Centre universitaire de santé McGill
McGill University Health Centre

X HME MCH X HGM MGH X HRV RVH
X HNM MNH X ITM MCI X CL LC

FMU-9997

Centre universitair

INFORMATION AND CONSENT FORM

Research Study Title:	Action for Positive Brain Health Now: Ready, Set, Go
Researcher responsible for the research study:	Dr. Nancy Mayo, Dr. Marie-Josée Brouillette & Dr. Lesley Fellows Center for Outcomes Research and Evaluation (CORE), MUHC-RI & Chronic Viral Illness Service of the Royal Victoria Hospital McGill University Health Centre (CVIS – MUHC), Glen site D 02.4110 – 1001 Decarie Montreal, Quebec H4A 3J1
Co-Investigator(s)/sites:	Dr. Réjean Thomas Clinique médicale L'Actuel, 1001 Boulevard de Maisonneuve Est, Bureau 1130, Montréal, Québec H2L 4P9 Dr. Benoit Trottier Clinique médicale Urbaine Quartier Latin, 1733 rue Berri, 2nd floor, Montréal, Québec H2L 4E9 Dr. Marianne Harris The John Ruedy Immunodeficiency Clinic St. Paul's Hospital Rm 524, 5th Floor 1081 Burrard Street, Vancouver BC V6Z 1Y6

INTRODUCTION

We are inviting you to take part in this research study because you are participating in Action for Brain Health Now and you reported some challenges with everyday activities.

However, before you accept to take part in this study and sign this information and consent form, please take the time to read, understand and carefully examine the following information. You may also want to discuss this study with your family doctor, a family member or a close friend.

This form may contain words that you do not understand. We invite you to speak to the researcher responsible for this study (the "study doctor") or to other members of the research team, and ask them to explain to you any word or information that is unclear to you before you sign this form.

BACKGROUND

Brain health in older people living with HIV is a priority concern. To address this concern, we have to take into account the effects of the virus itself, any other medical conditions, the person's lifestyle and social factors such as stigma and isolation. We know that many older people living with HIV could protect or improve their brain health through lifestyles changes but making these changes and sticking to them is can be very difficult. Our study will provide all participants with a healthy lifestyle program (HLP) which includes goal-setting, structured exercise, physical activity monitoring with feedback and social activities. With this HLP alone, some individuals might be able to make and stick to lifestyle changes that could be beneficial for their health. Other individuals may need additional tips in order to make and stick to lifestyle changes which could come in the form of Goal Management Training (GMT). The main objective of this study is to address the challenges of making and maintaining lifestyle changes.

PURPOSE OF THE RESEARCH STUDY

The purpose of this study estimate the extent to which cognitive rehabilitation before a personalized healthy lifestyle program (HLP) is associated with greater uptake of health recommendations, achievement of health-related goals, and better brain health and general health outcomes compared to the HLP alone.

For this research study, we will recruit 100 participants, men and women, aged over 35 years old living with HIV and from the parent study, Action for Positive Brain Health Now.

DESCRIPTION OF THE RESEARCH PROCEDURES

This research study will take place at the Research Institute of McGill University.

1. Duration and number of visits

Your participation in this research project will last 12 months and will include an initial visit for all participants which will last around 240 minutes. Some participants will also participate in 9 additional visits, each of which will be around 120 minutes in duration.

2. Study Intervention

When participating in this research project, you will be assigned to one of the following groups:

Group 1: Goal Management Training and Healthy Lifestyle Program
Group 2: Healthy Lifestyle Program

Furthermore, this study is randomized which means that you will be assigned to one of the groups. You may not choose the group to which you will be assigned; this process is done randomly like flipping a coin. One person out of 2 (50%) will be in Group 1 and one person out of 2 (50%) will be in Group 2.

This is a single blind study, which means that the research team will not know which group you were in during this project.

3. Description of the research procedures

Ready, Set Workshop

During the workshop which will last approximately 4 hours, you will go through the ready and set components.

