**41BF2 (PEP-2005): Effect of coffeeberry on mood and cognitive performance**

**Participant Information Sheet**

**Version 1.2: Approved 06.10.21**

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 research 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?

Research has shown that coffeeberry extract, derived from the whole coffee fruit, can lead to mood improvements including a reduction in mental fatigue and increased alertness during the performance of cognitively demanding tasks. The current study aims to replicate some of these previous findings and to assess the short-term effects of consumption of coffeeberry extract on cognitive performance and mood during and after repeated performance of cognitively demanding tasks.

**Why have I been invited to take part?**

**You have been invited because you meet the following criteria\*:**

* You are aged 18 to 49 years at the time of giving consent1
* You are in good health
* You are willing to maintain your habitual diet, physical activity pattern, and body weight throughout the trial
* You are willing to abstain from consumption of caffeine within 12 h of testing
* You are willing to abstain from alcohol consumption and avoid vigorous physical activity for 24 h prior to all test visits
* You are willing to refrain from ‘over the counter’ medications (e.g. pain medication) and stimulant medication for 12 hours, seasonal allergy/hayfever nasal antihistamine medications for 24 hours and oral antihistamines for 48 hours prior to all test visits
* You understand the study procedures and are willing to provide informed consent to participate in the study and authorization to release relevant protected health information to the research team and study investigator

1Age range is based on research demonstrating that natural decline in some cognitive performance measures is more likely to occur at 50+ years in the general population

**You are not eligible to take part in this trial if you:**

* Do not meet any one of the aforementioned inclusion criteria
* Are using any prescription medication except for contraception
* Report hypersensitivity to caffeine.
* Have experienced major trauma or a major surgical event within 6 months of screening
* Have extreme dietary habits, as judged by the Investigator (high fat, very high protein diets, intermittent fasting, etc.)
* Have had exposure to coffeeberry within 30 days prior to screening
* Have a history of cancer in the prior two years, except for non-melanoma skin cancer
* Have a visual impairment that cannot be corrected with glasses or contact lenses.
* Report any food allergies /intolerances/sensitivities to any ingredients in the study products (including coffee or related foods/beverages/products)
* Self-report excessive leisure time physical activity (> 7 strenuous bouts per week)
* Have a current gastrointestinal, sleep, or psychiatric disorder.
* Work night shifts or follow a variable work pattern that results in irregular sleep pattern
* Are pregnant, seeking to become pregnant, or lactating
* Smoke tobacco, vape nicotine or use nicotine replacement products
* Use illegal/recreational drugs
* Have participated in another clinical trial within past 30 days and/or participation in another PepsiCo trial in the past 6 months
* Have learning and/or behavioural differences such as dyslexia or ADHD
* Excessive caffeine intake (>500 mg per day) (this is assessed through a caffeine consumption questionnaire during appointment 1)
* Have taken dietary supplements e.g. vitamins, omega 3 fish oils etc. in the last 4 weeks (Note: participation is possible following a 4 week supplement washout prior to participating and for the duration of the study on the proviso that the supplements you are taking are out of choice and not medically prescribed or advised)
* Have any health condition that would prevent fulfilment of the study requirements (this includes non-diagnosed conditions for which no medication may be taken)
* 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 known active infections
* Do not have a bank account (required for payment)
* Have high blood pressure (systolic over 139 mm Hg or diastolic over 89 mm Hg)
* Have a Body Mass Index (BMI) outside of the range 18.5-35 kg/m2
* Unable to demonstrate adequate minimal performance on the cognitive tasks

\* Please note that this study utilises the listed criteria for methodological reasons and marketing purposes related to the investigational product. All criteria have been fully considered and have a sound rationale. Whilst it would be too lengthy to include here, these are available on request by emailing the study investigator; philippa.jackson@northumbria.ac.uk

If you are unsure about your eligibility with regard to any of the listed inclusion and exclusion criteria, we advise you check with the research team before committing to appointments.

NOTE: The study products are suitable for Kosher and vegetarian diets. The products in use have not received vegan certification and so, may not be suitable for vegan diets. This product does not meet PepsiCo Halal standards.

Do I have to take part?

No. It is up to you whether you would like to take part in the study. We are giving you this information sheet to help you make that decision. If you do decide to take part, remember that you can stop being involved in the study whenever you choose, without telling us why. You are completely free to decide whether or not to take part, or to take part and then leave the study before completion. NOTE: We may ask your reason for withdrawal for feedback purposes, but you do not have to tell us. We may also ask if we can use the data you have provided thus far; again, you do not have to agree to this.

