University of Reading OYSACO Study Information Sheet (UREC 22/37)

School of Psychology & Clinical Language Sciences
University of Reading OYSACO Study: Investigating the neurological, inflammatory and metabolic effects of veggie capsules.

Researchers: Prof. Claire Williams, Dr. Lynne Bell, Ms. Sara Cha

We hope to provide all the information you will need about the University of Reading LIMACO study in order for you to make an informed decision about whether you would like to participate. However, if you have any further queries or would like to discuss any aspect of the study, please do not hesitate to contact either Sara via email or telephone (indicated below).

What is the purpose and background of the LIMACO study?

We are interested in investigating the effects of veggie capsules in improving your efficiency to perform various daily activity tasks. The ingredients in these capsules contain high amounts of dietary fibre, protein, that other nutrients found in many vegetables and fruits, with known health benefits. This study extends our current research findings regarding the short-term and long-term benefits of other phytochemical rich substances, in improving general well-being. Since these substances are known to affect metabolic activity, we are also interested in tracking the course of inflammation markers and levels of neuronal growth factors measured in the blood following the consumption of the intervention capsules.

Who can take part in the study?

To participate in the LIMACO study you should be aged between 60-80 years old, be generally healthy, and be free from any diagnosis for a psychiatric or cardiometabolic condition, an eating disorder, or anaemia (please contact the researcher if you are not sure). Unfortunately, you will also not be eligible to take part if you are a current smoker, if you drink more than the recommended units of alcohol per week, if you are vegetarian/vegan, if you have unmedicated high blood pressure, if you take blood thinning or anticoagulant medication, or if you have any food allergies. If you regularly take vitamin or probiotic/prebiotic supplements you may be asked if you are happy to stop taking these for the duration of the study. In the consent form, there is the option to provide the details of your General Practitioner in order for us to get in touch in case we need further information about your health status or medication intake.

What would taking part involve?

The study involves five visits at the School of Psychology and Clinical Language Sciences Department at the University of Reading, each separated by 1 week. Initially, you will be emailed with two questionnaires to complete; a health and lifestyle questionnaire that will include the consent form and a dietary questionnaire to check your eligibility to participate to our study. Once your eligibility is confirmed, you will be asked to visit the School of Psychology for a familiarisation screening visit lasting no more than 2- hours and then for four

subsequent test visits where, throughout the day, you will be instructed to consume a capsule intervention meal, perform several cognitive and mood related tasks and have your blood drawn. A standardised breakfast and lunch will be provided. Each test visit will last approximately 8-hours. On each test day, you will consume veggie capsules that contain food ingredients commonly used in the food industry and are certified as safe for consumption. Allergy information is available on request.

Participation is voluntary, and you are free to withdraw from the study at any point without the requirement to give a reason for doing so. The principal investigator may also ask you to stop the study for several reasons, including non-compliance, health reasons or safety.

Familiarisation Visit: At the familiarisation visit, you will be asked to complete a consent form. Your height and weight will then be measured to determine your body mass index (BMI) as well as your blood pressure. Also, blood will be taken via finger prick and analysed using a Hemocue Analyser to determine whether you may be anaemic. You will then have an opportunity practice the cognitive tests twice, with further health and cognitive measures being completed between the practices.

Dietary requirements: Forty-eight hours before each test day you will be asked to consume a restricted low fibre and flavonoid diet. Then, you will be asked to fast for 12-hours and to consume only a slice of toast with butter and 1 glass of water at 07:00 a.m., before attending each test day.

Test Visits: On arrival for the study visit which will begin at approximately 08:00 a.m., you will be asked to perform the cognitive and mood tests for the first time, followed by the consumption of the intervention meal consisting of two croissants with cream cheese spread and the veggie capsules. Two-hours after consuming the intervention meal, you will be asked to complete the same cognitive and mood tests and a standardised lunch will be provided at noon containing a chicken sandwich, a packet of crisps and a glass of water. Then, you will be asked to complete the cognitive and mood tests a further two times (4-hours and 6-hours post-intervention) and a 9-millilitre blood draw (equivalent to 2 teaspoons) will be drawn 6-hours post-intervention.

In addition to the cognitive and mood tests, blood pressure will be measured, and ratings of subjective appetite and fullness will be recorded using an online analogue scale at baseline and at the 2-, 4- and 6- hours post-intervention. At the end of the study, we will ask you to complete a brief questionnaire requiring further information about your habitual diet.

What will happen to the samples and responses I give? Will my information be kept confidential?