Ready: You will be shown how to best interpret the *My Personal Brain Health Dashboard* which you were provided with as part of the Brain Health Now study. You will also be provided with a wearable device for physical activity monitoring. The Garmin vívofit 4 Activity Tracker tracks steps (differentiates walking and running), calories burned and monitors sleep. The Garmin vívofit 4 Activity Tracker is also connected to an app, called *MyHealth*, to allow you to see your information. If you do not have an app compatible device, you will be provided with one for the duration of the study. Moreover, the *MyHealth* app will allow you to have communication with a health coach who can comment on your results and provide encouragement. You will also be able to contact the coach through the *MyHealth* app should you face any difficulties with the device. Throughout the study, a question will also appear

on the *MyHealth* app every 48 hours and you will be given the 48 hours to respond to it before the next questions appears.

Set: For this study you will also have access to *MyGoals*, a mobile app which will be explained to you during the first study visit. The app will guide you through the steps to write and follow up on SMART goals; that is, goals that are Specific, Measurable, Achievable, Realistic and Timely. On this app you will have the option to make your profile with your goals visible to others in this study. The idea is that you can team up with others that have similar goals in order to help each other achieve the goals.

Healthy Lifestyle Program

Go: Following the Ready, Set Workshop you will start the Healthy Lifestyle Program (HLP) for the following 12 months. Some individuals will have Goal Management Training, a standardized cognitive rehabilitation program, which consists of 9 sessions each2-hous in duration. They will be asked to attend in person, at a location that is easily accessible. There is also some homework in between the sessions.

Everyone will participate in the HLP which includes physical activity monitoring and feedback with the Garmin vívofit 4 Activity Tracker, and recording and monitoring of goals with the *My Goals* app. You also have the option to participate in a community with the other participants so you can share information about different activities or resources which may help to reach your goals. Everyone will be provided with three training sessions with a person trainer paid from the research project and we will reimburse a gym membership up to 120$ per year. For people who do not have access to a personal trainer or a gym, we have a gym partner, Coop Sportive Santé (Fitness and Health Coop) who will provide these services.

Everyone will also be assigned a HLP coach which will provide you feedback, encouragement and suggestions for increasing activity via phone or text interaction on the MyHealth App.

Everyone will also be asked to track their goals on the MyGoals app and report their participation in any activities they do by taking a picture of something to represent the activity. For example, if you go to a yoga class or a painting class take a picture of the yoga studio or the art studio and send it to us by email. We will record the details of the activity (when, what, if it was alone or in a group) and then we will delete the picture. You do not have to appear in the picture and the reason we are asking for pictures is to make it easier for you; sending us the picture allows us to will write down the information instead of asking you to fill out logs.

BENEFITS ASSOCIATED WITH THE RESEARCH STUDY

You may or may not personally benefit from your participation in this research project. However, we hope that the study results will contribute to the advancement of scientific knowledge in this field and help us identify services and programs that would benefit people living with HIV

RISKS ASSOCIATED WITH THE RESEARCH STUDY

Potential psychological risks are low. The questionnaires used in this study have been administered without problems in first wave of the study (Brain Health Now) or in other studies.

VOLUNTARY PARTICIPATION AND THE RIGHT TO WITHDRAW

Your participation in this research project is voluntary. Therefore, you may refuse to participate. You may also withdraw from the project at any time, without giving any reason, by informing the study doctor or a member of the research team.

Your decision not to participate in the study, or to withdraw from it, will have no impact on the quality of care and services to which you are otherwise entitled, or on your relationship with the study doctor or clinical team.

The study doctor, the Research Ethics Board, the funding agency, or the Sponsor may put an end to your participation without your consent. This may happen if new findings or information indicate that participation is no longer in your interest, if you do not follow study instructions, or if there are administrative reasons to terminate the project.

However, before you withdraw from the study we ask that you return any equipment we have given you.

If you withdraw or are withdrawn from the study, the information already collected for the study will be stored, analyzed and used to ensure the integrity of the study.

