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

* F M U – 9 9 9 7 *

Centre universitaire de santé McGill
McGill University Health Centre

INFORMATION AND CONSENT FORM

Research Study Title:	Effectiveness of a Personalized Health Profile on Specificity of Self-Management Goals Among People Living with HIV in Canada: A Blinded Pragmatic Randomized Controlled Trial
Protocol number:	2020-5728
Researcher responsible for the research study:	Dr. Nancy Mayo, Ph.D. James McGill Professor Department of Medicine School of Physical and Occupational Therapy, McGill University Research Scientist, Center for Outcome Research and Evaluation, MUHC Research Institute Phone: (514) 934-1934, ext. 32147
Co-Investigator(s)/sites:	Maryam Mozafarinia, RN, Ph.D. student Division of Experimental Medicine Dr. Lesley Fellows, MD, Ph.D. Chronic Viral Illness service, Montreal Neurological Institute Dr. Marie-Josée Brouillette, MD Associate Professor, Department of Psychiatry, Faculty of Medicine, McGill University Research Scientist, Center for Outcome Research and Evaluation, MUHC Research Institute
Sponsor:	McGill University

INTRODUCTION

You are being asked to take part in this study because you had participated in the main "Brain Health Now" study or are participating in a new study, "Action for Brain Health Now".

Before agreeing to participate in this study, we would like to ask you to read the information provided in this form so that you understand the proposed study procedures. The following information describes the background, purpose, procedures, benefits and risks associated with this study. It also describes your right to refuse to participate or withdraw from the study at any time. Please take the time to read, understand and carefully examine the following information. In order to decide whether you wish to participate in this research study, you should understand enough about it to be able to make an informed decision. You may also want to discuss this study with 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

HIV is now known as a manageable chronic disease. Experiencing complications or developing multiple illnesses are often the case for people living with a chronic disease, which can affect person's well-being and quality of life. Since chronic illnesses persist throughout a person's life, a key strategy that can help individuals to improve their health outcomes is self-management. This way individuals set goals and make choices according to their own health condition. Some people are clear about their health priorities and can set their own health goals for areas they want to improve. Others prefer to receive a summary of their health profile so that they can make decision and set goals based on the reported results. The main objective of this study is to better understand the quality of the goals set by individuals. To this end, we prepared a personal profile on key areas of health based on your test results in the main Brain Health Now trial. This project is among people with HIV living across Canada and will assess the potential impact of the "Personal Brain Health Profile" on goal-setting. This will help us understand the information helpful for goal-setting and health priorities of the people living with HIV.

PURPOSE OF THE RESEARCH STUDY

The purpose of this study is to understand the extent to which the Personal Brain Health Profile affects the quality of self-management goals set by individuals. This study will be carried in Canada and include around 1000 people, men and women more than 35 years old living with HIV.

DESCRIPTION OF THE RESEARCH PROCEDURES

This research study will take place at Research Institute of McGill University. We will collect information on individuals' self-care goals through an online survey.
If you wish to participate in this study, you will have to:

- Have access to internet to login to the survey platform. You can open the survey either on your phone or your computer.
- Be randomized to either receive your Personal Brain Health Profile or not. Half of the participants in the study will receive their "Personal Brain Health Profile" for the purpose of this

study, and other half will not receive their profile until the end of the study. Randomization means that whether you receive your profile or not, will be determined by chance alone (like flipping a coin). This process will be done by computer and study staff who will receive and evaluate your goals will not know which group you belonged to, meaning whether you received your Personal Brain Health Profile or not. However, at the end of the study, Personal Brain Health Profiles of all participants will be sent to them by e-mail.

- Go to the survey platform (after reading this consent form by clicking on "agree" you will be automatically directed to the survey platform. However, you can always use the link provided in the e-mail to access the survey platform. There are two sections on the survey: 1) *Tips to Improve Your Brain Health* and 2) *Tips on Goal-Setting*. You can print or download both of these documents if you wish. You will also see blank boxes at the bottom of the survey page. You are supposed to *Write Your Self-Care Goals* in those boxes and answer few questions related to each goal you make.
- When ready, write goals on the top 3 to 5 actions you would like to take to improve your health condition. For this reason, you need to type your goals in the assigned boxes. For each goal you write there are three questions that you need to answer. When you are done writing all your goals, you can click "submit" button. You can familiarize yourself with how to write goals by reading the instructions given on "*Tips on Goal-Setting*". You can also use the "*Tips to Improve Your Brain Health*" to learn more about areas you can work on to improve your health. Your goals will only be viewed by study staff, and not by anyone involved in your clinical care. However, you can share your profile and goals with your primary health care provider if you wish to.

DURATION OF THE STUDY

This study will last until you write your health goals and submit it. We are expecting you to write us back your self-care goals within 2 weeks of receiving the e-mail. If you take time to familiarize yourself with the survey platform and read the instructions and prepare your goals, it will only take you 15 to 30 minutes to type them in and submit.

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 find better strategies to help patients improve their overall quality of life.

RISKS ASSOCIATED WITH THE RESEARCH STUDY

There are no known risks for participating in this study. However, if at any point during the study duration you feel you need help or you have any concerns about the items on your profile, we strongly encourage you to communicate with your health care provider.

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.

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.

Any new findings that could influence your decision to stay in the research project will be shared with you as soon as possible.

CONFIDENTIALITY

If you agree to join this study, you will be given a username and a password to log in to the "My Self-Care Goals" online survey. You will only be recognized by your username. All information that is collected for the study will be kept in a secure and password protected file at the Center for Outcome Research and Evaluation, MUHC Research Institute. Only the study team will be allowed to look at your records.

All information collected for this study will be kept confidential and will not be shared with anyone outside the study unless required by law. You will not be recognized in any reports, publications, or presentations that may come from this study.

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 the Brain Health Now study, including your demographic information, such as your 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.

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 "Brain Health Now" trial which has been funded by the Canadian Institute of Health Research.

COMPENSATION

You will not receive financial compensation for participating in this research study.

SHOULD YOU SUFFER ANY HARM

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, or to talk to someone not connected to this research study, 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.

DECLARATION OF CONSENT

I have read the contents of this consent form and I am satisfied with the information I have received about the study. I understand that my participation is completely voluntary and that I can withdraw from the study at any time, without any penalty or consequences. I understand that by clicking on "Yes, I agree", I am electronically signing this consent form and declaring my consent to participate in this research study.

Do you agree to participate in this research?

- ☐ Yes, I agree
- ☐ No