Helene Bertrand, M.D. Clinical Instructor, University of British Columbia Dept. of Family Practice
20120152

RESEARCH SUBJECT INFORMATION AND CONSENT FORM	
TITLE:	**Frequency of sacroiliac malrotation in low back pain and correction with a simple in-home exercise or a pelvic support belt. A randomized study comparing those treated immediately to those waiting one month for treatment.**

This consent form contains important information to help you decide whether to participate in a research study.

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about and discuss with family or friends before making your decision.

- **Being in a study is voluntary – your choice.**
- **If you join this study, you can still stop at any time.**
- **No one can promise that a study will help you.**
- **Do not join this study unless all of your questions are answered.**

After reading and discussing the information in this consent form you should know:

- Why this research study is being done;
- What will happen during the study;
- Any possible benefits to you;
- The possible risks to you;
- Other options you could choose instead of being in this study;
- How your personal health information will be treated during the study and after the study is over;
- Whether being in this study could involve any cost to you; and
- What to do if you have problems or questions about this study.

Please read this consent form carefully.

ETHICS #: H19 - 01224

SITE North Vancouver, Dr. Helene Bertrand's Office
1940 Lonsdale Ave., Suite 220, *North Vancouver, B.C., Canada V7M 2K2*
telephone: 604-985-5381 20120152

STUDY RELATED PHONE NUMBER Dr. Helene Bertrand MD: 604-985-5381

SUMMARY

You are invited to be in a research study. The purpose of this consent form is to help you decide if you want to be in the research study. Please read this form carefully. To be in a research study you must give your informed consent. "Informed consent" includes:

- Reading this consent form
- Having the study doctor or Rajneet Mattu, her research assistant explain the research study to you
- Asking questions about anything that is not clear
- Reviewing this consent form in advance. It has been provided on-line for pre-viewing at www.low-back-pain.info

You should not join this research study until all of your questions are answered to your satisfaction.

Things to know before deciding to take part in a research study:

- Taking part in a research study is voluntary. No one can make you take part.
- The decision to join or not join the research study will not cause you to lose any medical benefits.
- The main goal of a research study is to learn things to help others in the future.
- The main goal of regular medical care is to help the person receiving that care.

PURPOSE OF THE STUDY

The sacroiliac joints join your pelvic bones to the sacrum, the triangular bone, which is just below your spine. Dr. Bertrand has developed a new way to test this joint to see if one or both of the pelvic bones are displaced and whether they are displaced forward or backwards. If there is displacement, we are testing a new way to treat it using a simple two-minute exercise that you can do at home. We are carrying out this pilot project to see how many people with low back pain suffer from a displaced sacroiliac joint and how effective the corrective exercise or the use of a pelvic support belt are in providing long-term relief.

Dr. Bertrand reviewed the charts of 180 people who had come to her for low back pain. She found that only 9% had pain coming from their lumbar spine and most of the others had pain coming from a displaced sacroiliac joint. Using the corrective exercise she taught them, 78% found pain relief before they left the office. She now wants to see if people can get relief from their back pain by using only the exercise at home, wearing just the pelvic belt to help stabilize their pelvis, or by doing both the exercises and wearing the pelvic belt at the same time. To determine which method, if any, is effective in providing pain relief, participants found eligible for this study will be randomly assigned to one of three groups. During the first office visit, group one participants will learn how to find out in what direction their sacroiliac joint is displaced and how to do the appropriate corrective exercise, group two will be taught how to wear a pelvic support belt and group three will be given an appointment for a return visit one month later. One month later, group one participants will be taught how to also wear a pelvic belt, group two participants will also learn how to examine their sacroiliac joints and perform the appropriate corrective exercises and group

three participants will be taught how to examine their sacroiliac joints,do the appropriate exercises and wear a pelvic belt in the same visit. Therefore, by the end of the second office visit, all three groups will be wearing pelvic belts and performing corrective exercises for the next month. Participants will then return for the third and final office visit to assess the long-term effect of conducting the exercises and wearing a pelvic belt.

