The University of New Mexico Health Sciences Center

Consent and Authorization to Participate in a Research Study

Key Information for Myofascial and Articular Treatment of Adolescent Idiopathic Scoliosis, Preliminary Feasibility Study

You are being invited to take part in a research study about treatment of Adolescent Idiopathic Scoliosis.

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THE STUDY?

You are being asked to participate in a research study conducted by Selina Silva, M.D., the Principal Investigator, and Lucy Whyte Ferguson, D.C. the Co-Investigator, and Dr. Silva's associates. You are asked to participate because we need to scientifically evaluate a new approach for treatment of scoliosis, to see if we can reduce or control progression of spinal curvature and rib prominence. 56 participants will take part in this study at the University of New Mexico. This study will be funded as a Clinical & Translational Science Center (CTSC) Pilot Project. It will take place over the course of one year, but each participant will take part in the study for 6 months. We will use measurements from x-rays taken as part of your regular care at Carrie Tingley Hospital at the beginning of the 6 months and at the end of the 6 months. Nurses will also measure the rib prominence at the beginning and at the end of 6 months. They will also give participants a questionnaire about pain and another about quality of life at the beginning and at the end of the 6 months. The 56 participants will be randomly divided into two groups: an active treatment group and a control group. Active Treatment Group: A group of 28 participants will receive treatment: 2 sessions of care procedures per month for 6 months that will involve gentle spinal manipulation, moist hot packs, and gentle muscle and soft tissue release treatments. These participants will also be provided with free heel lifts, butt lifts, and/or arch supports if these seem to help balance the spine. These participants will also be prescribed home exercise regimens and will be provided with free doorway bars to perform stretching exercises and small balls to perform rib cage mobilizing exercises.
Control Group: The other 28 participants in the study will form the control group or comparison group. These participants will not receive the new treatment being studied in this research project. They will undergo the same measurements at the beginning and 6 months later, but they will receive only the usual treatment that is recommended by their doctors at Carrie Tingley Orthopaedic Clinic including standard physical therapy and bracing if and when indicated. Even if you are not chosen (by chance, random) to be in the treatment group, your participation in this study is very important so that we can compare what happens in the two groups.

WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You may or may not directly benefit from being in this study. However, your participation may help us find out if the combination of treatments being tested can decrease or control progression of spinal curvatures and/or rib prominence. If you are n the active treatment group, it is possible that your rib prominence or spinal curvature could decrease or that they might not worsen as quickly as they would have if you had not participated. But no particular benefit can be predicted or assumed.

WHAT ARE THE KEY REASONS YOU MIGHT NOT CHOOSE TO VOLUNTEER FOR THIS STUDY?

Every effort will be made to protect the information you give us. However, there is a small risk of loss of privacy and/or confidentiality as there is with records kept in any medical facility. Treatments or

exercises might cause soreness for a day or two. Filling out questionnaires might cause some embarrassment. This level of risk is considered minor because there is a slight increase of risk compared to your normal life experience.

For a complete description of the risks, and description of alternate treatment/procedures, refer to the Detailed Consent.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to participate.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of this study is Selina Silva, MD of the University of New Mexico Health Sciences Center, Carrie Tingley Hospital Department of Orthopaedics. If you have any concerns regarding this study or you want to withdraw from the study, contact Jude MacMullen, Dr. Silva's Administrative Assistant, (505)272-5214.

If you have any questions or concerns about your rights as a volunteer in this research, contact staff in the University of New Mexico Health Sciences (UNMHSC) Human Research Review Committee (HRRC) between the business hours of 8AM and 5PM, Mountain Standard Time (MST), Monday-Friday at 505-272-1129.

DETAILED CONSENT

Version 11, 10/16/2020

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

Participants will be between ages 10 to 15 and have spinal curvatures that measure from 15 to 30 degrees and will not have completed bone growth. Pregnant individuals are not eligible to participate because of the safety risks of x-rays during pregnancy. If there is another cause of your spinal curvature, besides Adolescent Idiopathic Scoliosis, you will not be eligible for this study.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The research procedure measurements will be conducted at Carrie Tingley Hospital and you will need to go there twice for the measurements for this study and these visits may be combined with visits for your regular x-ray procedures every 6 months, or they may be separate visits. Data collection will take less than a half hour above and beyond the time it takes to have your regular x-rays performed. Those in the active treatment group will choose whether to receive their treatment in Albuquerque or in Taos/El Prado, NM. Treatment will take place twice per month for 6 months during the study. Each of those visits will take about 40 minutes to 1 hour. You will also be asked to perform home exercises for approximately 15 minutes at least 5 days per week over the 6 months.

WHAT WILL HAPPEN IF YOU PARTICIPATE?

