) _____(Signature)

If you have any questions regarding this study, please with[redacted] please contact the Chair of the Institutional Review Board at[redacted]

_____ (Printed name, date) **_____(Signature)**

Supplemental Informed Consent

Pregnancy Statement

I state that I am of childbearing potential however, I am not currently pregnant. To avoid the risk of becoming pregnant, I agree to safety measures (such as contraception or abstinence, for example) as I participate in this research study.

_____ (Printed name, date) _____(Signature)

UNIVERSITY OF MARYLAND EASTERN SHORE

Department of Kinesiology

[redacted]

[redacted]

"The Implementation Of A Community Health-focused Intervention Using Combined Aerobic and Resistance Training Protocols In A Group Setting"

Date: February 21, 2023

Subject: Amendment to IRB Protocol #11-2022-004

This amendment requests the additional use of a Bod Pod to assist in analyzing body composition periodically, at the 8-week point and again at the 12-week point. The 8-week point would be the second week of March and the 12-week point would be the first week of April. The principal investigator (PI), myself, will operate the bod pod. The PI completed the 2-hour training session with the representative from COSMED, the Bod Pod manufacturer. The Bod Pod is in the new School of Pharmacy and Health Professions building in room 3114, on the campus of University of Maryland Eastern Shore, registered to the department of kinesiology room. The Bod Pod is a large egg-shaped device that uses air displacement to calculate body density (body mass/volume). The device predicts body fat percent and fat free mass from various body density equations depending on the subject's race or ethnicity, age, gender, and predicted thoracic gas volume. The thoracic gas volume may be predicted and determined by the device, or it may be completed manually. This protocol will have the Bod Pod device predict and determine thoracic gas volume while the subject is sitting inside the Bod Pod.

To increase the accuracy of the Bod Pod, subjects must wear tight-fitted clothing such as spandex/tights or single-layer compression shorts and a sports bra or camisole for females. The subject's hair is also secured under a tight-fitted cap supplied by the department of kinesiology. The department will supply each participant their own plastic shower cap to put between their hair and the required tight-fitted cap that comes with the Bod Pod. Jewelry is not allowed to be worn and cell phones cannot be taken inside the chamber. Socks may not be worn either. The subject's body weight is measured by a scale that is calibrated for use with the Bod Pod. The subject will be asked to stand on the scale and then step off the scale once body weight has been determined. The body weight will automatically be loaded to the software program on the connected computer. The software program is called Omnia which is where all the information collected will be stored. The computer that includes this software program is

username and password protected. Five individuals, including myself, know the username and password to log on to the computer to access the software. The individuals who know the log in information work in the department of kinesiology. The computer is attached to the Bod Pod and therefore, it cannot be removed from the room. The room is locked at all times. The administrative assistant in the office of the dean and, potentially, the campus police are the only individuals who have access to the room. Neither know the username nor password for the computer.

After stepping off the scale, the subject would then be asked to step in and sit in the Bod Pod chamber which includes a large glass window for the participant to look out of. The subject will be instructed to sit and remain still as possible while the analysis is taking place. The Bod Pod door will be closed and opened following on-screen prompts. The door will be opened twice in timed intervals while the subject remains seated and still as possible. The door opening and closing allows the Bod Pod device to calculate consistent readings in terms of the air that has been displaced by the subject sitting inside the chamber. The subject will be told that the entire process takes about three minutes, if there are no interruptions or errors with the device causing a repeat of the steps, including all the intervals with the door opening and closing. Once the on-screen prompt says the analysis is complete, the PI will open the door and allow the subject to put any additional clothing back on. The results will then be shared with the subject. The results may also be printed out for the subject and the PI to receive a copy. Individual subject data from the analysis will be identified on the software program as colors. The PI will have a key for these colors. The key will identify which color goes with which subject's middle name. The subject's middle name was initially used during the first week of the pre-assessment and preliminary fitness test. A color is now being used as a second layer since four other departmental members have access to the Bod Pod device and software program. The PI will not share the colors with anyone. The key for the colors and the Bod Pod analysis will be kept in the locked cabinet where the signed informed consents are.

