



**Northumbria
University**

NEWCASTLE

Faculty of Health & Life Sciences

Study Title: The cognitive effects of a multi-ingredient supplement in cognitively intact older adults experiencing subjective memory decline: A randomized, placebo controlled, parallel groups investigation

Investigator: Emma Wightman

Participant Information Sheet

You are being invited to take part in this research study. Before you decide it is important for you to read this leaflet so you understand why the study is being carried out and what it will involve.

Reading this leaflet, discussing it with others or asking any questions you might have will help you decide whether or not you would like to take part.

What is the Purpose of the Study

To investigate whether a supplement containing multiple potential active ingredients is able to boost cognitive function and mood in adults who may be experiencing natural age-related declines in ability. This supplement contains many plant-based compounds known as terpenes, polyphenols, micronutrients and polysaccharides that our lab, and others, have looked at in isolation before. Alone, we see that they are able to boost the above outcomes but actually, when you consume these compounds in your natural diet, you consume them as a mixture. We're interested to see whether this mixture is also active in these ways and whether, over a period of time, this is because it has beneficial effects on the bacteria in your gut.

Why have I been invited?

You are between the ages of 55-75 yrs and answer yes to the question 'would you say that your memory now is worse now than it used to be in your 20's?'. Some exclusions do apply to this study; as such, you are not able to take part if you:

- Have symptoms of COVID-19 or fall into the 'high' or 'moderate' risk categories from coronavirus as defined by [NHS UK](https://www.nhs.uk).
- Have a pre-existing medical condition/illness which will impact taking part in the study
NOTE: the explicit exceptions to this are controlled (medicated) arthritis, asthma, hay fever, high cholesterol' reflux-related conditions and some blood pressure medications. There may be other, unforeseen, exceptions and these will be considered on a case-by-case basis; i.e. participants may be allowed to

progress to screening if they have a condition/illness which would not interact with the active treatments or impede performance.

- Are currently taking prescription medications
NOTE: the explicit exceptions to this are contraceptive and hormone replacement treatments for female participants where symptoms are stable and treatment will not change during the course of the study, those medications used in the treatment of arthritis, high cholesterol and reflux-related conditions; and those taken 'as needed' in the treatment of asthma and hay fever. As above, there may be other instances of medication use where no interaction with the active treatments is likely and participants may be able to progress to screening.
- Have high blood pressure (systolic over 159 mm Hg or diastolic over 99 mm Hg)
- Have a Body Mass Index (BMI) outside of the range 18.5-36.5 kg/m² (Waist-to-hip ratio will also be measured for all participants and utilized where BMI appears not to be an accurate indicator of 'fatness')
- Are pregnant, seeking to become pregnant or lactating
- Have learning and/or behavioural difficulties such as dyslexia or ADHD
- Have a visual impairment that cannot be corrected with glasses or contact lenses (including colour-blindness)
- Smoke (including vaping)
- Consume excessive levels of caffeine (>500 mg per day)
- Have clinically diagnosed food intolerances/ sensitivities
- Have taken antibiotics, prebiotics or probiotics (including drinks; e.g. Yakult or Actimel) within the past 8 weeks
- Have any health condition that would prevent fulfilment of the study requirements (this includes non-diagnosed conditions for which no medication may be taken)
- Are unable to complete all of the study assessments
- Are currently participating in other clinical or nutrition intervention studies, or have in the past 4 weeks (8 weeks if a probiotic study)
- Have been diagnosed with/ undergoing treatment for alcohol or drug abuse in the last 12 months
- Have been diagnosed with/ undergoing treatment for a psychiatric disorder in the last 12 months
- Suffer from frequent migraines that require medication (more than or equal to 1 per month)
- Have any sleep disturbances (including night-shift work) and/ or are taking sleep aid medication
- Have any known active infections
- Do not have a bank account (required for payment)
- Are non-compliant with regards treatment consumption

Do I have to take part?

