



The Ottawa Hospital | L'Hôpital d'Ottawa

## Information Sheet and Consent Form

**Title:** Does a simple 3-item questionnaire reduce wait times for consultations for patients who would benefit from lumbar spinal surgery? A pilot prospective randomized controlled trial.

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**Co-Investigators:** Dr. Stephen Kingwell,  
**Research Coordinator:** Dr. Darren Roffey – Phone: 613-798-5555 x16818

**Institution:** The Ottawa Hospital – Civic Campus  
1053 Carling Avenue, Ottawa, ON, K1Y 4E9

### Introduction

You are being asked to participate in this research project because you went to see your family doctor with a complaint of an injury/condition causing pain in your lower back, and you have since been referred for a consultation appointment with a spine surgeon at The Ottawa Hospital. You must be able to read and understand English in order to participate in this study.

Please read this Patient Information Sheet and Informed Consent Form carefully and ask as many questions as you like before deciding whether to participate in this research study. You can discuss this decision with your family, friends and your health-care team. If you decide to participate in this study, you will be required to sign the Informed Consent Form.

### Background, Purpose and Design of the Study

Low back pain (LBP) is one of the leading causes of physical disability and physician referral. Unfortunately, spinal surgeons have some of the longest waiting times in Canada, with an average wait time of over 7 months from patient referral to surgical consultation. Patients on prolonged wait lists to see a spine surgeon are at an increased risk for their low back injury/condition getting much worse over time.

Given the demand for referrals to spine surgeons, prioritization of appropriate surgical candidates is very important. Promisingly, the benefits of such prioritization are obvious from studies conducted in other orthopedic disciplines; the general consensus being that even a modest reduction in wait times can significantly improve short- and long-term surgical outcomes. Recent studies that have trialed strategies to better effectively triage spine patients have been too small and poorly designed, or required significant increases in resources. In response, our research group at The Ottawa Hospital has developed a simple, cost-effective, self-administered 3-item questionnaire that has been shown to be highly sensitive in identifying elective lumbar surgical candidates.

The primary objective of this prospective randomized controlled study is to assess whether responses to the 3-item questionnaire can help to improve the identification of appropriate surgical candidates for elective lumbar surgery, and thereby reduce pre-surgical consultation wait times, improve post-surgical outcomes, and decrease health care utilization.

## **Study Procedures and Description of Treatment**

As per the current standard of practice at The Ottawa Hospital, your spine surgeon will use information in the referral letter from your family doctor/primary care provider and the accompanying radiology report to schedule an initial consultation appointment. Personnel from the spine surgeon's office will then mail out to you this study information sheet and informed consent form, along with the 3-item questionnaire and the outcomes questionnaires. If after reading this information sheet you decide you want to participate in the study, you must sign and date the informed consent form and complete both sets of questionnaires, and then return all the paperwork in the pre-paid envelope provided. The 3-item questionnaire is designed to capture as much information as possible about your low back injury/condition for diagnosis purposes, while the outcomes questionnaires provide information relating to your overall health and disability status as well as the amount and type of health care services you've used in the past 6 months. Combined, the questionnaires will take approximately 20 minutes to complete.

Once you've returned a signed and dated informed consent form and the questionnaires, the research team will assess your eligibility for inclusion into the study. If you are eligible for the study, you will be randomized into the treatment group or the control group of the study. Randomization means that you are put into one of the two groups by chance, a process similar to flipping a coin. If you are randomized to the treatment group, the research team will analyze your responses to the 3-item questionnaire in addition to reviewing the referral letter from your family doctor/primary care provider and the accompanying radiology report. According to your responses, you may be classified as having a low back injury/condition that could be helped by having a surgical procedure performed. For each group, the respective spine surgeon's secretary will contact you with details regarding your consultation appointment. Other than having responses to the 3-item questionnaire analyzed (treatment group only), both groups will receive the same co-interventions and outcomes assessments. During your scheduled consultation appointment at The Ottawa Hospital, you will be assessed for any surgical indications by your spine surgeon. Your spine surgeon will be blinded to the intervention group, meaning they will not know whether you are in the treatment group or the control group. At this consultation appointment, you will be asked to complete the outcomes questionnaires to determine any changes compared to the last time you filled them out.

Participants who are identified as surgical candidates, irrespective of the group to which they are randomized, will be provided with identical post-surgical information in terms of processes to follow that are consistent with the current standard of practice. At 12 months post-surgery, you will be required to complete the outcomes questionnaires one last time to assess your recovery. There is a chance you may not receive any direct benefit from your participating in this study. However, your participation in this research will allow the researchers to better understand the benefits of using the 3-item questionnaire to triage spine surgeon consultation referrals from family doctors/primary care providers, which may be of benefit to future patients. It is very important that you do not reveal to (or thank) your spine surgeon that your consultation visit has been rescheduled.

Your study data (i.e., questionnaire responses, surgical procedure details), which contains no personal health information and is identified only by your independent study number, will be stored in a password protected electronic database and kept on a secure hospital network

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accessed by a password-controlled computer. Your de-identified data stored on this electronic database may be used for future exploratory research studies.

### **Study Duration**

Your involvement in the study will be 12 months in duration. You will be required to complete questionnaires at three different time-points: 1) prior to your consultation appointment; 2) on the day of your consultation appointment; and 3) at your 12 months post-surgery consultation appointment (or by mail if unable to complete them in-person at The Ottawa Hospital).

