

Official title of the study: Feasibility and Implementation of a Healthy Lifestyles Program: A Pilot Study

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Appendix 2. Letter of information/consent – Participation in healthy lifestyles program

Title of study: Evaluating a healthy lifestyles program

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You are being invited to participate in a research study. The purpose of the study is to evaluate a healthy lifestyles program. Specifically, you are being invited to participate in a year-long program geared to helping people make healthy lifestyle changes. If you agree to participate in this study, you will be randomly assigned (chosen by chance) to either a more intensive program or a less intensive program. Either program will be run out of the David Braley Health Sciences Centre on 100 Main Street West in Hamilton, Ontario. You will need to secure transportation to and from the site. If you are not able to afford transportation, please ask the research assistant for possible supports, although they are not guaranteed.

Both programs, the more intensive and the less intensive programs, will help you identify health goals and track how you are doing in meeting those goals throughout the year.

The **more intensive program** will include hour-long evening group meetings once a week to either learn about health and wellness strategies or to have facilitated group discussions on meeting goals. If you are selected to be in the more intensive program, *please note* – the group meetings are considered confidential, and we ask that you and others do not share the information with people who are not part of the meeting. In addition, the more intensive program will include individual meetings with a healthcare team once a month. The initial meeting is expected to last three hours and the follow-up meetings are an hour each. These will be scheduled once the study begins.

The **less intensive program** will include individual meetings once every three months with a research assistant trained in health behaviour theories (five times total). The initial meeting is expected to last two hours and the follow-up meetings are an hour each. These will be scheduled once the study begins. If you are selected to be in the less intensive program, you will be offered the opportunity to participate in the more intensive program once the study ends, given the continuation of the program.

As part of the study in either program, information will be collected about you (for example, your age, marital status, etc.), your current and past health (for example, medical problems and medications you are taking to treat those problems, etc.), and current health habits (for example,

if you smoke, how often you exercise, etc.). You will be asked to fill out surveys about your health (for example, stress levels, symptoms of anxiety) and about the program (for example, what parts of the program are useful, recommendations for improving the program, etc.). In addition, you will be asked to have your height, weight, waist circumference (measurement around your waist), waist hip ratio (measurements around your waist and hips), and blood pressure taken. You may also be asked to have blood drawn once at the beginning of the study and up to five times throughout the year only if you meet the requirements for screening or if you have certain health conditions, such as diabetes or heart problems. If your doctor already has this information, we will ask you to provide this information instead of having you do additional bloodwork. Every three months, you will be provided and asked to fill out a nutrition journal for a week and a physical activity journal for a week (five times total) to help you reflect on your health goals and to gather information on lifestyles. You will receive reminders to complete these forms at the appropriate times. In addition, you will be asked to keep track of costs related to healthcare (e.g., transportation, parking, medications) and the use of medical services throughout the year through a log that will be provided. Lastly, you will be asked to participate in an exit interview to gather your thoughts on the program and ways to improve the future design of the program. These interviews will be audio-recorded, with your permission. Notes will be taken during these interviews and recordings will be transcribed.

Please note – even though there is a physician on the team, Dr. Elizabeth Alvarez, and she will review the findings or address concerns brought forward by the research assistants related to your health, you are expected to see your personal doctor for your healthcare needs. Dr. Alvarez will be in contact with your primary care doctor if any changes to your health status are noted or concerns are identified. You will be asked to sign a form to allow Dr. Alvarez and the team to share information about your health with your primary care doctor. This sharing of information will only happen if you agree to this. *Please note* - In the event it is deemed that you are at risk of self-harm or harm to others, appropriate protocols will need to be followed for ensuring your or others' safety. This means personal information may need to be provided to emergency care workers or the authorities, if others are involved.

As part of this study, we are also seeking to understand the role of family members in creating and maintaining healthy lifestyles. We will ask for you to provide information to your family members about halfway through the program about their participation in focus groups to help gather their perspectives. Your ability to pass on this information is voluntary, and their participation is also voluntary. More information will be provided at the appropriate time.

Appropriate and respectful behaviour is expected from all people participating in this study at all times, including participants and team members. If anyone becomes belligerent, swears, uses inappropriate language or behaviours, etc., s/he can be removed from the study at the discretion of the team members.