No, you have volunteered to take part but can withdraw consent at any time during the study without prejudice.

What will happen if I take part?

You will need to attend the laboratory on three occasions plus an initial screening appointment. This initial screening appointment will take place via a telephone call. During this session we will discuss the study requirements with you, answer any questions you may have, and consent and demographic information will be taken. The screening appointment will last approximately 30-45 mins.

The first of the Laboratory training visit, will take place between -28 and 1 day/s before the first testing day and, during this ~3 hr session, during which we will take eligibility measurements that we were unable to do via video/telephone call (height and weight to calculate BMI, waist-hip ratio, blood pressure readings). Provided these readings are within our required range, you will undergo training on the study assessments in preparation for your testing visits. No prior experience of computers is required. Between this time and the first testing lab visit, (including on the day itself) you will need to provide a stool sample (to measure your gut bacteria) and you can do so by dropping it off at a discrete location within the building. The subsequent x2 testing lab visits will take place on day 1 and day 90 (+/- 7 days) of the supplementation period and the procedure of the day is identical. You will arrive pre 8:30 am, having consumed breakfast at home no later than 7:30 am and begin the pre-dose battery of tasks and mood questionnaires at 8:30 am. Following this, you will consume your first treatment dose (either placebo or a multi-ingredient supplement) and, 90 minutes later (~10:50 am), complete two further repetitions of the post-dose battery of tasks. During the 90 minute break you will be offered the option of a snack; a decaffeinated cup of tea/coffee and/or digestive biscuits. You will be completed at ~12:00 pm.

Every 7 days (+/- 2 days) between then and day 90 you will complete a 10-15 minute battery of cognitive tasks and mood scales, at home, on your mobile phone. If you don't have an appropriate mobile phone then one will be provided for you.

Mid-way through the 90 days a researcher will give you a call to make sure that you are still adhering to the study criteria and in good health.

What are the possible disadvantages of taking part?

The study has been fully risk assessed in order to mitigate any risk/distress to you. As such, no disadvantages are foreseen.

What are the possible benefits of taking part?

Your data will contribute to a research project, which aims to further our understanding of how plant-based compounds, working together, can influence cognitive function and mood. You will also be recompensed £150 for completing this study to cover your time commitment and any other out-of-pocket expenses you might incur as a result of taking part.

How will my participation experience be impacted by COVID-19 and what measures are in place to protect myself and others?

The COVID-19 pandemic has caused severe disruption to all functions of the University including our research department. The health, safety and wellbeing of our participants and staff has to be the highest priority and we are confident that we have the appropriate measures in place to mitigate risk of transmission so that your risk of contracting or spreading the virus is no greater than that in your day-to-day life.

The University now has a policy where all University staff and students will complete a return to work induction in order to help keep themselves and visitors safe; no staff or students are permitted to return to work without an induction. We can confirm that all members of our research team have successfully completed this induction prior to returning to work. All members of the research team on campus will undergo regular lateral flow testing for COVID-19 in accordance with University policy.

More specifically, the University has adopted a new system regarding face-to-face research. In order to resume/start research projects, researchers must now apply for permission to do so explaining why the research must be conducted in person and how the safety of participants and the research team will be assured with risk assessments in place to demonstrate this. Each application is scrutinized by a committee of University executives and the Health and Safety team and no research may be conducted until approval has been granted. We can confirm that this study has been approved by this committee and is deemed safe to conduct with the following measures in place:

