**Study Title:** Psychological effects of 8 weeks supplementation with *Sceletium tortuosum* extract (Zembrin™): a randomised, double blind, placebo-controlled, parallel-groups

**Investigator:** Dr Emma Wightman

**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

Zembrin® is an extract of *Sceletium tortuosum*, a succulent plant commonly found in South Africa. Previous research has shown that Zembrin reduces anxiety and feelings of stress, and improves cognitive (mental) function, but more research is needed.

The aim of this study is to assess the effects of 8 weeks (56 days) supplementation with Zembrin® on cognitive function (including during cognitive demand), stress (including psychological and physiological stress responses during a laboratory stressor), fatigue, mood and sleep.

**Why have I been invited?**

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

* Self-report as being in good health
* Are aged 30 to 50 years at the time of giving consent
* Have access to a smart device (e.g. phone or tablet) with internet access at home for completion of Cognimapp tasks

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

NOTE: the explicit exceptions to this are controlled hyper/hypothyroidism, hay fever, high cholesterol and reflux-related conditions.

* Are currently taking prescription medications

NOTE: the explicit exceptions to this are contraceptive treatments for female participants, thyroid medications, topical skin treatments and those medications used in the treatment of high cholesterol and reflux-related conditions; and those taken ‘as needed’ in the treatment of asthma and hay fever.

* Have high blood pressure (systolic over 159 mm Hg or diastolic over 99 mm Hg). NOTE: that we must measure this in the lab using our blood pressure monitors and can only use our measurements to assess eligibility rather than home or GP readings.
* Have a Body Mass Index (BMI) outside of the range 18.5-35 kg/m2
* Are pregnant, seeking to become pregnant or lactating.
* Are menopausal/post-menopausal
* Have learning and/or behavioral difficulties such as dyslexia or ADHD
* Have a visual impairment that cannot be corrected with glasses or contact lenses (including colour-blindness)
* Smoke tobacco or vape nicotine or use nicotine replacement products (if you have recently quit smoking or using replacements you must have stopped using them altogether for a period of 3 months before participating in this study)
* Have excessive caffeine intake (>500 mg per day). Note: This will be calculated at screening but feel free to query this with the researcher prior to attendance
* Have relevant food allergies/ intolerances/ sensitivities (Please discuss with researcher prior to attendance if you are unsure of relevance)
* Have taken antibiotics within the past 4 weeks
* 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 are taken are out of choice and are not medically prescribed or advised). 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, or have in the past 4 weeks
* 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, including a medical diagnosis of anxiety or depression.
* Suffers from frequent migraines that require medication (more than or equal to 1 per month)
* Sleep disorders or are taking sleep aid medication (nightshift work is permitted provided you have not completed a nightshift the night before a testing visit and you feel well rested when attending your testing session)
* Have oral disease
* Have any known active infections
* Does not have a bank account (required for payment)
* Are non-compliant with regards treatment consumption

**Please contact the research team if you are unsure about any of the above and your eligibility status**

\* Please note that this study utilizes the following 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; emma.l.wightman@northumbria.ac.uk

Do I have to take part?

No. It is up to you whether you would like to take part in the study. I am 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 me why. You are completely free to decide whether or not to take part, or to take part and then leave the study before completion.

What will happen if I take part?

The study will require you to have 4 appointments: appointment 1 to be done remotely, appointments 2-4 involving 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 a telephone call with a member of the research team at a pre-arranged time. The screening appointment will last approximately 15 to 30 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 telephone call (height and weight to calculate BMI, waist-hip ratio, blood pressure readings). 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. The training session will last approx. 2.5 hours.

**Appointments 3-4.** If you are enrolled onto the study, you will have two subsequent laboratory based active testing visits which will be identicalActive testing visits occur 56 days apart and will follow this procedure:

You will attend the laboratory at a prearranged time in a fasted state as breakfast (cornflakes and semi skimmed milk) will be provided upon arrival. During your visit you will complete mood scales, computerized cognitive tests and a multitasking assessment where you will simultaneously complete mental arithmetic and tracking tasks whilst under observation (which will include being observed by a panel and video and voice recordings), with breaks in between each activity. The two testing visits are expected to take approximately 4 hours.

**Additional at home assessments:** On the evening of your training appointment and 7 and 28 days following your first testing visit, you will be required to undertake additional mood assessments using the online platform Cognimapp. The researcher will email a link to you to access this from home.

You will be required to take your assigned treatment daily for the 56 days between appointment 3 and 4.

After your final appointment you will be debriefed and your remuneration via bank transfer organized (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.

**What are the possible benefits of taking part?**

You will add to the research effort investigating whether extracts from natural sources can have a significant impact on brain function and stress.

You will also be recompensed £160 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?

* Zembrin® is classified as a food or food supplement and is available for purchase within the UK. Zembrin® is not associated with any significant deleterious side effects.
* You may find it uncomfortable to provide information on your mood/ anxiety and to be observed whist completing cognitive tasks. However, all data you provide contains only your participant code (e.g. 016) 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 anonymized code in order to destroy your data.
* Regarding any further stress you might experience from being observed during task completion, this aspect of the study has been fully risk assessed but if you did feel under too much pressure during the study then you are encouraged to stop the session and you may then resume, reschedule or withdraw at will without any reason needing to be given (we may ask your reason for feedback but you do not have to give this information).
* If you choose to withdraw the study team will ask if we can use the data provided so far or if you would like it to be removed from all analyses- this is entirely your choice. 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).
* Provision of saliva samples may also cause embarrassment but samples are provided using a relatively discreet method; using salivettes (chewing on a cotton swab for 1 minute or until the swab is sufficiently saturated).
* You will be required to remain seated at a desk for the duration of the cognitive and mood 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.

Will my taking part in this study be kept confidential and anonymous?

* Yes, as noted above, your name will not be written on any of the data we collect; the written information you provide will have an ID number, not your name.
* Your name 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.
* The data collected from you in this study will be confidential.
* The only exception to this confidentiality is if the researcher feels that you or others may be harmed if information is not shared.

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

We will store your data for a minimum of 7 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 7 year period will only be anonymized data rather than personally identifiable data.

During this 7-year period your consent forms will be kept on secure servers. 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 visits we will take demographic data from you and this documents such things as your height/ weight, waist-to-Hip ratio, blood pressure readings, race, lifestyle habits, handedness, use of glasses, medical history, medication use, years in education and that you do not meet any of the exclusion criteria.
* During the testing visits we will collect your cognitive performance/ mood data as well as your saliva, Heart Rate and Galvanic Skin Response (perspiration of skin) and these will be measured for markers of anxiety/ arousal/ stress.

**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 personal data. The funder of the study or the journal article that we publish the study within may request access to the study data but this will either contain only your participant code (e.g. 516) or no identifying information at all, never your 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 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 organizations/ 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 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 HG & H Pharmaceuticals (Pty) Ltd 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 at Northumbria University (Ref. 33660)

**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/).

**Contact for further information:**

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

**Investigator email:** **emma.l.wightman@northumbria.ac.uk**

**Name and contact details of the Data Protection Officer at Northumbria**

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