



INFORMATION SHEET

Title of Research Study: The Multicenter Schroth Exercise Trial for Scoliosis
(Multicenter SETS study)

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Why am I being asked to take part in this research Study?

Your child is being asked to participate in a research study on exercises for adolescents with idiopathic scoliosis (AIS).

In Canada, adolescents with small idiopathic scoliosis curves are only monitored with a radiograph and clinical exam every 6 months. Adolescents with larger curves are treated with brace or surgery.

Schroth exercises may improve spinal curves, slow the progression of scoliosis, correct posture, and increase muscle strength but this is not certain. Schroth exercises are done with the use of props while lying down, sitting or standing. Schroth exercises are taught by a certified instructor individually and in group sessions. Volunteers attend treatment sessions and do a **30 minute daily home practice for 6 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, Calgary and Montréal. A total of 258 patients will participate. We expect 102 patients will participate in Edmonton.

What is the reason for doing the study?

The goal is to determine the effect of Schroth exercises in adolescents with idiopathic scoliosis. We will compare results between patients treated with exercises over 6 months to patients receiving the usual clinic treatment for scoliosis.

We hope to learn which patients with scoliosis should be prescribed Schroth exercises.

Random Placement

Your child has an equal chance (50%) of receiving the exercise or the usual clinic treatment. The usual treatment is observation or bracing depending on curve severity. Your child or your doctor cannot choose which treatment your child will receive. This chance allocation is necessary to fairly test the exercises. Your child will remain in her group for 12 months if she receives exercises. Participants in the usual clinic treatment group will receive the exercises after 6 months.

What will I be asked to do?

Your child has an equal chance to be in the exercise group or the usual clinic treatment group. Your child will be examined before treatment, and at 3, 6, 9 and 12 months. The exams include your child's usual exams at the Scoliosis clinic. Your child will also complete questionnaires, and a physical exam at Corbett Hall. After 12 months, your child will attend routine visits until discharge from the Scoliosis clinic. Your child's x-rays and questionnaires from all visits until discharge from the scoliosis clinic will be used in our study. The exercise group will have therapy sessions at Corbett Hall for 6 months. Participants in the usual clinic treatment group will switch over and begin the exercise program after 6 months.

Physical Examination and Questionnaires:

Your child will complete the baseline, 6-month and 12-month exams **within 2 weeks** of the regular Scoliosis clinic visits. Your child will also have a follow-up exam at 3 and 9 months. Exams will take place in Corbett Hall (Room 3-78). The exam should take 1 hour. In the exam, your child will complete questionnaires. This will take 25 minutes. Questionnaires assess back pain, amount of exercise performed, feelings about exercise, quality of life, and general information. A physical therapist will do a physical exam (20 minutes). The physical therapist will assess your child's legs and back by simple movements. This exam will tell us about your child's spinal curve type, muscle strength, range of motion and flexibility. We will also detect, if your child has other physical issues.

A full-torso surface topography exam and the x-ray collected at your child's routine clinic visit will be used for the study. Surface topography measures the deformity in the body shape. It provides a 3D image of the torso using four scanners.

At 3 months, another full-torso surface topography exam will be scheduled in room 8-110K of the Clinical Science Building, with the physical exam and questionnaires in Corbett Hall. This surface scan will follow the same procedures as for your child's regular Scoliosis clinic visits. This exam is safe. The surface exam takes 10-15 minutes.

Procedures for the **treatment** group:

If your child is placed in the treatment group, the treatment will begin **during the week after the baseline exam**. Children with small curves in this group will receive exercises only. Children with larger curves meeting the criteria to receive a brace will have exercises and bracing treatment. Treatment consists of a total of 24-28 visits including:

- a) 5 private sessions- During the first 2 weeks, participants will attend five 1-hour long individual sessions with a Schroth therapist in Corbett Hall (Room 3-78). These sessions will teach your child postural principles and exercises. Your child will learn home exercises. We will confirm your child's ability to do the exercises with a checklist.
- b) Home exercises – Your child will be asked to do a 30-min. daily home exercise routine of 3 to 4 exercises. The equipment for home exercises will be provided. The home exercises will be adjusted gradually over 6 months. The Schroth therapists will ensure that your child performs the exercises correctly. Your child will be asked to note the exercises completed each day in a log book. Parents will sign the log book weekly to confirm your child completed prescribed exercises. The Schroth therapist will review log books each week and help your child find ways to make home practice easier.
- c) Group Classes- **Each week** your child will attend 1-hour long exercise classes in Corbett Hall (Room 3-78). A Schroth therapist leads the classes. The group classes will have up to 4 participants. We will record attendance at the classes. Adequate exercise performance will be assessed using the checklist. Your child's home exercise routine may be adjusted by the therapist.