- Wherever possible we will move research activities to be completed remotely e.g. screening to minimise the amount of time your participation will require you to be on campus. However, due to the nature of our data collection methods this will not be possible for all elements of the study including computerised cognitive testing visits. Please do not attend the research centre if:
 - You feel unwell or have experienced symptoms of COVID-19, in the past 10 days
 - Members of your household have experienced symptoms of COVID-19, in the past 10 days
 - You have knowingly been in contact with anyone displaying COVID-19 symptoms
 - You have tested positive for COVID-19 within the past 10 days
 - You are awaiting the outcome of a COVID-19 test
 - You have been advised to self-isolate
 - You have re-entered the UK in the last 10 days
- We will now operate with fewer participants attending the lab per day with dedicated times for testing and training. With this in mind, please be aware availability for bookings is limited and that it may not be possible for us to be as flexible with rescheduling as we have been in the past. Please do not sign up to a study or visit if you are unsure if you can attend. If something crops up urgently meaning that you need to be rescheduled, we will do our best to accommodate you but please note this may not always be possible and may result in delayed attendance and even withdrawal from the study.
- Participants are encouraged to choose, where possible, the safest way to travel to Campus. Free parking is already available to participants when pre-booked (24 hours notice required- subject to availability) and you will be encouraged to make use of this where possible (please contact the research team with your registration details in order to request a space). Government guidance on walking, cycling, travelling in private vehicles and on public transport can be accessed [here](#)

- At the time of writing, the current government guidance is that everyone must maintain social distancing and that adults (unless exempt) must wear face coverings in enclosed public places. You will find instructions for social distancing and face coverings at the entrance to all university buildings. Please follow this guidance at all times and ensure that you attend your visit with a face covering available. If you are exempt from wearing a face covering please let the research team know. In this instance we will source you a disposable visor. On arrival to our lab, you will be required to change to a type IIR face mask which we will provide.
- We now require research staff and participants to wear a type IIR (disposable surgical) face mask whenever we are testing including when seated 2m away from each other in the lab. On arrival to the research centre, you will be required to change to a type IIR face mask which we will provide. Research staff will wear these masks and in some cases visors where close up contact is required e.g. taking blood pressure and height and weight measures. Staff and participants will work side-to-side or back-to-back wherever possible. If you are exempt from wearing a face covering please inform the research team ASAP.
- You will be allocated an arrival time and we request you stick to this time as much as possible. If you find that there is a queue outside of (or within) the research centre, please observe social distancing by following the markings on the floor and keeping left. If you are going to be late please call the lab on 0191 243 7252 to check that it is still OK for you to attend. As before, we will do our best to accommodate you but please note this may not always be possible and may result in delayed attendance or even withdrawal from the study.
- Prior to arrival to the unit, you will be emailed and required to complete some questions to confirm that you do not currently have symptoms of COVID-19 and are not likely to have contracted COVID-19 in the days running up to the study visit.
- Universities, along with a number of venues, are required by law to use the NHS Test and Trace system in addition to any manual process we may also have in place for those who don't have a smartphone. Particularly venues within our university that are open to the public are required to collect details of customers, visitors and staff and display an official QR code poster to strengthen our Covid-19 safety measures on campus. We have an NHS Test and Trace QR within our research centre on the 4th floor. Please scan the QR code using the NHS COVID-19 app when you arrive within the research centre. You can download the app from the Apple app store or Google Play.
- Alcohol gel will be provided at entry and exit points to the University and throughout the campus including the research centre; please use at regular intervals and before and after handling equipment including your designated testing laptop.
- During your visit, avoid touching your eyes, nose, mouth with unwashed hands, cover your cough or sneeze with a tissue, and throw it away in a bin and wash/gel your hands.
- We will now be operating a one-way system in and out of the research centre. You will be required to enter Northumberland Building via the Digital Commons entrance (the entrance where the lifts are) from the Quad (the Quad is where the library, Habita and the Students Union are located). You will enter the BPNRC through the research centre main doors (where the intercom is) and exit via our fire escape (next to where the main testing labs and researchers' offices are) onto College Road. Note: when going to the toilet you can still use the usual corridor rather than going out of the building (just be mindful of social distancing and keep left).
- If you find yourself in a meet-meet situation in a corridor where social distancing cannot be adhered to please keep left and follow floor markings. One-way systems and directional signage are in place across the University Campus to guide visitors safely around the site.