What will happen if I take part?

The study will require you to have 6 appointments: appointment 1 will be done remotely, appointments 2-6 involve attending the Brain Performance and Nutrition Research Centre at Northumbria University (Newcastle City Campus).

Appointment 1. Initially you will have a screening appointment which will be completed via video/telephone call with the research team at a pre-arranged time. If using video call, the research team will send you a link which you will need to click at the arranged time to start the 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. You will also complete a questionnaire about your habitual caffeine consumption levels. The screening appointment will last approximately 30-45 mins.

Appointment 2. You will then be invited to attend the lab for the next appointment which is a training visit 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, cognitive tasks). 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. NOTE: The above eligibility assessments can only be done in person. Please be aware it is possible that if your measurements are out of the required range for this study this will not be known until appointment 2 and you will not be able to continue with the study. We apologise for any inconvenience or disappointment should this happen. This visit will last approximately 2 hours.

The lab-based training visit will take place between 28 and 2 day/s before the first testing visit. If more than 28 days elapse between training and the first testing visit, then you will be invited to return for a ‘refresher’ training visit before commencing the study.

Appointments –3 - 6. If you are enrolled onto the study, you will have four subsequent laboratory-based active testing visits which will be identical, with the exception that you will consume a different treatment beverage during each visit. These visits will take place 7 days apart, will last approximately 4-4.5 hours each and will follow this procedure:

You will attend the laboratory at a prearranged time having consumed a breakfast of cereal and/or toast at home no later than one hour prior to the visit. You will need to refrain from alcohol for 24 hours and caffeine from dinner on the previous evening. You will also need to avoid moderate-to-vigorous physical activity (for 24 hours) prior to testing and have a typical night of sleep prior to each visit (no more than + 1.5 h from usual amount of sleep). You will be asked to complete a questionnaire pertaining to this at home, prior to arrival at the lab.

On arrival, we will discuss your answers to the questionnaire and check compliance with study restrictions. You will then complete a 45 minute (approximately) computerised cognitive assessment which will include a range of tasks and self-report mood and motivation scales. You will then take your allocated treatment beverage for the day (a beverage containing either 100mg coffeeberry extract, 300mg coffeeberry extract, 75 mg caffeine, or a placebo). You will have 10 mins to consume the beverage in full. Neither you nor the researcher will know at this stage which treatment you are taking so as not to influence the results. You will then rest in the lab for 60 mins to allow for absorption. This will be followed by completion of further cognitive/mood assessments which will be completed at 60 minutes and 120 minutes post-dose with a 15 min break between these two post dose assessments.

After your final appointment you will be debriefed and your remuneration via bank transfer organised (please note that this can take as long as 2-3 weeks to reach your account).

Timings given here are approximate for illustrative purposes and may be subject to change due to implementation of COVID-19 safety measures and unexpected delays.

Some important things to note:

During the rest period you will be given the option to watch TV or read (hard copy material only- no electronic devices) and you must complete the same quiet rest activity at each visit.

We ask you to switch off your mobile phone during testing and to refrain from using for any purpose during the breaks.

No food or drink, except for water (maximum 12 oz/ 355 ml) may be consumed throughout the testing visit, this includes gum and mints.

What are the possible benefits of taking part?

Your data will contribute to a research project which aims to further our understanding of how coffeeberry extract can influence cognitive function and mood.

You will also be recompensed £200 for completing this study which is intended to cover your time commitment and any other out-of-pocket expenses you might incur as a result of taking part.

What are the possible disadvantages of taking part?

Coffeeberry extract is an extract of powdered whole coffee fruit standardized to contain 40% coffee polyphenols and is classified as a food or food supplement. Metabolism and safety data for coffeeberry extract has been reviewed by PepsiCo Scientific Affairs and is approved for this study exceeding no more than 300 mg per participant per visit.

You may find it uncomfortable to provide information on your mood and to be observed whilst completing cognitive tasks. All data you provide contains only your participant code (e.g. 516) and not your name. This data would only ever be linked to you if you asked us to withdraw your data from the study; here we would have to break your anonymised code in order to identify (and destroy) your data. If you have any concerns about your mental health, sources of help include your GP, Samaritans (116 123) or you can self-refer to talking therapies in Newcastle (talkinghelpsnewcastle.org).

