Study Title: Effects of a Whey Protein Supplement on Performance, Recovery, and Body Composition in Adolescent Soccer Players During the Competitive Season

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Consent and Authorization Document

BACKGROUND

STUDY SUMMARY

You are being asked to take part in a research study conducted by the University of Utah's Department of Health and Kinesiology. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends and relatives if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you would like to take part in this research study.

Your participation is voluntary, which means that you are free to decide whether to be in this study. The purpose of the study is to learn about how consumption of a daily whey protein supplement during the competitive soccer season may influence performance, body composition, recovery, and sleep in adolescent soccer players. You will undergo baseline measurements, complete the 10-12 weeks (pending soccer season length)supplementation intervention which will also include additional measurements, and post-intervention measurements. We will explain each of these procedures in this Consent Form. You are being asked to participate in this research because you are an adolescent soccer player. This study is being conducted by Tanya M. Halliday, PhD, RD, a faculty member at the University of Utah.

STUDY PROCEDURES

About 60 participants will be in the study. You will be in the study about 4-months. You will be screened to find out if you should be in the study.

Summary of the study: Eligible participants that elect to continue will complete baseline evaluations. You will then complete 10-12 weeks (pending soccer season length)of a consuming either a 20g dose of whey protein or a placebo drink every day, twice a day, once after practice or competition, and once 1-hour before bed. Post-intervention testing will take place following the 10--12 week study period (pending soccer season length)..

If you decide to participate, you will be asked to undergo the following steps:

1. **CONSENT:** If you elect to participate, you will be asked to fill out the consent document.

2. Pre-Baseline Testing: Before both testing days (pre- and post-intervention) we will ask that you record your diet and exercise for 2 days leading up to each of these visits. We will ask that you perform the same diet and activity behaviors that you report before the baseline intervention testing day for the post-intervention testing day. The morning of testing days, we will ask you to

consume a study provided granola bar. The granola bar is a Chocolate Chip CLIF BAR® containing 250 calories. Allergens include soy, and may contain peanuts, tree nuts, milk, sesame, and wheat.

3. **Baseline Testing.** You will be asked to come to the University of Utah's department of Health and Kinesiology via buses from Marsh Valley High School (at no cost) for measurements of body composition, blood samples, questionnaires, and various tasks to assess performance. Because this testing is not part of a clinical assessment, you will not get any feedback on the results of the testing.

    a. Body composition: First, you will have your height, weight and level of body fat and fat-free mass measured. We will use a special BodPod device. For this test you will be asked to wear spandex-like material or a sport-style bathing suit. You will be required to change into these clothing materials as well as wear a swim cap to cover your hair (as is required for this equipment). You will change in a private bathroom that is located in the same private room where the BodPod is located. You will only be measured by study personnel of the same gender. You will sit inside a small chamber during the measurement. The chamber will fill with air while you are inside of it, this test takes approximately 5 minutes and there is no pain associated with this test.

    b. Blood sample. Next, we will collect a blood sample out of a vein in the front of your arm so we can measure inflammatory biomarkers. We are doing this to see what inflammation is occurring before and after the 10-12 week soccer season. We will attempt no more than 3 sticks. The amount of blood we are collecting at each testing day is equal to 1 tablespoon or less. After the blood draw, study provided bagels will be distributed.

    c. Questionnaires: You will be asked to complete questionnaires that will give us information about your eating and sleep behaviors and habits.

    d. Cardiorespiratory Fitness Testing: For the exercise testing, we will ask you to run 1.5 miles as quickly as they can so we can estimate how much oxygen your body can use. Next, we will ask you to sprint 30-yards, starting from a standing position, as quickly as you can. This assessment will be used to measure your maximal speed over a short distance.

    e. Muscular Fitness Assessment: You will have their muscular fitness evaluated using a machine called a Humac Norm. We will ask you to contract your leg muscles to their maximal ability at a set weight that will be heavier than you can lift. This test is to fatigue your leg muscles.

    f. Sleep measures: After baseline testing ends, and before you leave UofU, you will be provided with a Fitbit® watch (Inspire 2). Fitbit's will be used measure sleep efficiency, duration, regularity, timing, and staging. We will use a program called Fitabase to collect the data from each Fitbit®. You will be instructed to wear the Fitbit® for 1-week

straight (except during training times and when you are showering/getting wet) so that baseline sleep habits can be evaluated. You will be able to keep your Fitbit® after the study ends.

