Participant Information Sheet

UCL Research Ethics Committee Approval ID Number: 21745/001

Title of the Research Study: The efficacy of algae on health and performance

Department: Division of Surgery and Interventional Science

Name and Contact Details of Principal Researchers:

Exercise Science

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Invitation

Thank you for considering to take part in this study which is investigating the effect of a commonly used dietary supplement obtained from freshwater micro algae on exercise performance.

The study aims to evaluate and compare the effect of different dosages of either Spirulina or Chlorella on haemoglobin and on exercise performance

Before you make any decisions please take the time to read the following information to gain an understanding of the proposed research and how we intend to use the collected data. It is important you are completely happy with all aspects of your possible involvement so please feel free to ask any questions.

The inclusion criteria for the study states that you may only take part in this study if you are above 18 years of age and have no medical conditions, injuries or neurological diseases that prevent you from exercising. If exercising is not safe for you, you should not be taking in part in this study.

COVID-19 guidance: You will be asked to exercise as part of this study. Please ensure you are following social distancing rules when exercising.

What is the projects purpose?

Global demand for freshwater algae such as Spirulina and Chlorella is slowly increasing, and it has been reported that algae has started to be consumed beyond the traditional benefits for nutrition and health. Freshwater algae are renowned for their multicomponent levels of vitamins, proteins, and minerals which thus makes it an exciting supplement to investigate.

Thus far, there has been a substantial amount of research conducted on both Spirulina and Chlorella within a clinical setting. Both algae are exceptionally rich in iron, with previous research suggesting Spirulina increases haemoglobin in healthy and anaemic individuals. However, to date there is an exceptionally limited amount of research being conducted into the ergogenic aid potential from freshwater microalgae. Notably, due to Chlorella and Spirulina being multi-component species, hitherto, research has struggled to understand the mechanisms behind its function.

The project therefore aims to assess the efficacy of Spirulina & Chlorella supplementation on health and performance through a variety of fitness tests. We hope to use this information to provide guidance on how to best administer freshwater algae for exercise performance!

1. Who are we?

The Institute of Sport, Exercise and Health (ISEH) at University College London (UCL) is a legacy project from the London 2012 Olympics games, dedicated to improving the performance, health and wellbeing of the general population through the advancement of scientific research in the area of Sport & Exercise Medicine.

2. Do I have to take part?

No. It is completely your decision as to whether or not you would like to take part. To ensure you are happy with all requirements it is important you read all this provided information and ask any questions that may be concerning you. If you do decide to become involved, you will be able to keep this information sheet and additionally sign a consent form. **If you are unhappy at any point through the study or if you are unable to attend for any personal reasons you are free to withdraw at any time.** This will not affect your place within the study. You are free to withdraw at any time without giving reason and if you decide to withdraw you will be asked what you wish to happen to the data you have provided up that point.

3. Exclusion criteria

- Individuals taking blood thinners.
- Known allergies to algae/mould and iodine.
- Any illness/conditions identified on PARQ (please see attached PARQ)
- Taking immunosuppressant medication

4. Inclusion criteria

- Aged 18-50
- Train regularly (3-4hrs a week)

5. How much time will I have to commit if I take part and what will happen if I take part in the programme?

After signing the consent form, we will invite you to come to the ISEH laboratory on Tottenham Court Road so we can take some basic baseline readings (explained below). This should last up to 60 minutes and will also include a **$\dot{V}O_{2max}$ Test**. After this, you will be randomly allocated to one of two groups: **Chlorella** or **Spirulina** intervention. You will then be further randomly allocated to either receive placebo or supplement first (Spirulina or Chlorella). After supplementation you will be required to **perform a series of exercise tests.** You will then be required to undergo the exact same loading period on the alternative supplement with the same exercise tests performed.

You will be required to come into the laboratory a total of **4 times.** Each visit should take no more than 1 hour.

See below for detailed info of supplementation and exercise tests that will happen throughout the course of this intervention.

6. Supplementation

A schematic illustration of each study design and timeline can be found below.

