INFORMATION AND CONSENT FORM

Title of the research project :	**THE HEALTH AND AGING BRAIN STUDY (HABS): An optional PREVENT-AD study**
Principal investigator:	**Maiya R. Geddes, M.D. FRCPC** Assistant Professor McGill University
Co-researcher(s):	**Judes Poirier Ph.D.,** Professor **Sylvia Villeneuve Ph.D,** Assistant Professor **Arthur F. Kramer Ph.D.,** Professor **Adrián Noriega de la Colina M.D. Ph.D.** **Caitlin Walker,** Ph.D. Candidate
Sponsor or granting agency:	Funded by Brain Canada/Alzheimer Society. Application to the National Institutes of Health (NIH) under review.
Protocol number :	**IUSMD-20-38**

1. Introduction

We invite you to take part in a research study, the Healthy Aging Brain Study (HABS), at the Douglas Hospital, McGill University which seeks to the influence of daily activities on brain health in aging. Taking part in this study is entirely voluntary. We urge you to discuss any questions about this study with our staff members. Talk to your family and friends about it and take your time to make your decision. If you decide to participate you must sign this form to show that you want to take part.

2. Nature and objectives of the research project

You are being asked to participate in this study because you are older than 60 years of age, and part of the Pre-symptomatic Evaluation of Experimental or Novel Treatments for Alzheimer's Disease (PREVENT-AD) cohort. Up to 120 men and women are being asked to participate. The purpose of this research study is to learn whether a 4-week program of daily messages impacts thinking, emotion, behaviour and brain structure/function in older adults followed for 3 months. This research study will be completed remotely, thus in the comfort of your home.

3. Conduct of the research project.

3.1 Location of the research project, duration and number of sessions

This research project will take place online and your participation will last three (3) months, including four (4) weeks of daily messages on your computer, tablet or smartphone as well as

periodic telephone or videoconference meetings with the research team. You will also have to complete four (4) evaluation sessions lasting approximately three (3) hours each. The evaluations will be completed remotely and will be administered by a member of the research team. You won't have to travel to the Douglas research center.

You may participate in this study with an intergenerational study partner who can either be your child, grandchild, friend, or a younger adult recruited from the community. You and your study partner may receive daily feedback over four weeks about your daily level of physical activity with the help of a small device measuring physical activity that will be mailed to you. This feedback will be sent to you via your smartphone or computer.

3.2 Participation details
Details of online testing sessions and various evaluations

Session 0: (duration approx. 1 hour)
- Signing the Informed Consent Form
- Questionnaires
- Mailing the study envelop and accelerometer (the device measuring physical activity) to the participant

Session 1: 1 week before the study starts (duration approx. 3 hours)
- Baseline assessment (questionnaires)
- Cognitive evaluation
- Physical evaluation
- Accelerometer is worn for 1 week

Session 2: 3 weeks into the study
- Accelerometer is worn for 1 week

Session 3: During the 4th (last) week of the study (duration approx. 3 hours)
- Cognitive evaluation
- Questionnaires

Session 4: 3 months after the study started (duration approx. 3 hours)
- Cognitive evaluation
- Questionnaires
- Accelerometer is worn for 1 week
- Mailing the accelerometer back to the research team

I. Baseline assessment
You will be asked to complete a remote meeting to learn about your physical health, cognition (the ability to maintain attention and remember information), and emotional functioning.

II. Cognitive Assessment:
You will be asked to complete three (3) cognitive assessments (see schedule above). There will be break periods at regular intervals for you to rest your fingers and eyes. You will complete these assessments online independently or over the phone or via videoconference with a member of the research team. Portions of the phone assessments audio recorded using the recording function in the videoconference platform.

During the cognitive assessments, you will be asked to complete measures of cognitive function, emotion, quality of life (general well-being), and symptoms associated with your physical and emotional state. For some tasks, you will answer surveys, and for others, letters, symbols, words, or faces will be presented on your monitor, and you will have to answer by pressing specific keys on your keyboard as quickly and accurately as possible. For some tests, there will be practice trials to allow you to understand the test before executing it. You will not receive feedback on your performance on the cognitive assessments, and please remember that there are no right or wrong answers during the assessment.

