

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

NCT Number: NCT05589129

Document Date: 4/18/2024

# BUILD Dairy: Whey Protein Supplementation in High School Athletes

## Protocol Summary

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<b>IRB Approval Date of Current Version:</b>	4/18/2024	
<b>University of Utah IRB #:</b>	IRB_00145632	
<b>Sponsor:</b>	UTAH STATE UNIVERSITY	
<b>Principal Investigator:</b>	Tanya Halliday	
<b>Internal Staff and Sub-Investigators:</b>	<b>Site Name</b>	<b>Staff Names</b>
	University of Utah	Tanya Halliday Grace Zimmerman Victoria Miranda

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## Background and Introduction

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Proper recovery from exercise training is necessary for training adjustments to occur and for performance to be maintained or improved. Dietary amino acid (the ‘building blocks’ of protein) intake has long been known to be important in the recovery process in order to repair damaged proteins and create new proteins that are important to athletic training and performance (Trommelen & Van Loon, 2016). Muscle recovery is regulated, in part, by nutrient availability, hormones, and inflammation, and is needed for improving a muscle’s ability to perform well. Because diet directly affects nutrient availability and sleep influences hormones and inflammation, diet and sleep are critical health behaviors involved in muscle recovery. Sleep loss can worsen inflammation (Thomas, Motivala, Olmstead, & Irwin, 2011). Protein supplementation and whey protein in particular, is a common sports nutrition strategy for making new proteins in combination with resistance exercise training (Cermak, Res, de Groot, Saris, & van Loon, 2012). During a soccer game, different efforts of exercise are important in raising sport performance. Protein supplementation has been shown to increase new proteins in cells in already trained muscles (Kritikos et al., 2021; Wilkinson et al., 2008). There is also an important link between the greatest amount of oxygen someone can use by their muscles (VO<sub>2</sub>max) and distance covered by players during a soccer match (Hoff, 2005). Evidence also suggests adding protein after a rigorous session of long-lasting exercise may reduce the muscle’s muscular damage and muscle soreness created by the exercise session (Saunders, Kane, & Todd, 2004; Saunders, Luden, & Herrick, 2007; Valentine, Saunders, Todd, & Laurent, 2008). It is also important for soccer players to have a strong lower-body muscles to perform at competing levels. Protein supplementation may further increase muscle growth with resistance training exercise. This is of help to soccer players who may see increases in sport performance during a game with protein supplementation. One study showed a significant increase in lower-body strength with a protein supplement taken for 10-weeks (Willoughby, Stout, & Wilborn, 2007). However, less is known about the role of whey protein supplementation on outcomes of interest to team sport athletes. Unlike resistance training or long-distance running, team sports (such as soccer) require a mixture of alternating high- and low-intensity effort. And although findings (Vyazovskiy, 2015) suggest sleep loss can impair muscle recovery, there are no known studies investigating the potential interactions between sleep physiology and nutrition to optimize muscle recovery. Whey protein supplementation is likely important in enhancing performance, recovery, and body composition outcomes in these athletes, but limited trails have been conducted to date, and findings are inconsistent. Furthermore, it is unknown how this sports nutrition strategy would impact teenage athletes.

## Purpose and Objectives

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The overall aim of the proposed project is to compare protein supplementation on performance, recovery, and body composition changes in adolescent soccer players between the whey protein and the control group in response to the 10-week intervention. Hypothesis: We hypothesize that the whey protein group will demonstrate more favorable changes in

performance, recovery, and body composition outcomes than the control group following the 10-week supplementation period.

Secondary outcomes will include investigating interactions between sleep physiology and dietary protein on muscle recovery and performance following the 10-week intervention.

*Hypothesis:* Sleep efficiency will be higher in the whey protein supplementation group versus the placebo control. *Exploratory* analyses will examine the impact of whey protein supplementation on dimensions of sleep including duration, regularity, satisfaction, alertness, timing, and sleep staging (e.g., stage N1, N2, SWS, rapid eye movement (REM))

The **expected outcomes** will provide support for whey protein supplementation to enhance exercise performance, recovery, and body composition in adolescent, team-sport athletes. Completion of the proposed objectives (see below) will add to the sparse evidence base on protein supplementation in this unique, athletic population, and provide preliminary data for future investigations in this area. Specifically, future work could address both mechanistic questions as well as evaluation of other protein options, such as milk consumption, which could be a more cost-effective and acceptable option for youth athletes.

Objective 1: Compare the impact of 10-weeks of whey protein vs. isocaloric control on performance in high school soccer players.