Contraindications associated with the addition of this body composition device include claustrophobia. In addition to this, subjects may be self-conscience or uncomfortable with wearing tight-fitted, spandex shorts and a sports bra or camisole. Other risks include emotional discomfort as a result of seeing the analysis results related to their body composition. To minimize risk associated with claustrophobia, subjects will be allowed to complete a practice analysis of which they will be allowed to remain fully dressed. If during or after the practice analysis, the subject chooses not to complete the Bod Pod assessment, the subject is free to leave the room but may continue with the intervention without this assessment. If after the practice analysis the subject desires to run through the real analysis but then midway through decides they do not want to, the PI may click the 'abort' button to stop the analysis to allow the subject to come out of the chamber. On the inside of the chamber, the subject also has the ability to stop the test as well. The subject would be informed that they may press the 'blue' button which is on the chamber seat. The chamber is not locked however the PI must open the door. To minimize the discomfort with the required attire, a large sheet will be placed over the room's front window. In addition, the subject may choose not to complete the Bod Pod analysis at all. The accuracy of the analysis requires tight-fitted clothing such as spandex and

this will be explained during the (updated) informed consent process. Lastly, to minimize emotional discomfort associated with seeing the results from the analysis, the subject will receive positive reinforcement and encouragement as having made it to the 8-week and/or 12-week point. The PI will emphasize to the subject that they should view the results as a motivational tool only.

To increase the accuracy of the Bod Pod analysis, subjects should restrict their eating and exercise up to two hours before the assessment takes place. As a result, all the subjects will be tested on a non-intervention (exercise) session day of their choice. Subjects may be hungry since they would not have eaten for two hours and therefore, the PI will have a supply of snacks in the room for the subject after the assessment. Snacks will include the normal post-intervention snacks that the subjects are already familiar with. These snacks include dried fruit, nuts, and protein bars.

Since jewelry cannot be worn, the subject will be asked to place their jewelry in a safe place with the other belongings that he/she has brought to the analysis session. Since the subject may be uncomfortable with this, the PI will re-emphasize that the analysis is about three total minutes, if there are no interruptions or errors with the device causing a repeat of the steps, and they are free to put the jewelry back on as soon as the chamber door opens back up at the conclusion of the analysis. Since a cellphone cannot be taken inside the chamber, the participant will be asked to place their cellphone in a safe place and/or in a place that is comfortable for him/her. When the chamber door opens at the end of the analysis, the PI will allow the subject an opportunity to get their jewelry and cellphone prior to any discussions about the analysis if that is what the subject desires to do. Socks may also not be worn during the analysis and therefore the PI will clean the floor on the inside of the chamber with a Clorox wipe while in the presence of the subject. On the contrary, the subject will be allowed to wear their socks while they are on the body weight scale. The restriction of jewelry, cellphones, and socks may also present risks for the subject that include a lack of comfort related to losing or forgetting something that is valuable. The PI will allow the subject to take off or put away all items right before entering the chamber and the PI will allow the subject to return and get all items right after the analysis is complete and the chamber door opens. The PI will wipe the floor in the chamber with a Clorox wipe and dry it with a paper towel so that the participant can see the floor has been sanitized.

Benefits associated with the addition of this body composition device have to do with its level of accuracy comparable to bioelectrical impedance analysis devices. Measuring body density is used as a criterion standard for assessing body composition. Underwater weighing and DEXA have since been considered the criterion measure. However, use of the Bod Pod reduces the challenges/risks associated with being submerged in water and/or being exposed to radiation (ACSM, 2021). The inclusion of the Bod Pod allows the body composition results to be more reliable.

American College of Sports Medicine. (2022). *ACSM's guidelines for exercise testing and prescription 11th edition.* Philadelphia: Wolters Kluwer.

Informed Consent

Title: The Implementation Of A Community Health-focused Intervention Using Combined Aerobic and Resistance Training Protocols In A Group Setting

Statement of Age of Subject
I state that I am over 18 years of age, in good physical and mental health, and wish to participate in the research study being conducted [redacted] in the Department of Kinesiology.