You will be required to remain seated at a desk for the duration of the cognitive assessments. Prolonged computer testing may cause some minor discomfort and you may feel tired at times. It is therefore important that the correct eyewear is brought along to the testing session and that you inform the researcher of any back/arm/wrist problems you may have.

The tasks used in this study will be a combination of memory, reaction time and attention tasks and are intended to be mentally demanding. It is likely you will feel fatigued whilst completing these tasks, but we require participants to try their best at all times when completing these tasks.

The study and its procedures have been fully risk assessed.

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.

All members of the research team on campus will undergo regular lateral flow testing for COVID-19 in accordance with University policy. Please see below our COVID-19 mitigation procedures and your role in helping us to implement them:

* Wherever possible we will move research activities to be completed remotely (e.g. the initial eligibility screen) 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

- 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 told to self-isolate by NHS Test and Trace

- You have re-entered the UK from abroad in the last 10 days. If this is the case, please let the researcher know which country you have arrived from and they will check the current guidance.

* 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](https://www.gov.uk/guidance/coronavirus-covid-19-safer-travel-guidance-for-passengers#travel-safely-during-the-coronavirus-outbreak)
* At the time of writing, the current government guidance is to limit close contact with persons you do not live with, respect the space of others, and that adults (unless exempt) are recommended to wear face coverings in crowded and enclosed areas where you come into contact with people you don’t usually meet. The University encourages the use of face coverings when moving around campus buildings. We encourage you to please follow this guidance at all times and to attend campus with a face covering available. Within our research centre specifically, we encourage research staff and participants to wear a type IIR (disposable surgical) face mask whilst in the department including when seated away from each other in the lab. On arrival to the research centre, you will be requested to change to a type IIR face mask which we will provide. Research staff will wear these masks and, in some cases, where very close contact Type IIR marks are mandated by the risk assessment for both researchers and participants 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 we can provide a disposable visor as an alternative if desired.
* The current government advice is that when indoors you should let fresh air in to reduce the risk of catching or spreading COVID-19 with the more fresh air you let into enclosed spaces, the less likely a person is to inhale infectious particles. As result we will have our laboratory windows open at all times. We appreciate that on colder days this may be uncomfortable and so advise participants to wear layers on attendance to the lab for their own comfort.
* 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 give space to others 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. 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. Please respond to these questions ahead of your arrival to the lab.
* We are using the NHS Test and Trace system in our research centre in addition to any manual process we may also have in place for those who don’t have a smartphone. We feel this is an important COVID mitigation procedure given that our research department welcomes members of the public on a daily basis. We have an NHS Test and Trace QR poster displayed within our research centre on the 4th floor. Please scan the QR code using the NHS COVID-19 app when you arrive to 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.
* 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).
* If you find yourself in a meet-meet situation in a corridor please give space, 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 is recommended to be avoided where possible. If you decide to use the lifts, please give priority to those who need to use a lift, follow any revised maximum occupancy as displayed outside the lift (if applicable) and give others space, adhering to floor markings where appropriate.
* We no longer have a water cooler. Please bring in your own water bottle when visiting the lab.
* Participants will be seated in testing labs with sufficient space between them. You are encouraged to continue to respect personal space 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 you should respect personal space 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 if 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 and respect your decision 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://one.northumbria.ac.uk/service/cs/hs/Pages/Covid-19.aspx)
* <https://www.gov.uk/coronavirus>
* [The Government review of the 2 metre rule](https://www.gov.uk/government/publications/review-of-two-metre-social-distancing-guidance/review-of-two-metre-social-distancing-guidance)
* [Working safely during COVID in offices](https://eur02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fassets.publishing.service.gov.uk%2Fmedia%2F5eb97e7686650c278d4496ea%2Fworking-safely-during-covid-19-offices-contact-centres-0310720.pdf&data=02%7C01%7Cjo.forster%40northumbria.ac.uk%7C6cd959be62d84490294708d83dffffb0%7Ce757cfdd1f354457af8f7c9c6b1437e3%7C0%7C0%7C637327517134146842&sdata=VRl%2Bd4F2ses8c0FuSE7DgfBfuUzs5eAxWlUSZp6yYpY%3D&reserved=0)
* [Working safely during COVID in labs and research facilities](https://www.gov.uk/guidance/working-safely-during-coronavirus-covid-19/labs-and-research-facilities)
* PHE quick guides for correct donning and doffing of PPE for [non-Aerosol generated procedures (AGPs)](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/878678/PHE_11606_Taking_off_PPE_064_revised_8_April.pdf) as well as for [AGPs](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/879103/PHE_COVID-19_Donning_quick_guide_gown_version.pdf).
* [Government advice on face coverings found here](https://www.gov.uk/government/news/public-advised-to-cover-faces-in-enclosed-spaces)
* [Government guidance on travel to England](https://www.gov.uk/guidance/travel-to-england-from-another-country-during-coronavirus-covid-19)