Objective 2: Compare the impact of 10-weeks of whey protein vs. isocaloric control on body composition in high school soccer players.

Objective 3: Compare the impact of 10-weeks of whey protein vs isocaloric control on hunger and satiety in high school soccer players

Objective 4: Compare the impact of 10-weeks of whey protein vs. isocaloric control on sleep duration and quality in high school soccer players.

## Study Population

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**Age of Participants:** 13-18 years old

**Sample Size:**

At Utah:

All Centers: 60

**Inclusion Criteria:**

A total of 60 subjects are expected to enroll in this trial with a total of 40 completing the study protocol in its entirety to perform statistical analyses on our primary outcomes. We will recruit soccer players between the ages of 13-18 who are healthy, have no underlying metabolic diseases and have no contraindications to exercise.

**Inclusion Criteria**

1. 13-18 years old; males and females
2. High school soccer players from Marsh Valley High School in Idaho
  - a. In season, competition and practices at least 6-days/week

**Exclusion Criteria:**

Exclusion criteria: non-adolescents; untreated or underlying metabolic or cardiovascular diseases; allergies to dairy, or any allergies ingredients in the study provided granola bar or bagels, such as soy, wheat, tree nuts, peanuts, milk, and sesame.

**Design**

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Blinded Trial (Single or Double Blinded)  
Placebo Controlled Trial  
Randomized Trial

**Study Procedures**

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**Recruitment/Participant Identification Process:**

In the Spring and Summer of 2022, student-athletes on a high school soccer team, and their parents will be informed of the trial by members of the study team at in in-person informational meeting. Study personnel will go over study information and protocol in detail at this time, and no coaches will be involved with this meeting. We will provide a copy of the consent and assent documents for parents and athletes to take home. If parents and athletes want to be part of this study, we will consent individually over Zoom.

**Informed Consent:****Description of location(s) where consent will be obtained:**

Parental informed consent and permission, and participant assent (for participants under the age of 18) and informed consent (for participants 18 years of age) will be obtained over Zoom.

**Description of the consent process(es), including the timing of consent:**

Parental informed consent and permission and participant assent or participant informed consent will be completed over Zoom, with a member of the study team and the potential participant, and their parent, if applicable. This will follow the in-person information session where the study is explained to participants and parents and copies of the consent and assent forms are provided for them to take home and review prior to scheduling an informed consent visit. During the explanation of the details of the Informed Consent, Parent Permission and Assent documents, athletes and their parents will be given the opportunity to voice their questions and concerns. Also, potential participants will be briefed on confidentiality and will be asked to not talk with their teammates or peers that they are involved in this study. Each participant will be asked to not repeat any identifying or personal information about other

teammates that may be with them on their study day. Additionally, a make-up day for baseline and post-intervention testing will be in place on the UofU campus so coaches and other athletes will not be made aware of who is and is not participating, because not everyone who participates will be going on the same study day. Coaches will not be involved in the consent process and will not be told who is and is not participating in the research study. Coaches will be instructed not to ask their athletes about the research study or if they are participating. Because baseline testing and post-season testing are not during the soccer season, coaches will not know who is going to be participating. On days when study personnel pick up and distribute supplement packets, participants will be instructed to report to the gymnasium of their High School, away from their coaches and other peers. Potential participants, and parents, will be told that they are free to take more time to decide if they wish to participate/allow their child to participate; and informed that they can withdraw consent and assent at any time after enrolling in the trial.

### **Procedures:**

**Informed Consent, Parental Permission and Assent:** These will be obtained over Zoom, prior to participation in any study procedures.

**Randomization:** Randomization will occur following pre-intervention testing. Participants will be randomized via random number generator stratified by sex, and blinded into either whey protein supplement group or placebo (isocaloric) control group.

**Pre- and Post-Intervention Testing Background:** Pre- and post-intervention testing will occur over a single day for each participant at the University of Utah campus. There will be three (3) separate days of pre-intervention and post-intervention testing. One day will be for members of the “Girls’ Soccer Team”. One day for members of the “Boys Soccer Team”. The final day will be a make-up day for participants who were unable to attend with their team, but wish to participate. According to the coaches, no student-athletes openly identify as non-binary nor transgender. However, in March of 2020 Idaho’s “Fairness in Women’s Sports Act” was signed in to law. While it has yet to go in to effect, if taken up, it will prohibit transgender women and girls from competing on teams that align with their gender identity in Idaho. Thus, it is possible that individuals may not be open about this. To address concerns re: outing anyone, participants will complete the testing day on their team’s assigned day, as mentioned above, or on the make-up day if they are not available on the main testing day. Furthermore, our strategy of having make-up testing options for both pre- and post-intervention means that not all members of each team will be tested on the same day. Thus, this mitigates potential risk of coercion as teammates will not know for sure who elected to participate or not in the trial.