Your participation in this research study is voluntary. You may refuse to participate in the research study and you may choose to withdraw from the study at any time. We cannot promise any personal benefits to you from your participation in this study. However, it is expected that you will be able to set healthy lifestyle goals. The program is provided free of cost to you. In addition, you will receive \$30 each time data is collected. This means that each time the research assistant meets with you once every three months (five times total), you will receive \$30.

There are minimal risks associated with this study. There are some risks involved in starting new exercise programs, such as injuries. Appropriate goal setting will help minimize this risk. You may feel anxious or fatigued when filling out documents or during the course of the program. If so, the team will help you identify these concerns and solve them or remove you from the study after discussing this with you. There is also a risk of disclosure where you or another participant may be able to identify comments made by you. Every attempt will be made to present information in a way that does not identify individuals.

Any information gathered about you during this study will be treated as confidential. We will ensure that documents are kept in a locked cabinet and electronic records are stored on a security protected computer and only the research team will have access to this information. The documents and records will be destroyed after 10 years from the end of the study, which is the standard for research in Canada. We will make the summary of our findings publicly available for use by others interested in improving their efforts to support healthy lifestyle changes and chronic disease management.

Your anonymity as a research study participant will be safeguarded. We will ensure that the list of study participants and their participant numbers will be stored in a different locked cabinet or security protected file from those where the documents or electronic records are kept for the purposes of the study. Every effort will be made to report information in a way that will not identify individual respondents; however, there is a slight chance that someone may be recognizable by his/her comments.

Please check yes or no to the questions below to indicate whether you consent to participate in our study. We would be pleased to provide you with additional information about our study and your potential participation. Please see contact information below if you have any questions about entering the study or while you are enrolled in the study. For the purposes of ensuring the proper monitoring of the research study, it is possible that a member of the Hamilton Integrated Research Ethics Board may consult your research data. However, no records which identify you – be it name or initials will be allowed to leave the university. By signing this consent form, you authorize such access.

| Request for consent | Yes | No |
|---|-----|----|
| 1. I am willing to participate in a year-long research program as described above | | |
| 2. I understand that I am able to withdraw from the study at any time with no consequences to my care from my current health providers | | |
| 3. I understand that my personal information will be kept confidential and all attempts will be made to keep my information anonymous | | |
| 4. I understand that in the event I am deemed to be a harm to myself or others, the team will follow appropriate protocols, which may mean information is provided to emergency personnel or authorities, if others are involved. | | |

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| 5. I understand that selection into the more intensive or less intensive programs will be based on chance selection. If I am in the less intensive program, I will be offered the opportunity to participate in the more intensive program once the study ends, given the continuation of the program. | | |
| 6. If I am selected to be in the more intensive program, I understand that information presented by others during group meetings is to be treated in a confidential way, that is, I will not share information with people outside of the meeting | | |
| 7. I understand there are some risks involved in starting new exercise programs, such as injuries, but efforts will be taken to minimize these risks | | |
| 8. I understand that I need to seek regular care from my family doctor outside of this program. The team will not provide acute care unless it is an emergency and does not replace my family doctor's care. Changes in drug treatment will not be done through this program, including the writing of prescriptions. | | |
| 9. I understand that the team will only communicate with my family doctor if I approve this. | | |
| 10. I understand that my exit interview will be audiorecorded. | | |
| 11. Please contact me. I would like additional information about the study and/or my participation. | | |
| <p>I will receive a signed copy of this form.</p> <p><u>Participant</u></p> <p>Print name: _____ Signature: _____</p> <p>Date: _____</p> <p><u>Person obtaining consent</u></p> <p>Print name: _____ Signature: _____</p> <p>Date: _____</p> | | |

This study has been reviewed by the Hamilton Integrated Research Ethics Board (HIREB). The HIREB is responsible for ensuring that participants are informed of the risks associated with the research, and that participants are free to decide if participation is right for them. If you have any questions about your rights as a research participant, please call The Office of the Chair, HIREB at 1-905-521-2100 x 42013.

Sincerely,

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