Participant Information Sheet

You have been invited to take part in our research study. However, it is important that you understand why the research is being conducted and what we will ask of you before you decide to take part.

Study title

The effects of 12-week whey protein supplementation on immune function and upper respiratory illness in active people.

What is the purpose of the research?

Research shows that prolonged/strenuous exercise significantly increases the risk of picking up upper respiratory tract infections (URTI), such as the common cold. This study aims to investigate the effects of a 12-week whey protein supplementation on illness incidence and markers of immune function and gut health.

Why have I been invited to take part in the study?

We are looking for volunteers who meet the inclusion criteria below.

Inclusion criteria:

- 18+ years old.
- Free from any injury, illness, or chronic medical conditions.
- Free from any respiratory conditions (asthma, etc.).
- Deemed 'healthy' via a pre-screening questionnaire.
- No allergies or intolerances to dairy or pea.
- Not taking any medication.
- Engage in moderate-intense exercise 3+ times per week.

How long will study participation last?

In total, participation will last 12 weeks. During this time, you will visit the School of Sport and Exercise Sciences every four weeks, making it four visits in total throughout the whole study (0-week, 4-week, 8-week, 12-week). Each visit should last ~30 minutes.

Do I have to take part in the study?

No, taking part is entirely voluntary, and it is your decision whether you want to take part or not. If you agree to take part, we will ask you to sign a written consent form, and you will receive a copy of this. However, you are free to withdraw from the study at any time without giving a reason. There are no consequences if you do not wish to take part or if you withdraw from the study.

What will I be asked to do if I agree to take part?

At home:

- You will be given a 12-week supply of a high-quality protein supplement. You will need to take a 40-gram serving of your designated protein every day, preferably on an empty stomach (first thing in the morning).
- Throughout the 12 weeks, you will be asked to complete a daily illness and weekly training questionnaires, asking you about any illness symptoms you may or may not be experiencing, and about your training volume/load and attendance (see 'illness monitoring' and 'training monitoring' sections below).
- On occasions when you are experiencing cold or flu-like symptoms, you will be asked to take a self-swab from your throat and nose, like those used in COVID-19 tests. This is to allow us to test for pathogens (viruses or bacteria, etc.), to see if we can identify the cause of your symptoms/URTI episode (see 'swabs' section below).

At the laboratory (all four visits):

- As previously said, these visits should only last approximately 30 minutes.
- Upon arrival, you will be asked to take a seat and rest for 10-15 mins. Following this, venous blood (via venepuncture from a vein on the inside of your elbow) and saliva samples will be taken.
    - Please drink at least 1 pint of water in the 1-2 hours prior to arrival.
    - The researcher taking the samples will be a certified trained phlebotomist.
    - Saliva samples will be taken via passive dribbling into a tube for a few minutes.
- You will also be asked to take a baseline throat and nasal swab on the first visit.

<u>Important</u>:

Prior to every laboratory visit, we ask that you perform a 10-hour overnight fast (i.e. no food after 11 pm the night before) and consume at least 1 pint of water, two hours before the visit. We also ask that you avoid strenuous physical activity and alcohol for the 48 hours before the visit and not consume caffeine on the morning of the visit.

Female participants:

Your menstrual cycle can influence factors such as your hormones or metabolism, depending on which phase you are in. For this reason, we will schedule each visit within the same phase of the menstrual cycle (mid-luteal phase). You will be asked to use a daily luteinizing hormone (LH) urine dipstick (a 'home ovulation' test). These dipsticks detect a surge in LH, which signals the beginning of the luteal phase of the menstrual cycle. You will be asked to begin using the tests 2-3 days before your predicted LH surge (please see the LH dipstick instruction sheet provided for the dates), and then the next visit will be scheduled for 5 days after this so as to be in the mid-Luteal phase.

If you do not have a 'natural' menstrual cycle (i.e. if using contraception or if post-menopausal), then you will be able to take part in the study without the need to do the LH dipsticks, assuming you have been on a stable/consistent contraceptive method for at least 3 months.

Supplement instructions:

Both protein supplements used in this study should be taken in the form of a protein shake. Using the shaker provided, please mix 40 grams (two very slightly heaped scoops) of protein with 250-300ml water and shake until mixed. If possible, please consume your shake on an empty stomach (first thing in the morning or late at night), this is to ensure it is digested properly.

Illness monitoring:

You would be required to complete a daily illness log, where you are required to self-rate whether you have any URTI illness symptoms, and if so, give a numerical rating of their severity. This will be performed using the online platform Qualtrics (meeting all necessary security and data protection requirements).

Training monitoring:

You would complete weekly training logs so that training volume/load, and training 'absence'/missed training figures can be calculated. This will be performed using the online platform Qualtrics (this platform meets all of the requirements for UK data protection, GDPR and security).

