A double blind Randomized clinical study to Evaluate Attention improvement in an adult population after CereboosT intake

PARTICIPANT INFORMATION SHEET

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INVITATION TO PARTICIPATE IN A RESEARCH PROJECT

We would like to invite you to take part in a research study conducted by the University of East Anglia (UEA). Before you decide to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully, and do not hesitate to contact us if anything is not clear or if you would like more information.

This study is organised by Dr. David Vauzour (the Principal Investigator).

The study is funded by Naturex (part of Givaudan).

Members of the study team who can be contacted are:

Ms Marrium Liaquat and Dr Jane Bradbury

To contact the study team:
Email: react.study@uea.ac.uk or **Tel:** +44 (0)1603 591995

This Participant Information Sheet tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully and contact the research team if you have any questions about anything that you do not understand or want to know more about.

Before deciding whether or not you would like to take part, you may wish to talk about it with a relative, friend or your local doctor.

If you decide to take part in the research project, you will first be asked to provide consent to participate in the study. You will be asked to sign a consent form electronically and in-person at the study site. A copy of the signed consent form will be provided to you. By signing it, you are telling us that you:

- Understand what you have read in this information sheet
- Consent to take part in the research project
- Consent to have the tests and treatments described
- Consent to the use of your personal and health information as described.

What is the REACT study?

The study will assess the immediate, short-term benefits of a single dose of a supplement containing 200mg of *Panax quinquefolius* (American Ginseng) on cognition (brain function) in healthy young adults. To understand the effect this product may have, you will complete a series of questionnaires and cognitive tests (tests of memory and brain function) at set intervals across a 6-hour period. Blood samples will also be collected to assess the impact of the study product on you.

Why are we doing this research and why is it important?

Lifestyle strategies such as nutritional interventions have received increased attention as they provide safe and effective solutions to improve cognition (brain function).

Ginseng, a popular herbal root extract obtained from plants of the Panax family, is widely regarded as a remedy in traditional medicine and has been used for centuries to treat mental and physical ailments and promote longevity. Among multiple species of ginseng, *Panax quinquefolius* (American ginseng) provides a particularly rich source of bioactives (chemicals found in small amounts in plants and certain foods) when compared to other ginseng varieties, and emerging research suggests that supplementation with American ginseng may elicit cognitive enhancement effects.

Further evidence is needed to support these findings and the development of the study product as a dietary supplement intended to support cognitive function.

Who can take part in this study?

We aim to recruit 200 male and female healthy volunteers aged between 18 and 40 years.

Unfortunately, you will not be able to volunteer if you/are/have:

- Pregnant or wish to become pregnant during the study
- Lactating and/or currently breastfeeding
- Food allergies or other issues with foods that would preclude intake of the study products
- Not willing to consume gelatine from bovine/porcine source
- BMI of less than or equal to 18.5 or more than or equal to 30 kg/m^2
- Blood pressure more than 140/90 mmHg
- Smoke or vape
- Have any significant acute or chronic coexisting health conditions that would prevent you from fulfilling the study requirements, put you at risk or would confound the interpretation of the study results as judged by the investigator on the basis of medical history and routine laboratory test results.
- Excluded health conditions include:
    - Cognitive disorders in the past 12 months
    - Current or past history of a major neuropsychiatric disorder, including bipolar disorder, schizophrenia and schizotypal personality disorder
    - Current or past history of a major neurological condition
    - Gastrointestinal disorders (e.g. IBS/IBD)
    - Attention deficit hyperactivity disorder (ADHD)
    - Learning disabilities
    - Current, uncorrected vision or hearing impairment

- Current or recent use of a medication that the investigator believes would interfere with the objectives of the study or pose a safety risk or confound the interpretation of the study results. Prohibited medications include:
    - Anti-psychotics
    - Anti-coagulants (including Warfarin)
    - Anti-platelets (including Aspirin and Clopidogrel)
    - Sedatives
    - Monoamine Oxidase Inhibitors (MAOIs)
- Taking any dietary supplements which you are unwilling to stop for two weeks prior to and for the duration of your participation in the study.
- Current or history of alcohol or drug abuse.
- Current or history of: HIV, kidney disease, liver or biliary disorders, cancer, cardiovascular disease, pulmonary disease (chronic respiratory trouble)
- Planned surgery within 2 weeks of participation in the study
- Do not agree to your GP being contacted about participation and screening results
- Participated in any other cognitive trials within the last month

If you are unsure whether you meet the criteria for our study, please get in touch with the study team and we can talk to you about your suitability.