III. Physical assessment:
You will be asked to report your height, weight, and resting heart rate to the research team three (3) times throughout the study. You will participate in some physical tests from your home during an online session with a member of the research team. This person will instruct you on how to measure and set up a short "walking course" in a hallway and will time you as you complete it. They will also ask you to do things like get up from a chair and sit back down, kneel on the floor and stand back up, do standing balance tests, etc.

You will be asked to wear an accelerometer, which is a small and safe device used to monitor physical activity. The accelerometer that will be used is the ActiGraph GT3X Link, worn on the wrist like a watch. You will be receiving the accelerometer by mail before the study starts and you will be mailing it back to us (mailing supplies will be provided) at the end of the study. You will be asked to wear the device for four (4) weeks. You will be asked to store the device, the charger, and other related materials in a safe, memorable place during the weeks you are not wearing it.

Detailed instructions as well as assistance through videoconference from a team member regarding the usage of the device (adjustments, charging the battery, transferring the data on your computer) will be provided. The accelerometer will be cleaned by the research team before configuring it following the procedure below:
1) The device cleaned in warm water and a mild detergent for 5 minutes.
2) Subsequently, it will be rinsed and dry with a soft cloth. No abrasives or alcohol are used.
3) The person preparing the device for shipping will wear gloves to ensure no surfaces are contaminated during the mailing process.

The accelerometer will be worn during daytime and nighttime, except for bathing and swimming. You will be asked to keep a sleep and activity log. At the end of each day that the accelerometer will have been worn, you will need to plug it into your computer to transfer your physical activity data. In select cases, we may ask you to wear the device for an additional week

(for instance, if there was a technical problem with the device that caused a loss of data). The research staff will help you upload an app to your phone at no charge and that data is transmitted securely between the accelerometer and the application and the research team without identifying you.

IV. Daily Messages:
You will receive daily messages for four (4) weeks after session 1. These messages will be followed by short multiple-choice questions that you need to answer during the day.

V. Long-term follow-up:
After a minimum of 6 weeks of the end of your participation in the study, you may be asked to participate in a different version of the study on which some of the elements of the study described before might or might not be present (like the study partner and daily messages). You will still be asked to wear an accelerometer for 4 weeks.

If you are invited to participate in this second period of the study, your new participation will follow a similar schedule as in the first period, and you will be entitled to a similar compensation schedule as mentioned in section 10, which would be in addition to the compensation offered after the first period of the study.

4. Disadvantages associated with the research project
This study requires a time-consuming engagement and can be a bit demanding, as it includes mailing material, handling material and transferring data.

5. Risks associated with the research project
I. Risks of privacy and breach of confidentiality
There is a possibility that study data could become accessed by unwanted third parties despite all our efforts to mitigate this risk.

II. Risks of physical activity
There is a possibility that during or after participation in any exercise, participants may have an injury to joints or muscles, or have muscle soreness or fatigue. Falling is another infrequent risk involved during exercise. Physical activity may be related to serious cardiac events in less than 1 per 20,000 exercising adults. This risk is minimized by starting the exercise session at low levels and increasing the level as tolerated. Your blood pressure will be taken at the beginning of the session to confirm you are not in a hypotensive or hypertensive condition. You will be asked to have someone nearby in case a fall happens. If that is not possible, at the onset of the remote fitness assessment, you will be asked for your address and the number of an emergency contact. During every remote research encounter, the research team member has a protocol in case a fall or other unexpected adverse event occurs. Research team members are trained in how to deal with this event. This way, if an adverse event occurs, the research team member can call 911 for help if necessary, and the emergency contact depending on the severity. The study team will keep the online connection with you until you get in-person help and their presence is no longer required.

III. Risks of cognitive and emotional measures

It is possible that during the completion of the cognitive and emotions questionnaire and computerized measures, you may become bored, frustrated, or fatigued. There is also a rare risk of slight eye strain. To prevent these risks, participants are offered breaks during testing periods.

IV. Risks of physical activity monitoring device

Although physical activity monitoring devices have been designed for comfort and wearability, they may cause slight discomfort. If you have any discomfort or skin irritation occurs with the device, we ask participants to inform a research team member as soon as possible. Participants will not be financially liable for damaged or lost equipment.

