Open-label, 12-month Investigation to Evaluate the Efficacy of Creatine Supplementation in Adolescent Athletes

IRB #: __23-87__

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Laboratory: _Exercise and Performance Nutrition Laboratory, Lindenwood University__

Study Overview

The purpose of this study is to evaluate the efficacy and safety of 12 months of creatine monohydrate supplementation in high school athletes. While creatine is well-researched in adults and several adolescent studies have demonstrated similar efficacy results (strength, power, body composition) with no harmful effects, long-term safety data in teens are limited, and female athletes have been especially underrepresented. Understanding how creatine may influence body composition and performance in this age group is an important gap in current research.

Creatine monohydrate is a naturally occurring compound that supports short-burst, high-intensity exercise. In this study, athletes will take a standardized daily creatine powder so researchers can closely monitor safety markers, body composition, and strength and power outcomes. Creatine has an established safety record in adults and in previous adolescent research, making it an appropriate supplement to study more thoroughly in youth athletes.

Participation at a Glance

- Total Study Duration: 12 months
- Number of Visits: 6
- Time per Visit: 30-60 min each
- Supplementation: Unflavored powdered creatine monohydrate (all participants, there is no placebo involved in this study)
- Participant Pre-Visit Requirements:
    - 8-hour food and fluid fast
    - Refrain from exercise for 12 hours and unaccustomed exercise for 24 hours
    - Wear athletic clothing (without hard metal/plastic components or reflective logos) and shoes
- Compensation: $25 gift card, EPNL T-shirt, EPNL shaker cup

How to Get Started

1. Sign up for an Information Session with a research team member
2. Our team will join the call with you to discuss what the study involves, eligibility, scheduling, and most importantly to answer any questions you may have.
3. Joining the call does not commit you/your child to participation.
4. If you are interested in moving forward with participation, we can work on getting you scheduled for Visit 1 either during the call or at a later date.

Study Visit(s) Outline

	Visit 1 (Day 0)	Visit 2 (Day 7)	Visit 3-6 (3, 6, 9, 12 months)
Visit Length	30-60 mins	30 mins	30-60 mins

Consent	X		
Screening	X		
Height & Body Mass	X	X	X
Resting Heart Rate & Blood Pressure	X	X	X
Body Composition (DEXA & Styku 3D Scan)	X		X
Body Water Scan	X	X	X
Injury & Illness Questionnaire		X	X
Blood Sample Collection	X	X	X
Urine Sample Collection	X	X	X
Lower Body Strength/Power Tests (Tier 2*)	X*		X*
Supplement Daily with Creatine	Loading Phase	Maintenance Phase	
Daily/Weekly Supplement Diary	Continuous Throughout Study		
Creatine Supplementation Compliance	X	X	X
Review Adverse Event Monitoring	X	X	X
Provide Compensation and Results			X

*Tier 2 is an opt-in option. It is entirely optional - if you opt-in you will complete the lower body strength & power tests

Procedure Details

- **DEXA Scan** – A DEXA scan is a low-dose X-ray that measures bone, muscle, and body fat. Participants lie still on a padded table while a scanner passes over the body. The scanner does not touch the body and the participant will not feel anything. The test takes about 7 minutes to complete.
- **Styku 3D Body Scan** – The Styku 3D scanner uses infrared light to create a full-body digital model to measure things like limb lengths and body circumferences. Participants will wear compression clothing and a swim cap, stand on a small platform, and remain still while it rotates a full 360 degrees. This tests takes about 3 minutes total with the actual scan taking about 45 seconds.
- **Body Water Assessment** – This test estimates body water levels using a safe, very small electrical signal. Electrodes are placed on the wrist and ankle after cleaning the skin with alcohol. Participants are asked to remain still during the measurement. Participants do not feel the signal. The test will take a total of about 5 minutes.
- **Injury & Illness Questionnaire** – This short questionnaire asks whether the participant has experienced any illness or injury since the previous visit. Athletes may skip any question they are uncomfortable answering. The questionnaire should take about 5 minutes.
- **Blood Sample Collection** – A trained research team member will collect a small blood sample (about 2 tsp) using standard phlebotomy procedures from the inside portion of the participant's elbow. The blood we collect will be analyzed for markers of health and evaluated by a doctor involved with the research study to ensure your eligibility and continued safe participation in the research study.
- **Urine Sample Collection** – Participants will provide a mid-stream urine sample. A standard dipstick test will be used to measure markers of hydration, kidney, and metabolic health. The results will be included with the blood sample results and evaluated by a doctor involved with the research study.
- **Creatine Supplementation** – The research team will provide the participants with third party tested creatine monohydrate for the entire duration of the study.

