The University of Texas Southwestern Medical Center at Dallas
Institutional Review Board

PROJECT SUMMARY

Principal Investigator:

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Study Title:

Scoliosis-Specific Exercises for At-Risk Mild AIS Curves: A Multi-Site Preliminary Randomized Trial

Sponsor/Funding Source:

Scoliosis Research Society

Purpose:

To investigate the feasibility and short-term effectiveness of scoliosis specific exercises as part of a multi-center randomized controlled trial in patients with mild AIS curves at the greatest risk of progression. Specifically, our study aims are as follows:

Aim 1: The primary aim is to assess the feasibility of a multi-site prospective randomized controlled trial in skeletally immature patients with mild AIS curves at high risk of progression. Participants instructed in scoliosis-specific exercises (SSE) provided by physical therapists certified in the Schroth-based method (SSE group) will be compared to the standard-of-care of observation (control group).

Feasibility will be evaluated according to participant:

1) recruitment rate at each site (measured by the number of participants enrolled per month at each site)
2) overall recruitment rate (measured by the total number of participants enrolled after 1 year)
3) treatment attendance in the SSE group (measured by the percentage of prescribed hours of physical therapy sessions attended)
4) home exercise adherence in the SSE group according to weekly e-mails (measured by the percentage of prescribed exercises completed from baseline to 1 year)
5) home exercise adherence in the SSE group according to a smartphone application (measured by the percentage of prescribed exercises completed from baseline to 1 year)
6) home exercise adherence in the SSE group according to an exercise log (measured by the percentage of prescribed exercises completed from baseline to 1 year)

Aim 2: The secondary aim is to assess whether scoliosis-specific exercises (SSE) will be more effective in skeletally immature patients with mild AIS curves at high risk of progression,

compared to the standard-of-care of observation (control).

The outcome quantifying the effect of 1 year of physical therapy intervention will include:

1) curve magnitude (measured by the Cobb angle on radiograph at baseline and 1 year)
2) curve progression (measured by whether the curve progresses >5° after 1 year)
3) brace prescription (measured by the percentage of participants prescribed a brace after 1 year)

Background:

Adolescent idiopathic scoliosis (AIS) is a three-dimensional deformity of the spine, affecting 1-3% of children ages 10-16 years.[1] Adolescents with AIS have the highest risk of curve progression during the period of rapid growth prior to achieving skeletal maturity.[1] Patients who are Risser 0 are at greatest risk for curve progression.[2] The standard medical management for AIS in the United States (US) includes observation for skeletally immature mild curves, bracing for skeletally immature moderate curves, and surgery for severe curves.

Managing AIS can be considered a quality-of-life issue, since it does not result in premature death.[3] Scoliosis may be associated with pain, torso deformity, psychological distress and pulmonary dysfunction.[4] Bracing may result in decreased quality-of-life such as reduced activity and self-image, especially those with smaller curves.[5] Patients commonly report discomfort with wearing a brace. Furthermore, most patients prescribed brace wear are not compliant.[6] In contrast to bracing, exercise for AIS has been found to be emotionally satisfying[7] and is the patient-preferred option.[8] Furthermore, supervised Schroth exercises for AIS have been shown to significantly improve self-image according to the SRS-22 as compared to a control group.[9] However, in North America, exercises are typically not offered to patients with smaller curves as part of the medical management of AIS. Exercise treatment during adolescence may prevent curve progression and its consequences, as less than 10% of curves kept below 29° at maturity continue to progress into adulthood.[1] At skeletal maturity, only 30% of curves greater than 30° continue progressing slowly, but 70% of the curves >50° progress at a rate of 1° per year.[10] The negative consequences of progressive scoliosis most commonly manifest themselves once curves exceed 40-50°, justifying efforts to prevent progression.[1,4] Furthermore, patients who are Risser 0 with mild curves are at a high risk of curve progression.[11] In a sample of 123 AIS patients with curves 10-49°, Bunnell (1986) reported a 68% risk of curve progression ≥10° in patients who are Risser 0, and a 44% risk of curve progression ≥10° in patients with curves <20°.[11] In a sample of 727 JIS and AIS patients with curves 5-29°, Lonstein & Carlson (1984) reported a 38% risk of curve progression ≥10° in patients who are Risser 0, and a 38% risk of curve progression ≥10° in patients with curves <20° who are Risser 0-1.[12] In a large cohort (sample size unknown) of AIS patients who are Risser 0 and 1, a 50% risk of curve progression ≥5° was found in patients with curves 15-30°.[13]

