Physiotherapy as a Triage for Orthopaedic Surgery Referrals Study

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INTRODUCTION

You are being invited to participate in this project because you have suffered a knee or shoulder injury which has resulted in a referral to an orthopaedic surgeon.

Your participation in this study is entirely voluntary, so it is up to you to decide whether or not to take part. Before you decide, it is important for you to understand what the research involves. This consent form will tell you about the study, why the research is being done, what will happen to you during the study and the possible benefits and risks.

If you wish to participate, you will be asked to sign this form. If you do decide to take part in this study, you are still free to withdraw at any time and without giving reasons for your decision.

If you do not wish to participate, you do not have to provide any reason for your decision not to participate, nor will you lose the benefit of any medical care to which you are entitled or are presently receiving.

Please take the time to read the following information carefully before you decide. Should you have any questions or require any clarification, please contact the Study Coordinator (Chris Napier 604-682-7788 or chris@restorephysiotherapy.ca) to discuss them before your appointment.

WHO IS CONDUCTING THIS STUDY?

The Principal Investigator in charge of this study is Dr. Robert McCormack, Head of the Division of Arthroscopy and Athletic Injuries and Associate Head of the Department of Orthopaedic Surgery in the Faculty of Medicine, University of British Columbia. Christopher Napier, Sport Physiotherapist and Director of Restore Physiotherapy Vancouver, and Dr. Alexandra Brooks-Hill, Clinical Instructor in the Department of Orthopaedic Surgery in the Faculty of Medicine, UBC, and Director of Sea to Sky Orthopaedics, are co-principal investigators in the study.

BACKGROUND

Knee and shoulder injuries are common referrals to orthopaedic surgeons. Wait times to see an orthopaedic surgeon for these injuries can often be 8 months to a year. This wait does not include the wait after seeing a surgeon to getting surgery. It is also possible that after waiting to see the surgeon, it is decided that surgery is not the best option and that a conservative (i.e. non-surgical) course of treatment is more appropriate.
We are trying to learn whether a physiotherapist with advanced training can appropriately diagnose and triage referrals to an orthopaedic surgeon in an effort to cut down on wait times for those patients who can benefit most from surgery, while offering advice about conservative treatment options and early intervention for those who are not appropriate for surgery. We are looking to recruit 50 people with knee or shoulder injuries to this study.

PURPOSE

The objectives of this study are to:

1) Determine if a physiotherapy screening service can increase the proportion of orthopaedic referrals that lead to surgery.
2) Examine whether there is an acceptable level of agreement between a physiotherapist and an orthopaedic surgeon regarding diagnosis and management decisions.
3) Determine if a physiotherapy screening service is an acceptable alternative to the status quo for patients, referring physicians, and orthopaedic surgeons.

WHO SHOULD PARTICIPATE IN THIS STUDY?

You will be able to participate in this study if you:

- are male or female aged 19 years or above
- have a knee or shoulder injury for which your family doctor has referred you to see an orthopaedic surgeon
- injury is deemed an elective referral by the orthopaedic surgeon

Exclusion Criteria:

You will not be able to participate in this study if any of the following conditions apply to you:

- are below the age of 19
- if your injury is the result of a motor vehicle accident and you have an ongoing insurance claim as a result of this accident
- if your injury happened while at work and you have an ongoing insurance claim with WorkSafe BC
- if your history suggests any disorder requiring urgent medical attention (to be determined by orthopaedic surgeon from referral letter)
- if you have been referred from another medical specialist (eg. Orthopaedic surgeon)
- if you are unable to provide informed consent. It is important that you are able to understand what participation in this study entails. If, for any reason, you are unable to make an informed decision regarding participation, then you will not be able to participate.
WHAT DOES THE STUDY INVOLVE?

If you decide to take part in this study, you can expect the following procedures:

You will have one visit to the clinic, and two follow-up questionnaires to assess your satisfaction with the visit and your long-term function and quality of life: 1) Following your visit, you will be asked to fill out and return a short questionnaire; 2) You will also be mailed another questionnaire at 6 months to assess your self-reported function and quality of life. The Clinic Visit will be either in Squamish or Whistler and will take approximately 2 hours. During this visit, you will first be assessed by a physiotherapist and then you will see an orthopaedic surgeon immediately after. In addition, we are asking your permission to access your medical intake form completed prior to your Clinic Visit. This form will be kept strictly confidential and used for relevant demographic information as part of the total study sample. As with all documents, your name will be stripped from the study dataset and assigned a confidential study number.

Detailed Study Procedures:

1. Screening and Assessment Visit

   If you wish to participate in this study, you will need to complete a screening questionnaire (included in the study information package), which will take about 2 minutes. You will then be contacted by the Research Assistant who will go over the questionnaire with you and ask you a few more questions to ensure that you qualify for the study (5-10 minutes). If you qualify, an appointment will be made for you at one of the study clinics to determine in more detail whether you qualify for the study. At this visit, you will be asked to complete questionnaires that ask about your current knee or shoulder injury, any past injuries, whether you have any health problems, allergies or whether you are taking any medications. Please keep in mind that you do not have to answer any questions that you do not feel comfortable with answering.

   Your knee or shoulder will then be examined by one of the study physiotherapists to find out what kind of injury you might have and he/she may suggest some conservative (non-surgical) options for treatment. You will then have your knee or shoulder examined by the orthopaedic surgeon and will be provided with a diagnosis and plan for surgical or non-surgical treatment. These examinations will take place on the same visit at one of the study clinics in Squamish or Whistler. You will then be asked to fill out a short questionnaire (less than 5 minutes) to assess your overall satisfaction with the visit. Please be aware that you will see the orthopaedic surgeon for a full standard visit regardless of the outcome of your physiotherapy assessment.

