Title: Pain Informed Movement for People With Knee Osteoarthritis

NCT Number: NCT06400329

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LETTER OF INFORMATION AND CONSENT

Title of study: Two different approaches to exercise for people with knee osteoarthritis: a pilot randomized controlled trial

Local Principal Investigator:

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Co-Investigators:

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Funding Source: The Arthritis Society STARS Career Development award

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

You are being invited to participate in this research study because you experience knee osteoarthritis (OA) pain. 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 was discussed with you. Once you understand the study, you will be asked to consent to be part of the study using our online system. 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 of the pilot randomized controlled trial and feasibility assessment of two different exercise and education programs for people with knee OA. We will use the results of this study to make changes to the program for when we test it in a larger study. The study consists of two different programs that will both include exercise and education for pain management for those with knee OA. If you agree to participate, we will randomly put you into one of two programs. Overall, this study aims to further our understanding of the potential impact that these two types of exercise and education programs have on pain and how it is processed to inform evidence-based pain management options for people with knee OA. As part of the program, we will be asking you questions about your pain, your health and function, and mood. We will also test your functional leg strength as well as how well your nervous system modulates pain by assessing your sensitivity to pressure stimuli.

Additionally, participants will be asked to have blood drawn in order for us to gain a greater understanding of your knee OA pain, and to provide recommendations for pain management. We are collecting blood to analyze the association of 2 biomarkers, Brain Derived Neurotrophic Factor (BDNF) and Nerve Growth Factor (NGF), that are indicators of nervous system functioning. These will help us understand the physiological effects of the two exercise programs. To assess these biomarkers, we will withdraw 5ml of blood. Measurement of BDNF and NGF requires 50µL of diluted plasma as per the ELISA kit. Samples will be stored at the McMaster University Health Science Center in co-investigator Dr. Fahnestock's lab for the duration of the study (8 weeks). Collected samples will be stored at -80^{C} with only the participants ID and date of collection on the label.

What will happen during the study?

Regardless of which of the two programs you will be randomly assigned to, it will be an 8-week in-person group exercise program held twice weekly at one of two local churches near McMaster University or on campus at the Physical Activity Centre of Excellence (PACE). During each in-person session, you will receive exercise instruction that will be 60-75 minutes in duration. As part of the program, we ask that you also do the program at home at least one other time during the week. These home sessions will be facilitated by exercise handout sheets. The exercise sessions will be led by experienced therapists. In addition, you will receive education in the format of online videos weekly for the first four weeks (each 15-30 minutes in duration).

You will also be asked to complete a series of questionnaires about your pain at the beginning and end of the 8-week program, which will take approximately 30 minutes to complete each time. The questionnaires at the end of the program will also contain questions about your opinions of the program. At the first and last session, you will complete testing to assess how well you modulate pain, physical performance tests, have your height and weight measured, and have blood drawn (if you consent to this) by one of the research staff. If you feel comfortable, we will ask you to disclose some personal information (e.g., sex, gender, age, education, etc.). These tests will take approximately 30-40 minutes to complete.

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

You will also be asked whether you would like to participate in a focus group with a researcher at the end of the study. If you agree to participate, we will ask you to sign another consent form for participation in the focus group.

How many people will be in this study?

A total of 66 participants from Hamilton and the surrounding area will be included in this study. All participants will receive one of the two exercise and education programs. Both programs will be 8 weeks in duration and in-person.

What are the possible risks and discomforts?

You may experience some temporary muscle soreness following exercise. This is a normal response to exercise if you are not used to it. It should feel better within a day or two. The programs should not

increase the pain associated with your knee OA. If this happens, you should tell the instructor, who will decide whether to modify your exercises or reduce the intensity if necessary.

You may feel tenderness in your arm for a day or two following each blood draw.

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

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

We hope that what is learned will help us improve the understanding of pain mechanisms among individuals with knee OA to enhance pain management. We also hope to gain a better understanding of the benefits of the two programs with individuals with knee OA pain. If you decide to participate in this study, you may benefit from the exercises and education sessions. The end goal is to make recommendations in the treatment of knee OA, as well as improve pain and function for individuals. 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. We will not use your name or any information that would allow you to be identified. The information you provide will be kept in a secure computer where only the research staff will have access to it. Information kept on a computer will be protected by a password on a secure virtual private network.

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 who complete the questionnaire and for those who choose to consent to having blood drawn. All access controls have 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 virtual private network (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 and the Hamilton Integrated Research Ethics Board may access your study records to monitor the research and verify the accuracy of study information. However, no records which identify you by name will be allowed to leave Dr. Lisa Carlesso's office. By signing this consent form, you or your legally acceptable representative authorize such access.

Participants will have the option to chose whether they would like their blood samples disposed of following analysis in the study or if they consent to allowing the research team to use their blood samples for future research studies approved by the Hamilton Integrated Research Ethics Board.

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.

Study information will 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 be a reason for excluding you from the study.

If you would like to withdraw from the study at anytime, you can contact Dr. Lisa Carlesso (Email: carlesl@mcmaster.ca, Phone: 289-426-2366)

Will I be paid to participate in this study?

We will provide a $50 gift card for completion of baseline assessments and a $50 gift card for completion of follow up assessments. The gift cards will be distributed after each phase has been completed.

Will there be any costs?

There will not be any costs associated with participating in this study. When you attend testing sessions or any classes on campus, parking costs will be reimbursed.

What happens if I have a research-related injury?

If you suffer an injury from participation in this study, medical care will be made available to you by your study doctor, or you will be referred for appropriate medical care. Financial compensation for such things as lost wages, disability, or discomfort due to this type of injury is not routinely 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 2023, and we will aim to publish the results in a scientific journal by August 2024. We will disseminate the link to the published article to all participants via email.

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. Lisa Carlesso (Email: carlesl@mcmaster.ca, Phone: 289-426-2366)

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. For the purposes of ensuring proper monitoring of the research study, it is possible that representatives of the Hamilton Integrated REB (HiREB), this institution, and affiliated sites or regulatory authorities may consult your original (identifiable) research data and medical records to check that the information collected for the study is correct and follows proper laws and guidelines. By participating in this study, you authorize such access.

Online consent [via REDCap]

You are now being asked to consent to participate in the study (including consent to answering our baseline questionnaires and completing the assessments)

I consent to participate in the study, completing study questionnaires and assessments, in addition to having blood drawn as participation in the study ☐

I only consent to participation in the study and completing study questionnaires and assessments ☐

If you have consented to having blood drawn as participation in the study:

I consent to allowing the research team to use my blood samples for future research studies on knee osteoarthritis not outlined in this consent form. All future research studies will be approved by the Hamilton Integrated Research Ethics Board and will not involve any genetic/DNA testing.

☐

I do not consent to allowing the research team to use my blood samples for future research studies on knee osteoarthritis not outlined in this consent form, and want my blood samples to be disposed of at the completion of this 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.

☐ Yes ☐ No

How would you like to hear about future studies?

_____

Person obtaining consent:

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

Name, Role in Study	Signature	Date