In the US, physical therapy (PT) is not widely prescribed by medical doctors to manage AIS due to a lack of evidence supporting the concept that exercise alters the natural history of scoliosis.[2,14] However, virtually no research studies from the US have evaluated the effectiveness of PT exercises in reducing curve progression. Before the year 2000, the only study from the US to examine whether exercise alone influences curve progression was a

pilot study by physical therapists who found no difference between exercise and observation.[15] Exercises consisted of pelvic tilts, leg lifts, partial sit-ups, and a lateral trunk bend to the convex side of the curve for 1 year. Since only 4 out of 41 subjects reported compliance with the prescribed exercises, the authors could not draw any conclusions on the effectiveness of exercises curve progression in patients with mild curves.[15] Since the year 2000, several pilot studies from the United States implemented trunk rotational strength training to treat AIS, resulting in significant short-term strength gains and curve reduction.[7,16,17]

Implementing PT exercises to treat AIS is controversial but shows promise.[18,19] In contrast to the standard-of-care in the US, other countries (mostly in Europe) utilize PT consisting of scoliosis-specific exercises (SSE) to reduce curve progression and brace prescription, to enhance brace wear, and to improve quality-of-life.[4,14] SSE are viewed as highly effective conservative treatments of scoliosis that should be offered to patients with AIS.[4,20] The Schroth-based method is a proposed conservative plan which began in Germany in the 1920's and has recently been introduced in North America. The Schroth-based method consists of SSE that teach patients with scoliosis to hold themselves in a straighter posture. The physical therapy intervention based on Schroth principles shows promising results to prevent curve progression in patients with AIS.[14,21-26]

Recent, growing evidence supports the role of SSE methods to treat AIS. Systematic reviews (SR) conclude that exercises may be effective in reducing curve progression and reducing brace prescription.[14,19] The evidence quality in the aforementioned reviews is low, with only one randomized controlled trial (RCT) included. Many of the studies are retrospective and most lack controls. Since the most recent SR, two recently published RCTs found SSE effective in reducing curve progression. One RCT of SSE consisted of SEAS (Scientific Exercise Approach to Scoliosis) in mild AIS compared to PT exercises that were not scoliosis-specific.[21] A significantly improved Cobb angle in the SSE group was found immediately after treatment (at skeletal maturity) and at 1 year of follow-up post-treatment.[21] The second RCT compared three groups of patients with AIS curves 10-60º: a supervised outpatient Schroth group, unsupervised home exercise Schroth group and a control group.[22] At 24-weeks of follow-up, the Cobb angle improved in the supervised Schroth group but worsened in the other 2 groups.[22] Another prospective controlled cohort study of SSE (Scientific Exercises Approach to Scoliosis) in mild AIS curves reported that brace prescription and curve progression were both significantly reduced compared to PT exercises that were not scoliosis-specific after 1 year of follow-up.[27] Brace prescription in patients was 6.1% in the SSE group compared to 25.0% in the non-SSE group. Curves improved in 23.5% and worsened in 11.8% of the SSE group compared to the non-specific exercise group in which 11.1% improved and 13.9% worsened.[27] Furthermore, a study of SSE (Schroth method) in children with idiopathic scoliosis reported significantly reduced curve progression in patients receiving intensive scoliosis in-patient rehabilitation compared to untreated patients.[24] Another study of the Schroth method described 50 patients with AIS treated on an out-patient basis for 4 hours a day, 5 days a week, for 6 weeks, followed by continued therapy at home. The average Cobb angle decreased from 26.1° pre-treatment to 23.5° at 6 weeks, 19.3° at 6 months, and 17.9° at 1 year.[25]