Swabs:

In addition to the subjective ratings, we would ask you to take a swab sample from your throat and nose at baseline (beginning of the study), and then repeat this process if you ever think you have a URTI (at the same time) on days 1, 3, 5 and 7 (where day 1 is the first day that symptoms are present). This will allow us to test for pathogens (e.g. viruses or bacteria) to see if we can identify the cause of your symptoms/URTI episode.

Prior to completing the swabs or dipsticks, you will receive verbal instructions. You will also be given an instruction sheet for both in case you would like more information. You will also be instructed on how to complete the illness/training log. If you have any further questions regarding the log, please contact the research team (details at the end of the document).

What are the potential risks of taking part?

Important:

The protein supplements will be of dairy or pea origin, so you should not take part in the study if you have any allergies or intolerances to dairy (including lactose and/or milk proteins) or peas. If you feel unwell after consuming the product, please let the research team know ASAP and stop taking it. Please consult a medical professional if the reaction is severe.

As blood will be taken, it is possible that you may suffer from bruising on the site where the needle enters. Bruises may be painful at times but are usually harmless and fade after a few days. Please let us know if you feel faint or dizzy at any time during or after the test so we are aware and can help you feel more comfortable. Only a small amount of blood is taken during each blood test (roughly 1-2 tablespoons). There is also a very small risk of infection at the site where the needle breaks the skin (very rare), however, we follow strict rules to ensure that the whole procedure is sanitary.

In accordance with the Human Tissue Act 2004, any blood samples stored will be treated (centrifuged) to remove all cellular material. Measures of immune cell function will be performed on whole blood (non-centrifuged) on the same day and will be discarded immediately after.

The collection tubes in the throat/nasal swab kit contains chemicals used to stabilise and protect the sample. Although the chemicals are not dangerous when coming into contact with the skin, it is still best to not let this happen. In the event that the liquid does come into contact with the skin, wash the exposed area as soon

as possible for at least one minute with running water. Please mop any spills with paper towels, rinse thoroughly with running water (for at least 1 minute), ring out and then dispose of in normal waste.

What are the potential benefits of taking part?

You will receive a free 12-week supply of high-quality protein products. You will also receive a payment of £50 (or a proportional payment if you do not complete the full study) to compensate you for the time and effort that you have given to take part in the study. Furthermore, at your request, we will provide you with a report of your results once the study has finished for all participants.

Will my taking part be confidential?

Yes. The consent form you sign will be stored securely within the School of Sport and Exercise Sciences' premises in accordance with the Data Protection Act 2018 and all relevant GDPR procedures and the University's own data protection procedures. You can access the University of Kent's privacy notice related to research here: https://research.kent.ac.uk/ris-research-policy-support/wp-content/uploads/sites/2326/2021/06/GDPR-Privacy-Notice-Research.pdf.

The consent form includes space for an anonymous code that will be written against your test scores and the questionnaires you complete. So, no one will be able to see what your test scores and questionnaire answers are except for the research team, who have the consent form with both your code and your name. The consent forms are kept for up to 12 months after the testing and are then securely destroyed. Anonymous data, such as your test scores and questionnaires, will be stored for up to 5 years after the study.

The weekly training and daily illness episode/symptom logs will be completed using Qualtrics, an online questionnaire platform. This platform is in accordance with all of the requirements for UK data protection, GDPR and security. Only the research team will have access to your answers, and all results will be anonymised.

What will happen to the results of the research?

No identifiable information will be passed on to any third party. The results may be published in scientific journals and/or conferences and presented to the funder (Volac International Ltd), but all data will be anonymous (i.e. you will be represented

only by a code). You can receive a copy of your personal results and/or a summary of the overall findings if you wish.

The anonymised results will also be used in the PhD thesis of Will Searle.

Who is organising and funding the study?

The study is organised by the School of Sport and Exercise Sciences at the University of Kent, with funding from both the University of Kent and Volac International Ltd.

Who has reviewed the study?

The study has been approved by the University of Kent, School of Sport and Exercise Sciences Research Ethics and Advisory Group (REAG).

Ethics ID: 40_20_23

Who can I contact if I need to ask more questions about the study?

You can contact the research team at any time using the contact details below.

Who can I contact if I want to complain about the study?

If you have any concerns or wish to complain about any aspect of the way you have been approached or treated during the course of the study, you may contact the Director of the Division of Natural Sciences, Professor Claire Peppiatt-Wildman (C.M.Peppiatt@kent.ac.uk), the Director of Research at the School of Sport and Exercise Sciences, Professor Lex Mauger (L.Mauger@kent.ac.uk), or the SSES Research Ethics and Advisory Group (REAG) representative, Dr Samuel Smith (S.A.Smith-75@kent.ac.uk).

What should I do now?

If you are happy to participate in the study, then please inform the research team below.

Research Team

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