Participants will take the creatine powder daily by mixing it into water or any other liquid of choice.
    - **Days 1-7:** Four 5-gram servings per day (loading phase). Participants will complete a daily supplement diary to track compliance and occurrences of adverse events.
    - **Weeks 2-52:** One 5-gram serving per day (maintenance phase). Participants will complete a weekly supplement diary to track compliance and occurrences of adverse events.
- **Lower Body Strength and Power Assessments (Tier 2 Only)** – This assessment is used to measure lower body strength and jump power.
    - **Countermovement Jumps:** Participants perform 5 vertical jumps on force plates after a warm-up. The goal is for the participant to jump as high as possible and to stick the landing.
    - **Isometric Mid-Thigh Pull:** Participants stand on force plates and pull upward on a fixed bar as hard as possible for about 5 seconds. This movement is similar to a deadlift without the bar moving. Participants will repeat this movement for a total of 3 attempts.
    - **Tier 2 Description:** These two assessments are optional. Participants and their legal guardian have the option to opt-in to these during the consent process. They add approximately 20 minutes to the testing visit duration.

Compensation & Benefits

- Total Compensation Amount: $25 gift card, EPNL T-shirt, EPNL shaker cup
- Compensation Distribution: The gift card, t-shirt, and shaker cup will be provided during the final research visit.
- Non-monetary Benefits:
    - Body Composition Results
    - Strength and Power Results (if opted into Tier 2 of the study)
    - Physician oversight of health markers measured in blood and urine throughout study involvement

Risks & Safety

- *Privacy and Confidentiality*: We are collecting data that could identify you, such as name, phone number, and email address. Every effort will be made to keep your information secure. Only research team members can see any data that may identify you.

- *Radiation Exposure:* You will have five DEXA scans completed to assess your body composition. This scan will expose you to a dose of radiation considered by medical experts to be small or trivial. The dose you will receive is similar to the same

amount of radiation you will be exposed to by living in a populated community. If you have any questions about the cumulative affects of radiation exposure, we are happy to discuss this with you.

- *Risk of Infection:* A total of six venous blood samples will be collected from you during the course of your involvement in this project. While the taking of blood samples may increase your discomfort and allow for the possibility of infection, we will ensure that you are in a comfortable, safe, and sanitary environment during all blood collection procedures. The risk of infection will be minimized by ensuring that all research team members are trained in effective phlebotomy techniques, thorough disinfection of the laboratory environment, as well as proper handling and disposal of all phlebotomy devices.

- *Risk of Gastrointestinal Discomfort from Supplement Ingestion:* In some cases, the supplement may cause gastrointestinal discomfort or distress. The dose you will be assigned to take is considered a loading or maintenance dose of creatine and has been used as part of hundreds of research studies prior to this study. If you experience nausea, vomiting, or illness, contact the research team immediately so that we can determine whether to discontinue your involvement in the study.

- *Risk of Injury or soreness:* Because you will be performing a muscular exercise test (if opted into Tier 2), it is possible that you will experience muscle soreness and fatigue. While possible you may experience an injury, it is, however, not likely. Injury risk is reduced as all tests and exercises performed are of an intensity presumed to be completed by individuals of good health and active fitness level.

