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Participant Information Sheet (General)

Project Title: Effectiveness of a Herbal and Nutritional Supplement on Cognitive Function in Older Adults with Subjective Cognitive Impairment.

Project Summary: You are invited to participate in a research study being conducted by Mrs Adele Cave, PhD candidate, at NICM, Health Research Institute, Western Sydney University.

This project aims to evaluate the efficacy of a commercially available herbal and nutritional supplement, Cognition Support Formula in an older population with Subjective Cognitive Impairment (SCI). This is important for understanding how the cognition support formula works and whether it has the potential to be a treatment for older adults with SCI. This project will compare the cognitive and emotional function, and brain activity of 120 people reporting SCI before and after 6 months of cognition support formula or placebo.

How is the study being paid for?
The study is being sponsored by BioCeuticals Pty Ltd and Western Sydney University.

What will I be asked to do?
If you decide to participate in this project, you will be asked over the phone to provide verbal consent before you complete a brief telephone screen and are invited to attend a face-to-face screening session. The face-to-face screening session will be at a comfortable place for you or at our laboratory at Western Sydney University, Campbelltown Campus. The face-to-face screening involves: reading and signing a participation consent form, completing a questionnaire on your general health, a brief cognitive test and a brief test on depression. If you are eligible to participate in the study you will then be booked in for a baseline assessment and then randomly allocated to either the treatment or placebo condition. You will also be asked to have a blood test completed prior to the baseline assessment, to make sure you are healthy enough to participate. The allocation is blinded so neither you nor the research team will know whether you will be taking the Cognition Support Formula or placebo.

The screening session will be followed by a (baseline) cognitive testing session that will take approximately 1 ½ hours. The 1 ½ hour cognitive testing session, will require you to complete a battery of computerised and pen-and-paper cognitive tests administered by the researcher. These tests are designed to assess your attention, processing speed, memory and executive function. If you are eligible to participate in the EEG component, it will take place on the same day and involves the completion of a series of computerised cognitive tests whilst having your brain activity recorded utilising EEG. This testing session will take place at Western Sydney University, Campbelltown Campus. You will be fitted with an electrode cap that will be used to record your brain activity from your scalp. Four electrodes will also be fitted to your face, to monitor eye movements. The EEG component will take approximately 2 ½ hours to complete (including EEG cap fitting). A small amount (10 mls) of gel is used to fill the electrodes, the gel is harmless, and brushes out of the hair as soon as it is dry. Tissues and baby wipes are available to clean around the eyes. You will be seated in an air-conditioned testing booth. The experiment involves the recording of ongoing brain waves during a series of tasks in which you will hear a series of sounds, see a series of pictures, letters, words or numbers, and asked to respond by pressing a button. The tasks are similar to the computerised and pen-and-paper

cognitive tests and also designed to test your attention/processing speed, memory and executive function. Because of their brevity, test results will not be an accurate index of cognitive abilities, and will therefore not be communicated to you. In total, the baseline testing session will take approximately 4 hours (including EEG testing).

If you are not completing the EEG testing, you will have a vascular Ultrasound (on the neck) which will take approximately ½ an hour. In total, the baseline testing session will take approximately 2 hours (without EEG testing).

After 3 months, you will have another blood test and receive the second half of the medication. You will also be asked to participate in the cognitive tasks again, which will only take 1 hour. You will then be booked in for a final (endpoint) follow up at 6 months. The endpoint assessment is the same as the baseline (an EEG session if you have participated at baseline, and a cognitive testing session). Please note, if you completed an Ultrasound measurement, you will not be measured again at endpoint, and your session will take approximately 1 ½ hours. We will call you 4 weeks after you have finished the trial to see if you have experienced any other side effects.

How much of my time will I need to give?
The study will take approximately 6 months to complete including: a screening interview, 3 cognitive testing sessions and 2 EEG sessions (at the same time as the baseline and endpoint cognitive testing sessions). We will ask you to attend Western Sydney University (Campbelltown campus) for testing sessions. We will also ask you to complete a diary detailing the date, if you have taken your tablets, how many you have taken, and if you have experienced any side effects.

What benefits will I, and / or the broader community, receive for participating?
There is the possibility that you will experience some cognition enhancing effects from the Cognition Support Formula. This research project also has the potential to produce evidence on the mechanisms of action, and the efficacy and safety of a novel, multi-target treatment for SCI. You will not be out of pocket for your involvement in this research. You will be reimbursed for your travel expenses ($30 per testing session (3 x $30) excluding the face to face screen) to the Western Sydney University Campbelltown Campus. If you drive, you will also be provided with free parking.

Will the study involve any discomfort or risk for me? If so, what will you do to rectify it?
EEG is non-invasive research, so there is very minimal discomfort involved. It is possible that there may be a very small amount of discomfort when the electrode cap is fitted on your head. The researcher will do everything possible to ensure that this experience is as comfortable for you as possible. This will be done by ensuring that your cap is the correct size, and the researcher will check with you throughout the experiment to ensure that the cap remains comfortable. Ultrasound is also a non-invasive measurement, with only a small amount of gel placed on the probe and your neck. You may also experience slight discomfort when taking your blood sample. The blood samples will be taken at a commercial laboratory (Laverty) by a trained phlebotomist so any discomfort would be very minor. There is also a small risk of gastrointestinal upset with the cognition support formula condition. Adverse events will be closely monitored throughout the duration of the study.

