Feasibility of a Train-the-Trainer Delivered Exercise Intervention in Firefighters

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University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants
Consent Form Version Date: 3/8/2023
IRB Study # 21-2522
Title of Study: Feasibility of a Train-the-Trainer Delivered Exercise Intervention in Firefighters
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CONCISE SUMMARY

The purpose of this study is to investigate the feasibility of a train-the-trainer delivered integrated exercise routine that includes a neuromuscular warm-up and high intensity interval exercise training.

If you enroll in this study, you will be assigned to the intervention or waitlist control group. All groups will attend two laboratory visits. If in the intervention group, you will take part in 6 weeks of twice a week exercise training designed to target risk factors common in the fire service between the laboratory visits. If you are in the waitlist control group, you will be asked to continue with your normal nutritional and physical activity habits. After the intervention period and second laboratory visit, you will be able to partake in exercise program should you choose.

The greatest risks of this study include the possibility of musculoskeletal injury during the exercise program or mild discomfort during the testing visits.

The benefits to you from being in this study may be that you improve your health and fitness.

If you are interested in learning more about this study, please continue to read below.

What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary.

You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care

provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this research study is to examine the feasibility of a peer-led exercise program specifically designed to target the risk factors associated with the primary fatal and non-fatal injuries in the fire service.

You are being asked to be in the study because you are a local career firefighter.

Are there any reasons you should not be in this study?
You should not be in this study if you are highly active (performing 4 or more days/week of vigorous aerobic exercise), are pregnant, have a recent injury preventing your participation in a exercise routine, or you are involved in an active workers' compensation or personal injury case.

How many people will take part in this study?
Approximately 40 firefighters from local fire departments will take part in this study.

How long will your part in this study last?
Your participation in this study will include 6 weeks of twice a week physical training where each session will be no longer than 30 minutes. Additionally, it will include two visits to the laboratory, one prior to and one following the 6-week intervention (2 hours each). You may be asked to take part in an interview after the intervention, which would be an additional 30 minutes of your time.

What will happen if you take part in the study?
If you decide to take part in this study, you will be asked to complete an informed consent document (this document), a health history, a physical activity questionnaire, and a nutritional questionnaire.

For the testing sessions before and after the exercise program, you will then have the following measurements taken:

1. You will have fasted (except for water) for at least 8 hours.
2. Women will be asked to complete a pregnancy test.
3. Body Composition
    a. You will undergo body composition analysis using DEXA and bioelectrical impedance spectroscopy (BIS). Beforehand, you will be asked to remove any jewelry. For both scans, you will be asked to lie still on your back while scan is completed. These assessments will allow us to measure how much fat, fat-free mass and water content you have.

4. Muscle Size and Quality
    a. We will use ultrasound and a peripheral quantitative tomography (pQCT) scanner to determine this size and quality of your thigh muscles. We will ask you to lay down while we scan your muscles.
5. Balance
    a. Your balance will be assessed by the Y-Balance test. While standing on one foot at the center of the three lines, you will reach as far as possible with the non-weight bearing foot in all three directions, in a rotating fashion. You will perform three trials per leg, switching legs between each trial.
6. Strength Testing
    a. The strength of your upper leg muscles will be assessed on a strength testing dynamometer, common in many Physical Therapy clinics. You will be seated in a chair and asked to push/pull against a padded lever arm that will not move at all and push against a lever arm at 40% of your max strength. You will perform 3 sub-maximal "warm-up" contractions followed by 2-3 maximal contractions for 3-4 seconds with a 90-second rest between each maximal effort for both the quadriceps and hamstrings (i.e. kicking out, pulling back). After another warm-up, we will ask you to perform 5 contractions where you push against a lever arm as fast as you can. We will also tape electrodes to your skin on your thigh muscles to see how active you muscles are when you push/pull as hard as you can.
7. Upper-body Power Test
    a. We will ask you to sit in a comfortable and sturdy chair and throw a 3-kg medicine ball in front of you (e.g. chest pass) as far as possible. You will repeat this 3 times with 30 seconds of rest in between each.
8. Vertical Jump
    a. We will ask you stand on a mat and jump up as high as you can 3 times, separated by 30 seconds of rest.
9. Muscular Endurance
    a. Lower back muscle endurance will be assessed using the prone double straight leg raise test. You will be positioned face-down on a mat with your arms under your head and legs straight. We will then ask you to raise your legs and keep them straight and off the group for as long as possible.
10. Cardiorespiratory Fitness (VO_{2peak})
    a. You will complete an exercise test on a stationary bike. You will be asked to pedal to fatigue, or until you can no longer continue. The test will start at an easy intensity (slower pace), but as the test goes on, the intensity will become more difficult. This test may increase the stress on your heart and lungs. To ensure your safety, we will monitor your heart and lungs continuously throughout the exercise test and for several minutes after the test has concluded. At the conclusion of the test, you will be allowed to cool down, stretch, and drink water as needed. This test will allow us to identify your fitness level and heart rate. This will take about 20 minutes.

<u>6-Week Exercise Program</u>

A fellow firefighter will lead you in 12 exercise sessions during the 6-week program (two sessions per week). Each session will be comprised of a warm-up followed by high intensity interval training (HIIT) on a stationary bike. Our research team will work with your fellow firefighter to help initiate this exercise training during the first 2 training sessions.