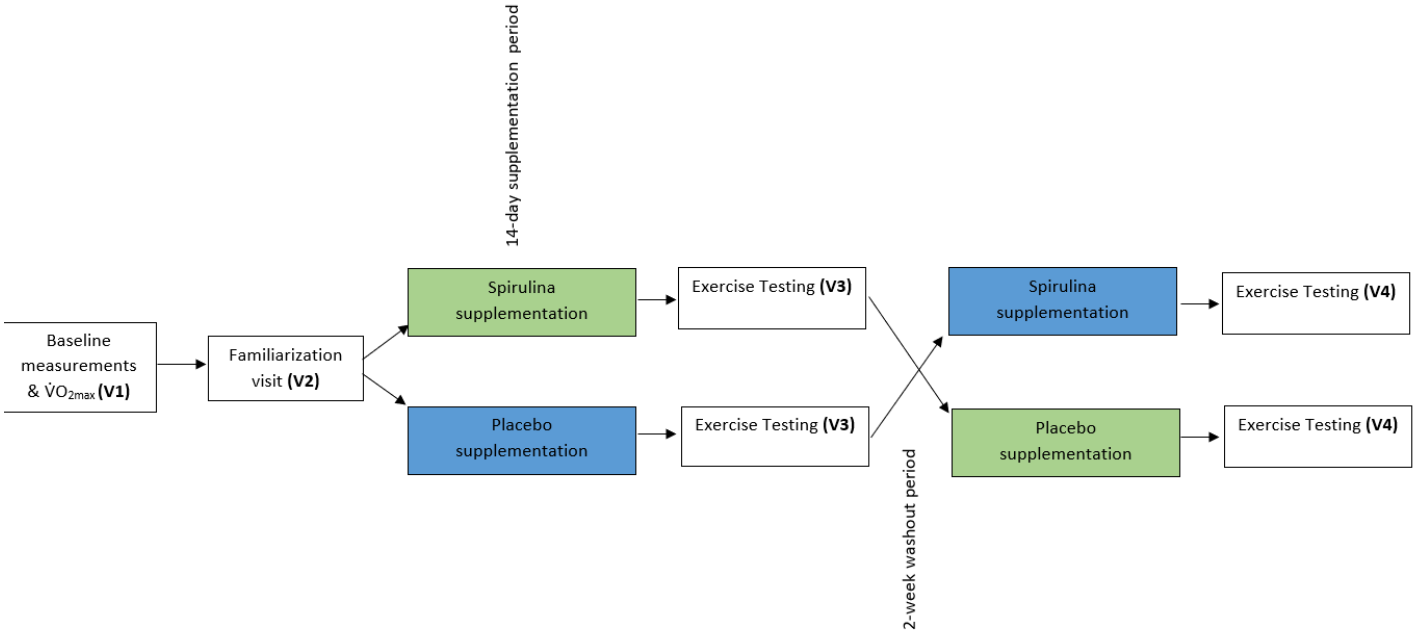
Although **rare**, there can be some small associated gastrointestinal side effects from taking the below supplements, these include:

- Flatulence
- Green discoloration of stools
- Nausea
- Stomach cramps
- Diarrhea

Please inform the researcher **immediately** should you experience any of these.

