Northumbria University
NEWCASTLE
Faculty of Health & Life Sciences

Study Title: The chronic cognitive effects of 6 and 12 weeks administration of a food supplement containing Sharp•PS® green: A double blind, randomized, placebo controlled, parallel groups study in healthy children aged 8 to 12 years

Principle Investigator: Dr Philippa Jackson

Participant Information Sheet

Your child is being invited to take part in this research study. Before you decide if they should take part it is important for you to read this leaflet so you both understand why the study is being carried out and what it will involve. As parent or legally responsible person, you will be required to give your consent to the participation of your child in the research study. Your child will also be required to give their assent to take part.
Reading this leaflet, discussing it with others or asking any questions you might have will help you decide whether or not you would like your child to take part.

What is the Purpose of the Study

Phosphatidylserine is a phospholipid that occurs naturally within the body, making up part of a cells structure. It also is found in many of the foods we eat. There is some research to suggest that increased ingestion of phosphatidylserine can improve cognitive function and memory in adults and in children. The aim of this study is to investigate whether taking a phosphatidylserine-containing supplement gummies daily for 12 weeks can improve brain functioning (attention, learning and memory) and mood in healthy children aged 8 to 12 years (school years 4 to 7).

Why have I been invited?

Your child has been invited because they meet the following criteria*:

- In good health as reported by themselves and their parent/guardian.
- Healthy children aged 8 to 12 years and enrolled in school years 4 to 7 at the time of giving consent.
- Have been speaking English at school since Reception.
- Have a normal sex and age-related BMI according to the local NHS guidelines (3rd to 90th percentiles).

Your child is not eligible to take part in this trial if they:

Have an allergy or known hypersensitivity to one of the following ingredients: Phosphatidylserine and other lipids from sunflower lecithin, maltodextrin, silicon dioxide, antioxidants (mixed tocopherols and ascorbyl palmitate), sulphur dioxide, sulfite, sulphate, glucose syrup (contains sulfite), sugar, citric acid, pectin, trisodium citrate, flavors, color (black carrot concentrate), soybeans and products thereof, fish and products thereof, crustaceans and products thereof.

The gummies contain the following allergens: Sulfite, sulphate and sulphur dioxide

The gummies may come in contact with the following allergens: soybeans and products thereof, fish and products thereof, crustaceans and products thereof.

- Are currently taking any illicit, herbal or recreational drugs including alcohol and tobacco.
- Have used dietary supplements within the last 4 weeks (for example: vitamins, minerals, and specialty products including omega-3 fatty acid, probiotics, prebiotics phosphatidylserine, antioxidants, etc.).
- Are diagnosed with ADHD, dyslexia or any neurodevelopmental disorder or learning difficulty.
- Suffer from visual (including colour blindness) or hearing impairment that may impact task performance.
- Have any serious illness, cognitive impairment or medical disorder that may confound with study results or interfere with compliance.
- Have any other active or unstable medical condition, that, in the opinion of the PI, may adversely affect the participant's ability to complete the study
- Are experiencing exceptional social/family stressors.
- Taking any prescribed or OTC medication used to treat chronic or non-chronic illnesses.
- Consume more than one portion (>100g) per week of the following dietary sources high in phosphatidylserine: Oily fish such as salmon, mackerel, herring, tuna and eel. Animal internal organs such as liver, kidney, brain and heart.
- Have followed a specific diet, e.g. high protein diet, within 30 days prior to study start
- Have had a serious diet change, e.g. Ketogenic or vegan, within 30 days prior to study start.
- Consume more than 250 mg/day of caffeine.
- Are unable to complete all of the study assessments
- Are currently participating in other clinical or nutrition intervention studies, or have done so in the past 8 weeks
- Are non-compliant with regards to the study’s treatment consumption

Please check with the research team if there is anything you are unsure of.

* Please note that this study utilizes the above 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 the rationale behind the inclusion/exclusion criteria, these are available on request by emailing the study principle investigator; philippa.jackson@northumbria.ac.uk

Does my child have to take part?

