

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

NCT Number: 03258138

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Appendix 4. Interview letter of information/consent – Staff semi-structured interviews

Title of study: Evaluating a healthy lifestyles program

Principal investigator: Elizabeth Alvarez, MD, MPH, PhD, CMCBT

Co-investigator(s): Lawrence Mbuagbaw, MD, MPH, PhD; Majdi Qutob, MD, MSc, MBA; Cynthia Lokker, PhD; Marjan Walli-Attaei, PhD candidate; John N. Lavis, MD, PhD; Zena Samaan, MD, MSc, MRCPsych, PhD

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 an interview about the program itself and how it is run. Your involvement would mean participating in a 30-60-minute (approximately) semi-structured in-person interview to be scheduled at your convenience. During the interview, a research assistant/student investigator will ask you questions about your role in the program, what aspects of the program work well and what aspects could be improved and how, what supports would be helpful to include to improve your work environment, and/or other recommendations for how to run the program better.

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 interview at any time. We cannot promise any personal benefits to you from your participation in this study. However, a possible benefit includes helping improve the healthy lifestyles program and related programs, research or policy.

Your interview will be treated in a confidential way. The research assistant/student investigator will take notes during the interview. With your permission, the interview(s) will be audio-recorded in case the research team needs to review the interview for completeness of information. Personal identifiers will be assigned to the notes, the audio-recorded digital file and the transcript (if needed). We will ensure that any confidential documents are kept in a locked cabinet, the digital files containing the audio-recordings and transcripts are stored on a security protected computer, and the digital files, transcript and confidential documents are destroyed 10 years after the last publication of our findings. We will make the summary of our findings publicly available for use by others interested in improving programs, research or policy around healthy lifestyles.

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 computer from those where the digital files, transcripts and confidential documents are stored. There is minimal risk expected from participating in this study. There is a slight chance that someone may be recognizable by his/her comments. However, every effort will be made to report information in a way which will not identify individual respondents.

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 30-60-minute (approximately) interview to be scheduled at my convenience.		
2. I am willing to have the interview audio-recorded		
3. Please contact me. I would like additional information about the study and/or my participation.		
I will receive a signed copy of this form.		
<u>Participant</u>	Date: _____	
Print name: _____	Signature: _____	
<u>Person obtaining consent</u>	Date: _____	
Print name: _____	Signature: _____	

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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