CAN-PROTECT

Participant Information and Consent Form

TITLE:

Canadian Platform for Research Online to Investigate Health, Quality of Life, Cognition, Behaviour, Function, and Caregiving in Aging (CAN-PROTECT)

SPONSOR:

Gordie Howe C.A.R.E.S Foundation

PRINCIPAL INVESTIGATOR:

Zahinoor Ismail, MD
Faculty of Medicine, Department of Psychiatry
Tel: 403-210-6900, Fax: 403-210-9665
Email: ismailz@ucalgary.ca

This consent form, a copy of which has been given to you, is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. If you want more details about something mentioned here, or information not included here, you should feel free to ask. Please take the time to read this carefully and to understand any accompanying information.

BACKGROUND

Our brains age as we get older, resulting in a declining of cognitive processes such as memory and reasoning. Yet, we do not fully understand how or why these changes occur, and why these processes affect people differently. Some evidence shows that demographics, lifestyle (e.g., smoking, exercise) and environmental factors may affect our cognition. As these links remain unclear, we aim to deeper examine the impact of these factors on the aging brain.

Currently, dementia affects 45% of people in long-term residential care facilities in Canada. The study findings could provide vital knowledge to help identify those individuals at risk of the disorder. Moreover, we must better understand the cognitive decline processes and their underlying factors in order to develop better preventative and treatment regimens for this devastating condition. Thus, we will address these issues by measuring the cognition in adults 18 years of age and over for 20 years through an online study. Our goal is to extend this study over the longer term. We will ask you at that point if you are still interested in continuing on participating in the study.

WHAT IS THE PURPOSE OF THE STUDY?

This study aims to explore how lifestyle and outside factors (e.g., demographics, environment, and education) affect our health as we get older and the way our brain ages. Specifically, the impact of such factors on health, quality of life, cognition, behavior, and function among Canadians ≥ 18 years of age. The findings may provide valuable information about the brain and could inform future research on prevention of conditions such as dementia. The study is being led by the University of Calgary, in partnership with University of Exeter. The researchers from both universities will analyze the data together and will jointly publish the results. The University of Exeter is located in the United Kingdom.

WHY HAVE I BEEN INVITED?

We are inviting adults 18 years of age and over from across Canada to take part in this study. We are looking to enroll 5,000 participants and 5,000 study partners for the next 2 years. A proportion of participants are caregivers and care partners.

In order to participate, you will also need to:

- Have a good working understanding of the English language
- Have the ability to use a computer or touchscreen device (i.e., tablet) with internet access
- Have a unique/personal email ID

WHAT WOULD I HAVE TO DO?

If you decide to enrol, the following steps will happen:

1. Your basic personal information (e.g., name, address, email) will be collected. These details allow us to contact you for research purposes and to send you important information.

2. You will be asked to confirm you have read this information sheet and sign the online study consent form on the study website.

3. You will be asked to provide basic demographic information and information to help assess your brain's resilience to performing tasks.

4. You will be asked to complete a series of online cognitive assessments to test your memory, reasoning, and attention on an annual basis.

5. You will be asked to complete a series of questionnaires on the website about health status, quality of life and daily function on an annual basis. Some of these are optional for you to complete. A table outlining these questionnaires is attached at the bottom of this section for your reference.

6. We will ask you to nominate a 'study partner', someone who knows you well (≥ 5 years) and spends time with you frequently, such as a spouse, child, or close friend. You will be asked to tick a box that states the potential study partner agrees to be contacted for the purposes of the study. The study partner will receive up to 4 reminder emails over 4 weeks' time. If they are not interested in participating, we will delete their email from our system permanently. We do not store the name/email of the study partner for more than 4 weeks. They are free to decline the invitation to take part in the study.

If your study partner agrees to take on this role, they will be contacted with information on the study and asked to complete a consent form on the CAN-PROTECT website. Your study partner will be asked to answer questions about you annually, for the duration of your participation. For confidentiality purposes, we will not be able to share these answers with you. If you decide you would like to continue participating in the study without their support, we will contact them to inform about your decision. You can change your study partner if you wish.

7. Each year you will be contacted by email asking you to repeat the cognitive assessments and to update your answers to the questionnaires. You will also be kept up to date with the study and its findings through a newsletter and the website. You may be contacted by mail (no more than once a year) or SMS/text message (no more than 3 times per year).