A major goal of this study is to learn if people suffering from low back pain can find long-lasting pain relief through:

- a simple corrective exercise they can do at home
- using a pelvic support belt.

WHO IS CONDUCTING THIS STUDY?
Dr. Helene Bertrand, M.D. is conducting the study.

SOURCE OF FUNDING FOR THE STUDY
Funding for this research study will be provided by the primary investigator or her study associates. No one is being paid to conduct this study. Serola Biomechanics, will be supplying the Serola belts.

WHO CAN PARTICIPATE?
You can take part in this study if:

- You are between the ages of 19 – 90.
- You have pain in your low back (below the waist) or at the level of your buttock.
- Your pelvis is not level on initial examination.
- You experience tenderness when one of your pelvic joints is felt.
- You are able to attend the clinic visits, with a friend or family member who can assist you with the corrective exercise.
- You and your helper are able to attend all 3 of the study visits at the doctor's office (first visit to assess the cause of your pain and place you into one of the three treatment groups, then a second visit one month later to learn how to either perform the exercise, use a pelvic belt or both depending on which treatment group you are in, followed by a final assessment visit one month later to find out how you are doing and to help prevent mistakes. You are willing to answer an email, mailed or telephone questionnaire before your first visit to assess whether you are eligible for the study

WHO SHOULD NOT PARTICIPATE?
You should not take part in this study if:

- Your back pain is coming from your lumbar spine. At the first visit, the doctor will examine you to determine if your pain is coming from your lumbar spine.
- Your back pain is coming from your hip. Again, at the first visit the doctor will examine you to determine if your pain is coming from your hip
- One of your legs is more than 1 ½ cm longer than the other. The doctor will measure this.
- You suffer from severe pain elsewhere in your body which would make it hard for you to judge how much back pain you have.
- You suffer from ankylosing spondylitis
- The doctor is unable to feel the exact position of your pelvic bones.

- You are unable to understand English and cannot attend the Doctor's office with someone who will translate for you.

PROCEDURES

As part of the study:

- You will receive a copy of this consent form and a questionnaire by mail or email as soon as you contact the doctor's office for low back pain. It will also be available for viewing online at www.low-back-pain.info.
- You can telephone the research assistant, Rajneet Mattu or Lori, the medical office assistant through Dr. Bertrand's office between Monday and Thursday to get answers to any questions you have about this research project before signing the consent form.
- When we receive your questionnaire, we will give you an appointment for your first visit.
- If during the first visit it is determined that a displaced pelvis is causing your low back pain, you will randomly be assigned to one of thee treatment groups. Group one will receive instructions on how to examine the pelvis to determine if it is displaced forward or backwards and how to perform the appropriate corrective exercises, group two will receive instructions for wearing and given the pelvic belt and group three will be scheduled for an appointment to return in one month's time.
- You will attend a total of 3 office visits: the first visit to assess the cause of your pain and place you into one of the three treatment groups: to learn how to do the pelvic examination and exercise, use a pelvic belt orbe put on a waiting list to be treated with both exercise and belt one month later.. One month later, at the second visit, your use of each of these treatments will be assessed and all the participants will be given both treatments to use together., At the third visit, one month after that, your use of both treatments together will be assessed.
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- The first office visit will last 1 and ½ hours, the other 2 visits will last one hour. The amount of time you spend at home doing the exercises may be about 2 minutes once a day, though it may be more or much less, depending on the stability of your sacroiliac joints. It will also take you less than two minutes to put on the pelvic belt. How long you wear it depends on the activities that improve if you wear the belt. If you do the exercise or put on the belt once a day, in the 60 days of the study, it will take you 120 minutes (2 hours) to complete it. In total, you will be spending about 3.5 hours on this study.

