**LETTER OF INFORMATION AND CONSENT**

**Title of Study:** BACK TO LIVING WELL: Implementation of a community-based program for the tertiary prevention of low back pain

**Local Principal Investigator:**Dr. Luciana Macedo, PT, PhD, McMaster University, Hamilton, ON, Canada

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**Why are you being asked to be part of this research study?**

You are being invited to participate in our research study as you have enrolled and have yet not started the YMCA Back to Living Well program and stated you may be interested in participating in our research study about the program. In this study we will be evaluating the implementation of the Back to Living Well program. 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 letter gives detailed information about the study that will be discussed with you. Once you understand the study, you will be asked to consent to be part of the study using our online system. If you prefer, you can consent to being part of our study by signing a consent form that we will mail to you with return postage. Please take your time to make your decision. Feel free to discuss it with your friends and family, or your family physician.

**Why is this research being done?**

You are invited to take part in this study aimed to evaluate the implementation of the Back to Living Well program. The program is an exercise and education program for people with low back pain (LBP) offered at the YMCA. Although the program was developed based on the best available evidence for managing LBP, we know that adherence to exercise and other factors may impact outcomes of the study. Thus, we are interested in understanding barriers and facilitators to the program as well as how you integrate the content within your life. We will use the results of this study to make changes to the program and determine factors that contribute to outcomes experienced by participants.

**What will happen during the study****?**

The first step in the study is an online appointment with a physiotherapist who will confirm your type of back pain and provide recommendations to the people delivering the program at the YMCA.You will be asked to complete a series of surveys including some personal information (e.g., sex, gender, age, education, etc.) before you start the program. We will also ask you to complete questionnaires about your pain, activity limitations, and psychosocial profile before you start the program, at the end of the 12-week program, as well as 6 and 12 months follow-up using McMaster University’s online system (REDCap). Surveys will take approximately 30 minutes to complete each time. At the same time points, before the intervention, 12-weeks, 6 and 12 months you will also be asked to participate in one-on-one interviews that should take approximately 45 minutes to complete. Participant interviews will be conducted to understand patient preferences, adherence, barriers or enablers to participation, and factors guiding selection of opting for receiving the program either in-person or online. Interviews will be conducted through McMaster University’s approved teleconferencing system (Zoom) by one of the study’s research team member.

We will also collect weekly information about your pain, mood and activity limitations using via smartphone application called MetricWire Inc. If you are unable to access a smartphone, weekly data will be collected using the same online system (REDCap) mentioned above. For those who prefer having these questionnaires mailed to them, we will be collecting your mailing address to accommodate for those who prefer to receive surveys from us through this method. We will also be collecting your mailing address should we be unsuccessful in contacting you in any other way to complete the surveys.

In addition, at the same follow-ups described above, you will be asked you wear an activity monitor for 7 days (Actigraph). You will have the option to pick up your activity monitor at the YMCA, otherwise it will be mailed to you with return postage.

Throughout both your participation in the 12-week program, as well as during the 1 year follow up for the study, your attendance at the YMCA will be tracked and provided to the research team. This information will assist in determining both short- and long-term adherence to physical exercise.

Your participation or not in this study will not impact your participation in the BacktoLiving Well program.

Finally, during the duration of your participation in the study, we ask that you do not enroll in other research studies.

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

A total of 90 participants from the Hamilton area will be included in this study. We will recruit 45 participants from the in-person and 45 participants from the online program.

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

You do not need to answer survey questions that you do not want to answer or that make you feel uncomfortable.

It may also not always be possible for YMCA staff to keep the identity of research participants and non-research participants separate while in the Back to Living Well program. Your Back to Living Well program will contain research participants and non-research participants. Regardless, both research and non-research participants will not experience any differences in how the Back to Living Well program is offered at the YMCA.

**What are the possible benefits for me and/or for society?**

We hope that what is learned will help us improve the understanding of barriers and facilitators of exercise among those with LBP. This research aims to better understand how patients navigate their LBP and integrate exercise and self-management into their everyday life. We hope to better understand how this relationship relates to improved outcomes, which may shed light into new more effective ways to deliver our program and the identification of strategies to avoid LBP flare ups. However, we cannot promise any personal benefits to you from your participation in this study.

**Who will know what I said or did in the study?**

Every effort will be made to protect your confidentiality and privacy. The information you provide will be kept in a secure computer where only we will have access to it. Information kept on a computer will be protected by a password on a secure virtual private network.

The YMCA will be sharing your attendance for both the online and in-person components of the Back to Living Well program with the research team. We will track completion of the online videos through a McMaster University hosted version of Moodle. To track long term commitment to exercise continuation, the YMCA will provide the research team with information about your attendance at the YMCA for a year after your enrolment in the program and whether you decide to discontinue your membership. No other information that you share with either the research team or with the staff at the YMCA will be shared between the research team and the YMCA. It will not be possible to keep the identity of those participating in our study anonymous, given that YMCA staff will be offering the YMCA membership at a discounted price for those who do participate in the study.