How do you intend to publish the results?
Please be assured that only the researchers will have access to the raw data you provide. All aspects of the study, including results, will be confidential and only the researchers will have access to information on participants. The data collected from you and other participants will be stored with a participant code and there will be no identifiable information recorded, apart from age and sex, to ensure your confidentiality is maintained. Data from your baseline testing session may be used in future studies.

The findings of the research will be published in academic journals and/or discussed/ displayed in conference presentations. In any case, only group information and trends will be presented. No reference will ever be made to individual results, or individual participants.

*Please note that the minimum retention period for data collection is five years post publication.

Can I withdraw from the study?
Participation is entirely voluntary and you are not obliged to be involved. If you do participate, you can withdraw at any time without giving a reason.

If you do choose to withdraw, any information that you have supplied will be de-identified and used in analyses.

Can I tell other people about the study?
Yes, you can tell other people about the study by providing them with the chief investigator's contact details. They can contact the chief investigator to discuss their participation in the research project and obtain an information sheet.

Data storage
There are a number of government initiatives in place to centrally store research data and to make it available for further research. For more information, see **http://www.ands.org.au/** and **http://www.rdsi.uq.edu.au/about**. Regardless of whether the information you supply or about you is stored centrally or not, it will be stored securely and it will be de-identified before it is made available to any other researcher.

What if I require further information?
Please contact Mrs Adele Cave should you wish to discuss the research further before deciding whether or not to participate.

Mrs Adele Cave Phone: 0487 472 273 Email: A.Cave@westernsydney.edu.au

What if I have a complaint?
This study has been approved by the Western Sydney University Human Research Ethics Committee. The Approval number is: H11958

If you have any complaints or reservations about the ethical conduct of this research, you may contact the Ethics Committee through the Research, Engagement, Development and Innovation office on Tel +61 2 4736 0229 Fax +61 2 4736 0905 or email humanethics@westernsydney.edu.au.

Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

If you agree to participate in this study, you may be asked to sign the Participant Consent Form.

WESTERN SYDNEY UNIVERSITY

Participant Consent Form

This consent form is not project specific. Participants baseline data may be used in future studies.

Project Title: Effectiveness of a Herbal and Nutritional Supplement on Cognitive Function in Older Adults with Subjective Cognitive Impairment.

I,_____ [name of participant] consent to participate in the research project titled: Effectiveness of a Herbal and Nutritional Supplement on Cognitive Function in Older Adults with Subjective Cognitive Impairment.

I acknowledge that:

I have read the participant information sheet or I have had it read to me and have been given the opportunity to discuss the information and my involvement in the project with the researcher/s.

The procedures required for the project and the time involved have been explained to me, and any questions I have about the project have been answered to my satisfaction.

I consent to participating in this 6 month trial. I understand that the trial involves a telephone screen, a face to face screen, 2 visits to a commercial pathology laboratory for blood testing, and travelling to Western Sydney University to participate in cognitive, ultrasound and EEG testing. I consent to completing a face-to-face screening interview and three separate cognitive testing sessions that will take approximately 1 ½ hours for each (baseline (0 months), and endpoint (6 months)) and 1 hour for midpoint (3 months), or for participation in the EEG component an additional 2 ½ hours for each (baseline and endpoint), and one follow-up safety check (via telephone). If I do not participate in the EEG testing, I will have an Ultrasound at the baseline appointment (0 months), which will take approximately ½ an hour. I understand that the screening interview will involve a member of the research team asking me a series of questions about my general health (including my mental health), and that I will be asked to complete a brief cognitive test and a brief depression test. I understand that in all three testing sessions, a member of the research team will administer a series of cognitive tests that will assess my attention/processing speed, memory and executive function.

I understand that if I am eligible to participate in the EEG component, in two testing sessions (baseline and endpoint), I will be fitted with an electrode cap and asked to listen to a series of sounds through a set of headphones, that I will be shown series of pictures, letters, words, and numbers on a screen and that I will be asked to respond by pressing a button. I consent to the measuring of my responses to these stimuli by recording the electrical activity of my brain using an electroencephalograph (EEG). I am aware that during the experiment, I will be in close contact with the experimenter at all times.

I understand that if I am eligible to be enrolled in this study that I will be randomly allocated to either the active treatment (Cognition Support Formula) or placebo group. I understand that this allocation is unknown (blinded) to both myself and the research team.

I understand that my involvement is confidential and that the information gained during the study may be published but no information about me will be used in any way that reveals my identity. I understand some of the data from my participation will be utilised in future studies.

I understand that I can withdraw from the study at any time, without affecting my relationship with the researcher/s now or in the future.

I would like the results from this study communicated to my doctor (tick which results you would like communicated):

- ❑ Blood tests
- ❑ Test of mental function
- ❑ I consent for my doctor to contact the research team directly for further information regarding my participation in this research study.

OR

- ❑ I DO NOT wish for my results to be communicated with my doctor

Signed:

Name:

Date:

Return Address: Mrs Adele Cave, Western Sydney University, Locked Bag 1797, Penrith NSW 2751

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