BEFORE YOU ARE GIVEN AN APPOINTMENT

When you contact Dr. Bertrand's office with low back pain, Lori, Dr. Bertrand's MOA will tell you about this research project. If you are interested she will mail or email you this consent form, together with a questionnaire about your condition to determine whether you are eligible to participate in the study. You can find out more about this if you go to the www.low-back-pain.info website. If you are not interested in taking part in the study, Lori can book you an appointment for a regular visit to see Dr. Bertrand.

When we receive your answers to this questionnaire, we will give you a call to give you an appointment for either a regular office visit or a first visit depending on if you are eligible for the study.

FIRST VISIT

When you come to the office Dr. Bertrand or her research assistant will discuss the consent with you and answer all your questions to make sure you understand the research project well before signing this consent.

For the first visit, come to the office with someone (which can be a spouse, a friend or a member of your family) who can assist you with the procedures

During this visit, the possible causes for your low back pain will be assessed in detail.

- You will answer a Brief Pain Inventory (BPI) pain and Oswestry low back pain disability (ODI) questionnaire about your pain levels and what you are doing to relieve your pain.
- The doctor will do a physical examination involving straight leg raises, leg reflexes, hip or knee range of motion, and determine if the lumbar spine, your pelvis, your hips and knees are tender to palpation.
- The movements of your hips will be checked as sometimes pain is coming from arthritis of the hips..
- The length of your legs will be measured to ensure you have relatively equal legs.
- Your sacroiliac joints will be marked, measured and photographed The muscles stabilizing this joint will also be assessed as they often get tendinitis: their tendons, which join these muscles to the sacrum, the ilium (the pelvic bone), the ischium (sitz bone), the front and the back of the thigh bone, the lumbar spine and the knee get overstretched and painful when the sacroiliac joints are unstable.

If these assessments determine that you have low back pain due to a displaced sacroiliac joint, you will then be randomly assigned to one of three treatment groups.

- **Group One[1]:** If you are randomly assigned to this group, you and your assistant will be taught how to examine and treat your sacroiliac joints depending on whether they are tilted forward or backwards. The treatment is a 2-minute procedure where your thigh pushes your pelvic bone backwards, if it is tilted forward, and the muscles of your thigh pull your pelvic bone forward, if it is tilted backwards. If you still have pain in your back and your pelvis is not level following this exercise, the exercise will be repeated up to two more times. After this is done, you will rate your current back pain. Your sacroiliac joints will once again be marked, and the space between the before and after marks will be measured and recorded. For the next month, you will use the exercise whenever your back pain recurs.

- **Group Two[2]:** If you are randomly assigned to this group, you will be fitted for a Serola pelvic support belt which will be given to you free of charge. You will then be taught how to put on and wear your Serola pelvic support belt. You will answer questions about your satisfaction with the belt. For the next month, you will wear the Serola pelvic support belt when you feel the need to stabilize your pelvis

- **Group Three:** If you are randomly assigned to this group, you will be given an appointment to return for a visit one month later where you will be given the exercises and the belt at the same visit. While you are waiting for this visit, you are free to use all other currently available treatments to control your back symptoms.

SECOND VISIT

One month later you will return for the second visit. You will answer a questionnaire about your current pain levels and what you are doing to deal with your pain following the treatment you were assigned. The doctor will mark, measure and photograph your sacroiliac joints and the treatment groups will proceed as follows:

- **Group One:** we will start by assessing how you perform the corrective exercises taught to you during visit 1 and correct your technique if needed. Then you will be fitted for a pelvic support belt, which we will provide to you free of charge. For the following 1 month you will

do the exercises whenever your back pain recurs and you will wear the pelvic support belt when you feel the need to stabilize your pelvis