Neuromuscular warm-up: You will perform a series of dynamic stretches, core stability, balance, and medicine ball exercises. The dynamic stretches will include 8 repetitions of 6 stretches targeting the hip and thigh muscles increasing in intensity, followed by 3 core stability isometric exercises (curl-up, side bridge, and bird dog). Then you will perform 2 sets (per leg) of hop-to-stabilization (with a reach) balance exercises, followed by 3 separate medicine ball exercises emphasizing explosive full-body movements. The warm-up exercises progress in difficulty.

HIIT session: Performing HIIT will include a series of high intensity exercise bouts on a stationary bike that includes a 1:1 work-to-rest ratio. Training intensity will be progressively increased by the number of bouts and intensity throughout the 6 weeks. The number of work bouts will increase from 6 to 8 bouts.

Fidelity Assessment of the Intervention: The research team will examine how well you perform the exercises during week 2 and week 6 of the training intervention. The research team will use a rubric that will examine your execution of the exercises and if you are exercising at the prescribed intensity for the HIIT cycling exercise.

You will be asked to complete a post-testing interview about your experience during the exercise intervention.

If you participate in the interview, you will be asked to sit in a quiet room with a member of our research team and answer questions regarding the exercise intervention and being led by a fellow firefighter within your fire department. Questions will be based on the acceptability of this exercise intervention and the peer-trainer model in the fire service. The total time of the interview will be approximately 30 minutes.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. The benefits to you from being in this study may be that you improve your cardiovascular health and fitness, body composition, and/or muscle strength.

What are the possible risks or discomforts involved from being in this study?

The strength and cardiorespiratory assessments as well as the high intensity interval training will always have inherent potential for risks. However, we mitigate these by providing warm-up procedures and all testing sessions will be performed in a supervised setting. With any exercise, there is a small risk for dizziness, muscle soreness, or even a cardiovascular event (<1%). Because of the short nature of the high intensity bouts, risk of dizziness is reduced; rest periods allow for greater blood flow, reducing the risk. Additionally, there will be three trained research personnel that will be present for maximal testing as well as a licensed professional on call and an operational AED (defibrillator) within 10 feet of the testing area. The risk for injury during

the tasks performed in this study are no different than the risk you would experience with regular exercise routines or with regular worksite tasks.

Many of the investigators have years of experience with these testing protocols and are certified strength and conditioning specialists through the National Strength and Conditioning Association. All study personnel are American Heart Association CPR and AED certified.

This research study also involves exposure to radiation from 2 DEXA and 2 pQCT scans. Please note that this radiation exposure is not necessary for your medical care and is for research purposes only.

The average person in the United States receives a radiation exposure of 0.3 rem (or 300 mrem) per year from natural background sources, such as from the sun, outer space, and from radioactive materials that are found naturally in the earth's air and soil. The dose that you will receive from participation in this research study is less than amount you receive from these natural sources in one year. Radiation emitted during one DEXA scan is approximately 0.15 - 0.8 mrem; this amount is approximately equivalent to the radiation exposure you receive in one day from background radiation. The amount of radiation you will receive in this study has a minimal risk and is below the dose guideline established by The University of North Carolina Radiation Safety Committee for research subjects.

There may be uncommon or previously unknown risks. You should report any problems to the researcher. Pregnancy tests will be done on all females who might be able to get pregnant at the start of the study at the cost of the research team.

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?
To protect your privacy and confidentiality, your data will be stored with an alpha-numerical identification code instead of your name. The principal investigator will create the key linking names to their respective codes, and this key will be stored separate from the data in a secure filing cabinet. Data from study documents will be transferred to a designated research computer with password protection access, which will only be accessible by members of the research team. At the end of the study, the key linked to participant names will be shredded and disposed of properly. Participants will not be identified in any report or publication about this study.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

Audio recordings will be taken during the entirety of the interview. These recordings will be saved and stored on an external hard drive with no other identifiable data and be used for data analysis. Once data analyses are completed, the video recordings will be kept for one year following the completion of the study. Participants will not be identified in any report or publication about this study. We may use de-identified data and/or specimens from this study in future research without additional consent.

What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or injury from being in this study. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. The University of North Carolina at Chapel Hill has not set aside funds to pay you for any such reactions or injuries, or for the related medical care. You do not give up any of your legal rights by signing this form.

If you think you have been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form. They will let you know what you should do.

By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped. Your participation in this study will have no influence on your employment status. If you withdraw or are withdrawn from this study, all data collected up until the point of withdrawal will be retained.

Will you receive anything for being in this study?

You will be receiving a free t-shirt and $100 for taking part in this study as compensation for your time and effort after completion of the exercise program and testing sessions. If you do not complete the entirety of the study, then the stipend will be pro-rated and you will receive ($20) following pre-testing. The t-shirt will be provided following pre-testing. You will receive 6-weeks of free training prescribed by exercise professionals. You will also receive free body composition assessments before and after the exercise program.

Will it cost you anything to be in this study?

It will not cost you anything to be in this study. You will be provided with a free parking pass to park outside of Fetzer Hall for the two laboratory testing sessions.

Who is sponsoring this study?

This research is funded by Centers for Disease Control and Prevention (CDC) (the Sponsor). This means that the research team is being paid by the sponsor for doing the study.

If you would like more information, please ask the researchers listed in the first page of this form.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____
Signature of Research Participant

_____
Date

_____
Printed Name of Research Participant

_____
Signature of Research Team Member Obtaining Consent

_____
Date

_____
Printed Name of Research Team Member Obtaining Consent