Northumbria University NEWCASTLE

Faculty of Health & Life Sciences

Study Title: The acute and chronic cognitive effects of a sage extract: a randomized, placebo controlled study in healthy humans

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

Our laboratory has investigated extracts of sage in the past and found improvements in aspects of cognitive performance and mood. These effects are probably due to 1 group of plant chemicals in sage called terpenes which can interact with chemicals regulating human brain function (the neurotransmitters acetylcholine and GABA). Sage also naturally contains another group of plant chemicals called phenolics but these are often not a constituent of the final sage extract despite cognitive and mood effects (and physiological mechanisms relevant to brain function; namely improving blood flow in the brain) also reported for this group of compounds. Previous research with sage, regardless of composition, also tended to focus on short-term effects and so little is known about longer-term effects. The current study aims to test a commercially available extract of sage, which contains both terpenes and phenolics, on cognition and mood following short term consumption (day 1) and longer-term supplementation (day 29). A 600 mg dose will be consumed every day in the interim and a mobile phone battery of cognitive tasks will be completed every 7 days.

Why have I been invited?

You are between the ages of 30-60 yrs and in full-time employment and/or higher education and/or caring i.e. caring for children or carer e.g. for relatives.

NOTE: You are not eligible to take part if you:

• Have any 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 and reflux related conditions. 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, 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 which, where no interaction with the active treatments is likely, 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 18.5-30 kg/m2
• Are pregnant, seeking to become pregnant or lactating
• Have learning difficulties, dyslexia
• Have a visual impairment that cannot be corrected with glasses or contact lenses (including colour-blindness)
• Smoker
• excessive caffeine intake (>500 mg per day)
• Have 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
• 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
• Has been diagnosed with/ undergoing treatment for alcohol or drug abuse in the 12 months
• Has been diagnosed with/ undergoing treatment for a psychiatric disorder in the 12 months
• Suffers from frequent migraines that require medication (more than or equal to 1 per month)
• Sleep disturbances and/ or are taking sleep aid medication
• Any known active infections
• Non-standard working time: main shift work during the night, or significant changing of shift work during entire study (from inclusion to final visit)
• Ever been diagnosed with breast cancer or had a mastectomy

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 come to the laboratory on 4 occasions and there will be some interim tasks that we need you to carry out on your mobile phone (see bullet points below):

1. Training/ screening session (~2.5-3 hrs)
    - Baseline mobile phone cognitive task battery completion (~10 minutes to be completed in the morning, before work/ university, and again in the evening, after work/ university)
2. Acute testing session (Day 1; ~6 hrs)
    - Day 7, 14, 21 and 28 mobile phone cognitive task battery completion (~10 minutes to be completed in the morning, before work/ university, and again in the evening, after work/ university)
3. Interim visit (Day 25; ~5 mins)
4. Chronic testing session (Day 29; ~6 hrs)

In the training/ screening session we will discuss your eligibility, take some demographic information and you will practice the cognitive tasks and mobile phone tasks which form part of this study.

In both the acute and chronic testing sessions you will come to the lab before 8.00 am having consumed a breakfast of cereal and/ or toast at home no later than an hour before arrival. You must have refrained from alcohol for 24 hours and caffeine for 18 hours. On arrival on each day you will complete some cognitive tasks, mood scales and a blood pressure (BP) reading will be taken. Immediately following this you will consume your treatment for that day and this will be either 600 mg sage extract or placebo. At about 11:00 am and 1:00 pm you will complete these same tasks, mood scales and BP but, at about 12:00 pm we will provide you with a standardized lunch of a white bread cheese sandwich, packet of ready salted crisps and custard pot. You must have no allergies to components in this meal and be willing to consuming it during both visits.

On day 25 you will be required to attend the lab for a 5 minutes to complete part 1 of the computerized location learning task. This will require you to memorise the location of several pictures on a grid for this information to be recalled a few days later as part of your final testing visit (part 2 of the location learning task).

Between the acute and chronic visit to the lab we will ask you to continue to consume your treatment every day at home and note down the time that you consume this. On day 7, 14, 21 and 28 following your acute lab visit we will also ask you to complete a battery of cognitive tasks on your phone; once in the morning (10 mins) and once in the evening (10 mins).

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 sage 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. 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.

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 Nexira. 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 Nexira and utilizes their product COGNIVIA™. The study was designed and is organized by staff at Northumbria University.

Who has reviewed this study?

This study has been reviewed by the Health and Life Sciences ethics committee.

Contact for further information:

Researcher email: b.spittlehouse@northumbria.ac.uk

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

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