- **Group Two:** you and your assistant will be taught how to examine and treat your sacroiliac joints depending on whether they are tilted forward or backwards. We will do this in the exact same way that we did for individuals assigned to Group one so the details are identical to those listed above under "FIRST VISIT, Group One[1]." How you wear the belt will also be assessed and corrected as needed. For the following 1 month you will now use the exercises whenever your back pain recurs and you will wear the pelvic support belt when you feel the need to stabilize your pelvis

- **Group Three:** During this visit you will learn how to use and wear the pelvic support belt and perform the corrective exercises. We will teach you how to perform the exercises in the exact same way that Group 1 participants were taught during the first visit. Therefore, please read the details under "FIRST VISIT, Group One[1]." The way that you will be taught how to wear the pelvic support belt is identical to what was taught to Group 2 participants in their first visit. Please read the details under "FIRST VISIT, Group two[2]." For the following 1 month you will now use the exercises whenever your back pain recurs and you will wear the pelvic support belt when you feel the need to stabilize your pelvis

THIRD VISIT
You will answer the questionnaire about your pain levels, what you are doing to relieve your pain and how effective the exercise and the use of the pelvic support belt have been in relieving it. How you do the exercises and how you wear the belt will be assessed and corrected as needed.

NEW INFORMATION
You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

RISKS AND DISCOMFORTS
The exercises you will be prescribed can sometimes be too strenuous or uncomfortable for people to perform. If one type of exercise is too difficult, we will teach you and your partner another one which will be easier. This is why we ask you to attend your visit with someone who can help you. To date, other than slight soreness, there have been no known side effects, however your condition may not get better or may get worse during this study. There may be risks or side effects that are unknown at this time.

WHAT IF SOMETHING GOES WRONG?
By signing this form, you do not give up any of your legal rights and you do not release the study doctor, participating institutions, or anyone else from their legal and professional duties. If you are physically injured as a result of participation in this study, medical treatment will be provided at no additional cost to you. The costs of your medical treatment will be paid by your provincial medical plan.
If you are injured as a result of being in this study, call the study doctor immediately. The study doctor will direct you to appropriate emergency medical treatment.

BENEFITS
The results of this study may help people with low back pain in the future. There is no guarantee that you will receive any medical benefits from being in this study. Your pain may not be altered by the exercises.

If the simple exercises used in the study are effective in eliminating or greatly reducing your back pain, it will help to stimulate further research and may change our understanding of why people have low back pain. We hope that the information learned from this study can be used in the future to benefit other people.

ALTERNATIVE TREATMENT
If you choose not to be in the study, you may still apply usual self-treatment measures for optimizing recovery such as rest, extra sleep, well balanced diet, exercises, hot or cold compresses, physiotherapy and manipulation. Alternative treatments also include anti-inflammatory, anti-seizure and antidepressant medication, and pain killers.

VOLUNTARY PARTICIPATION AND WITHDRAWAL
Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled. You may withdraw from this study at any time without giving reasons. You have the right to request the destruction of your information collected during the study or you may choose to leave the study and allow the investigators to keep the information already collected about you until that point. If you choose to have the data collected about you destroyed, this request will be respected to the extent possible. Please note, however, that there may be exceptions where the data will not be able to be withdrawn for example where the data is no longer identifiable (meaning it cannot be linked in any way back to your identity) or where the data has been merged with other data.
Your participation in this study may be stopped at any time and for any reason by the study doctor without your consent

- if it is in your best interest;
- if you do not consent to continue in the study after being told of changes in the research that may affect you.

You will be withdrawn from the study if you fail to return for your clinic visits.

PAYMENT FOR PARTICIPATION
You will not be paid for being in this study, but you will be supplied with a free Serola pelvic belt.

COSTS OF PARTICIPATION
There are no costs to participate in this study.

CONFIDENTIALITY
Your confidentiality will be respected. However, research records and health or other source records identifying you may be inspected in the presence of Dr. Bertrand or her designate by representatives of the UBC clinical research ethics board for the purpose of monitoring the research. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

You will be assigned a unique study number as a participant in this study. This number will not include any personal information that could identify you (e.g., it will not include your Personal Health Number, SIN, or your initials, etc.). Only this number will be used on any research-related information collected about you during the course of this study, so that your identity will be kept confidential. It will not be used for commercial purposes. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law.

