



## Participant Information Sheet and Consent Form Cohort Study

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**Title of Study** Technological Approaches for Advancing the Assessment of Early Mobility Limitation in Older Canadians: The McMaster Monitoring My Mobility - MacM3 - Prospective Cohort Study

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You are being invited to participate in a research study on mobility, technology, and aging, conducted by Dr. Beauchamp and colleagues because you reached out and agreed to hear more about the study.

In order to decide whether or not you want to be a part of this research study, you should understand what is involved and the potential risks and benefits. This form gives detailed information about the research study, which will be discussed with you. Once you understand the study, you will be asked to sign this form if you wish to participate. Please take your time to make your decision. Feel free to discuss it with your friends and family, or your doctor.

### Why is this research being done?

Problems with everyday mobility, such as walking or driving, are common as you get older and can impact your health. Some older adults do not notice early changes in how they are moving around their home or community. When an older adult begins to experience changes, they might

adjust how they do everyday activities, like starting to use a handrail to climb stairs, but they might not even notice they are having problems with moving around. The goal of this project is to identify these problems as early as possible before they have a major impact on the health of older people. Our project will use technology that can track how you move around your home and community, such as how many steps you take, the types of transportation used when you leave your home (e.g., car, bus, walking, bicycle), and how often you move around. From this technology, we aim to identify early changes in mobility so that we can develop ways to prevent these problems from happening in the first place and help maintain existing abilities so that older people can stay as healthy as possible and keep doing what matters most to them in their everyday lives.

### **What will my responsibilities be if I take part in this study?**

If you agree to participate in this research study, you will be asked to wear a device called a smartwatch (Model name: TicWatch) on your wrist. You will be mailed/given a smartwatch to wear for 10 days. You will be asked to wear the watch for 10 days every 4 months for 2 years (7 times in total). A group of participants will also be asked if they are willing to wear a second device called an ActiGraph. In addition to the smartwatch on the wrist, the ActiGraph will be placed on your thigh (using an adhesive patch). You will also wear this device for the same amount of time as the smartwatch (10 days every 4 months for a period of 2 years). If you agree to wear the ActiGraph, you will be asked to synchronize the ActiGraph with the TicWatch every morning before using the devices. The synchronization takes approximately 5 minutes and consists of holding the devices together and bending your forearm up and down 5 times. You do not have to agree to wear the ActiGraph to participate in this study.

Devices in this study only need to be worn during waking hours, except for when showering, bathing, or swimming. Both devices record information about your movement during the day (e.g., step count, body position). The smartwatch (TicWatch) also collects your heart rate (this will be recorded for descriptive purposes) and where you go (Global Positioning System [GPS] information). For the GPS data, only the destination information will be kept (e.g., restaurant, grocery store, entertainment, hospital, etc.) without naming the precise location you went to. In addition to the destination, the GPS will be able to help us track how far you travelled from your home and how you got there (e.g., walking, bus, car, bicycle). The smartwatch will need to be recharged daily (i.e., placed on its charger before you go to sleep) during each night of the 10-day trial period. The ActiGraph device does not need to be charged over the 10 days. However, if you agree to wear the device on the thigh, you will be asked to synchronize the devices every morning. This simple task involves holding the device in your hand while wearing the watch and extending and bending your forearm while counting to 10 for 5 times. The devices should be returned to McMaster Innovation Park (175 Longwood Rd S Suite 101A, Hamilton, ON L8P 0A1) after the 10 days. You will have the option to drop off the devices at a box located on the main floor (Room 101A - from 9 am to 4 pm, Monday to Friday) of McMaster Innovation Park or to receive a pre-addressed waybill to return the devices by mail.

At the start of the study, you will be asked to complete some questionnaires by phone and you will be invited to attend a physical assessment session at McMaster Innovation Park at a time convenient to you. You may be asked to complete these same questionnaires and the physical

assessment 1 year and 2 years later. These questionnaires will take approximately 60 minutes to complete. When you receive the devices at the 4-month check-ins (4, 8, 16, 20 months), you will be asked to complete a shorter series of questionnaires. These questionnaires will take approximately 10 minutes to complete. Some of the questionnaires can be completed online by having a link emailed to you, or you can complete these questionnaires when you come to the physical assessments at McMaster Innovation Park. The questionnaires will ask you about your age, health and wellbeing, how you move around, level of physical activity, nutrition, mood, and use of healthcare services. We will also ask you some questions about the recent COVID-19 pandemic. This study will also track if you have any problems with moving around, including falling. You will be provided with 24 pre-addressed, pre-stamped postcards that you will fill in each month and mail back to the study coordinator. For each month, you will circle whether you have had a fall. If a fall is reported, a member of the study team will call you to get some more details about what happened and ask if you had to seek medical attention.

During the in-person visits, you may be asked to complete the short tests of balance and mobility, described below, as well as to complete a vision test.