Some of the reasons you might not qualify are listed in the previous section. If you have any questions, please contact the study coordinator, Chris Napier (604-682-7788 or chris@restorephysiotherapy.ca) ahead of your visit.
2. Follow-up Questionnaire
You will be mailed a follow-up questionnaire at 6 months following your initial visit with the physiotherapist and orthopaedic surgeon. This questionnaire will take 5-10 minutes to complete and will assess your satisfaction with the visit and your self-reported function and quality of life at that point in time.

WHAT ARE MY RESPONSIBILITIES AS A SUBJECT?

As a subject in this study you will be responsible for the following:
- Attending your visit at the study clinic.
- Completing all forms and questionnaires accurately and truthfully.
- Should you change your mind and decide not to participate in this study, you are responsible for informing the study investigators immediately.

WHAT ARE THE RISKS ASSOCIATED WITH PARTICIPATING IN THIS STUDY?

We anticipate no risks as a result of participating in this study. The knee/shoulder examination by the physiotherapist or orthopaedic surgeon can involve some discomfort. If you experience discomfort during the examination, please inform the physiotherapist or surgeon.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

A potential benefit from your participation in this study is the additional information regarding your knee or shoulder injury that we will be able to give you. We will also provide you and your family physician or treating physician with a copy of the physiotherapist’s report and a conservative (non-surgical) treatment plan if recommended. We hope that the information learned from this study can be used in the future to benefit people with knee and shoulder injuries, including the potential to reduce waitlist times for people with knee and shoulder injuries.

WHAT HAPPENS IF I DECIDE TO WITHDRAW MY CONSENT TO PARTICIPATE?

Your participation in this research is entirely voluntary. You may withdraw from this study at any time without having to provide any reasons for your withdrawal. If you decide to enter the study and withdraw at any time in the future, there will be no penalty or loss of benefits to which you are otherwise entitled, and your future medical care will not be affected. Non-participation in the study will not impact upon any association you may have with the Sea to Sky Orthopaedic Clinic in anyway.

The study doctor(s)/investigators may decide to discontinue the study at any time, or withdraw you from the study at any time, if they feel that it is in your best interest.
If you choose to enter the study and then withdraw at a later time, all data collected about you during your enrolment in the study will be retained for analysis. By law, this data cannot be destroyed.

CAN I BE ASKED TO LEAVE THE STUDY?

On receiving new information, the study doctor(s)/investigators might consider it to be in your best interests to withdraw you from the study without your consent if they judge that it would be better for your health.

YOUR LEGAL RIGHTS

It is important for you to know that you do not waive any of your legal rights by signing this consent form.

CONFIDENTIALITY

Your confidentiality will be respected. All study documents will be identified only by code number and will be kept in a locked filing cabinet accessible only to the Principal Investigators and the Research Assistant. No information that discloses your identity will be released or published without your specific consent to the disclosure. However, research records and medical records identifying you may be inspected in the presence of the Investigator or his or her designate by the representatives of Health Canada and the UBC Clinical Research Ethics Board for the purpose of monitoring the research. However, no records which identify you by name or initials will be allowed to leave the Investigator’s offices.

CONTACT INFORMATION

If you have any questions about this study, you can contact the Primary Study Coordinator and Co-Principal Investigator, Chris Napier, at 604-682-7788 (chris@restorephysiotherapy.ca) or Dr. Alex Brooks-Hill’s office at 604-905-4075.

If you have any concerns about your rights as a research subject and/or your experiences while participating in this study, contact the Research Subject Information Line in the University of British Columbia Office of Research Services at 604-822-8598.

FUTURE FOLLOW-UP

Because we are interested in assessing the long-term outcomes of knee and shoulder injuries, the investigators may contact you in the future to participate in studies related to this one. Future studies may include clinical evaluations, and will be associated with this study, however you are under no obligation to participate in future studies.
Please indicate, by checking a box below, if you wish to be contacted regarding possible future studies related to this project. Please note that you will not be contacted regarding research unrelated to this project.

☐ Yes, I am willing to be contacted regarding future studies related to this one, and I understand I am under no obligation to participate in such studies.

☐ No, I am not willing to be contacted regarding future studies related to this one.
SUBJECT CONSENT

By signing this page I acknowledge and agree to the terms listed below:

• I have had the opportunity to read and understand the information and in this consent form.
• I have had sufficient time to consider this information and to ask for advice if necessary.
• I have had the opportunity to ask questions and they have been answered to my satisfaction.
• I understand that all of the information collected for this study will be kept confidential and that the results will only be used for scientific objectives.
• I understand that my participation in this study is entirely voluntary and that I am free to refuse to participate or to withdraw from this study at any time without providing reason, and that this will not compromise the quality of care I receive.
• I understand that I am not waiving any of my legal rights as a result of signing this consent form.
• I understand that, where applicable, my family physician will receive physiotherapy report(s) derived from this study, but that there is no guarantee that this information will provide direct benefits to me.
• I have read this form and I freely consent to participate in this study.
• I will receive a dated and signed copy of this form.

_____________________  __________________________  _____________
Subject Signature   Subject Name    Date
(Please print)

_____________________  __________________________  _____________
Signature of person   Name of person obtaining    Date
obtaining informed    consent (Principal Investigator/Designate) consent (Principal Investigator/Designate)
(Please print)