**What information will be kept private?**

The health information collected in this study will be kept confidential unless release is required by law. To ensure confidentiality, each participant will be given a unique identification number when completing the questionnaires and interviews. Documents linking the study participant to their unique identification number will be stored in a password protected file that only the research coordinator, principal investigator and postdoctoral fellow will be able to access through McMaster University’s virtual private network (VPN). The study database will be created in the REDCap system provided by McMaster University and hosted in the Department of Rehabilitation Science data centre. All access controls for the database held by the researchers has a two-factor authentication, time-limited user registration, automatic time-out and reporting of user access and privilege levels. Data encryption during transmission occurs via a secure socket layer (SSL) and VPN technology for authorized remote access. At the end of the study your anonymized data will be kept and will comprise a research resource database. Your information will only be used for secondary research after approval from an appropriate research ethics board.

The researchers, this institution and affiliated sites, and the Hamilton Integrated Research Ethics Board may access your study records to monitor the research and verify the accuracy of study information. By signing this consent form, you authorize such access.

This study will use a McMaster licensed Zoom account to collect data, which is an externally hosted cloud-based service. A link to their privacy policy is available here (<https://zoom.us/privacy#_Toc444148441>). Please note that while this service is approved for collecting data in this study by the Hamilton Integrated Research Ethics Board, there is a small risk with any platform such as this of data that is collected on external servers falling outside the control of the research team. If you are concerned about this, we would be happy to make alternative arrangements for you to participate, perhaps via telephone. Please talk to the researcher if you have any concerns.

Your identifiable data will not be shared with anyone except with your consent or as required by law. Participants are not permitted to make any unauthorized recordings of the content of these interviews. The video, audio recording and transcript will be stored on the Zoom software cloud, accessible only by Zoom passwords from password-protected computers. The video will be deleted from the Zoom cloud immediately, and the audio will be deleted once transcription is completed. The information/data you provide will be on a computer protected by a password and stored in an encrypted password protected McMaster University network. The video and audio records will be destroyed immediately after transcription. Your name will not appear in any report or publication of the research.

Weekly data collected by the smartphone application MetricWire will not collect any personal information, and the account is linked solely through an email account. All of the data and information collected through the MetricWire as part of your participation in this research is owned and controlled by the research team. MetricWire has no commercial interest in the data and information you submit through the MetricWire will never be accessed, used or disclosed to any third party except as required to support your participation in the study and the research team’s administration of the study. MetricWire privacy policy was written in accordance with the Canadian Personal Information Protection and Electronic Documents Act (PIPEDA). A link to their privacy policy is available here (<https://metricwire.com/participant-privacy-policy/>).

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.

In Canada, all study information is required to be kept on file for 10 years. After this time, all data will be permanently destroyed, and electronic copies will be permanently deleted.

**What if I change my mind about being in the study?**

If you consent to be in this study, you may withdraw at any time. You 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. Not following the study protocol will not be a reason for excluding you from the study. Whether you decide to take part in this study or not, there will be no impact on your relationship with McMaster University. However, if you choose to not to participate in this study you will not receive the study discount on your YMCA membership. If you choose to withdraw from the study, you will also loose your discount. There will be no penalty or loss of benefits from deciding not to participate in the studying or deciding to withdrawing.

If you would like to withdraw from the study at anytime, you can contact Dr. Luciana Macedo via phone: 289-426-0824 or email: macedol@mcmaster.ca.

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

If you choose to participate in this study you will get a 25% discount on your YMCA membership for 4 months. In addition, you will also receive an honorarium of $40 dollars for each interview that you complete.

**Will there be any costs?**

Since you have chosen to participate in this program at the YMCA you will be responsible for all program related costs, but you will receive a membership discount of 25% for 4 months as part of being apart of our study.

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

If you get injured or have side effects from participation in this study, medical care will be provided in the same way you would normally get medical care (for example, by going to your family doctor or seeking emergency medical treatment if needed). The costs of your medical treatment will be paid for by the provincial medical plan or by seeking reimbursement from your private medical insurer (if any) to the extent that such coverage is 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.

**How do I find out what was learned in this study?**

We expect to have this study completed by approximately December 2025. If you would like a brief summary of the results, please let us know how you would like it sent to you. Prior to this, participants will be informed of any new information relevant to their participation in this study in a timely manner.

**What do I do if I have questions about the study?**

If you have questions or need more information about the study itself, please contact Dr. Luciana Macedo via phone: 289-426-0824 or email: macedol@mcmaster.ca.

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| This study was 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 905.521.2100 ext. 42013 |

**Online consent [via REDCap]**

**You are now being asked to consent to participate in the study.**

I consent to participate in the study, assessments, completing study
questionnaires, and interviews at each follow-up as participation in the study.

I do not consent to participate in the study.

**STUDY CONSENT STATEMENT & SIGNATURES**

**Participant:**

I have read the preceding information thoroughly. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I agree to participate in this study. I understand that I will receive a signed copy of this form.

|  |  |  |
| --- | --- | --- |
| Name | Signature | Date |

*Optional:* Are you willing to be contacted by research staff in the future about maybe taking part in future studies? Please note that you can always decline to take part after hearing about any future study opportunity.

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| ☐ | Yes  | ☐ | No |

How would you like to hear about future studies?

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**Person obtaining consent:**

I have discussed this study in detail with the participant. I believe the participant understands what is involved in this study.

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| Name, Role in Study | Signature | Date |