Where is the study based? Who is involved?

The study will take place at the Norfolk and Norwich University Hospital's (NNUH) Clinical Research Facility (CRF) at the Quadram Institute (QI) based on the Norwich Research Park. The study is being conducted by the researchers at the University of East Anglia (UEA), Norwich. The study also involves research nurses who will take your blood samples.

Do I have to take part in the study?

It is up to you to decide whether or not you wish to take part. If you decide to take part, you will be free to withdraw at any time and without giving a reason. If you choose to take part, or withdraw from the study, this will not affect your future health care. An expression of interest does not commit you to participation.

What will I have to do if I take part?

If you agree to take part in this study, over approximately a 2-week period you will complete online questionnaires and attend 2 visits at the study site. The approximate time burden is outlined in the table below:

Table 1: Approximate time burden for participants

Session:	Approximate time:	Where:
1st consent and online screening	30 minutes	Home
2nd consent and onsite screening	3 hours	Quadram Institute
Test visit	8 hours	Quadram Institute

1st consent and online screening

You will be sent a link to register with the online testing platform. Once registered you will be required to complete an online consent form before completing some questionnaires to help us assess your suitability. The questionnaires will ask you questions about your age, sex, ethnicity, education and medical history, as well as questions relating to your stress, anxiety and depression levels.

A researcher will review your responses. If you are suitable to continue to the next stage of screening you will be invited to attend the Clinical Research Facility within the Quadram Institute.

2nd consent and site screening

You will be required to attend the appointment having fasted (except water) overnight (at least 10 hours).

A member of the study team will go through the details of the study with you, and you will be encouraged to ask questions. When you are satisfied with the information provided, and if you remain interested in taking part, you will be asked to complete a consent form for your participation in the study.

Your height, weight and blood pressure will be measured. A nurse will then take a small blood sample, approx. 17ml (just over 1 tablespoon). From this sample, 12 ml will be tested at an accredited pathology lab so that we can ensure you are well enough to take part in the study. Any fraction of the 12ml sample that remains following these pathology lab tests will be disposed of immediately. The remaining 5ml sample will be processed by UEA researchers for storage and future analysis.

We will then provide you with a breakfast before you complete two practice sessions, with a short break in between, to familiarise yourself with the computerised cognitive tests that you will complete during the test visit. At the end of the appointment, you will be provided with information about following a low polyphenol diet for 48 hours before the test visit (we will give you a list of what you can and cannot eat), asked to not consume alcohol in the 24 hours before the test visit, and you will be given a provisional appointment date. Following review of your screening results, if you fall outside of any of the eligibility criteria, you will receive a phone call from the research team explaining the reasons you cannot continue, and your appointment will be cancelled.

Test visit

Prior to your visit you will be asked to complete an online questionnaire asking you about your diet. You will be required to arrive at your appointment at 7.45am, having fasted (except water) overnight (at least 10 hours). A researcher will review your eligibility, asking about any changes to your health, medication or supplement use since your screening appointment. You may also be asked to take a pregnancy test.

You will then be provided with a breakfast (croissants) before completing your first test session (computerised cognitive tasks followed by questionnaires relating to your mood, levels of fatigue and sleepiness). Following this you will be given a capsule of either the study product (American ginseng) or placebo (dummy capsule). Neither you nor the researchers will know which capsule you are receiving. You will be assigned to a group at random and cannot choose which capsule you receive. You will have a 50% chance of being in the group receiving the study product (capsule containing American ginseng), and a 50% chance of being in the group receiving the placebo (capsule containing maltodextrin).

Two hours after consuming the capsule you will repeat the test session. A lunch will be provided during the break before you repeat the test session again four hours after consuming the capsule. The final test session will be completed at six hours following capsule consumption. Once the final test session is complete a nurse will take a small blood sample, 5ml (approximately 1 teaspoon), from you. You will now have completed the study.

