Sam Houston State University
Consent for Participation in Research

KEY INFORMATION FOR *Improving Firefighter Occupational, Physical, and Cognitive Performance with Short- and Long-Term Creatine Monohydrate Supplementation Coupled with Resistance Training*

You are being asked to be a participant in a research study about whether the effects of creatine monohydrate supplementation, compared with a placebo, combined with a structured resistance training program, can improve physical performance, cognitive function, and occupational readiness in firefighters. You have been asked to participate in the research because you are a career male or female firefighter with the Lake Travis Fire Department (LTFD) or Fort Worth Fire Department (FWFD), and may be eligible to participate.

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

The purpose of this study is to examine how creatine monohydrate (CrM) supplementation—during both a short-term loading phase and a long-term maintenance phase—combined with resistance training, affects firefighter occupational performance, physical fitness, cognitive function, and recovery. About 30 male and female career firefighters will be invited to participate. If you join, you will complete six total testing sessions (three lab-based and three field-based) over approximately 12 weeks. You will also participate in a structured, supervised resistance training program while taking either creatine monohydrate or a placebo.

During the study, you will complete a 7-day loading phase (20 g/day) followed by an additional 12-week maintenance phase (5 g/day) with either creatine or a placebo. You will be asked to take only the supplement provided to you during the study. At each testing session, you will provide small blood samples (about 20 mL/draw) to measure markers of health and safety; complete firefighter-specific tasks such as hose deployment, ladder carry, stair climb, and victim drag; and perform physical fitness tests including a vertical jump, a maximal treadmill cardiopulmonary exercise test, muscular strength testing (bench press and squat 1-RM), and muscular endurance tests. You will also complete computer- and paper-based cognitive tests that measure reaction time, attention, memory, and mood, along with questionnaires about stress, fatigue, and possible side effects. All sessions will be held at the LTFD or FWFD training sites and lab locations, where trained research staff and emergency medical personnel will be present for safety. By conducting this study, we hope to determine whether creatine monohydrate supplementation—when combined with resistance training—can enhance firefighter occupational performance, physical and cognitive capabilities, and recovery compared with a placebo. Your participation in this research will last about 12 weeks, including three 60-minute lab-based sessions and three 90-minute field-based sessions conducted at baseline, after the 7-day loading phase, and after 12 weeks of supplementation.

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

By participating in this study, you may benefit from receiving individualized feedback on your health, performance, and recovery (including blood markers, physical fitness testing, and

cognitive assessments). You will also receive compensation for your time and effort. In addition, participating in the supplementation and resistance training program may give you insight into how creatine monohydrate affects your performance, recovery, and overall well-being. While you may not experience a direct personal benefit, the information gained from this research may help improve firefighter training and performance strategies and contribute to better health and occupational readiness programs for first responders in the future.

For a complete description of benefits, refer to the Detailed Consent.

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

You might choose not to participate in this study because there are some risks, even though they are considered minimal. Blood draws may cause temporary discomfort, minor bruising, dizziness, or, in rare cases, fainting or infection at the needle site. Exercise testing may result in temporary fatigue, muscle soreness, or minor musculoskeletal strain. There is also a small chance of mild stomach upset from the creatine or placebo provided. Participation also requires a time commitment over several weeks, which may be inconvenient. This study is voluntary. Choosing not to participate will not affect your employment, training, or access to medical care. The alternative is to continue your normal diet and training routine without participation in the study.

For a complete description of risks, refer to the Detailed Consent.

DO YOU HAVE TO TAKE PART IN THE STUDY?
If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits, or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?
The person in charge of this study is Dr. Drew E. Gonzalez (PI) of the Sam Houston State University Department of Kinesiology. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: drewgonzalez418@shsu.edu or 210-788-8616. If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Office of Research and Sponsored Programs – Sharla Miles at 936-294-4875 or e-mail ORSP at sharla_miles@shsu.edu.

Sam Houston State University

Consent for Participation in Research

DETAILED CONSENT *Improving Firefighter Occupational, Physical, and Cognitive Performance with Short- and Long-Term Creatine Monohydrate Supplementation Coupled with Resistance Training*

Why am I being asked?