Purpose
The purpose of this project is to provide a 12-week intervention focused on a combination of aerobic and resistance training exercise for adults residing in Somerset County, Maryland.

Procedures
To participate in this study, you will need to read and sign this document. After the signing of this document, you will be asked to complete a Physical Activity Readiness Questionnaire Plus (PAR-Q+). An American College of Sports Medicine (ACSM) screening algorithm will be used to determine if medical clearance is needed prior to participation in this study. If medical clearance is needed to participate, you will be asked to visit your primary care physician for clearance to participate.

You will also be asked to complete preliminary fitness tests which will include the curl up, the pushup, bench press, vertical jump, and the Rockport 1-mile or 1.5 mile walk test. Physical assessments will include body weight, waist circumference, and body composition testing. These assessments will be completed at week 8 and week 12 of the intervention. Body composition assessments will include a Bioelectrical Impedance Analysis (BIA) device and a Bod Pod. You will be asked to hold the BIA device which is a few ounces or less and stand in a relaxed position. The Bod Pod is a large egg-shaped device that uses air displacement to calculate body density (body mass/volume). The device predicts body fat percent and fat free mass from various body density equations depending on your race or ethnicity, age, gender, and predicted thoracic gas volume. While the Bod Pod analysis is taking place, you will be asked to sit in a relaxed position inside of the chamber. The data collected from these assessments will be analyzed without any identifying information.

You will be a part of a 12-week intervention which will include a variety of flexibility, aerobic, and resistance training activities. Each session will last for 60 minutes, and the PI will oversee the entire session.

Confidentiality
The principal investigator is the only individual who will see and be able to access individual data that is collected from the assessments. The data will be kept on a password-protected laptop assigned to the PI by the university. This information will not be shared with anyone other than with the participant themselves, if asked.

_____ (Printed name, date) **_____(Signature)**

Results from this study may also be used for scientific purposes however, all pseudonyms used will be removed at the conclusion of the intervention and therefore the PI will not be able to disclose any information to program participants.

A description of the clinical trial will be available http://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.

Risks

Participation in this study may involve cardiovascular and/or muscular fatigue and delayed onset muscular soreness at the onset. Participation in aerobic and resistance training will result in an increase in heart rate and blood pressure which may be uncomfortable for you. The increase in heart rate and blood pressure is the result of low to moderate exertion. The results from the initial assessments may cause emotional discomfort due to increased awareness of your current physical state. A vertical jump, which is a part of the assessments may cause knee pain and/or discomfort. To minimize pain and/or discomfort that may be associated with a vertical jump, you would complete the jump on a cushioned exercise mat. You may also choose not to jump at all. Bioelectrical Impedance Analysis (BIA) is free of radiation and will be used to determine body composition and body mass index. There are no known associated risks with BIA.

Known contraindications associated with the addition of the Bod Pod device include claustrophobia. In addition to this, you may be self-conscience or uncomfortable with wearing tight-fitted, spandex shorts and a sports bra or camisole. Other risks include emotional discomfort because of seeing the analysis results related to their body composition. To minimize risk associated with claustrophobia, you will be allowed to complete a practice analysis of which they will be allowed to remain fully dressed. If during or after the practice analysis, you choose not to complete the Bod Pod assessment, you are free to leave the room but may continue with the intervention without this assessment. If after the practice analysis you desire to run through the real analysis but then midway through decides they do not want to, the PI may click the 'abort' button to stop the analysis to allow you to come out of the chamber. On the inside of the chamber, you also can stop the test as well. You will be informed that you may press the 'blue' button which is on the chamber seat. The chamber is not locked however the PI must open the door. To minimize the discomfort with the required attire, a large sheet will be placed over the room's front window. In addition, you may choose not to complete the Bod Pod analysis at all however, the accuracy of the analysis requires tight-fitted clothing such as spandex. Lastly, to minimize emotional discomfort associated with seeing the results from the analysis, the PI will provide positive reinforcement and encouragement. The PI will emphasize that you should view the results as a motivational tool only.