The clinical management of patients with mild scoliosis remains controversial. Although various conservative strategies have been proposed, there is no consensus in the literature on the optimal treatment. High-quality evidence for the Schroth-based method is

lacking. Given the persisting uncertainty among medical professionals regarding the true potential of SSE, the purpose of this trial is to objectively and rigorously evaluate SSE compared to observation (standard-of-care). The results from this trial will provide much needed high-quality evidence regarding the feasibility and efficacy of SSE. In particular, this study will limit the inclusion criteria to skeletally immature patients with mild AIS curves. These patients are at highest risk of curve progression and have a greater potential for a meaningful effect with early intervention before their growth spurt and curve acceleration phase. Many families hope to avoid the need for bracewear.[8] A smaller curve is more flexible[28] and may be more amenable to changes from exercise, especially before spinal growth is complete. In particular, mechanical wedging of the immature disc and vertebral body may still be reversible.[29]

Concise Summary of Project:

This study will be a multi-center, dual-arm randomized control study evaluating skeletally immature patients with mild AIS curves. At six institutions, patients will be randomized into either the scoliosis-specific exercise (SSE) treatment arm or a control group. The SSE group will receive training in SSE, posture, and activities of daily living by physical therapists certified in Schroth-based exercise methods. The control group will not receive SSE instruction and will only be observed by their treating orthopaedic surgeon (which is considered the standard-of-care treatment method). Results will be compared after one year of treatment.

Study Procedures:

All patients with AIS meeting the following inclusion criteria will be eligible to participate in this trial: diagnosis of AIS; ages 10 to 17 years; major curve Cobb angles 12° to 24°; thoracolumbar, lumbar, or primary thoracic curve patterns; and Risser grade 0. Patients will be excluded according to the following exclusion criteria: scoliosis other than AIS, upper thoracic or double curve patterns, developmental disorders that prevent understanding and compliance with an exercise schedule, current or previous brace wear, and previous participation in a SSE program, previous spine surgery, inability to commit to performing a home exercise program for 15 minutes a day, 5 days a week, and inability to commit to attend at least 8 hours of PT within 6 months.

Patient medical records will be reviewed for eligibility. If a patient is deemed eligible for inclusion in the study, a member of the research team will meet with the patient and his or her family to review the consent form in a private medical exam room. The family will be given ample time to review the consent form and ask any questions. If a participant chooses to participate, a consent form will be signed by both the patient and the legal guardian prior to any investigational procedures occurring.

Once a consent form has been signed, patients will be randomly assigned by the TSRH on site statistician to one of the two following groups:

1) **Standardization of Physical Therapy:**

Physical therapists from Texas Scottish Rite Hospital, Boston Children's Hospital, Columbia University Medical Center, Norton Leatherman Spine Center, Johns Hopkins University, and Texas Children's Hospital who received training and certification in the Schroth-based (BSPTS) method have been recruited as members of the study team. Physical therapists at each institution will deliver a standardized exercise intervention.