Mandatory non-cognitive self-reported questionnaires:

Questionnaire Name	**Frequency of Completion**
Demographics	Once at enrollment
Medical History	Annually

Menopause & Fertility Assessment*	
Everyday Emotions & Mental Health Symptoms	
Quality of Life	
Memory, Thinking and Function	

* Females, trans-men, and non-binary only

Mandatory cognitive assessment consists of the *PROTECT Cognitive Test Battery* which includes the following tasks:

- *Paired Associate Learning* task – Assesses visual memory
- *Self-Ordered-Search* task – Assesses spatial working memory
- *Digit Span* task - Assesses working memory
- *Grammatical Reasoning* task - Assesses verbal reasoning
- *Trail-making B* - Assesses visual attention and task switching
- *Switching Stroop Test* - Assesses visual attention and task switching

You will be asked to complete the battery in triplicate within one week (at least 12 hours apart) to improve data quality. Triplicate testing will not be mandatory.

Optional non-cognitive self-reported questionnaires:

Name	**Frequency of Completion**
Diet Questionnaire	Annually
Lifestyle Questionnaire	Annually
Brain Injury Screening Questionnaire	Once, edit if needed
Family History of Dementia Scale Questionnaire	Once
COVID Status Scale	Once at enrollment
Perceived Health, Feelings, & Attitudes Towards Aging Scale*	Annually
Past Mental Health History Questionnaire	Once
12 Brain Training Games *(Crates, Loop the Loop, Odd One Out, See Saw, Slider Game, Tower of London, Balloons, Card Pairs, Numbers, Scanner, Picture, Speed Card Pairs)*	Unlocked by completing cognitive tests at determined timepoints.

* For participants ≥ 65 years of age

Optional Physical Fitness Test Battery (questionnaires & tasks designed to give a robust measure of your current physical fitness):

Name	Frequency of Completion
Video-led tasks *(Chair Stand Test, Times Chair-Stand Test, 2-Minute Stand Test)*	Annually
Self-Reported Gait Velocity (Walking Speed)	Annually
The Activities-specific-Balance-Confidence (ABC) Scale (Balance Assessment)	Annually
Weekly Step Count & VO2 max Measurement Questionnaire*	Annually

*From your own device, if available.

The instructions for all the above-mentioned tasks will be provided in detail on the website.

Participants are enrolled for 20 years, but we hope to extend the study long-term. Time that is required:

- Online registration and consent: 20 minutes
- Baseline assessments: 90 minutes
- Annual follow-up assessments: 60-90 minutes

WHAT ARE THE RISKS AND BENEFITS?

This is not a clinical trial and there are no risks associated with any treatment or other intervention. This is an 'observational' study, meaning we only observe how you progress over time. There is a small risk that some people may find certain questions distressing or difficult to answer. For example, some of the cognitive tests are designed to be challenging, which may cause some stress. In addition, some of the optional questionnaires include questions about mental health and traumatic events, which may be distressing for some participants. In these cases, the study team will advise you to consult with your family physician.

The main advantage of this research is that participants will be taking part in an important Canada-wide research study that could provide valuable knowledge about how the brain works as we get older.

DO I HAVE TO PARTICIPATE?

No, it is up to you whether to join the study. Participants are free to withdraw at any time, without giving a reason. This will not affect the standard of care you receive through your Family Doctor or local health services. The purpose of this information sheet is to describe the research in detail to inform your decision.

WILL MY RECORDS BE KEPT CONFIDENTIAL?

Yes, we will not release your personal data to any third party without your written consent. Your data will only be used for the purpose of health care research and cannot be used to affect your care. This information cannot be used to impact services you receive in the future, such as health insurance coverage.

Only authorized members of the research team will have access to your data for the reasons outlined above.

All data collected on the CAN-PROTECT platform will be stored in Microsoft Azure Canada-East region SQL databases and uploaded nightly to the University of Calgary servers through a licensing agreement that enables both the University of Calgary and the University of Exeter sites to work in partnership.

This study is approved by the Conjoint Health Research Ethics Board, University of Calgary. The University of Calgary is the sponsor for this study. We will be using your information to undertake this study and will act as joint data controller for this study with the University of Exeter. This means that we are responsible for ensuring the security and confidentiality of your information.