4. **Intervention:** You will be randomly selected to go into one of two groups. What random selection means is that a computer will "flip a coin" so they will be randomly assigned to one of the two groups. You will not be able to choose which group you join. One group involves consuming 20g of a whey protein drink, and the other involves consuming 20g of a placebo (control) drink. You will mix the drink powder in 8oz of water in a shaker bottle provided by study personnel, and you can keep this bottle after the study is over. Only study personnel will collect empty supplement containers, monthly, to track adherence. Timepoints may vary by ± 1 week to allow for scheduling flexibility.

    a. **Placebo:** A placebo is a dummy treatment such as a beverage which looks the same as the beverage but does not contain the ingredients. Placebos are without the ingredients in the test beverage. Study participants are given placebos so that the effects of ingredients can be compared against no ingredients. Use of placebos also prevents the participant and the researchers from knowing whether or not the subject is getting the intervention.

    b. For 10-12 weeks (pending soccer season length), we will ask you to consume your given beverage every day, twice a day, once after practice or competition, and once immediately before bed, for 10-12-weeks. This is designed so we can assess the effects of a protein drink on performance, recovery and body composition.

    c. We will evaluate the quality and quantity of your sleep with the Fitbit® provided to you, that you will get to keep after the study is over. This will be used to track your sleep time and how well you slept during the night. At 2-, 4-, 6-, 8-, 10-, 12- weeks (pending soccer season length) we will collect the average, weekly Fitbit® data. We will also ask you to fill out sleep questionnaires regarding your sleep habits, how tired you may feel, and the hours in which you were in bed.

    d. We will provide questionnaires regarding your muscle soreness and GI symptoms at 2-, 4-, 6-, 8- and 10-, 12- weeks (pending soccer season length) of the study. We will also ask you to complete an online diet recall to list what you ate and drank on three separate days, including 2 weekdays and 1 weekend day at 5- and 10- and 12- weeks (pending soccer season length).

    e. You will receive text reminders throughout the duration of the study to consume your drink. Texting will be through Twilio® which is a texting software system that study personnel will use. Data and messaging rates may apply.

    f. You may be randomly selected during the study to provide a urine sample at weeks 4 and 8 for analysis for track your supplementation compliance.

5. **Post-intervention**. At the end of the intervention, you will be asked to complete #'s 2 and 3 again (except 3.c & 3.f).

RISKS

Risks, side effects, and discomforts you may experience while in this study include:

Questionnaires: Participants will be asked to answer questions that may make them feel uncomfortable or embarrassed. To minimize this risk, only the PI and trained study personnel experienced in delivering the questionnaires used in the study will interact with research participants.

Group Setting: There is a risk of confidentiality in a group setting during the cardiorespiratory fitness testing. To reduce this risk, all study participants will be briefed on group confidentiality. All study participants will be expected not to repeat any identifying or personal information outside the group setting. Additionally, all times for completion of this testing will be recorded silently on study forms and not shared with participants. Furthermore, all testing, except the cardiorespiratory fitness testing, will be performed individually and in a private location. Therefore, there is little risk of other members besides research staff seeing any individual participants' results or testing.

Allergies: There is a risk of an allergic reaction for individuals who have not had this product before. This risk will be minimized by first asking what the participants are allergic to and monitoring any potential symptoms.

Blood draws: Subjects may experience skin irritation, mild pain, or possible infection with a needle stick. These risks are very unlikely due to the universal safety precautions taken when obtaining a blood sample. We will limit the number of sticks to no more than 3.

Communicable disease risk: There is an increased risk of spreading infectious diseases such as COVID-19 in public or group settings. To reduce this risk, we will follow procedures consistent with those of Salt Lake County and the University of Utah. Researchers will follow handwashing procedures recommended by CDC and will wear a mask.

Body Composition Measures: There is a risk of some discomfort regarding the body composition assessment. As a study team, we will do everything we can to not make you feel uncomfortable. The scale which will be utilized to obtain your weight does not have a display; therefore, you will not see your weight. You will not be provided with your BodPod results, and therefore will not be aware of your weight, BMI percentile, or body composition. As it is done in private, no other participants will see your weight or body composition either. Your body composition and anthropometric forms will be printed at a later time by study staff and added to participant folders and our Data Set when you have left.

