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RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

Title of Study: “The Health Impact of Mindfulness Based Stress Reduction on Total Knee Arthroplasty: A Pilot Study”

Protocol Number: HS20925S (H2017:229)

Principal Investigators:

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Sponsor: *University of Manitoba Collaborative Research Program*

This is an informed consent form. You are being asked to participate in a Clinical Trial (a human research study). Please take your time to review this consent form and discuss any questions you may have with the study staff. You will have the opportunity to have this consent form explained further, if necessary, and to ask any additional questions. Please be assured that your participation is voluntary, and that you are free to quit the study at any time, and that there will be no consequences for choosing to participate or not participate. This consent form may contain words that you do not understand. Please ask the study doctor or study staff to explain any words or information that you do not clearly understand. If you are still interested and sign the consent form, you will be asked to fill out some brief questionnaires, which should only take around 15 minutes to complete. The questionnaires are standard assessment forms designed to assess pain, anxiety, depression, thinking, and sleep problems.

Before agreeing to participate in this study, it is important that you read and understand the following explanation of the proposed study procedures. The following information describes the purpose, procedures, benefits, discomforts, risks and precautions associated with this study. It also describes your right to refuse to participate or withdraw from the study at any time. In order to decide whether you wish to participate in this research study, you should understand enough about its risks and benefits to be able to make an informed decision. This is known as the informed consent process. Please ask the study doctor or study staff to explain any words you don't understand before signing this consent form. The study doctors and institution are receiving financial support to conduct this study. Make sure all your questions have been answered to your satisfaction before signing this document.

Purpose of Study

This Clinical Trial is being conducted to study the effectiveness of mindfulness based stress reduction (MBSR), a program that has been supported in research studies, for patients undergoing total knee arthroplasties (TKA), or knee surgery. You are being asked to take part in this because you are currently on the waitlist for your first TKA. Previous research has shown that MBSR is effective for improving both physical and mental health, which are important in the development of poor outcomes after surgery, such as pain and adjustment difficulties, including psychological difficulties. The success of this MBSR program in knee surgery patients has not been assessed. By comparing the post-surgical outcomes between individuals who receive this mindfulness training before their surgery and those that receive their treatment-as-usual before their surgery, we can see whether this mindfulness based stress reduction program results in different post-surgical outcomes between the two groups.

All previous studies on post-surgical knee surgery outcomes have been educational in nature. These educational courses have not shown to have the same benefit as MBSR has in other populations. In the current research, the doctors plan to evaluate a pre-surgical MBSR program on post-surgical outcomes, including satisfaction with surgery (as measured by the questionnaires already given to you after surgery, in clinic), post-operative pain, functioning, quality of life, emotional distress, thinking, and sleep. These outcomes will then be compared to the group that receives their treatment-as-usual (i.e., does not receive the MBSR training prior to their surgery). Importantly, the participants assigned in the treatment-as-usual will have the opportunity to participate after the study, receiving the same mental and physical benefits of MBSR. This research will provide

insight into the relationship between pre-operative MBSR and post-operative knee surgery outcomes and potentially reveal benefits of attending this program in this surgical population.

Mindfulness Based Stress Reduction will take place over 8 weeks, with a 2.5-hour session once a week and 1 full day session near the end of the program. It is offered in a group format, made up of up to 15 other people who are on the waitlist for their knee surgery. During these sessions, you will learn about mindfulness. Mindfulness is the practice of cultivating non-judgmental awareness in day-to-day life. These Mindfulness meditation practices can help you decrease suffering and bring you greater balance and peace, even in the midst of stress, pain and illness. Physicians are prescribing training in Mindfulness practice to help people deal with stress, pain and illness. Mindfulness consists of cultivating awareness of the mind and body and living in the here and now. In the course, you will engage in formal practices and informal practices, including Awareness of Breath, Body Scan, and mindful movements. The MBSR program will be led by an instructor with a lot of experience in MBSR and yoga, which is helpful to ensure you are comfortable and safe during this experience and aid in any posture (sitting or standing) changes that can be made to help in your comfort.

The doctors are approaching 30 participants for the pre-surgical MBSR condition and 15 participants in the treatment-as-usual condition.

Study procedures

You are receiving these documents because the following procedure occurred: you have provided preliminary permission for further contact about this pilot study over the phone. You were deemed eligible during the initial screen with Ms. Bilevicius, Dr. El-Gabalawy or Dr. Kornelsen. You are now reading through and completing the informed consent portion of this study.

