**Study Title:** 63O2: Immediate and residual effects of functional chewing gum on concentration

**Investigator:** Prof. Crystal Haskell-Ramsay

**Participant Information Sheet**

You are being invited to take part in this research study. Before you decide whether to take part, 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?

Previous research suggests that chewing gum may influence several functions including attention and alertness. Gum can also be used as a vehicle for delivering ingredients that have the ability to modulate attention and mood. This study will explore the effects of the plant extract Rhodiola rosea and B-vitamins [Biotin (Vitamin B7), Riboflavin (Vitamin B2) and Pyridoxine Hydrochloride (B6)] when administered in a gum. These effects will be compared to the effects of a basic sugar-free gum and to a tablet which will either include the same active ingredients as the gum or will be an inert placebo. Effects will be explored on computerised measures of attention/concentration and via ratings of current mood. The study will assess the immediate effects of chewing gum as well as the effects 1 hour later.

**Why have I been invited?**

You have been invited because you meet the following criteria:

* You self-assess yourself as being in good health
* You are aged 18 to 35 years at the time of giving consent
* You are a native speaker of English or fluent in English
* You self-report good oral health and chewing ability

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

* Have any pre-existing medical condition/illness which will impact taking part in the study
* Are currently taking prescription medications (except contraception and topical skin treatments and those taken as needed in the treatment of hay fever)
* Have undergone dental treatment 1 week before the test, or need or are planning dental treatments during the study (excluding routine dental check-up)
* Have a Body Mass Index (BMI) outside of the range 18.5-30 kg/m2
* Are pregnant, seeking to become pregnant or lactating.
* Have a visual impairment that cannot be corrected with glasses or contact lenses (excluding colour-blindness)
* Smoke tobacco or vape nicotine or use nicotine replacement products (occasional social smoking is permitted)
* Have relevant food intolerances/ sensitivities/ allergies
* Have taken dietary supplements e.g. vitamins, omega 3 fish oils etc. in the last 4 weeks. Existing and consistent use of vitamin D supplements and protein shakes are permitted
* 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
* Any known active infections
* Does not have a bank account (required for payment)

**IMPORTANT DIETARY INFORMATION:**

The product is suitable for vegans or vegetarians. It is not certified as suitable for Halal/Kosher. The product contains **soy** and a source of phenylalanine.

What will happen if I take part?

You will have an initial remote screening session (Appointment 1) followed by visits to the laboratory on 4 separate occasions: an introductory/training visit (Appointment 2) and three active study days (Appointments 3-5).

Appointment 1: The remote screening session will be completed via telephone call and will comprise: briefing on requirements of the study, obtaining of informed consent via completion of an online consent form, health screening, collection of demographic data (date of birth, biological sex, race, years in education, lifestyle habits, medical history, current medication use) and completion of the Caffeine Consumption Questionnaire (CCQ). This will take approximately 30 mins to complete.

Appointment 2: The introductory/training visit to the laboratory (Day 0) will begin with physiological eligibility measures that cannot be completed remotely (e.g. height and weight, waist-hip ratio) followed by training on the computerised measures of concentration and subjective mood measures. This will take approximately 1 hour to complete.

Appointments 3-5:

You will attend the laboratory at a prearranged time either at 10am or 2pm on three separate occasions having abstained from alcohol and over the counter medications including hay fever medication (24 hrs) and caffeine (5 hrs), following a standardised meal no later than 1 hour prior to arrival (there are no specific items you should consume/avoid but note that meal items should be kept consistent across visits).

On arrival on each testing visit we will check your continued eligibility and you will complete a 10-minute pre-treatment computerised assessment of concentration and mood. After the first assessment you will have a 10-minute break. You will then take your allocated treatment for the day which will be one of 2 types of chewing gum or a matched tablet (neither you nor the researcher will know at this stage which treatment you are taking so as not to influence the results) and complete your next 10-minute assessment whilst chewing the gum/tablet. Following this you will dispose of your gum and then complete a final assessment 1 hour later to assess the residual effects following chewing.

All testing visits (and the assessments completed during the visits) will be identical, with the exception that you will consume a different treatment gum/tablet at each visit.

Each of these visits will take approximately 2 hours to complete.

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

Note: Timings given here are approximates for illustrative purposes and may be subject to change due to unexpected delays.

You will also be recompensed £70 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.

**Will my participation involve any psychological discomfort or embarrassment?**

The active ingredients [Rhodiola rosea, Vitamin B2, Vitamin B6 and Vitamin B7] are not associated with any side effects at the doses to be administered.

The study involves completing scales assessing ‘alertness’, ‘stress’, ‘tranquillity’, ‘concentration’, ‘focus’ and ‘mental tiredness’. Your performance on the computerised tasks will also be checked against minimum values to ensure you understand how to complete the tasks. If you are not comfortable with these aspects of the study then you should not take part.

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 health, safety and wellbeing of our participants and staff is always of our highest priority and we have risk assessments in place to help mitigate the spread of COVID-19 so that your risk of contracting or spreading the virus is no greater than that in your day-to-day life. Your researcher will advise you of any specifics that you need to observe whilst in attendance. Note that the measures listed in our risk assessment are subject to change in line with University and government guidelines. 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 for your continued support and compliance with the above.

How will confidentiality be assured and who will have access to the information that I provide?

You will be provided with a code that will be used to identify your data, and no names will be used. Your name will not be written on any of the data we collect and will also never appear in any reports or documents resulting from this study. The consent form you have signed will be stored separately from your other data. Anonymised data from this study may be shared with the sponsor of the study or may be published in the public domain but any details which may potentially identify you will be removed from this dataset prior to sharing. All data will be stored and treated in line with the Data Protection Act.

**How will my data be stored, and how long will it be stored for?**

Paper records will be stored in a locked filing cabinet and electronic information will be stored on password-protected restricted access computer servers/cloud. All data will be treated in accordance with GDPR. Individual testing laptops will also hold data until it is transferred via USB or external hard drive to the aforementioned server. This data will all be pseudonymised as detailed above and accessible only to the research team.

All information and data gathered during this research will be stored in line with GDPR Legislation and will be retained for at least two years.

If the research is published in a scientific journal it may be kept for longer before being destroyed. During that time the data may be used by members of the research team only for purposes appropriate to the research question, but at no point will your personal information or data be revealed.

**What will happen to the results of the study?**

The general findings might be reported in a scientific journal or presented at a research conference, however the data will be anonymised and neither you nor the data you have provided will 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. We will send a summary of the results to you once the study has completed and the data has been analysed. Please note that this can sometimes be several months after the study has completed. Results will be sent to the email address that you have used to communicate with us throughout the study.

**Who is organising and funding the study?**

The study was designed and is being conducted by the research team here at Northumbria University. The funding is provided by Perfetti for the purposes of testing their investigational product.

**Who has reviewed this study?**

Before this study could begin, permission was obtained from Northumbria University and this study has been approved by the University Ethical Approval System (Ref. 46799) at Northumbria University.

**How can I withdraw from the study?**

If you would like to withdraw from the study at any point, please contact the researcher using the details below and ask to withdraw your data. This will be possible up until two weeks following study completion.

**Contact for further information:**

**Researcher email:** **hl.chewing.gum.study@northumbria.ac.uk**

**Investigator email:** **crystal.haskell-ramsay@northumbria.ac.uk**

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

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