You are being asked to be a participant in a research study about the effects of creatine monohydrate supplementation, compared with a placebo, combined with a structured resistance training program to determine whether this combination can improve physical performance, cognitive function, occupational readiness, and recovery in firefighters. This research is being conducted by Dr. Drew E. Gonzalez of the Department of Kinesiology in the College of Health Sciences at Sam Houston State University. You have been asked to participate in the research because you are a career male or female firefighter with the Lake Travis Fire Department (LTFD) or the Fort Worth Fire Department (FWFD) and may be eligible to participate. Please read this form and ask any questions you may have before agreeing to be in the research.

Your participation in this research is voluntary. Your decision whether or not to participate will involve no penalty or loss of benefits to which you are otherwise entitled, and you may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

Why is this research being done?

This research is being done to learn whether creatine monohydrate (CrM) supplementation, combined with a structured resistance training (RT) program, can help firefighters improve physical performance, cognitive function, recovery, and occupational readiness after performing demanding job-related tasks, compared to a placebo supplement. Firefighting is physically and mentally stressful, and optimal recovery and performance are important for health, safety, and job effectiveness. In this study, participants will complete a 7-day creatine loading phase followed by a 12-week maintenance phase while participating in a firefighter-focused RT program. During this time, participants will complete three lab-based testing sessions and three field-based testing sessions to measure changes in blood markers, physical fitness, occupational performance, mood, and cognitive abilities. The risks include temporary discomfort from blood draws, normal muscle soreness or fatigue from exercise, or mild stomach upset from supplementation. The potential benefits include receiving personalized information about performance, recovery, health, and supplementation practices; compensation for time and effort; and contributing to research that could improve firefighter training, readiness, and health practices. Participation is voluntary, and the alternative is simply to continue normal diet and training without joining the study.

What is the purpose of this research?

The purpose of this research is to find out whether taking creatine monohydrate (CrM) for a short loading period and a longer maintenance period, combined with a structured resistance training program, can help firefighters improve physical performance, cognitive function, recovery, and readiness after demanding job-related tasks. Specifically, this study will compare creatine monohydrate supplementation with a placebo to determine whether CrM reduces muscle fatigue, improves strength and power, enhances cognitive performance (such as attention and memory), and supports occupational performance (such as job-specific firefighter tasks).

To answer this question, about 30 healthy male and female firefighters from the Lake Travis Fire Department and Fort Worth Fire Department will take part in a randomized, double-blinded, placebo-controlled study. Each participant will complete six testing sessions over approximately 12 weeks, including a 7-day loading phase and a 12-week maintenance phase of supplementation. This design will allow us to directly compare how creatine monohydrate versus placebo influences physical, cognitive, and occupational performance in the same individuals across different stages of the intervention.

What procedures are involved?

If you agree to be in this research, we would ask you to do the following things:

Screening and Enrollment: You will first complete an online screening and a short health history questionnaire to determine your eligibility. If you qualify, you will be invited to an orientation session where the study will be explained, you will sign informed consent, and basic measures such as your height, weight, heart rate, and blood pressure will be taken. You will also practice the computer-based and performance tests so you are familiar with the procedures.

Supplementation: During the study, you will receive either a creatine monohydrate supplement or a placebo. You will complete a 7-day loading phase (20 g per day) followed by a 12-week maintenance phase (5 g per day). The supplements will look identical so that neither you nor the research team knows which one you are receiving (this is called a double-blind study). You will be asked to take only the supplement provided to you during the study.

Resistance Training: During the 12-week maintenance period, you will participate in a structured resistance training (RT) program designed for firefighters. Training sessions will occur while on shift and will be supervised by a tactical strength and conditioning facilitator (TSAC-F). The program will include strength, power, core, accessory, and circuit-style workouts that mimic firefighter occupational tasks.

Testing Days: At baseline, after the 7-day loading period, and again after 12 weeks of supplementation, you will arrive to the testing site after fasting overnight. You will:

- Provide a blood sample taken by a trained phlebotomist.
- Answer questionnaires about side effects, stress, fatigue, and mood.

- Complete computer- and paper-based tests measuring attention, memory, reaction time, and cognitive performance.
- Perform physical fitness assessments, including a one-repetition maximum (1-RM) bench press and squat, muscular endurance tests, and a maximal cardiopulmonary exercise test (CPXT).