In this study, you will be “randomized” into one of 2 study groups described below. “Randomized” means that you are put into a group by chance, like flipping a coin. You will have a two in three chance of being placed in the pre-operative MBSR group and one in three chance of being placed in the treatment-as-usual group.

If you take part in this study, you go through the following steps:

- 1) After mailing back your signed consent form and being randomly assigned to a condition, you will be asked to complete a series of brief questionnaires before your surgery. If you are placed in the pre-surgical MBSR group, you will complete an 8-week pre-operative MBSR program (2.5 hours a week; you will complete the questionnaires on the first day of MBSR, and have 1 full day session near the end of the 8 weeks) before your surgery date. If you are placed in the treatment-as-usual condition, you will not have to complete this set of questionnaires.
- 2) Approximately two weeks before the surgery at your scheduled appointment in the pre-anesthesia clinic, both groups (all individuals) will receive a set of short questionnaires that will take about 15 minutes and can be completed while in the waiting room.

- 3) After your surgery, you will receive the typical orthopedic questionnaires along with some other short questionnaires, which will take approximately an additional 10 minutes. You will receive these questionnaires at your regularly scheduled post-operative appointments at the Hip and Knee Institute: 6-8 week, 6 month, and 1 year. Clinic personnel, who are unaware of whether you complete MBSR before surgery or not, will administer these questionnaires with all other regularly distributed clinical questionnaires. If in the pre-surgical MBSR group, you will be asked to submit a form that includes the number of hours spent on home activities throughout the entire 8-week program. This is useful information as *practice* is important in the program, and the more you practice, the more it becomes habit and part of your life.

Participation in the study will take place from the time you consent to approximately 1 year after your surgery.

You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the study staff first. Although there are no serious consequences of a sudden withdrawal from the study, it is helpful for the study staff to understand why you are withdrawing or in what ways we could have made your visit more comfortable, as this may inform future studies.

If you are interested in receiving the results of this study, please provide the doctors with your contact information in the space provided at the end of this form. You will receive an email summary of the study once it has been completed. Please provide your email in the space provided at the end of this form if you are interested.

Risks and Discomforts

Although there are no known risks of taking a MBSR program, you could find discomfort in some of the practices or meditation postures. Some of these involve paying attention to uncomfortable sensations within the body. However, there are no physical risks or discomforts in this study. The MBSR program will be taught by a highly-trained instructor in both MBSR and yoga. She will be able to work individually with you to make any changes based on any physical limitations you may have.

You may also feel temporary discomfort when responding to questions about your emotional health. If you would like information related to mental health community resources after responding to the questions, these can be made available to you. If you require immediate assistance, a staff psychologist who is involved in this study, Dr. Renée El-Gabalawy.

If you become uncomfortable during this training, you are free to immediately stop participating in the study.

Benefits

The knowledge you learn from this scientifically supported 8-week course can be applied to various areas of your life. You may also experience better outcomes after surgery, such as better emotional health, less pain, and/or better sleep, but you may also not experience these benefits.

We hope the information learned from this study will benefit people undergoing knee surgery in the future and improve their surgical experience, both pre-and post-operatively.

Costs

MBSR, which will be performed as part of this study, is provided at no cost to you (free).

Payment for participation

You will be given \$5 every time you complete a set of questionnaires in clinic for a total of \$20.

Confidentiality

Information gathered in this research study may be published or presented in public forums such as research conferences; however, your name and other identifying information will not be used or revealed. All volunteers will be assigned a de-identifying (“subject ID”) so that all identifying information (e.g., name, date of birth, etc.) can be removed from individual data sets, and the key linking subjects to their identifiers will be kept in a locked filing cabinet, separate from the data. However, despite our best efforts to keep your personal information confidential, absolute confidentiality cannot be guaranteed. Your personal information may be disclosed if required by law, and The University of Manitoba Health Research Ethics Board or the Concordia Hospital Research Review Committee may review any records related to this study for quality assurance purposes.

Medical records that contain your identity, such as your waitlist information, will be treated as confidential in accordance with the Personal Health Information Act of Manitoba. All records will be kept in a locked secure area that can only be accessed by the study coordinator or members of her research team. No information revealing any personal information such as your name, address, or telephone number will leave The University of Manitoba or Concordia Hospital.

All information obtained during the study will be held in strict confidence. You will be identified with a study number only. No names or identifying information will be used in any publication or presentations. No information identifying you will be transferred outside the investigators in this study or this hospital.