To increase the accuracy of the Bod Pod analysis, you should restrict eating and exercise up to two hours before the assessment takes place. As a result, you will be tested on a non-intervention (exercise) session day of your choice. You may be hungry since you would not have eaten for two hours and therefore, the PI will have a supply of snacks in the room for you after the assessment.

_____ (Printed name, date) _____(Signature)

Snacks will include the normal post-intervention snacks that you are already familiar with. These snacks include dried fruit, nuts, and protein bars.

Since jewelry cannot be worn, you will be asked to place your jewelry in a safe place with the other belongings that you have brought to the analysis session. Since you may be uncomfortable with this, the PI will re-emphasize that the analysis is about three total minutes, if there are no interruptions or errors with the device causing a repeat of the steps, and you are free to put the jewelry back on as soon as the chamber door opens back up at the conclusion of the analysis.

Since a cellphone cannot be taken inside the chamber, you will be asked to place your cellphone in a safe place and/or in a place that is comfortable for you. When the chamber door opens at the end of the analysis, the PI will allow you an opportunity to get their jewelry and cellphone prior to any discussions about the analysis if that is what you desire to do. Socks may also not be worn during the analysis and therefore the PI will clean the floor on the inside of the chamber with a Clorox wipe while you are present. On the contrary, you will be allowed to wear your socks while you are on the body weight scale. The restriction of jewelry, cellphones, and socks may also present risks for you that include a lack of comfort related to losing or forgetting something that is valuable. The PI will allow you to take off or put away all items right before entering the chamber and the PI will allow you to return and get all items right after the analysis is complete and the chamber door opens. The PI will wipe the floor in the chamber with a Clorox wipe and dry it with a paper towel so that you can see the floor has been sanitized.

The Bod Pod device is free of radiation.

Freedom to Withdraw & Ask Questions
I understand that I can ask questions at any time during my participation and that I can withdraw from the study at any time without penalty. I also understand that I can take rest as needed and it will not affect my participation in the study.

Benefits
Expected benefits are individualized and may include improved weight maintenance, body composition, and/or health-related physical fitness levels with consistency. You may receive a copy of pre and post assessment results for personal use.

You can also expect to learn proper form and technique with flexibility, calisthenics, and resistance training exercises. You may also expect to gain knowledge about how to continue being physically active despite the conclusion of the intervention. This study will also contribute to existing research on health-focused community-health intervention programs in rural areas.

Benefits associated with the addition of this body composition device have to do with its level of accuracy comparable to bioelectrical impedance analysis devices. Measuring body density is used as a criterion standard for assessing body composition. Underwater weighing and DEXA have since been considered the criterion measure.

_____ (Printed name, date) _____(Signature)

However, use of the Bod Pod reduces the challenges/risks associated with being submerged in water and/or being exposed to radiation (ACSM, 2021). The inclusion of the Bod Pod allows the body composition results to be more reliable.

Conflict of Interest
A potential conflict of interest includes the PI receiving a grant from Somerset County Health Department for the development and implementation of a health intervention program for adults in Somerset County. This research effort and collection of data is not a condition of the funding received. The funding covers the equipment, supplies, and salary.

Where Medical Care is Available
In the event of injury resulting from participation in this study, I understand that immediate medical treatment is available nearby at Tidal Health. However, I understand that the University of Maryland Eastern Shore does not provide any medical or hospitalization insurance coverage for participants in the research study nor will the University of Maryland Eastern Shore provide any compensation for any injury sustained as a result of participation in this research study except as required by law.

Conclusion
You are making a decision whether or not you will participate in this study. If you give consent, you are agreeing to participate based on your reading and understanding of this form.

If you have any questions regarding this study, please with[redacted]

_____ (Printed name, date) _____(Signature)

Supplemental Informed Consent

Pregnancy Statement

I state that I am of childbearing potential however, I am not currently pregnant. To avoid the risk of becoming pregnant, I agree to safety measures (such as contraception or abstinence, for example) as I participate in this research study.

_____ (Printed name, date) _____(Signature)