CONFIDENTIALITY

During your participation in this study, the study doctor and their team will collect and record information about you in a study file. They will only collect information required to meet the scientific goals of the study.

The study file may include information from Action for Brain Health Now, including your identity, concerning your past and present state of health and your lifestyle, Your research file could also contain other information, such as your name, sex, date of birth and ethnic origin.

All the information collected during the research project will remain strictly confidential to the extent provided by law. You will only be identified by a code number. The key to the code linking your name to your study file will be kept by the study doctor.

Software development, maintenance, and support for the *My Smart eHealth framework (MSH)* project will be provided by DataRiver Srl, a Contract Research Organization by AIFA (Italian Medicines Agency). DataRiver has built a solid and valuable know-how in both the management and the maintenance of Information Systems in the medical field, including the implementation, maintenance and customization of the web application and the management of all aspects concerning security and data quality in compliance with the standards and international guidelines (**Good Clinical Practices**).

By consenting to participate in this project you are consenting that your unidentifiable research data that is collected by the My Smart eHealth framework (MSH) will be stored by DataRiver for the duration of the study. This inlcudes your step count, calories burned, sleep and responses to questionnaires sent on the mobile application. This research data will be stored with an anonymous code. Matching this code to your identification will not be done by DataRiver, it will be done by the researchers.

Software development, maintenance, and support for the MyGoals application will be provided by Applied R&D Technology and Funding Solutions Inc. Applied R&D has 15 years of application development experience, working with l'Institut universitaire en santé mentale de Montréal, le Centre d'Études sur le Stress Humain, and l'Université de Montréal. It is responsible for one of the largest biological, psychosocial, and clinical mental health big data banks in Canada.

Data for the *My Goals* mobile application will be managed and stored on a physical BHN server behind the McGill University Health Center (MUHC) firewall. We will adhere to the security and privacy requirements from the Chief Information Security Officer (CISO), MUHC Information security governance. A full security audit will be performed by his team to ensure that the system meets MUHC data security and privacy requirements. A secure private network tunnel will be established between an authorized mobile device and the BHN server. Access to the data will be protected with authentication levels (password, and 2-step verification), session management, and SSL encryption. A contract between the MUHC and Applied R&D, that includes a confidentiality agreement, will be completed prior to individuals at Applied R&D will have access to any of the data.

The study data will be stored for 7 years by the study doctor.

The data may be published or shared during scientific meetings; however it will not be possible to identify you.

For monitoring, control, safety, security, and marketing of a new study drug, your study file as well as your medical charts may be examined by a person mandated by Canadian or international regulatory authorities, such as Health Canada, as well as by representatives of the study sponsor, the institution, or the Research Ethics Board. All these individuals and organizations adhere to policies on confidentiality.

You have the right to consult your study file in order to verify the information gathered, and to have it corrected if necessary.

FUNDING OF THE RESEARCH PROJECT

This study is under the main Action for Brain Health Now study which has been funded by the Canadian Institute of Health Research.

COMPENSATION

You will not receive financial compensation for participating in this research study.
You will be able to keep the Garmin vívofit 4 Activity Tracker but if you were provided with an app compatible device it must be returned.

SHOULD YOU SUFFER ANY HARM

Should you suffer harm of any kind following any procedure related to the research 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 study doctor, the sponsor or the institution, of their civil and professional responsibilities.

CLINICAL TRIAL REGISTRATION

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Website at any moment.

CONTACT INFORMATION

If you have questions or if you have a problem you think may be related to your participation in this research study, or if you would like to withdraw, you may communicate with the study doctor or with someone on the research team at the following number: (514) 934-1934, ext. 32147

For any question concerning your rights as a research participant taking part in this study, or if you have comments, or wish to file a complaint, you may communicate with:

> The Patient Ombudsman of the McGill University Health Centre at the following phone number: (514) 934-1934 ext. 35655.

OVERVIEW OF ETHICAL ASPECTS OF THE RESEARCH

The McGill University Health Centre Research Ethics Board reviewed this research and is responsible

for monitoring the study.