2) Study Groups:

A) Scoliosis-Specific Exercise (SSE) Group

Each patient assigned to the SSE group will attend at least 8 hours of supervised exercise training led by a Schroth-based certified physical therapist over the course of 6 months. Ideally, patients will be seen for 7 sessions:

1) First session: 2 hours
2) Session 2: 1 hour (1 week later)
3) Session 3: 1 hour (1-2 weeks later)
4) Session 4: 1 hour (2-3 weeks after Session 3)
5) Session 5: 1 hour (3-4 weeks after Session 4)
6) Session 6: 1 hour (1-2 months after Session 5)
7) Session 7: 1 hour (1-2 months after Session 6)

The exact number of training sessions and time frame will be determined by the patient's ability to perform the exercises. All therapists will use a standardized exercise prescription algorithm and performance checklist similar to Dr. Parent's Schroth scoliosis exercise study. Patients will perform a home exercise program for 15 minutes a day, 5 days a week, when they can independently execute their prescribed exercises according to the following criteria:

1) Correctly move the pelvis so the body weight is over the base of support and neutral.

2) Accurately set up exercises per curve pattern in different positions. Exercises progress from static to dynamic and passive to active corrections.

3) Proficiently perform a minimum of 8 exercises integrating scoliosis-specific corrections which include auto-elongation to increase the spaces between the pelvis, vertebrae, and ribs. Various kinesthetic, mental imagery and proprioceptive strategies are used to further open concavities and depress convexities.

4) Perform scoliosis-specific corrections during activities of daily living. The overall goal is for patients to maintain a corrective posture throughout the day.

Patients will be asked to use a smartphone or tablet application (app) when performing the home exercise program which will be one method of tracking exercise adherence. A paper version of the app will be available to patients without access to a smartphone or tablet. Patients will also be sent electronically via email that is collected with a demographic intake form on the patient's initial visit, a weekly survey regarding home exercise adherence through a secure research database, the Research Electronic Data Capture (REDCap). An exercise log initialed by the guardian will help families keep track of their exercise adherence and serve as a way to monitor exercise adherence for patients who may not have a smartphone, tablet, or computer.

Patients will also be able to meet with the therapists at their return-to-clinic visits and every 2-3 months thereafter until their 1 year follow-up to assess performance quality, maintain motivation, and progress intensity. Patients may be withdrawn if they do not maintainexercise adherence within 6 months.

B) Control Group

Patients randomized to this group will continue receiving standard-of-care treatment from their orthopaedic physician which includes regularly scheduled clinic visits and observation. Observation consists of no treatment of the scoliosis, only routine clinical assessment by the orthopaedic surgeon to detect curve progression every 3 to 6 months.

Once all measurements have been collected at the patient's enrollment and one year follow-up, patients in this group will continue to be tracked through observation until skeletal maturity in order to record whether the patient experienced curve progression, was prescribed a brace, or proceeded to surgical treatment.

Patients randomized to the exercise group who never initiate physical therapy (do not attend even one session of physical therapy or begin a home exercise program) may be switched to the control group and observed in the same manner.

3) Outcome measures

Patients and their legal guardians will be asked to fill-out three self-reported outcome scores at their initial appointment and 1 year post the initiation of their participant in the study. The questionnaires to be completed include:

SRS-22:

The survey is a valid instrument for the assessment of the health related quality of life of patients treated for idiopathic scoliosis. This Heath Related Quality of Life (HRQL) questionnaire is designed to assess the effect that idiopathic scoliosis has on the patient in regards to pain, activity level, medications used, and satisfaction with treatment to date, and mental health status. The SRS-22 is one of the frequently tested scoliosis questionnaires and has been shown to have high levels of both reliability and validity.

Patient and parent survey:

A 3 question survey (one for patient, one for parent) that asks patients and parents questions regarding their/the child's attitudes toward SSE, their/their child's posture, and their/their child's scoliosis.

Once all measurements have been collected at the patient's enrollment at and one year follow-up, patients in this group will continue to be tracked through observation until skeletal maturity in order to record whether the patient experienced curve progression, was prescribed a braced, or proceeded to surgical treatment.

While the SSE training will be considered for research purposes only, all regularly scheduled clinic visits with the patients' treating physicians and x-rays will be considered standard-of-care.