No. It is up to you and your child whether you would like them to take part in the study. I am giving you this information sheet to help you make that decision. If you do decide that you are happy for them to take part, remember that they can stop being involved in the study whenever they or you choose, without telling me why. They and 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 my child takes part?

You will attend the laboratory (Brain, Performance Nutrition Research Centre within Northumbria University's City Campus) with your child on 4 separate occasions.

The first appointment is a screening/training visit that will take place at a pre-arranged time in the afternoon (after school or on weekends) that will comprise briefing on requirements of the study, obtaining of informed consent from you and assent from your child, health screening (self-reporting on your child's behalf, as well as measuring height and weight to determine BMI) and collecting demographic data (age, sex, eligibility for free school meals, parental occupation/income etc). Your child will then have the chance to practice the cognitive tasks that will be used within the study (which include tasks assessing learning, memory, attention and mood). You will also be asked at this visit if your child would be willing to be part of an optional sleep monitoring subgroup (only 60 participants will be able to be included in this subgroup and spaces will be allocated on a first-come-first-served basis). If your child chooses to opt in to this element of the study, they will be given an ActiGraph sleep watch that should be worn (on their non-dominant wrist) for the 7 days prior to their next visit. The device must be worn continuously throughout this period except when bathing. A sleep diary will also be provided and should be completed every day noting bedtime and wake time. This procedure will be repeated in the 7 days prior to the final appointment; therefore you will be required to come in for an extra, short appointment at least 7 days prior to the final visit to collect the sleep watch and diary. Sleep watches and diaries should be brought in with you to the appointment following each sleep-monitoring period. The screening/training appointment will last approximately 2.5 hours. This first appointment will be followed within 1-28 days by the second appointment.

If more than 28 days elapse between training and the second appointment, then your child will be invited to return for a 'refresher' training visit before commencing the study. The second appointment will take place at a pre-arranged time in the morning at weekends. Please see Figure 1 for a timeline of testing sessions.