Testing Days (Field-Based Sessions): At the same three time points (baseline, post-loading, and post-12 weeks), you will also complete field tests. These will include:

- A vertical jump test to assess power.
- A 10-minute Fire Ground Test (FGT) that includes job-specific tasks such as hose pulls, ladder carries, stair climbs, and a victim drag performed while wearing full firefighting gear.
- Heart rate monitoring and blood lactate measurements before and after the FGT.
- Questionnaires about stress, arousal, and exertion before and after the FGT.Provide a blood sample taken by a trained phlebotomist.

Time Commitment: Your participation in the full study will last approximately 12 weeks, consisting of a 7-day loading phase, a 12-week supplementation and training phase, and six total testing sessions (three lab-based and three field-based).

Voluntary Participation: Taking part in this study is completely voluntary. You may stop at any time, and you will not be penalized if you decide not to continue.

Assignment to Groups: You will be randomly assigned to receive either creatine monohydrate or a placebo. Neither you nor the research team will know which supplement you are receiving at the time (double-blind study).

Your participation will take about 12 weeks from start to finish, including all testing sessions and the resistance training program.

Frequency of Procedures: You will complete three full testing cycles (baseline, after the 7-day loading period, and after 12 weeks). Each cycle includes one lab-based session and one field-based session.

Location of Procedures: All procedures will take place at the Lake Travis Fire Department (LTFD) and Fort Worth Fire Department (FWFD) training facilities and laboratory testing sites. Supplements will be provided to you in pre-measured containers for daily use.

Number of Participants: About 30 firefighters from the Lake Travis Fire Department and the Fort Worth Fire Department will take part in this study.

What are the potential risks and discomforts?

Participation in this study involves minimal risks, similar to those firefighters may encounter during routine occupational training and standard medical procedures. The primary risks include:

Blood Draws (Venipuncture): Temporary discomfort, minor bruising, dizziness, or, in rare cases, fainting or infection at the needle site. These risks are generally mild, short-lasting, and reversible. All blood draws will be performed by trained phlebotomists using sterile techniques, and participants will be monitored closely.

Exercise and Performance Testing: Participants may experience fatigue, muscle soreness, or minor musculoskeletal strain, which are consistent with the physical demands of firefighting training. Testing will be conducted under supervision by trained research staff, Lake Travis Fire Department (LTFD), and Fort Worth Fire Department (FWFD) personnel. Emergency medical technicians (EMTs) will be present during testing to provide immediate medical support if needed.

Supplementation: The creatine monohydrate supplement used in this study is a standard, commercially available product that has been widely studied and is generally recognized as safe. Potential risks are limited to mild gastrointestinal discomfort, such as bloating, cramping, or stomach upset, which may occur in some individuals during the loading phase or if taken without adequate fluid intake. Rarely, participants may experience temporary water retention or mild weight gain due to increased creatine storage in muscles. Participants with known kidney disease or medical conditions that contraindicate creatine supplementation will be excluded from the study.

All procedures will follow established safety protocols. If a participant experiences any unusual or severe symptoms, testing will stop immediately, and medical evaluation will be provided if necessary. Participants may also withdraw from the study at any time without penalty.

This study does not involve experimental drugs or medical devices, and therefore, the risks are minimal and consistent with everyday activities firefighters already encounter in their occupation.

Are there benefits to taking part in the research?

There may not be any direct health benefits to you from participating in this study. However, you may benefit from receiving information on your physical performance, recovery, and nutrition to better understand your health.

You will receive $100 as compensation for your time and effort in completing the study procedures. Please note that this payment is not considered a direct benefit of research participation, but rather compensation for your time and effort.

The primary benefit of this study is to help researchers gain a deeper understanding of how creatine monohydrate supplementation, combined with a structured resistance training program, affects firefighter recovery, occupational performance, cognitive function, and overall well-being. This knowledge may be used to develop future supplementation and training strategies to support firefighters and other tactical athletes, thereby improving health, readiness, and performance in physically demanding professions.

In addition, findings from this research may benefit society by advancing scientific understanding of creatine's role in physical and cognitive performance, recovery, and occupational demands. This information may help inform broader recommendations for athletes, first responders, and the general public.

What other options are there?

The only option is not participating in the study.