<b>Tests</b>	<b>Description</b>
Timed-Up-and-Go usual and fast pace	You will be asked to rise from a chair, walk three meters, turn around, walk back to the chair and sit down. You will do this once at your usual and then at a fast pace. This test is an indicator of your mobility.
Timed-Up-and-Go-cognitive usual pace	You will be asked to rise from a chair, walk three meters, turn around, walk back to the chair and sit down. You will do this once at your usual pace. You will complete the task while counting backwards from a randomly selected number between 50 and 90. This test is an indicator of your mobility and cognition.
5x-Chair Stand	You will be asked to stand up and sit down on a chair 5 times as fast as possible. You will do this once with your arms crossed on your chest. This test measures your lower body strength and balance.
Single leg stance	You will be asked to stand on one leg as long as possible. You will do this once. This test measures of your balance.
Gait speed	You will be asked to walk for 3 meters once at your usual pace and once at a fast pace. This test is an indicator of your mobility.
400-meter walk	You will be asked to walk in a 400-meter marked corridor as fast as possible using a watch on your wrist. We will count your steps and record the time as you perform the test. You will be asked to perform this test once. This test measures your aerobic capacity.
Pulmonary Function	You will be asked to perform a lung function test that consists of blowing air in an out of a device. This test will measure how much and how quickly you can move air in and out of your lungs. This test measures your lung capacity.
Handgrip strength	You will be asked to squeeze a device twice with each hand with all your strength. This test measures your grip strength.

Gait kinematics	You will be asked to walk over a carpet that measures your walk speed, stride, and step length. You will be asked to walk over the carpet 5 times. This test measures your walk characteristics.
Stair climbing	You will be asked to climb a flight of 4 stairs as fast as you can. You will perform this once. This test measures lower body strength.

**What are the possible risks and discomforts?**

You may feel that your movements are being tracked because of the GPS device. However, it is important to know that the researchers cannot view the GPS information while you are wearing the device, rather the information is logged by the device (time/day). This means that your GPS data is safe from being viewed externally and can only be accessed by our research team. Once the watch is returned to us, data is downloaded securely and then erased from the device. All other information collected by the smartwatch does not include GPS data.

You may feel generally tired from the testing session. The physical tests used in this study are commonly used in rehabilitation programs in Canada. However, because we might challenge your balance during the testing session, there is a small risk of falling. To minimize this risk, we will be watching you closely so that we may provide any necessary assistance should you lose your balance.

As part of your participation in this study, we require that you inform Dr. Beauchamp (email: [macm3@mcmaster.ca](mailto:macm3@mcmaster.ca) or call at (905) 525-9140 x26894) if you experience any symptoms that concern you either during the testing session or during the days following any of the sessions. Specifically, you must tell the researcher if you experience any dizziness, irregular heartbeat, upset stomach, chest, neck, or arm pain.

There is a risk of COVID-19 transmission from coming to the in-person visit. However, all research staff will be following Public Health COVID-19 guidelines and McMaster Workplace Health and Safety Guidelines where appropriate, to ensure your safety. However, because you will be completing balance tests, it is not possible for the research staff to maintain a 2-meter distance from you as they need to be close to you in the event you were to fall over.

There may be questions from the questionnaires that make you feel uncomfortable. You do not have to answer questions that you do not want to answer and can skip those questions. If you choose to take part in this study, you will be told about anything new that is being added to the study, which might affect your willingness to continue to participate in this research.

**How many people will be in this study?**

We will be inviting 1,500 community-dwelling older adults 65 years of age and over to participate in this study.

**What are the possible benefits of this study?**

This study will help us to understand early changes in older adults' mobility and to identify those who may benefit from further follow-up and early preventative treatment.

### **What if I do not want to take part in the study?**

Your participation in this study is completely voluntary. If you agree to be in this study, you may withdraw at any time. If you decide to withdraw, you also have the option of removing your data from the study. You may also refuse to answer any questions you do not want to answer and remain in the study. The investigator may withdraw you from the study if a reason warrants doing so, or it becomes unsafe for you to continue.

### **What information will be kept private?**

Your data will not be shared with anyone without your consent or as required by law. All confidential personal information will be removed from the data and will be replaced with a number. A list linking the number with your name will be kept in a secure locked place, separate from your file. The data will be securely stored in a locked office. If the results of the study are published, your name will not be used, and no information that discloses your identity will be released or published without your specific consent to the disclosure. Electronic data will be captured through REDCap, which is a secure web application for building and managing online surveys and databases. Data in REDCap is stored on secure McMaster servers.

For the purpose of ensuring the proper monitoring of the research study, it is possible that a member of the Hamilton Integrated Research Ethics Board and this institution and affiliated sites may consult your research data for quality assurance purposes. However, no records that identify you by name or initials will be allowed to leave the research office. By signing this consent form, you authorize such access.

### **Will I be paid to participate in this study?**

If you agree to take part, you will receive a \$25 gift certificate at baseline, 1 year, and 2 years at the in-person physical assessment. This combines to a total of \$75 in gift certificates over 2 years.

### **What happens if I have a research-related injury?**

In the unlikely event that you suffer a physical injury as a direct result of participating in the study, you will obtain medical care in the same manner as you would ordinarily obtain any other medical treatment. Financial compensation for such things as lost wages, disability, or discomfort due to this type of injury is not usually available. However, if you sign this consent form it does not mean that you waive any legal rights you may have under the law, nor does it mean that you are releasing the investigator(s), institution(s), and/or sponsor(s) from their legal and professional responsibilities.

### **If I have any questions or problems, whom can I call?**

If you have questions about the research, if you wish to withdraw from the study, or if you think you have a research-related injury, please contact:

Dr. Marla Beauchamp  
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This study has been reviewed by the Hamilton Integrated Research Ethics Board. If you have any questions regarding your rights as a research participant, you may contact the Office of the Chair of the Hamilton Integrated Research Ethics Board at (905) 521-2100 x42013.