Representatives of the University of Manitoba Ethics Board may come to the hospital to look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study followed proper laws and guidelines.

Absolute confidentiality cannot be guaranteed.

Voluntary Participation/Withdrawal from the Study

Your decision to take part in this study is voluntary. You may refuse to participate or you may withdraw from the study at any time. Your decision not to participate or to withdraw from the study will not affect your care. If the study staff feels that it is in your best interest to withdraw you from the study, they will remove you without your consent.

We will tell you about any new information that may affect your health, welfare, or willingness to stay in this study.

Questions

You are free to ask any questions that you may have about this research project and your rights as a research participant. If any questions come up during or after the study or if you have a research-related injury, contact the researchers: Dr. Renée El-Gabalawy, University of Manitoba: 204-787-2212; Renee.el-gabalawy@umanitoba.ca & Dr. Jennifer Kornelsen, University of Manitoba: 204-787-5658; jennifer.kornelsen@umanitoba.ca.

For questions about your rights as a research participant, you may contact The University of Manitoba, Bannatyne Campus Research Ethics Board Office at (204) 789-3389.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

Statement of Consent

I have read this consent form. I have had the opportunity to discuss this research study with Drs. Renée El-Gabalawy and Jennifer Kornelsen and/or their study staff. I have had my questions answered by them in language I understand. The risks and benefits have been explained to me. I believe that I have not been unduly influenced by any study team member to participate in the research study by any statements or implied statements. Any relationship (such as employer, supervisor or family member) I may have with the study team has not affected my decision to participate. I understand that I will be given a copy of this consent form after signing it. I understand that my participation in this study is voluntary and that I may choose to withdraw at any time. I freely agree to participate in this research study.

I understand that information regarding my personal identity will be kept confidential, but that confidentiality is not guaranteed. I authorize the inspection of any of my records that relate to this study by The University of Manitoba Research Ethics Board or the Concordia Hospital Research Review Committee for quality assurance purposes.

By signing this consent form, I have not waived any of the legal rights that I have as a participant in a research study.

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has knowingly given their consent.

**Printed Name: _____ Date _____
(day/month/year)**

Signature: _____

Role in the study: _____

Relationship (if any) to study team members: _____

The health impact of mindfulness based stress reduction on total knee arthroplasty: A pilot study

[Optional] I agree to be contacted for future follow-up in relation to this study:

Yes ____ No ____

Participant signature _____ Date _____
(day/month/year)

Participant printed name: _____

[Optional] If you are interested in receiving a summary of the results at the completion of the study, please provide your name and email address (this is entirely voluntary):

Name: _____

Email Address: _____

8-WEEK MINDFULNESS-BASED STRESS REDUCTION PROGRAM

with Bernice Parent, BA, Certified Yoga and Mindfulness Instructor

Wednesdays, dates TBD (fall 2017), 9:30 a.m. -noon and 4:30 p.m. – 7:00 p.m.

Orientation: TBD, 4:30-6:00 p.m.

Full Day: TBD, 9:00 a.m. – 4:00 p.m.

Location: Renaissance Centre, 844 Autumnwood Drive, Windsor Park

Tuition: Sponsored by the University of Manitoba Collaborative Research Program

Program Description: Explore ways to reduce stress and face the demands of everyday life in this 8-week course inspired by Jon Kabat-Zinn, PhD. In this intensive training, you will learn to cultivate your natural capacity to actively participate in caring for yourself. As a result, you will find greater balance, ease and peace of mind.

This 10-session course is offered over eight consecutive weeks and offers numerous benefits for dealing with chronic pain, anxiety and stress and learning how to practice mindfulness into your everyday life. The program starts with an orientation session followed by eight weekly sessions of 2.5 hours each. It includes a full day commitment on a Saturday, part way through the course. The program includes:

- Guided instruction in mindfulness meditation practices
- Group discussion
- Mindful movement, gentle stretching
- Weekly assignments, informal mindful practices
- Home practice with audio files and handbook

If you are looking to...

- Approach your life with more composure, energy, understanding and enthusiasm
- Develop the ability to cope more effectively with both short-term and long-term stressful situations
- **Enhance your ability to manage and reduce pain levels**
- Improve your focus, resilience and capacity to recover more quickly from challenging events

Learn to access and cultivate your natural capacity to care for yourself, finding greater balance, ease and peace of mind.