Study Partner 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

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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 THIS 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, theimpact 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?

You were nominated as a study partner by a participant in the CAN-PROTECT study, someone you have known for the past five years or more and spends time with you frequently. We are recruiting one study partner with each primary participant in this research study and hope to recruit 5,000 study partners over the next two years.

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
- Be 18 years old or older

WHAT WOULD I HAVE TO DO?

If you decide to take part the following steps will happen:

1. During registration you will be asked to confirm some basic personal details including your name, email address, and relationship to the participant. 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. Once you have registered and signed the consent form, we will inform your friend or family member that you have accepted their invitation to become their study partner.
4. You will then be asked to complete a series of questionnaires on the website about yourfriend or family member's health status, behaviour, quality of life and cognitive function. These include the following questionnaires, completed at baseline and then on an annual basis:

    A. Study partner demographics

    B. Study partner reports on participant health (non-cognitive markers of dementia, frailty, pain, falls)

    C. Study partner reports on participant emotions

    D. Study partner reports on participant quality of life

    E. Study partner reports on participant memory, thinking, and function

5. Every year you will be contacted by email to remind you to repeat the questionnaires. We may also keep you up to date with the study and its findings through a newsletter and the website and may contact you by mail (no more than once a year) or SMS/text message (no more than three times per year).

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 will only observe how you progress over time.

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

DO I HAVE TO PARTICIPATE?

No, it is up to you whether or not to join the study. Participants are free to withdraw at any time without giving a reason. The purpose of this information sheet is to describe the study in detail to help you make 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 toundertake 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 CANPROTECT 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 & de-identified 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 sectionof the website or by contacting us atCAN.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) or whether you would like us to destroy that information. Please note we will retain the full names and registration ID's of any withdrawn study partners to ensure we have a record of your consent at enrollment. We will retain all de-identified data that we have collected up to the time you withdraw. This includes all anonymized data questionnaires.

Once you have withdrawn, a notification email will be sent to your friend or family member who may choose to nominate a new study partner. If you withdraw from this role but you are already taking part in CAN-PROTECT as a study participant or as a study partner for another friend or family member, your participation will not be affected.

In the event that your role as a study partner comes to an end before the study has finished (i.e., your friend or family member chooses to withdraw from CAN-PROTECT) we will contact you to inform you and ask if you would like to remain involved with the study (i.e., continue to receive our quarterly newsletter).

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 totally 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.

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 https://www.can-protect.ca. If this does not answer your query you can contact the research team at (403) 210-7737 or email us atCAN.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 by calling the study helpline on (403) 210-7737 or emailing your query to 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.

Study Partner Consent to Take Part

- I am aged over 18 or older, live in Canada and have access to a computer or touchscreen device with internet access with a separate email ID.
- I confirm that I have read and understand the information for 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 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 in point 5, 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 and consent form.
- Should my friend or family member withdraw from the study or opt to participate in the project without me, I understand that I would be removed from my role as their study partner.
- 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.