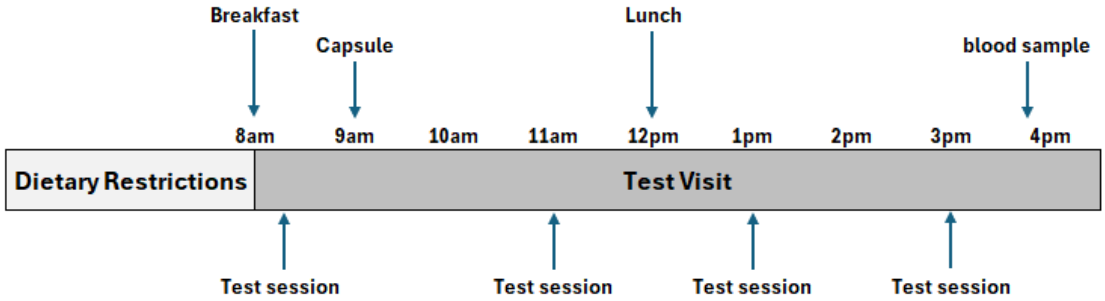

Figure 1: Timeline of events at the test visit

What are my responsibilities?

We expect that you will complete an online screening, on site screening visit and a test visit at the time and date agreed upon with the study investigator. You will be asked to consume *either the active study product or a placebo* at the test visit of the study. Once you have started the study you should not change your diet or exercise habits for the duration of your participation (screening to test visit).

What are the possible risks and benefits of taking part?

Benefits

You may or may not benefit from taking part in this study. However, in the future other people may benefit from this research.

You will receive a health check (i.e., blood pressure, blood glucose, blood safety profile, depression, anxiety, stress questionnaire) if you participate in this study. The results of this health check will be reviewed by the clinical team. Abnormal results will be communicated to your GP following your screening visit and they might be in touch with you to discuss further, if needed.

Potential risks

There are a small number of potential side effects that may happen as a result of introducing any change to the normal diet, and there are some reported mild side effects of American Ginseng including:

- Sleep disturbances (insomnia)
- Headaches
- Gastrointestinal upset (including nausea/diarrhoea)
- Increased feelings of anxiety/restlessness

If during the study visit, you note any unusual symptoms or disturbances, you should inform a researcher. Everyone taking part in the study will be monitored for any adverse effects of consuming the study product. Based on the current safety information available, there have been no serious adverse events related to taking the study product.

It is normal that you feel some discomfort when giving a blood sample and there is a risk of slight bruising. The research nurses and phlebotomists involved in our study are experienced at taking blood samples. In the event of a failed attempt at obtaining a blood sample (or a partial blood sample which did not collect the amount of blood required for analysis) a second attempt may be made on the opposite arm. In the event of failed analysis of the sample obtained you may be asked to return for an ‘unscheduled visit’ to provide another blood sample.

What samples will be stored for analysis?

From the blood samples taken at your screening and test visit appointments, a total of 5ml serum (the liquid part of blood), 2.5ml per appointment, will be extracted and stored for analysis of metabolites (substances made by the body when breaking down a food) related to ginseng (the study product). The remaining fraction of the blood sample will be disposed of immediately. Whether any additional analysis is useful and necessary will depend on the other main outcomes of the study and will be decided once that data is seen.

Stored samples will be identified by your unique study identification code only. Stored samples will be analysed and destroyed within 5 years after the end of the study.

Is there Insurance for the Study?

Yes, insurance for the study is provided by the University of East Anglia and covers both public liability, professional negligence and clinical trials indemnity. Insurance coverage is a legal requirement of regulations of clinical studies and good clinical practice and does not imply that the sponsor is expecting any damages or complications.

What happens if something goes wrong?

In the event that something does go wrong, and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of East Anglia or the Norfolk and Norwich University Hospitals NHS Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

Expense payments

Transportation costs to and from the Quadram Institute will also be reimbursed up to £20. Participants travelling by car will be reimbursed at 45p/mile. Free parking will be available. Participants travelling by public transport will be reimbursed costs on production of a ticket or receipt.

If you complete all study tasks as described above, you will receive a £50 voucher for your time, or you can choose to have £50 transferred to your bank account. Please note that if you choose bank transfer, this money will count as income for tax and benefit purposes.

You can receive an extra £10 if you ‘refer a friend’ as long as they meet the eligibility criteria and successfully complete the study.

Am I free to withdraw from the study?

Your decision to take part in this study is entirely up to you. If you decide to take part, you will be given this letter of information to keep and you will be asked to sign the informed consent form and will receive a copy. You may remove yourself from this study at any time simply by notifying the study investigator or staff. You do not need to provide a reason for withdrawal. Please note that withdrawal of your consent to participate in this study shall not affect any activities already carried out and the use of data obtained based on the consent provided before that withdrawal.