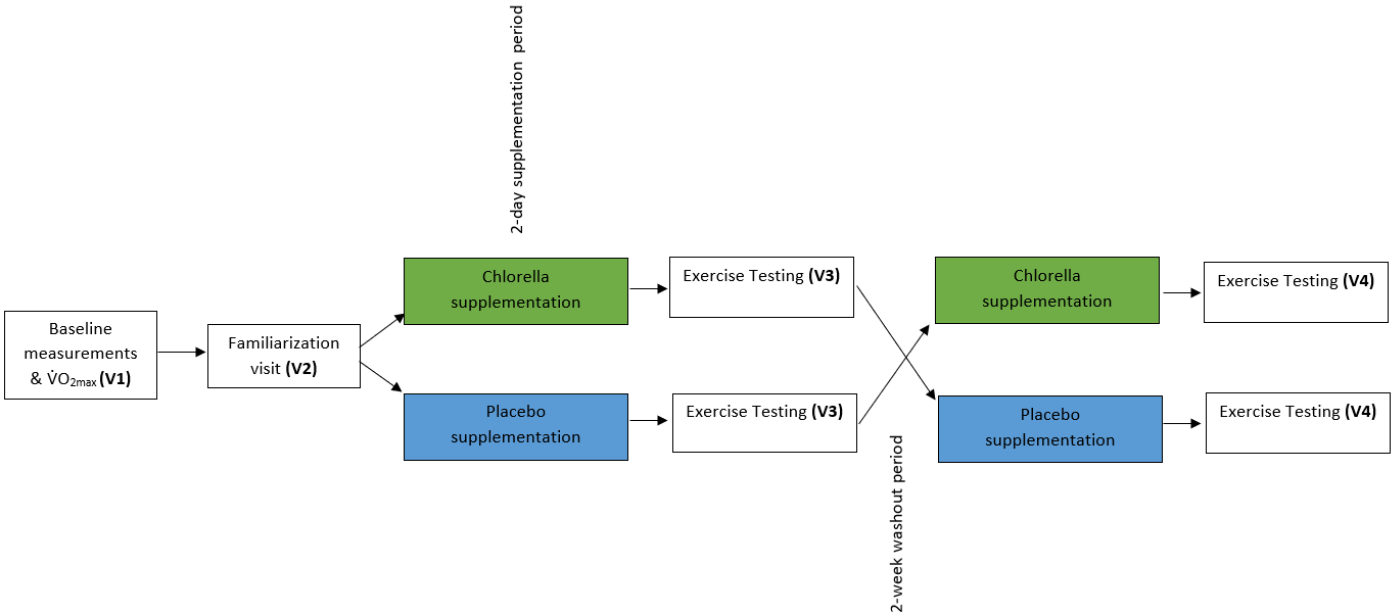
Spirulina Intervention

You will be randomly allocated to receive either Spirulina or Placebo and will be instructed to ingest 6 grams (12 capsules) each day for 14-days. A 2-week washout period will follow whereby you will be asked to repeat the supplementation process on the alternative capsules and repeat the exact same study procedure.



Chlorella Intervention

You will be randomly allocated to receive either Chlorella or Placebo and will be instructed to ingest 6 grams (12 capsules) each day for 2 days. A 2-week washout period will follow whereby you will be asked to repeat the supplementation process on the alternative capsules and repeat the exact same study procedure.



Am I allowed to come in if we're under lockdown?

Instructions will be adapted in accordance with government guidelines.

Visit 1 (Baseline measurements & V̇o2max Test)

Anthropometric Values and Health Screening

Before testing, we will ask you to measure your height, weight, waist circumference, body fat %, muscle mass and resting heart rate (these measurements are pain free and non-invasive). Females and males can be measured by researchers of the same sex if requested. We will also collect a very small finger prick resting blood lactate, glucose and haemoglobin sample.

Incremental $\dot{V}O_{2max}$ Test

You will be required to perform one maximal exercise test to volitional exhaustion on either the treadmill or bicycle ergometer. This will comprise a 3-minute warm up with a light resistance (75W) after which the power output will increase by 25W each minute until you can no longer continue. The rate of exercise will be self-selected between 70-90 repetitions per minute. You can terminate the test at any point. Respiratory and heart rate values will be collected throughout the maximal exercise test. The $\dot{V}O_{2max}$ variables measured will establish the power output for the Submaximal Endurance Exercise Test in subsequent visits

Visit 2 (which will be exactly the same for Visit 3 & 4)

Anthropometric Values

You will complete the exact same anthropometric measurements as per Visit 1.

Submaximal Endurance Exercise Test

The work rate will be self-selected between 70-90 repetitions per minute at an intensity of 40% your $\dot{V}O_{2max}$ score. Respiratory and heart rate values will be collected throughout, therefore you

will be required to wear a mask and heart rate monitor during this test. Blood finger prick samples will also be taken every 10 minutes during this test.

In total, you will be required to perform three 20-minute bouts of moderate intensity exercise on separate occasions (visit 2, 3 & 4) following the supplementation of Spirulina or Chlorella.

Incremental $\dot{V}O_{2max}$ Test

Following a 15-minute break, you will complete the exact same Incremental $\dot{V}O_{2max}$ Test as per Visit 1.

In total, you will be required to perform four $\dot{V}O_{2max}$ Tests on separate occasions (Visit 1, 2, 3 & 4) following the supplementation of Spirulina or Chlorella.

7. What are the possible disadvantages and risks of taking part?

Physical exercise puts our body under stress and could lead to a risk of injury or feeling unwell. Please remember to listen to your body and never push too hard.

