

**A COMPARISON BETWEEN A STANDARDIZED (GLA:DTM CANADA) AND
AN INDIVIDUALIZED (JOINTEFFORT) EXERCISE PROGRAM ON
FUNCTIONAL MOBILITY, QUALITY OF LIFE, PAIN MANAGEMENT, AND
INFLAMMATORY BIOMARKERS IN KNEE OSTEOARTHRITIS PATIENTS**

INFORMED CONSENT FORM

August 30, 2018

STUDY INFORMATION AND CONSENT FORM

Research Project:	A comparison between a standardized (GLA:D™ Canada) and an individualized (JointEffort) exercise program on functional mobility, quality of life, pain management, inflammatory biomarkers and willingness to pay in knee osteoarthritis patients
Principal Investigator:	Dr. Jackie Whittaker PT PhD (1-780-492-5970)
Co-Investigators:	Kristen Barton Dr. David Hart Dr. Ania Kania-Richmond Emma Smith Dr. Ryan Martin Dr. Prism Schneider Dr. Deborah Marshall Darren Mazzei
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Sponsor/Funder(s):	McCaig Institute for Bone and Joint Health ENCORE Catalyst Award

INFORMED CONSENT

You are being asked to participate in a research study that will compare the influence of a standardized (GLA:D™ Canada) and an individualized (JointEffort) exercise program on functional mobility, quality of life, pain management, blood-based inflammatory markers and willingness to pay in knee osteoarthritis (OA) patients. Before you make a decision one of the researchers will go over this form with you. You are encouraged to ask questions if you feel anything needs to be made clearer. You will be given a copy of this form for your records.

BACKGROUND

Osteoarthritis is a leading cause of disability and affects more than 4.4 million people in Canada (13% of Canadians). Osteoarthritis can cause joint pain, stiffness, loss of range of motion, and inflammation, which can impact quality of life. Current guidelines for OA treatment recommend weight loss, patient education, exercise therapy, bracing, joint injection, and anti-inflammatory/pain medications prior to joint replacement surgery. Unfortunately, current approaches to OA treatment are not always consistent with these guidelines and focus largely on joint replacement. Recently, research from a group in Denmark has shown reduced knee symptoms, pain medication use, sick leave, and physical inactivity 12 months after a combined patient education and standardized group exercise therapy program (GLA:D®). Based on the Danish success, the GLA:D® program has been made available in Canada. It is unclear if the GLA:D™ Canada program will have similar outcomes to those seen in Denmark, or how the GLA:D™ program compares to existing individualized OA care programs (i.e. JointEffort).

WHAT IS THE PURPOSE OF THE STUDY?

The objectives of the study are to:

- 1) Assess for changes in function, quality of life, pain medication use, and levels of blood-based inflammatory markers in knee OA patient who participate in the GLA:D™ standardized program,
- 2) Assess for changes in function, quality of life, pain medication use, and levels of blood-based inflammatory markers in knee OA patient who participate in the JointEffort individualized program,
- 3) Assess if there are any differences in function, quality of life, pain medication use, and levels of blood-based inflammatory markers between the standardized (GLA:D™) and individualized (JointEffort) exercise programs.
- 4) Assess how the cost of the programs compare to health outcomes and how much participants are willing to pay to participate in the GLA:D and JointEffort programs.

WHAT WOULD I HAVE TO DO?

Exercise Program Participation: If you agree to participate in this study you will be assigned at random, (like flipping a coin), to participate in one of two exercise programs: 1) The GLA:D™ program or 2) The JointEffort program. You will have a 50% chance of participating in the GLA:D™ program and a 50% chance of participating in the JointEffort program.