Anticipated Results:

We predict that at one-year follow-up:

I. A multi-site prospective randomized controlled trial in skeletally immature participants with mild AIS curves at high risk of progression is feasible as evidenced by acceptable participant recruitment rates (≥18 participants per site after 1 year), treatment attendance (≥80%), and home exercise adherence .

II. Scoliosis-specific exercises will be effective and will demonstrate:
1) Significantly smaller change in curve magnitude
2) Significantly reduced incidence of curve progression
3) Significantly reduced incidence of brace prescription

Criteria for Inclusion of Subjects:

All patients diagnosed with Adolescent Idiopathic Scoliosis who meet the following inclusion criteria will be eligible to participate in this trial:

1) Age 10 to 17 years
2) Major curve Cobb angles of 12° to 24°
3) Compensatory curve should be less than 5° of the main curve (ex: 10° if the main curve is 15° or 15° if the main curve is 20°)
3) Risser Grade 0
4) Single thoracic, thoracolumbar, or lumbar curve patterns

Criteria for Exclusion of Subjects:

Patients will be excluded according to the following exclusion criteria:

1) Scoliosis other than AIS (congenital, neuromuscular, etc)
2) Upper thoracic or double curve patterns
3) Diagnosis of a developmental disorder that prevents understanding and compliance with an exercise schedule
4) Current or previous brace wear
5) Previous participation in a SSE program
6) Previous spine surgery
7) Patient inability to commit to attend at least 8 hours of PT within 6 months

Sources of Research Material:

After the consenting process, patient demographics will be collected from the patient chart. All demographic information, clinical, and radiographic measurements will be recorded after informed consent is obtained during the patient's appointments.

Texas Scottish Rite Hospital will serve as the lead institution for this study and will create/maintain a REDCap database to house all study data. All other participating sites will obtain IRB approval from their own institutions and will enter into a Data Use Agreement contract with Texas Scottish Rite Hospital in order to access the database and run data analysis. Only a limited data set will be shared between the institutions, and all patient information will be entered into the database in a de-identified fashion. The data to be shared between institutions includes:

- Patient study number (to be generated for each institution in a de-identified format through REDCap)
- Date patient is consented to the study
- Date physical therapy/control status is initiated
- Age
- Initial curve Cobb angles
- Risser sign
- De-identified x-ray images (AP and Lateral views)
- Height, Weight, and BMI
- Physical activity level
- Curve pattern (classification as thoracic, thoracolumbar, or lumbar)
- Schroth curve pattern
- Trunk rotation
- Triradiate status
- Menarchal status
- SRS-22
- 3 question parent survey about attitudes toward SSE, posture, and scoliosis
- 3 question patient survey about attitudes toward SSE, posture, and scoliosis
- Number of participants enrolled per month at each site
- Total number of participants enrolled after 1 year
- Number of hours (exercise session length and number of sessions) of physical therapy prescribed
- Total number of hours of physical therapy sessions attended
- Number of prescribed exercises completed from baseline to 1 year

The following PHI will be reviewed prior to the consenting process in order to determine a patient's eligibility. In the event that the patient does not consent to participate in the study, no PHI will be recorded. If the patient does consent to participate, PHI will be recorded and stored at each patient's home institution (PHI will not be shared with any outside institution, only de-identified information). All PHI will be destroyed at the conclusion of the study. This data includes:

- Name
- Medical Record Number
- Date of Birth
- Past Medical History
- Age
- Gender
- Ethnicity
- Radiographs

Recruitment Methods and Consenting Process:

