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 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/m^2 (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. The first of these, a screening/training visit, will take place between -28 and 1 day/s before the first testing day and, during this ~3 hr session, consent and demographic information will be taken and training on the assessments will be provided. 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.

On day 90 (-7 days and +1 day) you will provide another stool sample and ~ 3 weeks later you will be asked to complete some follow-up questions about the study and complete the mobile phone tasks again.

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.

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:

(emma.l.wightman@northumbria.ac.uk)