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INFORMATION SHEET

Title of Research Study: The Adult Idiopathic Schroth Exercise Trial

Principal Investigator(s): University of Alberta
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Why am I being asked to take part in this research Study?

You are being asked to participate in a research study on exercises for adults with idiopathic scoliosis. In Canada, adults with small scoliosis curves are only monitored with a radiograph and clinical exam as needed.

Schroth exercises may improve pain levels, quality of life, function, spinal curves, slow the progression of scoliosis, correct posture, and increase muscle strength but this is not certain. Schroth exercises are done with props while lying down, sitting or standing. Schroth exercises are taught by a certified therapist one on one and in group sessions. Volunteers attend treatment visits and do a **30 minute daily home practice for 3 months**. Schroth exercises have not been verified in a rigorous controlled study. We want to conduct a rigorous study before deciding to offer Schroth treatments at Scoliosis clinics in Edmonton. Twenty patients will participate in this feasibility study.

What is the reason for doing the study?

The goal of this study is to:

- 2.1) Determine the recruitment of patients for planning a larger study;
- 2.2) Demonstrate the feasibility of the testing and treatment protocol; and
- 2.3) Estimate the effect for all measures.

The goal of the larger study to follow will be to determine the effect of Schroth exercises in adults with idiopathic scoliosis. We will compare results between patients treated with exercises over 3 months to patients receiving the usual clinic treatment.

Random Placement

You have an equal chance (50%) of receiving the exercise or the usual clinic treatment. The usual treatment is observation and continuing with medication as needed for your clinical condition. You or your doctor cannot choose which treatment you will receive. This chance allocation is needed to fairly test the exercises. You will remain in your group for 6 months if you receive exercises. Participants in the usual clinic treatment group will receive the exercises after 3 months and have a complete follow-up duration of 9 months.

What will I be asked to do?

You will be examined before treatment, and at 3, and 6 months if you are in the exercise group and at 3, 6, and 9 months if you are in the control group. The exams include questionnaires (10-15min.), and a 30min.-long physical exam. Exams will be done in the clinical science building room 6-107 at the University of Alberta. The exercise therapy sessions will be offered at Curvy Spine 10041 81 Avenue NW in Edmonton, once each week for

3 months. Participants in the usual clinic treatment group will switch over and begin the exercise program after 3 months.

Physical Exam

In the exam, we will review your questionnaires completed at home. Questionnaires assess back pain, medication use, difficulty with activities, quality of life, and general information. A physical therapist will do a physical exam (30 minutes). The physical therapist will assess your legs and back by simple movements. This exam will tell us about your spinal curve type, muscle strength, range of motion and flexibility. We will also detect, if you have other physical issues.

A full-torso body shape exam (15min.) and a 3D ultrasound scan (10min.) of your scoliosis severity will be collected at each exam. You will be asked to wear sunglasses and a stick-on bra during the body shape exam. It provides a 3D image of the torso using four laser scanners. The Ultrasound imaging replaces the radiograph to measure your scoliosis curves without radiation. For this exam the evaluator will apply gel over your back and follow your spine with the scanning probe.

Procedures for the **treatment** group:

If you are placed in the treatment group, treatments will begin **during the week after the baseline exam**. Treatment consists of a total of 14 visits including:

- a) 5 one on one visits- During the first 2 weeks, you will attend five 1-hour long one on one sessions with a Schroth therapist at the Curvy Spine Clinic on Whyte Avenue or online via videoconference if you prefer. These visits will teach you good posture and your home scoliosis exercises. The total discounted ($\approx 50\%$) cost of those visit is \$860 and can be charged to your benefits.
- a) Home exercises – You will be asked to do a 30-min. daily home exercise routine of 3 to 4 exercises. The home exercises will be adjusted gradually over 3 months. The Schroth therapist will ensure that you perform the exercises correctly. You will be asked to note the exercises completed each day in a log-book. Your therapist will sign the log-book weekly. The Schroth therapist will help you find ways to make home practice easier.
- b) Group Classes- **Each week** you will attend a 1-hour long exercise class and then 3 visits 2 weeks apart at the Curvy Spine clinic or online as you prefer. A Schroth therapist leads the classes. The group classes will have up to 4 participants. We will record your presence. Adequate exercise performance will be noted with a checklist. Your home exercise routine may be adjusted by the therapist.

Procedures for Usual Treatment Group:

If you are placed in the usual treatment group, you will complete the baseline exam, and follow-up exams at 3, 6, and 9 months. You will not receive exercise treatment between baseline and 3 months. If you have been taking medication, we will ask you to continue with the same plan and record what you take. This is the current clinic standard for patients not planning surgery. You will receive the supervised exercise treatment between 3 and 6 months.