- Your *identifiable* personal information (e.g., name, contact information) will be stored in a secure database and will only be available to select members of the CAN-PROTECT study team at the University of Calgary and to members of the PROTECT development team at the University of Exeter. It may be used for communication, monitoring and inspection purposes (to ensure compliance with regulations).
- Research data, such as your answers to the questionnaires, will be collected online through the study website over the study period. Only authorized members of the research team have access to this data. It will be completely *de-identified* (will not include your name, just a study number) and thus, the people who analyze the data will not be able to identify you in any way. These data may be used by our researchers in the future.
- Authorised members of the study team who are *not* involved in research may contact you to invite you to additional studies, but they will *not* see your study results.

The research sites must keep your identifiable information from the study for at least 5 years after the study has finished, separate from the study questionnaires.

CAN I STOP BEING IN THE STUDY?

You can withdraw from the study at any time without giving a reason. You can do this through the Manage Account section of the website or by contacting us at CAN.PROTECT@ucalgary.ca. If you withdraw from the study, you can tell us whether you want us to retain any personal information that could be used to identify you (email address, home address and full postal code) or whether you would like us to destroy that information. Please note, we will retain the full names, partial postal codes and participant ID's of any withdrawn participants to ensure we have a record of your consent at enrollment. We will retain all anonymized data that we have collected up to the time of withdrawal. This includes all de-identified data from assessments and questionnaires.

WHAT WILL HAPPEN AT THE END OF THE STUDY?

At the end of the 20-year study period you will complete your final annual assessments on the website. We will contact you to inform you that the study has ended. The results of the study will be published in a scientific journal. We will provide you with a lay summary of our findings in the form of a newsletter. The findings will also be available on the study website. The information collected is completely confidential and no individuals will be identified in any reports, publications or presentations. However, we do hope to extend the study for a longer period.

WHAT IF RESEARCHERS DISCOVER SOMETHING ABOUT ME?

There is a very small chance that people taking part in this study may develop dementia over the study period. In the unlikely event that we detect a clinically significant drop in your performance in the cognitive tests, you can choose whether you would like to be contacted by email to know our concerns and give you the opportunity to discuss them with one of our study doctors.

FUTURE RESEARCH STUDIES

It is possible that you might be eligible to participate in additional research studies in the future. If you wish, you may provide permission for us to contact you with information about other research studies that you might be eligible to participate in.

WHAT IF THERE IS A PROBLEM?

If you have a concern about any aspect of this study, information and Frequently Asked Questions are available on the study website www.can-protect.ca. If this does not answer your query, you can contact the research team at (403) 210-7737 or email us at CAN.PROTECT@ucalgary.ca.

FURTHER INFORMATION

Thank you for taking the time to read the information about this study. If you would like to participate, please register for the study at https://www.can-protect.ca. If you would like more information about the study before enrollment, you can contact a member of the study team at (403) 210-7737 or emailing us at CAN.PROTECT@ucalgary.ca.

If you have any questions concerning your rights as a possible participant in this research, please contact the Chair, Conjoint Health Research Ethics Board, University of Calgary at (403) 220-7990.

Consent to Take Part

- I am aged 18 or older, live in Canada and have access to a computer or touchscreen device with internet access with a unique email ID.
- I confirm that I do not have an established diagnosis of dementia or Alzheimer's disease.
- I confirm that I have read and understand the information about the study. I have had the opportunity to consider the information, seek clarification and understand my involvement in the study.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.
- I understand that relevant data collected during the study may be looked at by individuals from the research team at the University of Calgary and the University of Exeter or from regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data.
- In the event that a significant drop in my performance on the cognitive tests is detected during the study, I give permission for the study team to inform me and recommend further testing.
- In the event that I lose capacity to consent during the period of this research I understand that I would immediately be withdrawn from the study.
- If I chose to withdraw or lose the capacity to consent as described above, I understand that all de-identified data will be retained in the study, and that I will have the choice to destroy all identifying data about me that is held in the study with the exception of my name, partial postal code and consent form.
- I understand that the data collected will be stored securely.
- I understand that de-identified data from this study may be used by other researchers in the future.