- 1) The GLA:D™ program consists of 1) pre- and post-program outcome measurement (self-reported and functional outcomes); 2) two, 1-1.5 hour education sessions including information on OA disease characteristics, treatments and self-help strategies; and 3) a neuromuscular exercise (warm-up, circuit training, and cool down) training program administered in 1 hour, small (up to 10 persons) group-based, supervised sessions twice weekly for 6 weeks. The goal of the exercises is to restore alignment of the legs by building muscle strength and control.
- 2) The JointEffort program consists of: 1) one 1-1.5 hour appointment to individualize the program to your needs; 2) one 1 hour nutritional seminar taught by a registered dietician explaining dietary recommendations for OA patients, including weight loss and/or management; and 3) an individualized exercise (strength and neuromuscular training, balance training, and range of motion exercises) training program administered in 1 hour, small (up to 10 persons) group-based, supervised sessions twice weekly for 6 weeks.

Questionnaires: You will be asked to complete the following questionnaires at baseline (first study visit), at 2 months, and at 12 months:

- 1) A **Study Questionnaire** will be used to capture information about your age, sex, height, weight, and other health conditions
- 2) The **Knee Injury and Osteoarthritis Outcome Score** will be used to assess your knee-related pain, stiffness, and physical function
- 3) The **Intermittent and Constant Osteoarthritis Pain Score** will be used to assess your knee OA pain
- 4) The **EQ-5D-5L questionnaire** will be used to assess your overall health status
- 5) The **Patient Knowledge Questionnaire on OA** will be used to assess your knowledge of OA
- 6) The **Arthritis Self-Efficacy Questionnaire** will be used to assess your view of how comfortable you are with managing your knee osteoarthritis
- 7) A **Cost Questionnaire** will be used to capture information about your employment status, gross income, insurance coverage, willingness to pay, and health care visit

expenses) to assess financial impact. This questionnaire will only be asked at baseline and 2 months.

Each questionnaire will take about 7-12 minutes to complete. Attendance, exercise log, and medication use details will be recorded at each visit.

Functional Testing: You will be asked to complete the following functional tests at baseline, 2, and 12 months:

- 1) The 40m Face-Paced Walk Test will assess how quickly you can safely walk 40 meters. This will involve walking four times along a 10m walkway
- 2) The 30s Chair Stand Test will assess your lower body strength and dynamic balance. You will be asked to stand-up and sit down as many times as you can from a stable chair in 30 seconds.

Blood Draw: A 4ml blood sample will be collected at baseline, 2, and 12 months and will be analyzed to assess for inflammatory markers. The blood drawn will not be tested for any other purposes.

WHAT ARE THE RISKS?

There are no anticipated risks or harms related to your participation in the GLA:D or JointEffort programs. The GLA:DTM Canada and JointEffort programs do involve an exercise program so it is possible to experience some level of stiffness or discomfort after exercising. However, you will be taught to monitor your exertion throughout the program, with the goal of any increase in soreness returning to the pre-exercise level by the next day. Any 'red flags' such as prolonged increase in pain that may occur will be addressed by the program instructors.

You will complete questionnaires that will require your time. The blood sample will be drawn in a standardized fashion as it would in any laboratory by a trained technician. Although very rare, there is the possibility of local pain, bruising or infection within days of the blood draw. If there is an infection you would need to see a physician for this and be treated with antibiotics.

WILL I BENEFIT IF I TAKE PART?

You may or may not directly benefit from participating in the GLA:DTM Canada and JointEffort exercise programs. Completing exercises that improve the strength and endurance of muscles near your affected knee joint(s) is important for protecting joints, reducing symptoms, and improving mobility. These exercise programs may prevent the progression of knee OA and reduce the need for future joint replacement surgery. Information learned from participating in this study may help other people who have knee OA.

DO I HAVE TO PARTICIPATE?

Your participation in this study is entirely voluntary, and is based upon your full understanding of the study and written consent. You are free to withdraw from the study at any time by informing the principal investigator or research coordinator (written or verbal withdrawal). You will have the option of including the data that you have provided up until the point of withdrawal in the study. This will in no way affect the quality of care you receive at this institution. You may also refuse to answer any questions you do not want to answer and remain in the study.

WHAT ARE THE COSTS FOR PARTICIPATING IN THIS STUDY?