### **Possible Side Effects and/or Risks**

No adverse side effects and/or risks will occur as a result of your participation in this study.

### **Benefits of the Study**

Possible benefits of your participation in this study include a chance that your initial consultation appointment may be prioritized as “urgent” if your low back injury/condition could warrant performance of a surgical procedure, as assessed by your responses to the 3-item questionnaire. As a virtue of this appointment reschedule, your wait time for a consultation appointment may be reduced, you may see your spine surgeon at an earlier date, and if you end up having surgery, your outcomes post-surgery may be improved due to the fact you were assessed sooner than you would have been if the current standard of practice was followed. It is very important that you do not reveal to (or thank) your spine surgeon that your consultation visit has been rescheduled.

### **Alternative Treatments Available**

You do not have to participate in this study to receive treatment for your low back injury/condition. If you choose not to participate, you will not be entered into the study, and your treatment plan will follow the current standard of practice at The Ottawa Hospital.

### **Withdrawal from the Study**

You have the right to withdraw from the study at any time without any impact to your current and future care at The Ottawa Hospital. If you decide to withdraw, you should discuss this with your spine surgeon or research coordinator before you stop the study. If you do withdraw from the study, the final outcomes questionnaires will need to be completed if at all possible; this is important for your safety and well-being, and also to the completeness of our study. You also have the choice of having your data withdrawn from the study completely. You have the right to check your study records and request changes if the information is not correct. However, to ensure the scientific integrity of the study, some of your records related to the study may not be available for your review until after the study has been completed.

### **Study Costs**

You will not be paid to participate in this study. There are no additional requirements from you regarding your participation in this study, other than the completion of the 3-item questionnaire and the outcomes questionnaires at the three distinct time-points mentioned above.

## **Confidentiality**

All personal health information will be kept confidential, unless release is required by law. Representatives of the Ottawa Hospital Research Ethics Board, as well as the Ottawa Hospital Research Institute, may review your original medical records under the supervision of Dr. Wai and Dr. Roffey for audit purposes.

You will not be identifiable in any publications or presentations resulting from this study. No identifying information will leave The Ottawa Hospital. All information which leaves the hospital will be coded with an independent study number.

Your study data (i.e., questionnaire responses, surgical procedure details), which contains no personal health information and is identified only by your independent study number, will be stored in a password protected electronic database and kept on a secure hospital network accessed by a password-controlled computer. Your de-identified data stored on the electronic database may be used for future exploratory research studies.

The link between your name and the independent study number will only be accessible by Dr. Wai and Dr. Roffey. The link and the study files will be stored separately and securely. Both files will be kept for a period of 15 years after the study has been completed.

All paper records will be stored in a locked file and office. All electronic records will be stored in password protected files on a secure hospital server, again only accessible by Dr. Wai and Dr. Roffey. At the end of the 15 year retention period, all paper records will be disposed of in confidential waste or shredded, and all electronic records will be deleted.

## **Voluntary Participation**

Your participation in this study is voluntary. If you choose not to participate, your decision will not affect the care you receive at The Ottawa Hospital at this time, or in the future. You will not have any penalty or loss of benefits to which you are otherwise entitled to.

## **New Information About the Study**

You will be told of any new findings during the study that may affect your willingness to continue to participate in this study. You may be asked to sign a new consent form.

## **Questions about the Study**

If you have any questions about this study, please contact Dr. Darren Roffey, PhD at 613-798-5555 x16818. The Ottawa Hospital Research Ethics Board (OHREB) has reviewed this protocol. The OHREB considers the ethical aspects of all research studies involving human subjects at The Ottawa Hospital. If you have any questions about your rights as a research subject, you

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may contact the Chairperson of the Ottawa Hospital Research Ethics Board at 613-798-5555, extension 14902.



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## Informed Consent Form

**Title:** Does a simple 3-item questionnaire reduce wait times for consultations for patients who would benefit from lumbar spinal surgery? A pilot prospective randomized controlled trial.

### Consent to Participate in Research

I understand that I am being asked to participate in a research study to assess whether responses to the 3-item questionnaire can help to improve the identification of appropriate surgical candidates for elective lumbar surgery, and thereby reduce pre-surgical consultation wait times, improve post-surgical outcomes, and decrease health care utilization. I have had all of my questions answered via a conversation over the phone with Dr. Eugene Wai and/or a delegate.

I have read this five page Patient Information Sheet and Informed Consent Form (or have had this document read to me). All my questions have been answered to my satisfaction. If I decide at a later stage in the study that I would like to withdraw my consent, I may do so at any time.

I voluntarily agree to participate in this study.

A copy of the signed Information Sheet and/or Consent Form will be provided to me.

Signatures

\_\_\_\_\_  
Participant's Name (Please Print)

\_\_\_\_\_  
Participant's Signature

\_\_\_\_\_  
Date

Investigator Statement (or Person Explaining the Consent)

I have carefully explained to the research participant the nature of the above research study. To the best of my knowledge, the research participant signing this consent form understands the nature, demands, risks and benefits involved in participating in this study. I acknowledge my responsibility for the care and well being of the above research participant, to respect the rights and wishes of the research participant, and to conduct the study according to applicable Good Clinical Practice guidelines and regulations.

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Name of Investigator/Delegate (Please Print)



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Signature of Investigator/Delegate

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Date