**Selection of School:** Marsh Valley High School in Marsh Valley, ID was selected as the test site for this study due to the following connection:

The Track and Field coach at this school comes from a family of Dairy farmers and is also a Paralympic athlete who has had a relationship with the Western Dairy Center (study sponsor) for a number of years. He inquired with WDC about doing a trial on his student-athletes, so the WDC connected the PI (Halliday) with this school for the trial. Due to large differences in athlete type and training load in track and field (sprinters, distance, jumpers, throwers),

utilizing the track and field team was not a good scientific decision. Thus, we elected to conduct this study on adolescent soccer players.

**Travel to the University of Utah:** Travel via charter buses from Marsh Valley High School in Marsh Valley, ID to the University of Utah, and back to Marsh Valley will be provided free of charge to participants. We will utilize Salt Lake Express bus charter, which is the transportation provider for Marsh Valley High School athletics. The University of Utah's Risk Management Department does not have concerns with this transportation modality (see emails in Other Documents). The charter bus will be paid for utilizing grant funding awarded to the PI (Halliday) from the study sponsor (Western Dairy Center).

**Pre-Intervention Procedures:** Before both testing days (pre- and post-intervention) we will ask that all participants record their diet and exercise for 2 days leading up to each of these visits. We will ask that they perform the same diet and activity behaviors that they report before the baseline intervention testing day for the post-intervention testing day. The morning of testing days, before departure from Marsh Valley High School, we will have them consume a study provided granola bar. The granola bar is a Chocolate Chip CLIF BAR<sup>®</sup> containing 250 calories. Allergens include soy, and may contain peanuts, tree nuts, milk, sesame, and wheat. Student-athletes will report to the Skeletal Muscle Exercise Research Facility in the morning, where they will undergo the following measures:

**Questionnaires:** Athletes will fill out gastrointestinal (GI) and sleep questionnaires. Specifically, the Munich Chronotype Questionnaire (MCTQ) (Shahid, Wilkinson, Marcu, & Shapiro, 2011), Pittsburg Sleep Quality Index (PSQI) (Smyth, 1999), a GI symptom questionnaire (Pereira, Dora IACouto Irving, Susana SLOmer, Miranda CE Powell, Jonathan J. 2014). Participants will fill out a 3-day, 24-hour ASA diet recall at baseline. This data will be uploaded to REDcap.

**Anthropometrics and Body Composition Assessment:** In a private room, all athletes will undergo non-invasive measurements of height and weight (which will be used to calculate BMI-percentile) (Kuczmarski, 2002). Each athlete will next be measured for body composition via the BodPod. The BodPod requires participants to wear spandex-like material or a sport-style bathing suit for the body composition assessment. Participants will be required to change into these clothing materials as well as wear a swim cap to cover the hair (as is required for this equipment). They will change in a private bathroom that is located in the same private room where the BodPod is located. Importantly, the scale in which participants will have their weight measured on does not have a display. The weight is displayed only on the computer, which participants will not see. Participants will not be provided with their BodPod results, and will not be aware of their weight, BMI percentile, nor body composition. As it is done in private, no other participants will see other's weight or body composition either. Participant body composition and anthropometric forms will be printed at a later time by study staff and added to participant folders and our REDcap Data Set when participants have left.

**Blood Sample:** A blood sample will be obtained via the antecubital vein, by a trained member of the CTSI Clinical Services Core (CSC). The sample will consist of about a tablespoon of blood. We will use blood samples to measure the following biomarkers: IL-6, follistatin,

adiponectin, FGF21, decorin, and cathepsin B (CTSB)(Chow et al., 2022). IL-6 will be measured to assess systemic inflammation. Follistatin is measured to assess long-term muscle growth. Adiponectin is measured to assess inflammation. FGF21 is measured to assess the function of various metabolic pathways. Decorin is measured to assess inflammation. CTSB is measured to assess correlating protein levels in the blood. Blood samples will be centrifuged, and plasma samples will be stored in a -80-degree freezer for batch analysis at the end of the study. Study provided bagels will be distributed after the blood draw.