Procedures for Usual Clinic Treatment Group:

If your child is placed in the usual clinic treatment group, your child will complete the exam within 2 weeks of her regular clinic visit, and again at 3, 6, 9 and 12 months. Children with small curves will not receive other treatment during that time. Children with larger curves meeting the criteria for brace prescription will only have bracing treatment. This is the current clinic standard for adolescents with curves like your child's. For the study you child will complete some questionnaires and the physical exam at baseline, 3, 6, 9 and 12-month. Your child will cross-over and begin the exercise treatment at 6 months.

What are the benefits to me?

There are possible benefits for being in this study. Some studies suggest that Schroth exercises can improve spinal curvature, slow the progression of scoliosis, correct posture, and increase strength. However, 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 determine the effects of Schroth exercises on idiopathic scoliosis. The study will help determine who benefits from and who should receive exercise treatment. The study results will help determine whether this exercise treatment is appropriate to offer at Scoliosis clinics in Montréal, Calgary and Edmonton.

What are the risks and discomforts?

Exercise Treatment Protocol: The risks will be kept to a minimum. Your child will be closely monitored during the study to detect if negative effects develop. Exercises will be adapted to your child's capacity level. Exercises will be progressed gradually. Your child 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. Your child could be referred to a physician if needed. The exercises and their intensity will be adjusted so that your child can tolerate them.

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

Other tests: Radiographs, surface topography and some of the questionnaires are all part of routine scoliosis clinic visit. Your child will not be exposed to added risk by participating in the study.

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 your child. 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

The investigator or their study staff may need to look at your personal health records or at those kept by other health care providers that you may have seen in the past (i.e. scoliosis clinic records). Any personal health information that we get from these records will be only what is needed for the study.

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 your personal health records as 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 child's decision to continue in the study.

Will I be paid to be in the research?

We will ask you and your child to commit time for the exams, the treatments, and the home exercises. No funds will compensate you or your child for your time. Exams and treatments 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 coupons for visits to Corbett Hall.

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
Elise Watkins, PhD student-therapist	780 248-1857
Doug Hill, Clinical Engineer	780 735-8289

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?

The Institution and the research team are getting money from the study sponsor to cover the costs of doing this study. The study is funded by the SickKids Foundation of Canada. You can request any details concerning this compensation from the Principal Investigator.



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PARENT CONSENT FORM

Title of Project: The Multicentre Schroth Exercise Trial Study (SETS study)

Principal Investigator: Eric Parent

Phone Number: 780 492 8889 or 780 991 6038

Part 2 (to be completed by the parents of the research subject):

	Yes	No
Do you understand that your child has been asked to participate 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 your child is free to leave the study at any time, without having to give a reason and without affecting your child's 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 child's records, including personally identifiable health information?	<input type="checkbox"/>	<input type="checkbox"/>

Who explained this study to you? _____

Child's Name _____

I agree for my child to take part in this study: YES NO

Signature of Parent or Guardian _____ Date & Time _____

(Printed Name) _____

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to have his/her child participate in the research.

Signature of Investigator or Designee _____ Date & Time _____

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

PARENT/GUARDIAN OF THE RESEARCH SUBJECT



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What is a research study? A research study is a way to find out new information about something. Children do not need to be in a research study if they don't want to.

Why are you being asked to be part of this research study? We would like you to participate in research to determine the effects of Schroth exercises compared to the standard treatment. Schroth exercises are posture exercises to correct spinal curves. About 258 adolescents with idiopathic scoliosis will take part in this study. Adolescent idiopathic scoliosis is the diagnosis for the spinal curve you have.

If you join, what will you have to do? You have an equal chance of being in the exercise or usual clinic treatment group. You cannot choose which group you are in. Schroth exercises are not available outside of this study in Edmonton.

At baseline, 3, 6, 9 and 12 months you will complete questionnaires. We will test how flexible you are. We will record the shape of your torso using a surface scanner. We will use the radiograph and questionnaires from your scoliosis clinic visits at baseline, 6, 12 months and every visit afterwards until you are discharged.

Patients in the exercise group will come to our office for exercises once a week during 6 months. You will attend 24 to 28 visits. During the first 2 weeks, you will attend five 1-hours long sessions alone with the Schroth therapist to learn your home exercises. Then, you will attend a 1-hours long group class once a week with other girls from the study. You will do home exercises for 30 minutes every day.

Patients in the usual clinic treatment group will only attend exams at baseline, 3, 6, 9 and 12 months. After 6 months, you will transfer to the exercise group.

Will it help? You will learn about your flexibility and body shape. You will learn exercises that might help your condition. Exercises may prevent the need for a brace or surgery. This is not guaranteed.

Will it hurt? The physical assessment involves simple movements and tests. You should not feel pain. If you feel pain, tell the researchers. They will change the test to help you. If changes do not help, you can stop the testing.

Department of Physical Therapy