V. Risks with the 4-week daily phone messaging:

Messages taking approximately 1-2 minutes to read will be sent to the participant's phone or computer. Risks include slight eye strain and distraction from the task at hand when a message is received. Messages mustn't be read while driving or operating equipment, as they will diminish attention and your ability to safely perform the task. We ask participants to read the messages in a safe environment without distractions.

6. Benefits associated with the research project

You will receive no personal benefit from your participation in this research project. However, we hope the results obtained will contribute to the advancement of scientific knowledge in the field of age-related brain health.

7. Voluntary participation and the possibility of withdrawal

Your participation in this study is voluntary. You are therefore free to refuse to participate. You can also withdraw from this study at any time, without having to give reasons, by informing the research team. Your decision not to participate in or withdraw from this research project will not affect your ongoing participation in the PREVENT-AD study cohort.

The researcher in charge of the research project, the Research Ethics Board of the CIUSSS de l'Ouest-de-l'Île-de-Montréal may terminate your participation, without your consent. This can happen if discoveries or information indicate that your participation in the project is no longer in your interest if you do not follow the instructions of the research project, or if there are administrative reasons for abandoning the study.

If you withdraw from the project or are excluded from the project, the information and data already collected under this project will nevertheless be retained, analyzed or used to ensure the integrity of the project. You can withdraw your information and data from the study by alerting a study team member about this preference. Any new knowledge gained during the project that could have an impact on your decision to continue to participate in this project will be communicated to you quickly.

8. Confidentiality

During your participation in this research project, the researcher in charge of this project as well as the members of its research staff will gather, in a research file, the information concerning you and necessary to meet the scientific objectives of this research project.

This research study will include the collection of current and/or future identifiable medical information. The information that will be collected will be limited to information concerning your demographics (e.g., age, date of birth, education, occupation, marital status, etc.) and your name. In addition, we will collect information about your physical health, as well as the results from your cognitive tests and procedures.

All information collected will remain confidential to the extent permitted by law. In order to safeguard your identity and the confidentiality of this information, you will only be identified by a code number. The key code linking your name to your data will be kept by the researchers in charge of the study in a password-protected document. Only the principal investigator and authorized members of the research team will have access to this key.

All documents containing your name will be stored in a secure, locked location at the SToP-Alzheimer Centre at the Douglas Mental Health University Institute, and screening information will be stored using a PIPEDA (Personal Information Protection and Electronic Documents Act) compliant software designed for research documentation. The research coordinator and the principal investigator are the only people who will have access to these documents.

Research data will be administered through REDCap or Research Electronic Data Capture, a secure, web-based application housed in a secure local data center, behind the Tufts Medical Center firewall (www.tuftsctsi.org/research-services/informatics/redcap-research-electronic-data-capture). As REDCap is hosted in the U.S., American privacy laws might apply.

Coded research data may be shared by the principal investigator with researchers at Northeastern University in Boston, Massachusetts who are governed by United States laws and not Canadian or Quebec laws. However, the researcher in charge and the persons to whom he will transmit the research data are obliged to respect the confidentiality rules in the present consent form, regardless of the country.

For purposes of surveillance, control, protection, and security, your search folder will be accessible by a person mandated by regulatory agencies, by the institution or by the ethics committee of the CIUSSS de l'Ouest-de-l'Île-de-Montréal. These individuals and organizations adhere to a privacy policy.

You have the right to consult your research file to verify the information collected and to have it corrected if necessary. However, access to certain information before the end of the study could require that you are removed from the project to preserve its integrity.

These research data will be kept for a maximum period of 7 years after the end of the study by the researcher responsible for this research project. Research data may be published or scientifically discussed, but it will not be possible to identify you from the data alone. The de-identified information and results gained in this study will be posted on the website *clinicaltrials.gov* and disseminated for knowledge dissemination and translation. In addition the NIH, a study sponsor, may review the research documents related to your participation in this study.

9. Financing of the research project
Brain Canada/Alzheimer Society.
Application to the National Institutes of Health under review.

10. Compensation
You will receive up to $*100.00*: an amount of $20.00 per study session for a total of four (4) sessions, plus an additional $20.00 for the return of the accelerometer device for a total amount of $100.00 for costs and inconveniences incurred during this research study. If you withdraw from the study or are withdrawn before it is completed, you will receive compensation proportional to the number of sessions you have completed.