Participation in this study may cause some inconvenience to you (e.g., finding time to participate). Parking costs will be covered for assessments (program design, 2 month follow up visit, and 12 month follow up visit). Participants will not incur any further costs as a result of participation in the study.

WHAT HAPPENS IF I AM INJURED BECAUSE OF THIS RESEARCH?

If you become ill or injured as a result of being in this study, you will receive necessary medical treatment, at no additional cost to you. By signing this consent form you are not releasing the investigator(s), institution(s) and/or sponsor(s) from their legal and professional responsibilities.

WILL MY RECORDS BE KEPT PRIVATE?

During the study we will be collecting data about you. We will do everything we can to make sure that this data is kept private. No data relating to this study that includes your name will be released outside of the researcher's office or published by the researchers. Sometimes, by law, we may have to release your information with your name so we cannot guarantee absolute privacy. However, we will make every legal effort to make sure that your information is kept private.

Any personal information that we collect during this research study will be only what is needed for the study. During research studies it is important that the data we get is accurate. For this reason your data, including your name, may be looked at by people from: the McCaig Institute for Bone and Joint Health, the University of Alberta auditors and members of the Research Ethics Board. By signing this consent form you are giving permission for the study researcher/staff to collect, use and disclose information about you as described above.

After the study is done, we will still need to securely store your data that was collected as part of the study. At the University of Alberta, we keep data stored for 5 years after the end of the study. If you leave the study, we will not collect new information about you, but we will keep the data that we have already collected unless you specifically request a withdrawal of your data. You have up to 2 weeks after the last data collection point (i.e., 12 month data collection) to request a withdrawal of your data (i.e., questionnaires, physical function outcome measures, and demographic data).

You have the right to be informed of the results of the study. Upon request, results will be sent to you. Note that there is typically a period of months to years between your participation and publication of final results.

The study is being sponsored by the McCaig Institute for Bone and Joint Health Encore Catalyst Award. The Institution and study team are getting money from the study sponsor to cover the costs of doing this study. You are entitled to request any details concerning this compensation from the Principal Investigator.

DO THE INVESTIGATORS HAVE ANY CONFLICTS OF INTEREST?

There are no conflicts of interest to declare related to this project.

CONSENT

Title of Study: A comparison between a standardized (GLA:D™ Canada) and individualized (JointEffort) exercise program on functional mobility, quality of life, pain management, and inflammatory biomarkers in knee osteoarthritis patients.

Principal Investigator(s): Jackie Whittaker PT, PhD

Phone Number(s): (780) 492 5970

Study Coordinator: Kristen Barton

Phone Number(s): (403) 827-2182

	<u>Yes</u>	<u>No</u>
Do you understand that you have been asked to be in a research study?	<input type="checkbox"/>	<input type="checkbox"/>
Have you read and received a copy of the attached Information Sheet?	<input type="checkbox"/>	<input type="checkbox"/>
Do you understand the benefits and risks involved in taking part in this research study?	<input type="checkbox"/>	<input type="checkbox"/>
Have you had an opportunity to ask questions and discuss this study?	<input type="checkbox"/>	<input type="checkbox"/>
Do you understand that you are free to leave the study at any time, without having to give a reason and without affecting your future medical care?	<input type="checkbox"/>	<input type="checkbox"/>
Has the issue of confidentiality been explained to you?	<input type="checkbox"/>	<input type="checkbox"/>
Do you understand who will have access to your study information, including personally identifiable information?	<input type="checkbox"/>	<input type="checkbox"/>
Do you want the investigator(s) to inform your family doctor that you are participating in this research study? If so, give his/her name: _____		
Who explained this study to you? _____		
I agree to take part in this study:		
Signature of Research Participant _____		
(Printed Name) _____	Date: _____	
I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.		
Signature of Investigator or Designee _____	Date _____	
THE INFORMATION SHEET MUST BE ATTACHED TO THIS CONSENT FORM AND A COPY GIVEN TO THE RESEARCH PARTICIPANT		