In total, throughout the intervention the researcher will obtain **10 finger prick samples** from you – although uncommon, this may cause mild pain/bruising. The study concedes there are risks associated with exercise performance, particularly maximal exercise tests. Such risks include fainting or irregularities of the heart, although these are **highly unlikely**. Procedures will be put into place to prevent the occurrence of such events such as a medical examination prior to the test, emergency equipment and technicians trained in first aid will be present in the laboratory during testing.

You will be required to fill out and sign a questionnaire before testing declaring that you have no medical conditions that might affect your participation in physical activity.

8. What are the possible benefits of taking part?

Potential benefits of involvement in the study include:

⇒ Expert advice on health and fitness

9. What if something goes wrong?

If you are unhappy with any aspect of the study and wish to make a complaint, you should contact The Principal Researchers – Mr Tom Gurney (t.gurney@ucl.ac.uk) or Dr Flamina Ronca (f.ronca@ucl.ac.uk).

However if you feel your complaint has not been handled to your satisfaction, you can contact the Chair of the UCL Research Ethics Committee – ethics@ucl.ac.uk

If you are harmed during the process of data collection there is no set compensatory action in place, however, if someone has been negligent in any way to account for this then you will have grounds for legal action.

10. Will my taking part in this project be kept confidential?

Yes. This project has been registered with the Data Protection Office at University College London and the required ethical, data protection and risk assessment forms have all been approved. To use any personal data legally we are required to comply with the 8 data protection principles as outlined by the Data Protection Act 2018 and enforced by the Information Commissioner's Office.

All your personal details will be kept strictly confidential and separate to the pseudo-anonymised data in a locked cabinet. The information will only be available to the researchers and will be stored on a private laptop and USB memory stick that is password protected.

The management of any personal data is extremely serious and will be managed strictly. Any personally identifiable data collected will not be kept any longer than the duration of the study. Pseudo-anonymised data will be kept up to 5 years after the study. Within this time, a participant's information can be retrieved (and if requested, removed) by matching their ID

code to their information. After this, ID codes will be deleted, and fully anonymised data will be stored for up to 15 years after publication of the results in an academic paper. Data cannot be removed after a scientific result has been published in a scientific journal or similar (however these data will never identify an individual).

11. Limits to confidentiality

Please note that assurances on confidentiality will be strictly adhered to unless evidence of wrongdoing or potential harm is uncovered. In such cases, the University may be obliged to contact relevant statutory bodies/agencies.

12. What will happen to the results of the research project?

We aim to present and publish the final research study in a peer reviewed research journal and at medical conferences, so that the body of evidence relating to exercise, health and cognition can be advanced. Any data published will not be identifiable to any individual who took part in the study. All data will be reported as group mean scores.

The data collected will be securely deleted 15 years after the project has been published.

13. Data Protection Privacy Notice

The controller for this project will be University College London (UCL). The UCL Data Protection Officer provides oversight of UCL activities involving the processing of personal data, and can be contacted at data-protection@ucl.ac.uk

This 'local' privacy notice sets out the information that applies to this particular study. Further information on how UCL uses participant information can be found in our 'general' privacy notice:

For participants in health and care research studies, click here

The information that is required to be provided to participants under data protection legislation (GDPR and DPA 2018) is provided across both the 'local' and 'general' privacy notices.

The lawful basis that will be used to process your personal data is: 'Public task' for personal data.

Your personal data will be processed so long as it is required for the research project. If we are able to anonymise or pseudonymise the personal data you provide we will undertake this, and will endeavour to minimise the processing of personal data wherever possible.

If you are concerned about how your personal data is being processed, or if you would like to contact us about your rights, please contact UCL in the first instance at data-protection@ucl.ac.uk.

If you remain unsatisfied, you may wish to contact the Information Commissioner's Office (ICO). Contact details, and details of data subject rights, are available on the ICO website at: https://ico.org.uk/for-organisations/data-protection-reform/overview-of-the-gdpr/individuals-rights/

14. Who is organising and funding the research?

This research study is organised by University College London (UCL) and The Institute of Sport & Exercise health (ISEH).

15. Contact and further information

If you wish to contact anyone for further information, please refer to the first page for the relevant contact information.

You will be given a copy of the information sheet and the signed consent form.

Thank you for reading this information sheet and for considering taking part in this research study.