NICM Health Research Institute
Western Sydney University
Locked Bag 1797
Penrith NSW 2751
Australia

Ms Joelle Metri
Telephone: 0411 622 021
Email: j.metri@westernsydney.edu.au

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 A/Prof Genevieve Steiner 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 74 people reporting SCI before and after 6-months of Cognition Support Formula® (containing extracts of: *Ginkgo biloba*, *Panax ginseng*, *Bacopa monniera* (brahmi) and alpha-lipoic acid) or placebo.

Please note that according to Public Health Orders implemented by NSW Health, all clinical trial staff and participants must be fully vaccinated with an approved COVID-19 vaccine.

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. Prior to the face-to-face screen, you will be asked to read and sign the participation consent form, complete a blood test at Laverty pathology, and two health questionnaires via phone. These will assist in determining your suitability in the study. The face-to-face screening session will be at Western Sydney University at either the Westmead or Campbelltown campus (depending on your preference) and involves completing a few brief cognitive tests and one additional health questionnaire on depression taking around 40-minutes. 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. 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 which 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.

After 3-months, you will be asked to participate in the cognitive tasks again (either at Westmead or Campbelltown) and receive the second half of the medication. The midpoint testing session will take 40-minutes. You will then be booked in for a final (endpoint) session at 6-months, which will also take around 40-minutes. Additionally, you will be required to have a blood test prior to the final testing session at Laverty

Pathology. 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 and three cognitive testing sessions. If you are found to be eligible, you will have the option to complete your first cognitive testing session immediately following your screening interview, meaning you will need to visit us three times in total. We will ask you to attend Western Sydney University at either Westmead or Campbelltown campus (depending on your preference). We will also ask you to attend a Laverty Pathology center on two occasions. 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 (up to 3 x $30 gift cards) excluding the face-to-face screen) to either Campbelltown or Westmead locations.

Will the study involve any discomfort or risk for me? If so, what will you do to rectify it?
You may also experience slight discomfort when taking your blood sample. Two blood samples will be taken at a commercial laboratory (Laverty), by trained phlebotomists 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 5-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 several 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 Ms Joelle Metri should you wish to discuss the research further before deciding whether to participate.

Ms Joelle Metri Phone: 0411 622 021 Email: j.metri@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.

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,_____ 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, two visits to a commercial pathology laboratory for blood testing and travelling to Campbelltown or Westmead participate in cognitive testing sessions at baseline, midpoint, and endpoint. I consent to completing a face-to-face screening interview, three separate cognitive testing sessions and one follow-up safety check (via telephone).

I will abide by COVID infection control measures as outlined in the check list for endpoint testing sessions document, provided by the researcher. I consent to having my temperature checked by an infrared thermometer and documented, at the endpoint testing session.

Each session will take approximately:
Baseline (first session- 0 months): 2-hours (cognitive testing)
Midpoint (second session- 3 months): 15-30 mins (completing questionnaires) and 30-45 mins (cognitive testing) (1 hour approximately in total)
Endpoint (last session-6 months): 20-40 mins (completing questionnaires) and 40-60 mins (cognitive testing) (1.5 hours approximately in total)

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 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:	

Name of Doctor:	
Doctor's Contact Number:	
Doctor's Email:	
Doctor's Address:	

Return Address: Ms Joelle Metri, Western Sydney University, Locked Bag 1797, Penrith NSW 2751

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