School of Psychology and Clinical Language Sciences
Whiteknights
Reading RG6 6AL

**Principal Investigator:** **Email:**
Lynne Bell l.bell@reading.ac.uk

# Haskap Berry Study (HACVAC) Information Sheet

We would be grateful if you could assist us by participating in our study investigating the effects of haskap berry powder blends on cognitive, metabolic, and vascular function. We hope to provide all the information you will need about the study in order for you to make an informed decision on whether you'd 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 (see contact details below).

**What is the purpose of the study?**

Berries have previously shown benefits to health (physical and cognitive) due to their high content of certain natural plant-based compounds called polyphenols, however fresh berries are seasonal and prone to degradation/spoilage leading to food waste. Therefore freeze-dried berry powders have become popular. Haskap berries are extremely rich in a type of purple-coloured polyphenol called anthocyanins. The berries have recently been designated a traditional food by the European Food Safety Authority (EFSA) and are new to the UK market. This project aims to investigate the immediate benefits (up to 2 hours after consumption) and longer-term benefits (following 4 weeks daily supplementation) of a vitamin- and mineral-enhanced haskap berry supplement made from freeze-dried, powdered haskap berries. We aim to determine any cognitive, metabolic, or cardiovascular effects over and above haskap powder alone or a placebo powder.

**Am I eligible to participate?**

To participate you must meet the following criteria:

- Aged 50+
- Daily fruit and vegetable intake ≤ 4 portions per day
- Good understanding of the English language

Unfortunately, the following would make you ineligible to take part in this particular study:

- Diagnosis of any psychiatric, cardiometabolic or gastrointestinal disorders
- ADHD or dyslexia diagnosis
- Antibiotic use within 3 months of signing up
- Blood thinning or anticoagulant medication
- Unmedicated high blood-pressure
- Any food allergy or intolerance
- Smoking
- Regular consumption of more than the recommended units of alcohol per week
- Following a vegan or vegetarian diet

If you regularly take vitamins and/or prebiotic/probiotic supplements, you will be asked if you are happy to stop taking these for the duration of the study. In the consent form, you will be asked 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 does the study involve?**

This study involves three visits to the School of Psychology and Clinical Language Sciences at the University of Reading, over a five-week period. Initially, your eligibility will be confirmed using an online questionnaire. Once your eligibility is confirmed, you will be asked to visit the School of Psychology for a familiarisation visit lasting no more than 2 hours, followed a week later by a baseline test visit. After 4 weeks you will then be asked to attend a final visit. During the test visits, you will perform several cognitive and mood related tasks, have a glucose finger prick test, and take part in flow mediated dilation (FMD), which is measured from your arm using ultrasound. Further details regarding the familiarization visit, test visits, dietary requirements, and FMD procedures can be found below. Taking part in this study is completely voluntary; you may withdraw at any time without having to give any reason. Please feel free to ask any questions that you may have about this study at any point.

Familiarisation visit

At the familiarisation visit, your height and weight will be measured to determine your body mass index (BMI) as well as your blood pressure. You will also complete a number of health and lifestyle questionnaires to establish your general level of health, amount of physical activity you do and your habitual diet. You will then complete an IQ test, and have an opportunity to practice the computerised cognitive tests. Additionally, you will get the chance to experience FMD to ensure you are comfortable with the procedure.

Dietary requirements

For 24 hours before each test visit you will be asked to consume a restricted diet free from specified plant-based nutrients (polyphenols), alcohol, and caffeine. Then, you will be asked to fast for 12-hours overnight, consuming only a light breakfast of toast with butter before attending each test visit.