Should you have any queries or concerns please contact your lead researcher who will be happy to discuss any queries or measures 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 you will be allocated a unique subject identification number (e.g. 516), which will identify your subsequent data. Regarding anonymisation, the only document containing the full names of participants alongside their related anonymised code is the participant identification list and this will be stored as a password protected document on secure computers/servers accessed only by the research team. Should this document need to be printed it will be stored in a locked filing cabinet separate from all other forms of data pertaining to this study. Your electronic data will be stored on a secure cloud system and downloaded onto secure computers/servers accessed only by the research team. Any IP addresses collected via online survey systems will be deleted as soon as data collection is complete. Clouds and computers/servers used for data storage in this study are password protected and will be accessed only by the research team.

This study complies with GDPR legislation regarding the processing, storage and use of personal data.

How will my data be stored?

All study documentation and data generated in connection with this study will be retained for at least two years after the last approval of a relevant marketing application and until there are no pending or contemplated marketing applications, or at least two years have elapsed since the formal discontinuation of development of the investigational product. These documents should be retained for a longer period, however, if required by the applicable regulatory requirements or by an agreement with the study sponsor.

During this period all electronic data will be kept separately on a secure cloud and computer server which is password protected. All paper records will be kept in a locked storage facility. All data will be stored in accordance with University guidelines and GDPR.

What categories of personal data will be collected and processed in this study?

During the screening and training visits we will take demographic data from you and this documents such things as your age, height/ weight, Waist-to-Hip ratio, blood pressure readings, biological sex, race, lifestyle habits, years in and level of education and that you do not meet any of the exclusion criteria. Prior to testing visits you will be asked to report your lifestyle habits from the day prior to testing (exercise, sleep, diet etc.). During the testing visits we will collect your cognitive and mood data.

**What is the legal basis for processing personal data?**

The legal basis for processing the personal data required for the purposes of this study is that the research is necessary for scientific research purposes.

Who are the recipients or categories of recipients of personal data, if any?

The research team here at Northumbria University will have access to your personal data. We also have a data sharing agreement with the study sponsor so that during any monitoring of the study for quality purposes, the sponsor’s monitor will have access to source data/identifiable information as a 3rd party processor. This data will be kept confidential. All pseudoanonymised data (using participant code e.g., 516, as an identifier) will be transferred to PepsiCo in the USA at the end of the study. It may also be a requirement of the publisher of the eventual journal article that pseudoanonymised data are made available in a public data sharing repository.

**What will happen to the results of the study and could personal data collected be used in future research?**

The general findings might be reported in a scientific journal or presented at a research conference; however, the data will be pseudoanonymised and you or the data you have provided will not be personally identifiable. The findings may also be used in future studies (e.g. when conducting meta-analyses) or shared with other organisations/ institutions that have been involved with the study but again you and your data will not be personally identifiable. We can provide you with a summary of the findings from the study if you email the researcher at the address listed below.

**Who is Organizing and Funding the Study?**

The study is funded by PepsiCo and is a replication of a previously published study entitled: Acute Low and Moderate Doses of a Caffeine-Free Polyphenol-Rich Coffeeberry Extract Improve Feelings of Alertness and Fatigue Resulting from the Performance of Fatiguing Cognitive Tasks (Reed et al, 2018).

**Who has reviewed this study?**

This study has been approved by the University Ethical Approval System (Ref: 33646) at Northumbria University.

**What are my rights as a participant in this study?**

Under the GDPR legislation you have right of access to your personal data (to do so you should submit a Subject Access Request); a right in certain circumstances to have inaccurate personal data rectified; and a right to object to decisions being taken by automated means. If you are dissatisfied with the University’s processing of personal data, you have the right to complain to the Information Commissioner’s Office. For more information see [the ICO website](http://www.ico.org.uk/).

**further information:**

**Lead Researcher: Charlotte Kenney**

**Researcher email:** **hl.coffeeberry.study@northumbria.ac.uk**

**Investigator email:** **philippa.jackson@northumbria.ac.uk**

**Name and contact details of the Records & Information Manager at Northumbria**

**University: Duncan James (****dp.officer@northumbria.ac.uk****).**