Eligible patients will be screened based on the research coordinator's review of the scoliosis clinics at TSRH or from the recommendation of the patient's treating physician. The Investigators in this study will have the ability to suggest their own patients. Once deemed eligible, a member of the study team will meet with the patient and his or her legal guardians in order to review the consent form. The patient and family will be given ample time to review the consent form and ask any questions. In order to respect the privacy of potential patients, all consenting procedures will occur in a private clinic exam room. The research coordinator will explain to the family that their participation in the study is voluntarily and they will receive their participation (or lack of) in the study will not affect their standard treatment or relationship with their treating physician. Appropriate patient assent and caregiver consent will be obtained by a member of the study team prior to any study activities occurring (per IRB protocol) Patients meeting the study criteria who consent to participate will be randomly assigned to either the treatment or control arm in a 2:1 ratio. Patients will be assigned a group using a block-randomized, within site method. Patient assignment will be done by utilizing a computer-generated list and pre- sealed envelopes that will be distributed to the participating sites before enrollment. The list and envelopes will be generated by the statistician at Texas Scottish Rite Hospital.

If an eligible patient is missed in clinic whom the research team has an existing relationship with through a medical staff member on the study team, they may be contacted by a member of the research team via phone. The patient family will be identified and then told the following:

Schroth Ex-Trial Phone Solicitation Script:

I am a [researcher or physical therapist] from Scottish Rite Hospital for Children. I'm calling you because I wanted to tell you about an opportunity to participate in a study that is looking at what happens to small curves and whether physical therapy exercises can slow the progression of the curve. Patients in this study are assigned randomly, like a flip of a coin, to one of two groups: a group that does exercises and a group that does not do exercises but only receives standard observation by the physician. You have twice the chance of being assigned to the exercise group. The group that does exercises is asked to do exercises 15 minutes a day, 5 days per week for one year. If you decide to participate, whether you are

assigned to the exercises group or the observation group, there is a $200 stipend paid to you at the end of one year. You can choose to stop participating for any reason at any time, and this will not affect the way you are treated. We will also keep your health information confidential. Does this sound like something you are interested in getting more information about at your next visit?

If the family and patient are interested in participating in the study, the patient and family will be invited to return to the hospital for consent. The patient will then be consented according to the format listed above and be given ample time for questions and review. If the patient is not interested in participating in the study, they will be thanked for their time and a note will be made in the research documents that the patient declined participation.

Potential Risks:

Identifiable risks associated with participation in this study would be a potential loss of confidentiality and tired or sore muscles from the exercises.

Subject Safety and Data Monitoring

All information obtained through medical and radiographic records will be reviewed solely by the primary investigators, co-investigators, and other study team personnel. Publically reported information will be in the form of a statistical summary only: no information will be divulged that could be linked to a specific patient involved with the study. No patient information will be disclosed outside of the study team. The University of Texas Southwestern Medical Center Institutional Review Board may review the research information for auditing purposes. The team will keep the consents and study files in both a locked cabinet as well as electronic copies within the electronic study folder (this folder will be stored on password encrypted hard drive which may be accessed by members of the study team only). All other electronic data collected will be stored on a password protected electronic database with access limited to the study team.

Procedures to Maintain Confidentiality:

All normally used means for protecting patient confidentiality will be strictly followed. All consents, clinical and radiographic measurements, and patient demographics will be stored in a secure electronic database. This database will be password protected and access will be limited to only individuals on the study team. Data will be de-identified for each patient by assigning a Study ID in the database. All PHI and the unique study ID for each patient will be stored in a separate password-protected and encrypted spreadsheet that only members of the study team at TSRH will have access to. Only a statistical summary of the information will be published: at no time will any data published include information that can be linked to a study participant. All requirements for HIPAA compliance in regards to patient confidentiality will be followed and the University of Texas Southwestern Medical Center's Institutional Review Board will have the right to inspect all medical records related to this study for the purpose of ensuring patient confidentiality.

Biostatistics

Continuous variables will be summarized with means, standard deviations and ranges and analyzed using student t-tests; categorical variables will be summarized as counts and percentages and analyzed using Fischer's exact tests. Data will be checked for normality and equal variance.

Potential Benefits:

There are no direct benefits for patients choosing to participate in this study. However, in learning more about this population, the results of this research study may benefit others prescribed and treated with scoliosis specific exercises for their idiopathic scoliosis.

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