

Title: The Effects of Ashwagandha (*Withania Somnifera*) Supplementation on Exercise Performance in Female Footballers

Reference: NCT06264986

Document date: 01/04/2024

****INFORMED CONSENT****

****Purpose of the study:****

1. To evaluate the effect of ashwagandha on muscle strength in soccer players.
2. To evaluate the effect of ashwagandha on the perception of recovery in soccer players.
3. To evaluate the usual dietary intake through food diaries of soccer players.

****Participant Information:****

- Name:
- Date of Birth:
- Medical conditions or allergies:
- Years playing soccer:
- Height (meters): _____
- Weight:

****Information about the study:****

Ashwagandha is an ancient medicinal herb with several possible health benefits. Studies show that it can help reduce anxiety and stress, promote restful sleep, and improve cognitive functioning. Additionally, it can help increase muscle mass, reduce body fat, and increase strength in men. Currently, there are no studies on muscle strength in women.

You are invited to participate in this study to evaluate the effects of ashwagandha supplementation for 28 days on subjective muscle strength and recovery. Another aspect of the study is to analyze and compare dietary intake in soccer players against published recommendations.

****Study Procedures:****

If you agree to participate in the study, you will:

- Complete a 3-day food diary.
- Make three visits to the club gym within a month.
- Have reference measurements taken for hand grip strength using a dynamometer, countermovement jump, squat jump, medicine ball throw, and rate of perceived exertion (RPE) through the Borg scale at the end of each session.
- Measure subjective delayed onset muscle soreness (DOMS) using the visual analogue scale (VAS) and general recovery using the total quality recovery questionnaire (TQR).
- Receive printed copies of the questionnaires, which can be returned via WhatsApp or email.
- Follow specific guidelines including abstaining from alcoholic beverages (at least 48 hours prior), caffeinated drinks (at least 12 hours prior), and physical exercise (24 hours prior) before each test session.

****Supplementation Information:****

- It contains 600 mg of organic ashwagandha and the capsule is made of HPMC, suitable for vegans and vegetarians.
- The type of ashwagandha used is KSM-66, a well-studied and considered safe type of ashwagandha.
- If assigned the placebo, it will be made with the same capsule and contain chickpea flour.
- Both ashwagandha and placebo should be taken with a meal at lunchtime for 28 days.

****How to make a food diary:****

The food diary will last 3 days. In exchange, you will receive a nutritional report detailing your average macronutrient, micronutrient, vitamin, and mineral intake. The report will include personalized advice on improving your nutrition to enhance soccer performance and recovery techniques.

****How to make a food diary using the 'Snap-N-Send' method:****

1. Take a photo of your meals and send them via WhatsApp to the nutritionist.
2. Include a brief description of each food.
3. There is no limit to the number of messages you can send.
4. Remember to include beverages.

****Consent:****

Once you have read this information and had any questions answered, you will need to sign your consent to participate in the study.

****I, [Participant Name], declare that:****

- I have read the information sheet provided.
- I have had the opportunity to ask questions about the study.
- I have received sufficient information about the study.
- I have been informed by ([Researcher's Name], the study researcher).
- I understand that my participation is voluntary.
- I understand I can withdraw from the study at any time without needing to provide explanations, and this will not affect my relationship with any professionals involved in the study.

****Place, Date, and Consent Signature:****

I hereby consent to participate in the proposed study.

Participant Signature: _____ Date: _____

Researcher Signature: _____ Date: _____

****Place, Date, and Signature of Consent:****

I hereby revoke my previous authorization to participate.

Participant Signature: _____ Date: _____

Researcher Signature: _____ Date: _____

****Data Protection:****

All personal data and information collected or generated during the study will be protected in accordance with current legislation on the protection of personal data (Organic Law 3/2018 of December 5). Only personnel directly related to the study will have access to this information.