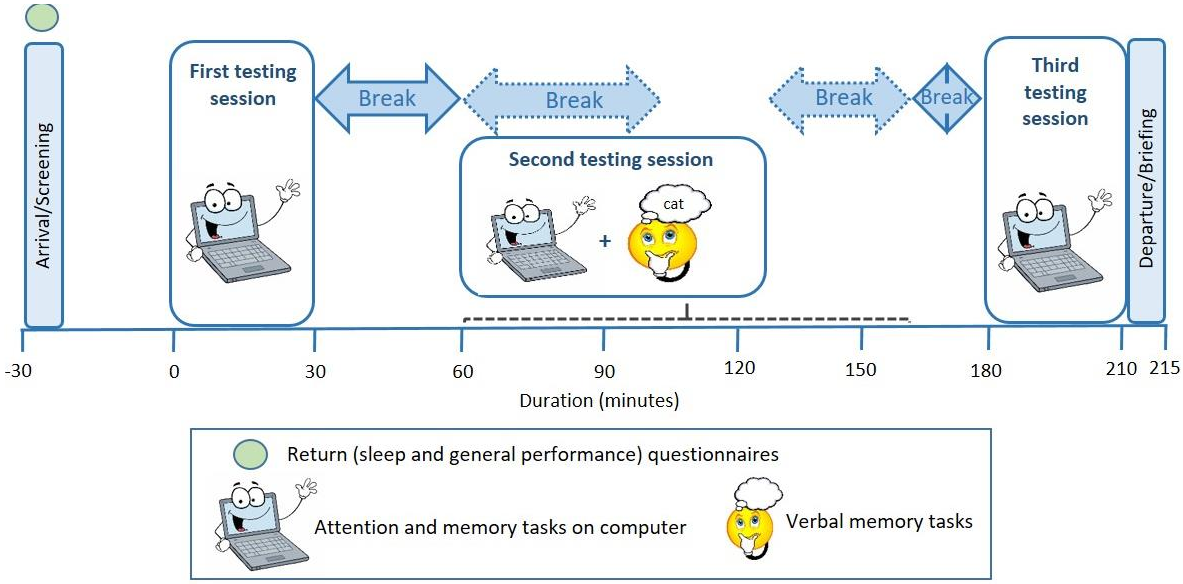

Figure 1: Timeline of testing sessions

Your child should avoid all caffeine containing food and beverages from waking until the end of the study visit. Some examples include chocolate, hot chocolate, chocolate cereals, chocolate milk, cola, tea and coffee. Please also avoid all sugary soft drinks (either caffeine containing or not). Your child will attend the laboratory having consumed breakfast (of cereal and or toast, to be replicated prior to each visit) at home no later than 7.30am. Please note, your child will not be able to consume anything other than water until the end of the study day (at approximately 12.30pm) once they have finished their breakfast at home. Prior to attending you will be asked to confirm via an online form that your child continues to meet the inclusion and none of the exclusion criteria. Upon arrival you and your child will answer some brief screening questions and you will return completed/confirm completion of three different questionnaires. The Sleep Self Report is a paper questionnaire completed by your child asking about their sleep habits. The Children's Sleep Habits questionnaire is an online questionnaire completed by you, their parent/guardian, asking questions about your child's sleeping habits and the parent Visual Analogue Scales are completed online and ask you about your child's general performance. Your child will then commence the first cognitive testing assessment (lasting approximately 30 minutes). This will be followed after a short break (approximately 30 minutes), by the second cognitive testing assessment which will be slightly longer (1 hour and 10 minutes) and include two additional tasks assessing memory. A final completion of the cognitive testing assessment (approximately 30 minutes) will commence after another short break (approximately 50 minutes). The first and the last testing assessments are identical and include a range of computerized memory and attention tasks. The second assessment includes many of the same tasks (with an additional computerized memory task) and also a verbal memory task. During the breaks, your child is permitted to watch TV or read a book but is not permitted to play on computer/video games.

Physical activity also should be kept to a minimum. Once all assessments are completed you will be provided with the treatment your child will be required to take for the next 42 days (6 weeks) (either active treatment or a matched placebo – 2 x gummies in the morning with food). Forty-two and 84 days later you and your child will return to the lab for two further appointments (appointments 3 and 4), that will be identical to the 2nd appointment, with the exception that prior to the Day 42 and Day 84 visits your child will be required to take their allocated treatment at home before testing commences. On day 42 you will also receive a further supply of study treatment for your child to take between days 43 and 84 (2 x gummies in the morning with food). At each appointment, you will be required to remain with your child within the research centre, in a waiting room, separate to the testing labs. Please see figure 2 for a timeline of study visits.