11. In case of harm
Should you suffer harm of any kind due to your participation in this study, you will receive the appropriate care and services required by your state of health.

By agreeing to participate in this research project, you are not waiving any of your legal rights nor discharging the doctor in charge of this research study, or the institution, of their civil and professional responsibilities.

12. Identification of contacts
If you have questions or experience problems in connection with the research project or if you want to be removed from participation, you can contact the researcher in charge of the research project or a member of the research staff at the following number

Dr. Adrián Noriega de la Colina
Study Coordinator
514-398-8980
geddes-lab@mcgill.ca

Dr. Maiya R. Geddes
Principal Investigator
maiya.geddes@mcgill.ca

13. Complaints

For questions about your rights as a participant in this research project or if you have any complaints or comments, you can contact the Commissioner for Complaints and Quality Services CIUSSS de l'Ouest-de-l'Île-de-Montréal at 1 844 630-5125 or by email at

commissariat.plaintes.comtl@ssss.gouv.qc.ca

14. Declaration of interests
The principal investigator states that she has no personal interest that could conflict with her role as a researcher.

15. Monitoring of the ethical aspects of the research project
The Research Ethics Board of the CIUSSS de l'Ouest-de-l'Île-de-Montréal approved the research project and assures monitoring.

Consent options:

Audio recording
Do you accept to be audiotaped during interviews? The audiotape(s) will be included in your research file and be kept for a maximum period of 7 years after the end of the study by the researcher responsible for this research project. The content of the tape(s) may be published or scientifically discussed, but it will not be possible to identify you.

Yes No

Video recording
Do you accept to be videotaped (which includes audiotaping) during interviews? The videotape(s) will be included in the research files and be kept for a maximum period of 7 years after the end of the study by the researcher responsible for this research project. Content of the tape(s) may be published or scientifically discussed, but it will not be possible to identify yourself.

Yes No

Re-contact for additional data/sample collection for this study
Do you agree to be re-contacted, in the future, to provide additional data and/or samples for this research project? This additional data and/or sample collection will then be presented to you, and a new free and informed consent will be sought. Only additional data and/or sample collections that are approved by a research ethics committee will be presented to you.

Yes No
Indicate your coordinates for re-contact: _____
_____
_____
_____

Transmission to the attending physician
Do you authorize the researcher or his/her team to inform your attending physician of your participation in this project and to transmit to him/her any relevant information?

Yes No

Name and coordinates of attending physician: _____
_____
_____
_____

Future research projects (secondary use)
Do you agree that your research data be used by the researcher in charge of the main research project to carry out other research projects in the same research area? This secondary use will comply with the data use conditions mentioned in the Informed Consent Form, including section 8 on confidentiality and destruction date requirements. Only research projects that have obtained ethics approval will be allowed to use your data for secondary use.

Yes No

Re-contact for participation in other studies, including biobanking projects and the Brain Bank
Do you agree to be contacted in the future to be invited to participate in other research projects, including biobanking projects and the Brain Bank? These other research projects will then be presented to you and project-specific free and informed consent will be sought. Only projects that have obtained ethics approval will be presented to you.

Yes No

Indicate your coordinates for re-contact: _____
_____
_____
_____

Declaration of Consent

THE HEALTH AND AGING BRAIN STUDY (HABS):

Title of research project:

1. **Participant's consent**

I have reviewed the information and consent form. Both the research study and the information and consent form were explained to me. My questions were answered, and I was given sufficient time to make a decision. After reflection, I consent to participate in this research study in accordance with the conditions stated above.

Name and signature of participant	Date

2. Signature of the person obtaining consent

I have explained to the participant and/or his parent/legal guardian all the relevant aspects of this study. I answered any questions they asked. I explained that participation in a research project is free and voluntary and that they are free to stop participating at any time they choose.

Name of person obtaining consent (print)	Signature	Date

3. COMMITMENT OF THE PRINCIPAL INVESTIGATOR

I certify that this Informed Consent Form was explained to the research participant, and that the participant's questions were answered. I undertake, together with the research team, to respect what was agreed upon in the Informed Consent Form, and to give a signed and dated copy of this form to the research participant.

Name of the Principal Investigator	Signature	Date