In accordance with relevant data protection laws, your data will be pseudonymised with only a number identifying it. Information linking that number to your name will be stored securely and separately from the data you provide us. All personal data will be fully anonymised, by destroying the information linking your data to your name, after the period of 1 year from the completion of the project has elapsed.

Blood samples will be processed immediately after collection to separate the serum from the remaining blood cells. Serum samples contain no identifiable DNA. These serum samples will be frozen to preserve them. All other material will be disposed of as clinical waste. Once all

samples have been collected, they will be analysed to examine inflammatory, metabolic and neuronal markers.

It is planned that the results of this study will be published in an academic journal. Full anonymity will be respected in this publication. The research data collected from participants in this study will be preserved and made available in anonymised form, so that they can be consulted and re-used by others. Only the overall group results will be reported, and no direct reference will be made to any contributing individual. Additionally, upon your request, the results of the study will be forwarded to you following its completion either by post or email.

Will I be paid to participate?

Yes, your time and contribution is highly valued by the University, and you will be paid £200 for your involvement. Should you withdraw early, a pro-rata amount will be paid reflecting the amount of time you have taken part in the study.

What are the possible advantages of taking part?

Your participation in our study is highly valuable, allowing us to examine the potential cognitive and metabolic effects of veggie capsules. The information we obtain from this study will contribute to raising public health awareness about the benefits of specific vegetable ingredients on the factors relating to neuronal and metabolic health.

What are the possible disadvantages/risks of taking part?

Participation in the study will require a considerable time commitment, but we hope that the offered financial compensation will help offset this. The overall risk of participation is extremely low. The study involves well-practiced procedures and all researchers associated with this project have successfully completed phlebotomy and first aid training. The ingredients included in the intervention meals are based on authorised Nutrition & Food Guidelines. The research team will be always available to help you should you have any concerns while participating in our study. Finally, it should be noted that participation in this study is voluntary, and you are free to withdraw at any time in case you feel so, without having to give an explanation.

What if something goes wrong?

If you feel you have reason to complain about any aspect of the study, or you have experienced any adverse effects, we encourage you to please raise this with one of the research investigators as soon as possible. We will do our best to address any problems as quickly as possible. The specific contact details of the researchers can be found in the first page of this document.

Who is organising and running the study?

The study is organised and run by research staff in the School of Psychology and Clinical Language Sciences at the University of Reading.

Who has reviewed this study?

The study has been reviewed by the University Research Ethics Committee (UREC) and has been given a favourable ethical opinion for conduct (UREC 22/37), which means that an independent group did not raise any objections to the study on ethical grounds and have

permitted the study to proceed. Also, the study is adhering to the University of Reading approved Covid-19 secure procedures.

Data Protection information

The organisation responsible for protection of your personal information is the University of Reading (the Data Controller). Queries regarding data protection and your rights should be directed to the University Data Protection Officer at imps@reading.ac.uk, or in writing to: University of Reading, Information Management & Policy Services, Whiteknights House, Pepper Lane, Whiteknights, Reading , RG6 6UR, UK.

The University of Reading collects, analyses, uses, shares and retains personal data for the purposes of research in the public interest. Under data protection law we are required to inform you that this use of the personal data we may hold about you is on the lawful basis of being a public task in the public interest and where it is necessary for scientific or historical research purposes. If you withdraw from a research study, which processes your personal data, dependant on the stage of withdrawal, we may still rely on this lawful basis to continue using your data if your withdrawal would be of significant detriment to the research study aims. We will always have in place appropriate safeguards to protect your personal data.

If we have included any additional requests for use of your data, for example adding you to a registration list for the purposes of inviting you to take part in future studies, this will be done only with your consent where you have provided it to us and should you wish to be removed from the register at a later date, you should contact Professor Claire Williams (Claire.williams@reading.ac.uk)

You have certain rights under data protection law which are:

•Withdraw your consent, for example if you opted in to be added to a participant register

•Access your personal data or ask for a copy

•Rectify inaccuracies in personal data that we hold about you

•Be forgotten, that is your details to be removed from systems that we use to process your personal data

•Restrict uses of your data

•Object to uses of your data, for example retention after you have withdrawn from a study

Some restrictions apply to the above rights where data is collected and used for research purposes.

You can find out more about your rights on the website of the Information Commissioners Office (ICO) at https://ico.org.uk

You also have a right to complain the ICO if you are unhappy with how your data has been handled. Please contact the University Data Protection Officer in the first instance.

Thank you for reading this information and for considering participation in our study.

The LIMACO Study Team

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