Other Potential Risks: It is possible that you may not be open about your gender identity. To address concerns, you will complete the testing day on your team's assigned day, as mentioned above, or on the make-up day if you are not available on the main testing day.

CONFIDENTIALITY

Another potential, but unlikely, risk is a breach of confidentiality. Many steps have been taken by the research team to make sure that the confidentiality of all data collected are protected. All study data will be stored on secure servers and password-protected hard drives. Any identifying information (e.g., names) will be removed from our records and replaced with a code. A list linking the code and any identifiable information will be kept separate from the research data in a locked file cabinet in a locked room at the university. All data collected will be identified only by that code (not by your name). As a result, no one outside of the research team will know what answers you have given to any question. The fact that you participated in the research will also be confidential. Forms including your name will be kept in a locked file cabinet within a locked office, accessible only by the research team.

BENEFITS

This study is designed for the researcher to learn more about whey protein supplementation in adolescents on performance, body composition, and recovery. We cannot promise any benefits to you from your being in the study. However, possible benefits may include: increases in athletic performance; feeling better when you perform in a soccer game; improvements in your sleep.

PERSON TO CONTACT

If you have questions, complaints or concerns about this study, or if you think you may have been injured from being in this study, please contact Dr. Tanya Halliday at 801-213-1364 or tanya.halliday@utah.edu

Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

VOLUNTARY PARTICIPATION

Research studies include only people who choose to take part. You can tell us that you don't want to be in this study. You can start the study and then choose to stop the study later. We will still answer any questions you have. Your decision will not affect your relationship with the study team in any way.

COSTS AND COMPENSATION TO PARTICIPANTS

You will not be charged, nor will your insurance company be charged, for any test or visit that is completed solely for the purpose of this study. Text messaging rates may apply for reminder text messages.

You will be compensated up to a total of $195.00 in gift cards for participation on this study. Compensation will be prorated as follows:

- $50.00 for completion of baseline assessments
- $50.00 for completion of post-intervention assessments.
- $5.00 for completion of each of the ten to twelve (10-12) weeks you adhere and are compliant
- $5.00 for each sleep questionnaire completed (up to $35)
- Totaling up to $195.00.

AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION

A description of this clinical trial will be available on http://www.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.

Signing this document means you allow us, the researchers in this study, and others working with us to use some information about your health for this research study.

This is the information we will use and include in our research records:

- Demographic and identifying information like name, address telephone number, and email address
- Related medical information about you like family medical history, allergies, current and past medications or therapies

How we will protect and share your information:

- We will do everything we can to keep your information private but we cannot guarantee this. Study information will be kept in a secured manner and electronic records will be password

protected. Study personnel and athletic directors may be able to see this information.

- In order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with us on this research:
    - Members of the research team and University of Utah Health Sciences Center

- The University of Utah Institutional Review Board (IRB), which reviews research involving people to make sure the study protects your rights

- If we share your information with groups outside of University of Utah Health Sciences Center, we will not share your name or identifying information. We will label your information with a code number, so they will not know your identity.

What if I decide to Not Participate after I sign the Consent and Authorization Form?

You can tell us anytime that you do not want to be in this study and do not want us to use your health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

This authorization does not have an expiration date.

CONSENT

I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep.

I agree to take part in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.

_____
Participant's Name

_____ _____
Participant's Signature Date

_____
Name of Person Obtaining Authorization and Consent

_____ _____
Signature of Person Obtaining Authorization and Consent Date

NATIONAL INSTITUES OF HEALTH
Reporting Race and Ethnicity Data

Date of Birth	Sex/Gender □ Male □ Female

Ethnicity

1. Do you consider yourself to be Hispanic or Latino? (See definition below.) Select one.
Hispanic or Latino*. A person of Mexican, Puerto Rican, Cuban, South or Central American, or other Spanish culture or origin, regardless of race. The term, "Spanish origin," can be used in addition to "Hispanic or Latino."*

□ **Hispanic or Latino**
□ **Not Hispanic or Latino**

Race

2. What race do you consider yourself to be? Select one or more of the following.

□ **American Indian or Alaska Native**. A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliation or community attachment.

□ **Asian.** A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent, including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. (Note: Individuals from the Philippine Islands have been recorded as Pacific Islanders in previous data collection strategies.)

□ **Black or African American.** A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black" or "African American."

□ **Native Hawaiian or other Pacific Islander**. A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

□ **White.** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

□ Check here if you do not wish to provide some or all of the above information.