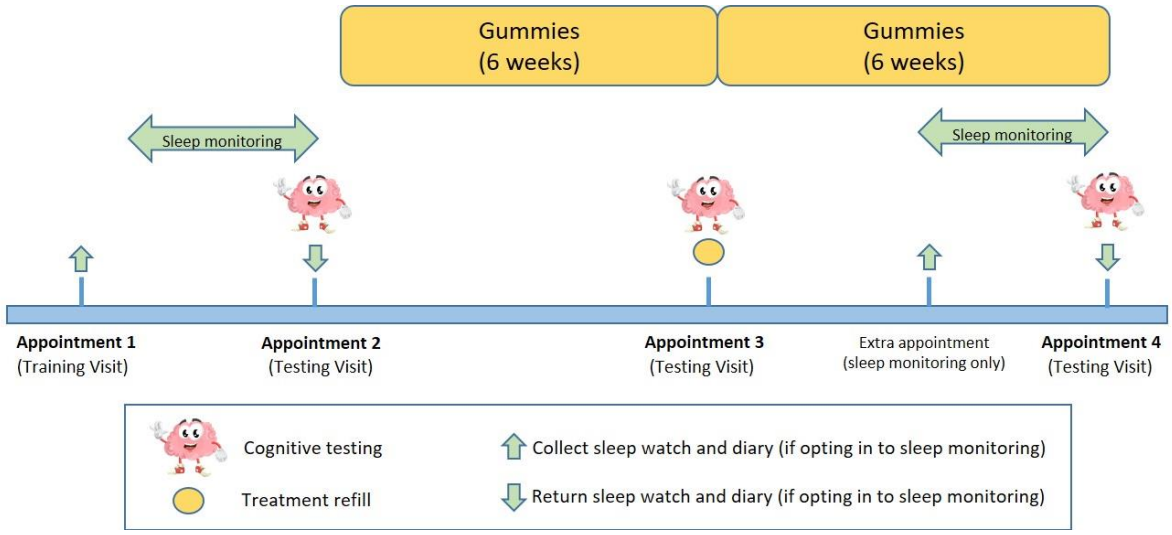

Figure 2: Timeline of study visits

After your child's final testing session, you and your child will be debriefed and your child will receive £140 in vouchers for their time in a sealed envelope (participants opting in to the sleep monitoring element of the study will receive an additional £40 in vouchers). Should your child not go on to complete the study in its entirety, they will receive a proportion of the vouchers as recompense for their time.

What are the possible disadvantages of taking part?

The study product Sharp•PS® Green consists of chewable grape flavour 'gummies' containing phosphatidylserine. Phosphatidylserine containing supplements are classified as a food or food supplements and are available to purchase within the EU as such. There are no known side effects of taking phosphatidylserine. In this study your child will be asked to take 2 gummies per day which equates to approximately 100mg of phosphatidylserine.

You may feel reluctant for your child to take part in a study assessing their cognitive performance, however, all data your child provides contains only their participant code (e.g. 016) and not their name. This data would only ever be linked to your child if you asked us to withdraw your data from the study; here we would have to break your child's anonymized code in order to destroy their data.
Your child 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 your child 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 your child may have.

What are the possible benefits of taking part?

Your child's participation will hopefully add to the growing amount of evidence showing that phosphatidylserine (a food component that is also synthesized endogenously in the body) is able to boost brain function.

Will my child's participation in this study be kept confidential and anonymous?

Yes, as noted above, your child's name will not be written on any of the data we collect; the written information you/your child provides will have an ID number, not their name. Their name will also never appear in any reports or documents resulting from this study. The consent form you and your child have signed will be stored separately from your child's other data. The data collected from you/your child in this study will be confidential. The only exception to this confidentiality is if the researcher feels that your child or others may be harmed if information is not shared.

How will the data be stored?

We will store the data for a minimum of 15 years following completion of this study unless the sponsor of the study or the journal article we publish within requires an extension of this period. Please note that the data retained after the 15 year period will only be anonymized data rather than personally identifiable data.
During this 15 year period the consent forms you and your child provided will be kept in locked storage. All electronic data will be stored on the University U drive (within the restricted access BPNRC server), which is password protected. 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/training visit (appointment 1) we will take demographic data including age, sex, height/weight (used to calculate BMI), race, eligibility for free school meals, parental occupation and income and will ask you to confirm that your child does not meet any of the exclusion criteria. During the testing visits (appointments 2-4) we will collect their cognitive performance/mood data as well as data on sleeping habits.

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?

Only the research team here at Northumbria University will have access to your child's personal data. The funder of the study, Frutarom, or the journal article that we publish the study within may request access to the study data but this will either contain only their participant code (e.g. 016) or no identifying information at all, never their name, and this will be shared using encrypted passwords or the secure 'SharePoint' tool.

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 anonymized and your child's data will not be personally identifiable. The findings may also be used in future studies (e.g. when conducting meta-analyses) or shared with other organizations/ institutions that have been involved with the study. We can provide you with a summary of the findings from the study if you email the researcher at the address listed on page 7.

Who is Organizing 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 Frutarom 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 received ethical approval from the Northumbria University Psychology Staff Ethics Committee, reference 23091.

What are my rights as a participant in this study?

Under the GDPR legislation you have right of access to your child's 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.

Contact for further information:

Researcher email: hl.gummiesstudy@northumbria.ac.uk

Name and contact details of the Data Protection Officer at Northumbria University: Duncan James (dp.officer@northumbria.ac.uk).