The study investigator or sponsor can also withdraw you from the study at any time, even if you want to stay in the study. This could happen if:
the study investigator believes it is best for you to stop being in the study;
you do not follow instructions required by the study;
the study is stopped for any reason.

In the event of early withdrawal before the study finishes, for any reason, the study investigator or staff may ask you some questions about being in the study. The information collected from the day you signed the informed consent and up to your withdrawal, will be used for statistical analysis. Following your withdrawal, no new data will be collected and added in the database. You may request for all previously retained data and identifiable samples to be destroyed to prevent further analysis.

New information about the Study

Sometimes, important new information is found during a study. If this happens, you will be informed as soon as reasonably practical. Your study investigator will discuss with you whether you wish to stay in the study or not. You can then decide if you wish to keep taking part.

How will we handle your personal data?

By consenting to participate, you will be sharing your personal data with the University of East Anglia, a registered data controller. The UEA will use the information you provide for research purposes as mentioned in this information sheet and is permitted to do so when you have freely given your informed, specific consent.

The personal data you provide will be shared with the research team and with NNUH to review your blood test results. We will also use external platforms to collect some data from you, such as Mantal academic clinical research management platform and the University of Aberdeen's dietary assessment service. It will not otherwise be shared unless required by law. The UEA will always store your personal data safely and it will only be kept for as long as it is necessary for the purpose it was collected. The personal data you provide will be retained for up to 12 months following completion of the study. Participants will be sent a copy of the outcome prior to the personal data being securely destroyed. We will only retain personal data for long-term for those who have consented to being contacted for future studies.

You have the right to request access to; rectify; erasure of; restrict; portability of; object to; and withdraw your consent to the processing of your personal data.
If you have concerns and queries about the protection of your data, please contact dataprotection@uea.ac.uk. For further information on how we may use your data, who it may be shared with, see the specify section.

How will we use information about you?

We will need to use information from you for this research project.

This information will include your

- Name
- Contact details

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

The University of East Anglia is the sponsor of this research and is responsible for looking after your information. We will keep all information about you safe and secure by:

- Any personal information supplied by you during the study will be handled by trained research staff and will be treated as strictly confidential and not shared.

- All participants will be assigned a random code number when they enrol into the study, and all paperwork, samples and results will be coded with this number to protect their identity.
- Any documents that link your name to this code will be stored securely and will be only accessible to delegated members of the research team.

We may share data about you outside the UK for research related purposes to:

- allow for further scientific analysis

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following sorts of organisations:

- Atlantia Clinical Trials, Cork
- Givaudan Naturals, France

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- (some of) the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK
- we use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details visit the Information Commissioner's Office (ICO) website
- we do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
- we need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing
- we have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when we legally have to. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for a maximum of 10 years. The study data will be fully anonymised and securely archived or destroyed.

What are your choices about how your information is used?

- you can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have
- you have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

Where can you find out more about how your information is used?

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK.

- our leaflet www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to the University of East Anglia's Data Protection Team: dataprotection@uea.ac.uk, or
- by ringing us on 01603 591732

What will happen to the results of the research study?

The results of this research study will be published in scientific journals and presented at national and international scientific meetings. Your data could also be used in marketing materials or health claims aimed at consumers of American Ginseng. All results will be in an anonymised format so that no individual can be identified. The information will only be used for the purpose of health and care research and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance. Unfortunately, we cannot report on the findings of specific individuals.

Who has reviewed the Study?

The study is sponsored by the UEA and has been reviewed and received a favourable opinion from the Health Research Authority and the associated South West – Central Bristol Research Ethics Committee who works independently and have a duty to protect research volunteers' safety, rights, wellbeing, and dignity.

Who to Contact?

Your study investigator and staff involved should have answered all your questions before you sign the informed consent form. If you have additional questions during the course of this study about the research or your rights as a research participant, or if you note any unusual symptoms or disturbances during the study, you may address them to the study investigator or staff.

What if I want to complain?

If you have any concerns about the study and your participation in it, or wish to make a complaint, please contact Professor Anne-Marie Minihane, Head of the NUTRIGENETICS group within the Department of Nutrition and Preventive Medicine, UEA (A.Minihane@uea.ac.uk).

Contact for eligibility and further information

Thank you for reading this and for showing an interest in the study. If you would like us to check your suitability for the study, or if you would like further information about the study, you can contact the study team on:

Email: react.study@uea.ac.uk

Thank you for reading this Participant Information Sheet.

An expression of interest does not commit you to take part this study.