University of Reading OYSCOG Study Information Sheet

School of Psychology & Clinical Language Sciences
University of Reading OYSCOG Study: A randomised controlled trial to investigate the cognitive, mood, anti-inflammatory and metabolic effects of a vegetable powder intervention in older adults (OYSCOG).

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Study Information Sheet

University of Reading OYSCOG Study

We hope to provide all the information you will need about the University of Reading OYSCOG 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 us via email or telephone (indicated above).

What is the purpose and background of the OYSCOG study?

We are interested in investigating the effects of a freeze-dried vegetable powder in improving your memory and mood. The powder contains high amounts of dietary fibre and ergothioneine, that are 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 well-being. Since these substances are known to affect metabolic activity, we are also interested in tracking the course of metabolic and inflammation markers measured in the blood following consumption of the vegetable powder.

Who can take part in the study?

To participate in the OYSCOG study you should be aged between 60-80 years old, be generally healthy, and be free from any diagnosis for a psychiatric disorder, diabetes, heart-related disease, liver/kidney disease, 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

supplements you may be asked if you are happy to stop taking these for the duration of the study.

What would taking part involve?

The OYSCOG study involves three visits at the School of Psychology and Clinical Language Sciences Department at the University of Reading. Initially, you will be emailed with two questionnaires to complete; a health and lifestyle questionnaire 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 30 minutes.

Screening 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.

After your familiarisation you will be asked to attend two subsequent test visits; a) a week after your familiarisation visit and b) 12-weeks after your testing visit.

Dietary requirements: Twenty-four hours before each test day you will be asked to consume a restricted low fibre and flavonoid diet (diet information sheet is attached). Then on the test visits, we will ask you, before coming to our laboratory, to consume a slice of toast with butter and a glass of water.

Test Visits: In both testing visits, you will be instructed to perform several cognitive and mood related tasks. In addition to the behavioural tests, blood pressure and body weight will be measured, and electroencephalogram (EEG) measurements will be recorded using electrodes placed on your scalp for detecting electrical brain activity. Finally, a blood test will be performed (equivalent to 2 teaspoons). Each test visit will last approximately 2-3 hours.

At the end of your first testing visit depending on whether you have been allocated to the control or intervention group, you will receive a 12-week supply of the vegetable powder, or control powder in sachets and you will be asked to consume one sachet daily, added to your usual meals. The sachets will look identical so neither you nor the researcher will know which sachets you are taking. The ingredients present in the sachets are all commonly used in the food

industry and are certified as safe for consumption. Allergy information is available on request. At the end of the study (on week 12), we will ask you to complete two questionnaires 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 the General Data Protection Regulation of 2018, your data will be kept confidential and securely stored, with only an anonymous 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.

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 £100 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 mood effects of a freeze-dried vegetable powder. 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 with only a minor risk of bruising and haematoma from blood sampling. 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 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 by emailing or phoning the PhD researcher, without having to give an explanation. In the unlikely event of a problem (such as non-compliance, health reasons, or safety), the principal investigator may also ask you to withdraw from the study.

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.

Will I be informed about my results?

We will be able to disclose the results with you upon the completion of our study. If you wish to receive a copy of the study results, please do not hesitate to email the PhD researcher after you complete our study. Also, we can inform you if we find any unusual results in the physiological markers measured during the study which you may wish to discuss with your GP. We will be able to also inform your GP regarding any unusual results, if you authorise us to do so in the consent form. The results from the completed study will be published in a scientific journal. The results will be presented in an anonymous way.

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, which means that an independent group did not raise any objections to the study on ethical grounds and have permitted the study to proceed.

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 OYSCOG Study Team

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Study location

School of Psychology and Clinical Language Sciences

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