As part of this research project, photographs will be taken of your lower back and transferred to your encrypted, password-protected electronic medical record in Dr. Bertrand's office. As soon they are transferred, they will be erased from the camera's memory card. Only Dr. Bertrand, Dr. Garcia and Dr. Bertrand's MOA, Lori, will have access to those medical records. In Dr. Bertrand's presence, the photographs in your medical record may be inspected by the UBC clinical research ethics Board for the purpose of monitoring the research. After 16 years, these medical records will be destroyed.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to insure that your privacy is respected. Further details about these laws are available on request to your study doctor.

Any study related data sent outside of Canadian borders may increase the risk of disclosure of information because the laws dealing with protection of information, may not be as strict as in Canada. However, all study related data that might be transferred outside of Canada will be coded (this means it will not contain your name or personal identifying information) before leaving the study site. By signing this consent form, you are consenting to the transfer of your information to organizations located outside of Canada:

- K. Dean Reeves, MD, FAAPM&R, University of Kansas Dept. of PM&R, Kansas City, KS, USA, will provide oversight of the database and forward the database to An Lin Cheng, PhD for statistical analysis. He will participate in interpreting the statistical analysis.
- An Lin Cheng, PhD., University of Missouri – Kansas City, School of Nursing and Health Studies will carry out the statistical analysis of the data. This will help us find out how effective the exercises in the pelvic belt are in treating low back pain.
- These 2 people will each have a copy of the database, but this database will be "de-identified": it will not include any personal information which could identify you, only your research number to go with the data that has been generated through your answers to the questionnaires.

The de-identified data we collect will be used for the purpose of publication. The results of this research study may also be presented at meetings. Your identity will not be disclosed in these presentations.

Your de-identified research data may be published or deposited into a publicly accessible location at the time of publication. This data could include your study number and the data we collect about your painful back and the treatments you receive. At no time will identifying information such as your name, birth date or street address be included in such data. This means that other researchers may analyse the data for different reasons other than those described in this consent form. Once the data is made publicly available we will not be able to withdraw your data. The extent of the risk of you

being identified through public data is unknown, but currently appears to be low.

The Squarespace website advertising this research project, www.low-back-pain.info, is located in the United States were the laws dealing with protection of information may not be as strict as in Canada

QUESTIONS

Contact Helene Bertrand, M.D., or Rajneet Mattu, her research assistant, at 604 985 5381 for any of the following reasons:

- If you have any questions about this study or your part in it.
- If you feel you have had a research-related injury or side effects.
- If you have questions, concerns, or complaints about the research.
- If your pain disappears for more than three days.

Who do I contact if I have any questions or concerns about my rights as a participant?

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, you may contact the Research Participant Complaint Line in the University of British Columbia Office of Research Ethics by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598 1-877-822-8598). Please reference the study number (H19-01224) when calling so the Complaint Line staff can better assist you.

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Do not sign this consent form unless you have had a chance to ask questions and have gotten satisfactory answers.

Participant Consent

My signature on this consent form means:

- I have read and understood the information in this consent form.
- I have had enough time to think about the information provided.
- I have been able to ask for advice if needed.
- I have been able to ask questions and have had satisfactory responses to my questions.
- I understand that all of the information collected will be kept confidential and that the results will only be used for scientific purposes.
- I understand that my participation in this study is voluntary.
- I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time, and that this will not change the quality of care that 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 there is no guarantee that this study will provide any benefits to me.

I will receive a signed copy of this consent form for my own records.

I consent to participate in this study.

_____	_____	_____
Participant's Signature	Printed name	Date

_____	_____	_____	_____
Signature of Person Obtaining Consent	Printed name	Study Role	Date