PARTICIPANT INFORMATION STATEMENT

HREC Project Number:	HRE2023-0599
Project Title:	Cancer-related cognitive impairment: Neuropsychological function, neurogenesis biomarkers, and a nonpharmacological intervention (Stage I)
Investigators	Mr Siddharth Ganesh – Doctoral Candidate Dr Yu Yu – Chief Investigator Dr Blake Lawrence – Co-Investigator
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What is the project about?

This study explores cancer-related cognitive impairment (CRCI) in people living with cancer and undergoing treatment. CRCI is the development of thinking and mental deficits associated with cancer and cancer treatments, affecting 30-40% of individuals before treatment and 50-75% during and following treatment (Mayo et al., 2021). CRCI can be associated with poorer quality of life (Janelsins et al., 2018; Mayo et al., 2021), but there are limited treatments mainly due to the lack of understanding on the underlying workings (Oppegaard et al., 2021). As such, further research is required to understand these workings. Previous studies either focussed on overall mental impairment, largely disregarding biological factors (e.g., Janelsins et al., 2018), or vice versa (e.g., Oppegaard et al., 2021), highlighting a gap in literature. Our study will adopt a collaborative approach to explore the connection between mental function and blood factors in people living with cancer. We will then apply a validated brain training treatment informed by recent literature reviews (e.g., Cheng et al., 2022), and clinical trials for similar conditions, such as early dementia (e.g., Kallio et al., 2017; Kang et al., 2019).

This project involves one large study separated into two stages. Stage I includes a cross-sectional assessment of at least 150-180 participants, to create a machine learning model, using factors of mental function (e.g., memory, attention, learning), mood, quality of life, and wellbeing, as well as blood markers, medical history, and personal information. Data collected from Stage I will be used as the baseline to identify a subset of 60-100 participants, who demonstrate deficits in mental domains, for Stage II.

Stage II will be a randomised controlled trial of cognitive (brain) training to improve CRCI. We hypothesise that cognitive training will improve mental functioning, mood, quality of life, and wellbeing, and potentially revert biological changes associated with CRCI.

This information sheet and consent form pertain to Stage I of the study.

Who is conducting the research?

The project is being conducted by Siddharth Ganesh, Dr Yu Yu, and Dr Blake Lawrence. The results of this research project will be used by Siddharth Ganesh to obtain a Doctor of Philosophy at Curtin University and is funded by the University and the Commonwealth of Australia. There will be no cost to you for taking part in this research and you will not be paid for taking part.

Why am I being asked to take part and what will I have to do?

We are looking for 120-150 people living with cancer currently undergoing treatment. Both people experiencing AND not experiencing cancer-related mental decline are encouraged to participate. The eligibility criteria for Stage I are as follows. We are also looking for 30-45 healthy volunteers to use as a comparison group; the same eligibility criteria apply, except they would have no current nor any previous diagnosis of cancer.

Inclusion Criteria	**Exclusion Criteria**
- Currently have cancer diagnosis - Currently undergoing cancer treatment - Adult (18 years and older) - Living in Perth / Peel region of Western Australia, or be willing/able to attend Curtin University for appointment(s). - Working proficiency of English	- Central nervous system cancer/metastases - Pre-existing neurodegenerative conditions (e.g., Alzheimer's disease) - Severe psychological / psychiatric conditions (e.g., intellectual disabilities) - Pregnancy - Enrolled in another clinical trial (some exceptions)
Considerations	
○ Hearing impairment ○ Visual impairment ○ Severe trypanophobia ○ Anything that might prevent/hinder meaningful participation	

Stage I entails a 90–120-minute appointment at the clinical suites at Curtin University. Participation in Stage I involves completing multiple thinking and memory assessments, as well as mood, quality of life, and wellbeing questionnaires. Some things you will be asked to do are complete timed tasks, recall information, and answer questions regarding your overall mental wellbeing. Further, at the end of this appointment, we will need to take blood samples from you. All these tests are conducted in person, and are only conducted once for Stage I. Participants will also need to provide a full medical history from their GP before/at this appointment.

At the end of the Stage I appointment, all participants with cancer will be invited to consider participation in the Stage II of the study. Stage II entails a six-week long clinical trial of a brain training treatment. At the end of this trial, participants will attend a follow-up appointment (90-120 min) mirroring that of Stage I. Participant enrolment in Stage II is conditional upon meeting certain eligibility criteria. Namely, eligible participants will demonstrate possible cancer-related mental decline in test scores, and will have access and ability to use a phone/tablet/computer with internet for six weeks. Participation in Stage I does not mean you have to participate in Stage II. Once you have received the Stage II information and consent form, you can decide if you want to take part.