What about privacy and confidentiality?

The only people who will know that you are a research participant are members of the research team. No information about you, or provided by you during the research will be disclosed to others without your written permission, except:

- if necessary to protect your rights or welfare (for example, if you are injured and need emergency care or when the SHSU Protection of Human Subjects monitors the research or consent process); or
- if required by law.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity. If photographs, videos, or audiotape recordings of you will be used for educational purposes, your identity will be protected or disguised.
Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law.

No information that could identify you will be released to anyone outside of the research team without your written permission, unless required by law. Data collected in this study will be de-identified using participant codes, and your name or personal information will not appear in any reports, presentations, or publications.

We will not be audio- or videotaping you during this study. Only written questionnaires, blood samples, and performance testing data will be collected.

All personal information (e.g., consent forms, health questionnaires) will be kept separate from your coded research data. Paper documents will be stored in a locked filing cabinet in the principal investigator's office, and electronic files will be password-protected and encrypted. Only the research team will have access to the data.

Survey and questionnaire responses will be stored securely and linked only to your participant code. Once data entry and analysis are complete, paper forms will be securely shredded, and electronic data will be retained in encrypted storage indefinitely, in accordance with SHSU IRB policy.

If researchers ever wish to use your data for any other purposes outside of this study, you would be asked for additional consent.

What if I am injured as a result of my participation?

In the event of injury related to this research study, you should contact your physician or the University Health Center. However, you or your third-party payer, if any, will be responsible for payment of this treatment. There is no compensation and/or payment for medical treatment from Sam Houston State University for any injury you have from participating in this research, except as may by required of the University by law. If you feel you have been injured, you may contact the researcher, Dr. Drew E. Gonzalez at 210-788-8616.

What are the costs for participating in this research?

There is no cost to the participant for participating in this research study.

Will I be reimbursed for any of my expenses or paid for my participation in this research?

You will be compensated for your time and effort in this study. The total payment for completing the entire study is $100. This amount reflects the time commitment required, including multiple testing sessions and blood draws. Payment will be prorated if you withdraw before completing all study sessions. Participants who complete only one part of the study will receive $30 (approximately one-third of the total commitment). Those who complete two parts will receive $30, and those who complete all three parts will receive the full $100. You will not be reimbursed for any additional expenses such as transportation, parking, or childcare.

Can I withdraw or be removed from the study?

You can choose whether to be in this study or not. If you volunteer to be in this study, you may withdraw at any time without consequences of any kind. You may also refuse to answer any questions you don't want to answer and still remain in the study. The investigator may withdraw you from this research if circumstances arise that warrant doing so.

You may choose to stop participating in this study at any time and for any reason without penalty or loss of benefits to which you are otherwise entitled. If you decide to withdraw, please inform the research team so we are aware, but you do not need to provide a reason. If you complete only part of the study, you will receive prorated compensation: $30 for completing one session, $60 for completing two sessions, and $100 for completing all three sessions.

Although rare, the investigator may withdraw you from the study if you do not follow the study protocol (for example, if you do not follow the dietary requirements or testing instructions), if it is determined that continued participation could put you at risk, or if other circumstances arise that make continuation unsafe or impractical.

Who should I contact if I have questions?

The researchers conducting this study are Dr. Drew E. Gonzalez. You may ask any questions you have now. If you have questions later, you may contact the researchers at: Phone: 210-788-8616.

What are my rights as a research subject?

If you feel you have not been treated according to the descriptions in this form, or you have any questions about your rights as a research participant, you may call the Office of Research and Sponsored Programs – Sharla Miles at 936-294-4875 or e-mail ORSP at sharla_miles@shsu.edu.

You may choose not to participate or to stop your participation in this research at any time. Your decision whether or not to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Agreement to Participate

I have read (*or someone has read to me)* the above information. I have been given an opportunity to ask questions, and my questions have been answered to my satisfaction. I agree to participate in this research.

Consent: I have read and understand the above information, and I willingly consent to participate in this study. I understand that if I should have any questions about my rights as a research subject, I can contact Dr. Drew E. Gonzalez at 210-788-8616 or by email at drewgonzalez418@shsu.edu. I have received a copy of this consent form.

Your name (printed): _____

Signature: _____ Date: _____