**Cardiorespiratory Fitness Testing:** Athletes will then be escorted by study personnel to the university track and field to begin field testing. Athletes will perform a *1.5-mile test*, and a *30-yard sprint* test to measure fitness. The purpose of the 1.5-mile test is to evaluate how fast athletes can run, covering an allotted distance. This test will measure how much oxygen is being used by the muscle in a field test. The purpose of the sprint test is to assess athletes rapidly accelerating from a standing position and to measure their maximal speed over a short distance.

**Muscular Fitness Testing:** Finally, athletes will perform muscle strength and endurance tests. Muscle endurance will be measured by having our participants contract their leg muscles against a specific force at a particular speed for a certain number of repetitions. Muscle strength will be assessed by having the participants contract their leg muscles with as much force as possible against a non-movable bar.

**Sleep measures:** After baseline testing ends, and before participants leave, each participant will be provided with a Fitbit<sup>®</sup> watch (Inspire 2). Fitbit's will be used measure sleep efficiency, duration, regularity, timing, and staging, similar to prior studies. We will use a program called Fitabase to collect the data from each Fitbit<sup>®</sup>. Participants will be instructed to wear their Fitbit<sup>®</sup> for 1-week straight (except during training times and when they are showering/getting wet) so that baseline sleep habits can be evaluated. Participants will be able to keep their Fitbit<sup>®</sup> after the study ends.

## INTERVENTION:

In-season soccer practices and competition will occur 6-days per week across a 10- or 12-week period (pending soccer season length). During the 10- or 12-weeks, participants will consume their assigned supplement or placebo, every day, immediately after practice or competition (or midday on rest days), and immediately before bedtime. Participants will be alerted that it is time to consume their assigned product with a REDCap-delivered text message. Each dose will consist of 20g of whey protein, or 20g of isocaloric control, and will be mixed with 8oz of water in a shaker bottle, which participants will be provided with and will be able to keep at the end of the study. Participants will be provided with a random number of packets of products above the amount they need in order to evaluate compliance. Additionally, they will have a checklist in their bags to mark intake and if they accidentally lost any packets. Study personnel will distribute these bags at the beginning of each month. Participants will store all their empty containers in a separate provided bag, and each bag with



empty containers will be collected to track compliance by study personnel at the end of each month. Time points may vary by  $\pm 1$  week to allow for scheduling flexibility.

Sleep measures: Sleep measures will be evaluated as described above. Sleep measures will be collected at 2-, 4-, 6-, 8-, 10-, and potentially 12-weeks (pending soccer season length) and will be averaged at the end of each of the weeks listed.

Questionnaires: Participants will fill out a 3-day, 24-hour ASA diet recall at 5-, 10- and potentially 12-weeks (pending soccer season length). This data will be put into REDcap. Pittsburgh Sleep Quality Index (PSQI), DOMS questionnaire (Vickers, A. J. (2001)), and the GI symptom questionnaire will be completed at 2-, 4-, 6-, 8-, 10-, and potentially 12-weeks (pending soccer season length). Study personnel will send questionnaires to participants and will use REDCap to complete the questionnaires.

Urine Samples: We will randomly assign participants to provide urine samples at weeks 4 and 8 as a sham adherence measure. These samples will be discretely disposed of following collection and will not be saved nor stored. We are using this method as a sham adherence measure so that participants will think that we can know if they are consuming their allotted supplement, which may help with their compliance. We will tell participants at the end of the study we did not take any measurements from their urine samples.

Post-testing will be the same as pre-testing and will commence after the 10- or 12-weeks (pending soccer season length). All measures described above in Pre-Intervention testing will take place again, with the exception of a week of Fitbit<sup>®</sup> monitoring following completion of the 10- or 12-week (pending soccer season length) intervention.

Debrief: Following completion of post-intervention testing, participants will be debriefed (see Debrief Document in Other Documents) regarding the sham urine collections which were used to increase adherence.

### **Procedures performed for research purposes only:**

## **Statistical Methods, Data Analysis and Interpretation**

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A two-way (group x time) repeated measures analysis of variance (ANOVA) will be used to compare change between groups in body composition, performance, and recovery. If a significance in group x time interactions occur, an independent t-test will be performed for each dependent variable between groups. An alpha level will be set at  $p < 0.05$ .

Sample size and power analysis: For a total of 60 participants, we anticipate a 30% attrition, leaving us with  $n=40$  ( $n=20$  per group). This provides  $>90\%$  power for detecting differences in our main outcome variables. Based on preliminary data, a similar study used  $n=18$  for their sample sizes. This sample size will be used for sample size calculations for a future well-

powered trial. Estimates for effect sizes will be implemented due to the limited sample size. Effect sizes ( $n^2$ ) will be defined as small (0.20), medium (0.50), and large (0.80).