Stage I takes place at Curtin University (Bentley) in Building 305 Level 2 clinical suites. Stage II will largely take place in your own home, with the follow-up appointment happening in the same clinical suites as Stage I. There will be no cost to you for taking part in this research, apart from your time and effort, and you will not be paid for taking part. We will cover parking expenses for your appointment(s) at Curtin.

NECESSARY AND OPTIONAL CONSENT

Necessary consent refers to terms that must be agreed upon to proceed with study participation. Optional consent regards terms that are not necessary to be agreed upon for Stage I participation. Note that if you decide to participate in Stage II, the consent you give on this document will carry forward.

- Necessary Consent: Audio Recording: In this study for, the memory and thinking tests, we will need to make audio recordings to double check scoring is accurate. These audio files will be kept on secure devices and will not have your name directly linked to them.

- Necessary Consent: Access to Medical Records: In this project we need to collect and use health information in your medical records from your GP / treating health professional. Please bring a copy of your medical history to our appointment. When acquiring this information from your health professional, please request that the full medical history at least contains the following:
  Medical history items of interest include premorbidities, comorbidities, current health conditions (particularly psychological/psychiatric), cancer histology/stage/receptor status/grade, time since cancer diagnosis etc. The treatment regimen items of interest include type of cancer treatment, therapeutic agent composition, dosage cycles and levels, and adjunct/other medications.

- Necessary Consent: Sending Health Information to Practitioner: It is possible we uncover health information that could be of importance to you and your treating practitioner(s). We will send pertinent health information to your treating practitioner(s) once analyses have been conducted, which may take between 2-5 months. Information we will send includes (but is not limited to):
  - Possible genetic vulnerability to certain brain and heart conditions
  - Results of cognitive and psychological testing
  - Other concerning health information

  Please note that we will send health information regardless of various protective/risk levels. The reason we do not directly give you these results is that such information needs to be carefully interpreted by your health practitioner, who knows your medical history well, before disclosing it to you. If you do not wish to be directly informed about these matters, you can request your practitioner(s) to keep the test results undisclosed. Furthermore, it is also important to note that there is a difference between research and clinical testing – so, your practitioner may conduct follow-up assessments, should they see fit.

- Optional Consent: Future Research: We would like you to consider allowing us to send you information about future research projects. Once you receive the information, it is your choice if you decide to take part or not. You may change your mind at any point.

- Optional Consent: Other Researchers: We would like you to consider letting us share the information we collect during this research with other researchers working in this area. This information will be deidentified. Should other researchers wish to contact you, they will need to go through us; that is, we will reach out and ask you if you wish to be contacted by another research group. You may change your mind at any point.

Are there any benefits to being in the research project?

There may be no direct benefit to you from participating in this research. However, people sometimes appreciate the opportunity to discuss their experience with cancer and cancer-related cognitive impairment. You may also receive useful health information from your treating practitioner(s).

We hope the results of this research allow us to further our understanding of cancer, cancer-related cognitive impairment, and other mental and psychological effects of cancer. We also hope that our findings help cancer-related cognitive impairment detection, management, and treatment, as well as improve the quality of life, mood, and psychological wellbeing of people living with cancer.

Are there any risks, side-effects, discomforts, or inconveniences from participating?

There may be some minor risks and discomforts associated with this study. We have been careful to make sure that the questions cause minimal/no emotional/psychological distress. However, as with all research, some parts of our study may be distressing. If the questions cause any concerns or upset you, please let us know, so we can take a break. We can also provide you with appropriate resources and helplines, if needed. As previously mentioned, there is also the possibility we uncover important health information that may be distressing. We will send this information to your GP / treating health professional, so that they may inform you appropriately. Blood sampling may potentially cause mild discomfort, bruising, and sometimes light headedness; to minimise this, the blood will be collected by a trained researcher, and you will be able to sit/lie down during the procedure. COVID-19 and other viral infections remain a risk for immunocompromised individuals. The researchers will take appropriate precautions before, during, and after the appointments to mitigate risk of contraction for both participants and researchers. The precautions include, but are not limited to, sanitising the testing facilities and equipment before/after each use, minimising participant contact with non-essential Curtin personnel, rescheduling appointments if either party have cold-like symptoms etc.

Lastly, aside from what has been mentioned above, the other inconvenience we foresee will be giving your time and effort required for participation. If you want psychological support around your cancer diagnosis, please call Cancer Council WA (13 11 20) during business hours. If you feel substantial psychological distress, call Lifeline (13 11 14) at any time.

If you feel you are in immediate danger, call 000 at once.

Who will have access to my information?