Test visits

On arrival at approximately 9:00 am for the baseline visit, you will be asked to perform the cognitive and mood tests for the first time, as well as FMD and a glucose finger prick. Following this, you will consume a yoghurt and cereal-based breakfast containing the intervention powder. Two-hours after consuming the breakfast, you will be asked to carry out the same cognitive, mood, glucose, and FMD tests again. You will then be supplied with a 4-week supply of the powder to take home with you and consume daily. At the final visit, you will carry out the cognitive, mood, glucose, and FMD tests only once. We will also ask you to complete a brief questionnaire requiring further information about your diet during the 4-week intervention period.

Flow Mediated Dilation (FMD)

FMD is an ultrasound technique used to measure the flow of blood through the brachial artery in the right arm. We are interested in using this technique as previous research suggests that certain plant-based nutrients (polyphenols) in our berry intervention may improve vascular function and blood flow, which can positively influence cognitive function. The procedure requires you to lie down and relax for 15 minutes, before the researcher uses an ultrasound probe to locate the brachial artery in your right arm. Once located, the probe will be held in position for 1 minute before a cuff (like the kind used when taking blood pressure) is inflated around your forearm for 5 minutes to cause occlusion of the blood vessels. This should not cause significant discomfort but you are free to stop the trial at any point if it does, in which case the experimenter would deflate the cuff. Once the 5 minutes is over, the cuff is then deflated, and the brachial artery scanned for a final 3 minutes. In total the procedure takes 25 – 30 minutes, and this will be carried out before completing the cognitive tasks at each timepoint (baseline, 2-hours, 4-weeks post-intervention). The procedure is safe, non-invasive and should not cause any pain or lasting side effects,

but some individuals do experience a temporary 'pins-and-needles' sensation in the right hand after the cuff is deflated.

**Are there any benefits to taking part?**

**Your participation in our study is highly valuable, allowing us to examine the potential cognitive, metabolic, and vascular effects of enhanced haskap berry powder. The information we obtain from this study will contribute to raising public health awareness about the benefits of specific plant-based nutrients such as polyphenols on the factors relating to neuronal, metabolic, and vascular health.**

**Will I be paid for taking part?**

Yes - your time and contribution is highly valued by the University. Volunteers will receive £100 upon completion of the study. Should you withdraw early, a pro-rata amount will be paid depending on the number of testing sessions completed (familiarisation, baseline, 2h, 4 weeks), reflecting the amount of time you have taken part in the study.

**Are there any risks or disadvantages to taking part?**

Participation in the study will require a moderate 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 the researchers associated with this project have successfully completed finger prick, FMD, and first aid training. The haskap berry powder used in the study is supplied by Haskapa Ltd, and is commercially available. It therefore meets all UK food safety requirements. The additional ingredients included in the enhanced haskap berry blend include iodine (as potassium iodide), zinc bisglycinate, vitamin B5, and vitamin B12, at levels based on authorised Nutrition & Food Guidelines, and with food-safe certification. These compounds all have existing cognitive health claims upheld by either the UK or European Nutrition and Health Claims Committees (UKNHCC or EFSA). The research team will always be 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, without having to give an explanation.

**What if something goes wrong?**

If you feel you would like to discuss 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 on the last page of this document. Any complaints about the study or conduct of the research team can also be directed to the Head of School for Psychology & Clinical Language Sciences (hos-pcls@reading.ac.uk) who will investigate the matter in consultation with the Principal Investigator.

**What happens to my data?**

Your data will be pseudonymised and deidentified using a numerical code, and stored securely and confidentially. Data collected from this study will be preserved and made available in anonymised form, so that data can be re-used by others.

**Who can I contact about data privacy and storage?**

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

**Who has reviewed this study?**

This application has been reviewed by the University of Reading Research Ethics Committee and has been given a favourable ethical opinion for conduct: UREC 25/08.

**Where can I get more information/who I can contact about this study?**

If you have any questions or concerns about the research, please feel free to contact the researchers

Researchers:

Dr Lynne Bell (Principal Investigator), l.bell@reading.ac.uk

Professor Claire Williams (Co-Investigator), claire.williams@reading.ac.uk

Thank you for your help.