Please take note of these signs and all other signage, e.g. use of face coverings, handwashing advice, and adhere to them across Campus.

- Lift use should be avoided where possible. If you decide to use the lifts, please give priority to those who need to use a lift, follow the revised maximum occupancy as displayed outside the lift and maintain social distancing, adhering to floor markings where appropriate
- Using the toilet: Social distancing should be maintained in the corridor whilst waiting. Guidance to be displayed on poster outside the toilet. Anyone waiting to use a toilet cubicle or sink must ensure social distancing and stand at least 1 m back to allow the previous occupant space to leave.
- During study day breaks participants will be required to remain in their testing lab until the next assessment start time. With this in mind, we request that participants bring in their own bottled water as access to the water coolers is currently prohibited. We also strongly advise that you bring a book, newspaper, magazine or tablet (with headphones if using an app with audio) to pass the time during these breaks (note you must take all newspapers and magazines home with you).
- We also ask that participants bring their own pens to all sessions to complete study paperwork and take them with them upon leaving. If you forget we will issue you with a pen, but this must be returned to us at the end of testing for sterilising
- Participants will be seated in testing labs with a 2-metre gap between them. You are encouraged to observe social distancing guidelines and keep physical interaction with others to a minimum.
- All surfaces and door handles will be cleaned frequently with desks cleaned by staff after each use.
- Fire procedures remain unchanged (the researcher will direct you to your nearest assembly point where you should remain until told by Fire Marshals/Security that it is safe to re-enter the building), but social distancing must be observed when leaving the building and when congregating in the assembly points.
- We appreciate that these are uncertain times and that participating in our research may add to stress or anxiety you are already experiencing as a result of the COVID-19 pandemic and the difficulties it has caused. Please be assured that your participation is, and always has and always will be, completely voluntary. You can withdraw from the study at any time, even if it is the middle of a testing session, and do not have to give a reason why (although we may ask why for feedback but you do not have to give an answer). The health, safety and wellbeing of our participants is of our highest priority and we understand should you decide to withdraw your interest.

For more information and guidance here are links to some of the University's COVID-19 policies and wider government advice:

- [Northumbria's COVID 19 pages](#)
- <https://www.gov.uk/coronavirus>
- [The Government review of the 2 metre rule](#)
- [Working safely during COVID in offices](#)
- [Working safely during COVID in labs and research facilities](#)
- [PHE quick guides for correct donning and doffing of PPE for non-Aerosol generated procedures \(AGPs\) as well as for AGPs.](#)
- [Government advice on face coverings found here](#)

Should you have any queries or concerns please contact your lead researcher who will be happy to discuss any queries or restrictions with you.

We thank you in advance for your patience and compliance with the above.

Will my taking part in this study be kept confidential and anonymous?

Yes, when you consent to take part in the study and progress from the screening/ training stage you will be allocated a unique participant number, which will identify your subsequent data (including biological samples). Your consent form, the only document which contains your name, will be stored away from this data in a locked filing cabinet.

How will my data be stored?

Your consent form will be stored in a locked filing cabinet and away from any other hard copy information/ data you might provide. Your electronic data will be stored on password protected computers/servers and the mobile phone battery data will first be stored on a password protected cloud before being transferred to these computers/server. Your biological samples will be stored in a freezer within a pass-protected room until ready for analysis. After analysis the samples will be disposed of via clinical waste.

What will happen to the results of the study?

The results will likely be disseminated at conferences and in peer reviewed journal articles and will also be utilized for scientific and marketing purposes by Pukka Herbs. At all stages of the study your results will be anonymous and not attributable to you.

Who is Organizing and Funding the Study?

This study is funded by Pukka Herbs. The study was designed and is organized by staff at Northumbria University.

Who has reviewed this study?

This study has been reviewed by the Psychology Staff Ethics Committee.

Contact for further information:

Researcher email: julie.khan@northumbria.ac.uk

Name of another person who can provide independent information or advice about the project:

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