Frequently Asked Questions (FAQs)

Q: Will I receive my test results?

A: Yes. You will be provided with a summary of your results for body composition and strength and power assessments (if you opted into Tier 2 testing) at the end of your participation.

Q: Can I withdraw from the study at any time?

A: It is always your choice to participate in this study. You may withdraw at any time. You may choose not to answer any questions or perform tasks that make you uncomfortable. If you decide to withdraw, you will not receive any penalty or loss of benefits. If you would like to withdraw from a study, you can contact the research team at epnl@lindenwood.edu or (636) 949-4676; the Principal Investigator, Chad Kerksick, PhD directly at (636) 627-4629 or ckerksick@lindenwood.edu. You may also contact the laboratory coordinator, Anthony Hagele at (636) 949-4785 or ahagele@lindenwood.edu.

Q: Will my information be kept private?

A: We will do everything we can to protect your privacy. We do not intend to include information that could identify you in any publication or presentation. Any information we collect will be stored by the researcher in a secure location. The only people who will be able to see your data are: members of the research team, qualified staff of Lindenwood University, representatives of state or federal agencies.

Q: What if I miss a visit?

A: Contact the research team as soon as possible. We will attempt to reschedule within the study timeframe, when possible.

Q: Do I have to be an athlete or highly trained?

A: You do not need to be a year-round or highly trained athlete to take part. You just need to have participated in a team or individual sport at some point within the last 12 months. The sport can be school-sanctioned or something you do on your own (like rock climbing). You also must be currently cleared by your school or a medical professional to participate in sports.

Q: Can I bring a friend or family member to visits?

A: Yes, you are welcome to bring a friend or family member to your visits. They will not take part in the study procedures, but they are welcome to wait in the designated areas during your appointment.

Q: What if I have dietary restrictions or allergies?

A: If you have dietary restrictions or allergies, please let the research team know. We will review them with you to ensure the study procedures and any provided products are safe and appropriate for you.

References

1. Kreider RB, Kalman DS, Antonio J, Ziegenfuss TN, Wildman R, Collins R, et al. International Society of Sports Nutrition position stand: safety and efficacy of creatine supplementation in exercise, sport, and medicine. J Int Soc Sports Nutr. 2017;14:18.
2. Wax B, Kerksick CM, Jagim AR, Mayo JJ, Lyons BC, Kreider RB. Creatine for Exercise and Sports Performance, with Recovery Considerations for Healthy Populations. Nutrients. 2021;13(6).
3. Kreider RB. Long-term creatine supplementation does not significantly affect clinical markers of health in athletes. Mol Cell Biochem. 2003;244.
4. Greenwood M. Cramping and injury incidence in collegiate football players Are reduced by creatine supplementation. J Athl Train. 2003;38.

5. Cooke MB, Rybalka E, Williams AD, Cribb PJ, Hayes A. Creatine supplementation enhances muscle force recovery after eccentrically-induced muscle damage in healthy individuals. J Int Soc Sports Nutr. 2009;6:13.
6. Hespel P, Derave W. Ergogenic effects of creatine in sports and rehabilitation. Sub-cellular biochemistry. 2007;46.
7. Jagim AR, Kerksick CM. Creatine Supplementation in Children and Adolescents. Nutrients. 2021;13(2).
8. Jagim AR, Stecker RA, Harty PS, Erickson JL, Kerksick CM. Safety of Creatine Supplementation in Active Adolescents and Youth: A Brief Review. Front Nutr. 2018;5:115.
9. Metzl JD, Small E, Levine SR, Gershel JC. Creatine Use Among Young Athletes. Pediatrics. 2001;108(2):421-5.
10. Unnithan VB, Veehof SH, Vella CA, Kern M. Is there a physiologic basis for creatine use in children and adolescents? J Strength Cond Res. 2001;15(4):524-8.

Location

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