The information collected in this research will be re-identifiable (coded). This means that we will collect data that can identify you, but will then remove identifying information on any data or sample and replace it with a code when we analyse the data. Only the research team have access to the code to match your name when necessary. Any information we collect will be treated as confidential and used only in this project unless otherwise specified. The following people will have access to the deidentified information we collect in this research: the research team, research colleagues, and, in the event of an audit, staff from the Curtin University Office of Research and Development. If you have consented, pertinent health information will also be forwarded to your GP / treating healthcare professional. Although unlikely, re-identifiable information may be made available to legal bodies in certain extenuating cases.

Electronic data will be password-protected and hard copy data (including audio tapes) will be in locked, restricted-access rooms/laboratories. The data we collect in this study will be kept under

secure conditions at Curtin University for a minimum 15 years after the research is published and then it will be kept indefinitely. The results will be published in that thesis and various papers to scientific journals; summary of results may also be presented in information sheets to oncology care providers, newsletters, and conferences. You will not be identifiable in publicly available results.

Will you tell me the results of the research?

We will write to you at the end of the research (in about 18-24 months) and send you the summary of our findings. Results will not be individual but based on all the information we collect and analyse as part of the research. As previously mentioned, we will send individual important health information we uncover to your GP / treating health professional, so that they can inform you appropriately. The primary aim of this research is to be submitted as a doctoral thesis for Siddharth Ganesh. As such, the results will be published in that thesis and various papers to scientific journals; summary of results may also be presented in information sheets to oncology care providers, newsletters, and conferences. If you would like to receive any of these documents, you are more than welcome to ask for a copy when we send you the summary of our findings. Please note published information will NOT be identifiable.

Do I have to take part in the research project?

Taking part in a research project is voluntary. It is your choice to take part or not. If you do not want to, you do not have to agree to participate. If you decide to take part and then change your mind, that is okay – you can withdraw from the study at any time. If you choose to leave the study, we may still use any information collected, unless you request otherwise. If you wish to also withdraw your data, we can destroy hardcopies, as well as delete electronic data. Please note that withdrawing data may not be possible once data analysis has been completed and the final writeup has been commenced.

What happens next and who can I contact about the research?

If you decide to take part in this research, we will ask you to sign the consent form. By signing the form, you are telling us that you understand what you have read and what has been discussed. Furthermore, signing also indicates that you agree to be in the research project and have your health information used as described. Please take your time and ask the researcher any questions you have before making your decision. You will be given a copy of this information sheet to keep.

If you have any questions, concerns, or feedback, please contact Siddharth Ganesh at: siddharth.ganesh@postgrad.curtin.edu.au or +61 493105286. If you want psychological support around your cancer diagnosis, please call Cancer Council WA (13 11 20) during business hours. If you feel substantial psychological distress, call Lifeline (13 11 14) at any time.

If you feel you are in immediate danger, call 000 at once.

Curtin University Human Research Ethics Committee (HREC) has approved this study (HRE2023-0599). Should you wish to discuss the study with someone not directly involved, in particular, any matters concerning the conduct of the study or your rights as a participant, or you wish to make a confidential complaint, you may contact the Ethics Officer on (08) 9266 9223 or the Manager, Research Integrity on (08) 9266 7093 or email hrec@curtin.edu.au.

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CONSENT FORM

HREC Project Number:	HRE2023-0599
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Necessary consent refers to terms that must be agreed upon to proceed with study participation. Optional consent regards terms that are not necessary to be agreed upon for Stage I participation.

NECESSARY CONSENT

☐ I do	☐ I do not	consent to being audio-recorded
☐ I do	☐ I do not	consent to the researchers accessing/using my medical history, which I shall obtain from my treating practitioner and bring to the appointment.
☐ I do	☐ I do not	consent for the researchers to contact my GP/treating practitioner with important health information.

OPTIONAL CONSENT

☐ I do	☐ I do not	consent to be contacted about future research projects that are related to this project.
☐ I do	☐ I do not	consent to the storage and use of my *deidentified* information in future ethically approved research projects related to this area of research.
☐ I do	☐ I do not	consent to the researchers continuing to use any data I provided, should I withdraw from the study.

- I have read the information statement version listed above and I understand its contents.
- I believe I understand the purpose, extent, and possible risks of my involvement in this project.
- I voluntarily consent to take part in this research project.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I understand that this project has been approved by Curtin University Human Research Ethics Committee and will be carried out in line with the National Statement on Ethical Conduct in Human Research (2007).
- I understand I will receive a copy of this Information Statement and Consent Form.

Participant Name:	Date:
Participant Signature:	

Declaration by researcher: I have supplied an Information Letter and Consent Form to the participant who has signed above, and believe that they understand the purpose, extent, and possible risks of their involvement in this project.

Researcher Name:	Date:
Researcher Signature:	

Note: All parties signing the Consent Form must date their own signature.