Covid-19 procedures

Due to the nature of this study, the ability to maintain 2m or more of physical distance is not possible. As such, all visits will be conducted with several additional measures in place. Prior to arriving at the lab, both researchers and research participants will need to pass the Covid-19 screening tool provided by the Government of Alberta and Alberta Health Services. Participants will be asked to wash their hands prior to entering the lab, and hand sanitizer will be available in the lab itself. Researchers will be wearing masks, face shields, gloves and gowns for the duration of the visit where physical distancing measures cannot be maintained. Participants will need to wear a mask throughout the entirety of the visit. The research lab and all equipment will be cleaned and disinfected regularly after patient visits.

What are the benefits to me?

There are possible benefits for being in this study. Some studies suggest that Schroth exercises can improve pain, spinal curvature, slow the progression of scoliosis, correct posture, and increase strength. However,

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you may not get any benefit from being in this research study. Participants doing Schroth exercises in the past have not always had good outcomes.

The results from this study will help decide if a larger study is feasible on the effects of Schroth exercises for idiopathic scoliosis. The study will help measure the impact of exercise treatment. The study results will help decide if this exercise treatment should be offered at Scoliosis clinics.

What are the risks and discomforts?

Exercise Treatment Protocol: The risks will be kept to a minimum. You will be closely monitored during the study to detect if negative effects develop. Exercises will be adapted to your capacity level. Exercises will be progressed gradually. You will be instructed on how to perform the exercises. It is possible and normal to feel soreness after exercising, especially when beginning the exercises. Soreness will be temporary. You could be referred to a physician if needed. The exercises and their intensity will be adjusted so that you can tolerate them.

Physical Exam: The physical exam includes simple movements and tests. You should not feel pain. Rarely, people feel sore during the days after a simple physical exam. If you feel soreness it should disappear in a few days.

Other tests: 3D Ultrasound imaging, body shape scanning and the questionnaires have all been part of evaluations in our research projects. These procedures are safe. You will not be exposed to added risk by participating in the study.

Covid-19: You will have an increased risk to Covid-19 as it will not be possible to maintain 2 metres or more of physical distancing throughout your appointment. We have put in place several protocols as mandated by the Government of Alberta and the University of Alberta to help keep you safe during the physical exam.

It is not possible to know all of the risks that may happen in a study, but the researchers have taken all reasonable safeguards to minimize any known risks to a study participant. If we find out anything new during this research project which may change your willingness to be in the study, we will tell you about these findings.

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 investigators, institutions and/or sponsor from their legal and professional responsibilities.

Will my information 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. We cannot guarantee that others in the group will not share what takes place during group sessions.

During research studies it is important that the data we get is accurate. For this reason, your health data, including your name, may be looked at by people from the University of Alberta, and Health Research Ethics Board.

By signing this consent form, you are saying it is okay for the study team to collect, use and disclose information about you from the evaluations described above.

After the study is done, we will still need to securely store your health data that was collected as part of the study. At the University of Alberta, we keep data stored for a minimum of 5 years after the end of the study.

If you leave the study, we will not collect new health information about you, but we may need to keep the data that we have already collected.

Do I have to take part in the study?

Being in the study is your choice. If you decide to be in the study, you can change your mind and stop being in the study at any time. If you stop being in the study, it will in no way affect the care that you are entitled to. We will let you know if we learn information that could influence your decision to continue in the study.

Will I be paid to be in the research?

We will ask you to commit time for the exams, the treatments, and the home exercises. No funds will compensate you for your time. Exams are provided at no charge to you or your insurance. Transportation to the exams and treatments are your responsibility and will not be reimbursed. We will provide you with parking for visits to Corbett Hall. Parking at Curvy Spine is free. Therapy sessions will be charged to you or your insurance if you have one at a discounted cost. The cost will cover only the salary of the physical therapist (\$60/hourly session).

What if I have questions?

If you have any questions about the research now or later, please contact:

Eric Parent, assistant professor/clinician-scientist

780 492 8889 or 991 6038

Kathleen Shearer

780 993-6224

If you have any questions regarding your rights as a research participant, you may contact the Health Research Ethics Board at 780-492-2615. This office has no affiliation with the study investigators.

Who is funding this study? This study is funded by the Faculty of Rehabilitation Medicine at University of Alberta.

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CONSENT

Title of Study: The Adult Degenerative Schroth Exercise Trial

Principal Investigator(s): University of Alberta

Eric Parent, PT, M.Sc. Ph.D.,

780 492 8889

Study Coordinator

Kathleen Shearer

780 248-2064

	<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 records	<input type="checkbox"/>	<input type="checkbox"/>
Future Contact		
Do you agree to be contacted for follow-up or to facilitate future research?	<input type="checkbox"/>	<input type="checkbox"/>
Who explained this study to you? _____		
I agree to take part in this study:		
Signature of Research Participant _____		
(Printed Name) _____		
Date: _____		
Signature of the researcher or designate: _____		

THE INFORMATION SHEET MUST BE ATTACHED TO THIS CONSENT FORM AND A COPY GIVEN TO THE RESEARCH PARTICIPANT