Random assignment:

You will be randomly assigned to the control group or the treatment group. The identity of each child or adolescent who would qualify for this study is entered into a computer program that makes a random assignment of each potential subject to the active treatment group or the control group. This would be like shuffling a deck of cards and then picking a card by chance. The doctors and staff members will not be able to influence this process.

Control Group:

If you are in the control group, your scoliosis care will proceed as it would ordinarily at Carrie Tingley Childrens' Orthopaedic Clinic with x-rays every 6 months and prescription of any other standard care including bracing if necessary, physical therapy if recommended, with the following additions:

a. We will pull the curve measurements from your x-ray records and use this data in our study analysis.
b. You will be asked to fill out 2 questionnaires: a Pain Questionnaire, and a Quality of Life Questionnaire, at the beginning of the 6-month study, and at the end of the 6-month study.
c. A measurement will be made of the size of rib prominence, by using a scoliometer which is a tool that works like a level. This is a quick and non-invasive measurement. This measurement will be repeated at the end of the 6-month period.
d. You will not have access to the new care procedures being studied in this research project.

Active Treatment Group

If you are in the active treatment group, the same curve measurements from your x-ray records will be used as data for our study, you will be asked to fill out the same 2 questionnaires mentioned above, and rib prominence will also be measured, both at the beginning of the 6 month period of care and at the end of the 6 month period of care. As a member of the active treatment group, you will be asked to attend sessions that will last approximately 40 minutes to 1 hour, twice per month for 6 months and study care procedures will be provided during these sessions. (You will be able to choose the most convenient treatment location: Albuquerque or Taos/El Prado.)
Study Procedures will entail:

a. Gentle manipulation and mobilization of the thoracic spine, lumbar spine, and pelvis (upper and lower back), mobilization of the cervical (neck) spine if indicated (but no popping adjustments of the neck vertebrae) as well as manipulation or mobilization of the shoulder, hip, or any other joints involved.
b. Procedures will also involve gentle techniques to release tight muscles and fascia (tissue that surrounds muscles like gristle around a piece of meat) and connects large groups of muscles and joints, and moist heat (hydrocollator packs) will be used to relax the muscles and fascia.
c. The active treatment will also involve assessing whether a heel lift will help balance hip height while standing, and whether a lift (magazine) under one buttock will help balance the hip height while seated. These lifts will be provided and arch supports will probably also be provided.
d. The active treatment will also involve performing regular daily exercise (at least 5 days per week). These exercises are likely to include:
    1. Partial hanging, using a doorway bar (provided) 2-5 minutes once or twice per day.
    2. Lying on a ball (provided) next to the spine in the area of rib prominence 2-5 minutes, once per day.
    3. Postural exercises including reverse push-ups to strengthen middle back muscles and buttock strengthening exercises, 8 to 20 repetitions once or twice per day.

At the end of the study period, participants in the active treatment group will be able to keep the doorway bar, the ball, and any arch supports or heel lifts that have been provided.

Participants in the active treatment portion of this study will undergo a total of 9-12 hours of care procedures and 40 to 50 hours of home exercise over a period of 6 months.

Two or three participants in the active treatment group will be asked whether or not they will allow video filming of evaluation and treatment session 3 or 4 times during the study duration (2 at beginning, 1 in middle, and 1 at ending). Video will be altered so that the face of the participant will be blurred and unrecognizeable. These videos will be used to teach other health care providers how to evaluate and treat according to this protocol. Whether participants will or will not allow video filming of their evaluation and care procedures will not have any effect on their care in the active treatment group. Participants may review the video upon request. The purpose of the video is to document this treatment process, because many different modes of joint and soft tissue treatment are being combined to form a novel combined care protocol. Documenting examination and how care procedures are applied may help others to learn about this mode of care for scoliosis.

Please place an X to select one of the two responses below:

_____It is all right to ask me to have my examination and treatments videotaped.
_____I would rather not be asked to have my sessions videotaped.

How will my information be kept confidential?

Your name and other identifying information will be maintained in locked files, available only to authorized members of the research team, for the duration of the study. For any information entered into

a computer, the only identifier will be a unique study identification (ID) number. Any personal identifying information and any record linking that information to study ID numbers will be retained until the subject reaches age 22 and will then be destroyed.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

1. Research has shown that chiropractic care has minor risks for children and adolescents. The riskiest aspect of chiropractic care for children is that a chiropractor may rarely miss a serious diagnosis. This study minimizes such risk because participants will be medically monitored by Dr. Silva to the extent necessary. Any participants with symptoms beyond mild soreness that ends within 24 to 48 hours will be referred for medical evaluation.
2. Risk of soreness from treatment: The risks of the chiropractic care to children and adolescents and the risks of the massage or muscle and fascia release techniques are essentially the same: you may have some soreness for 24 to 48 hours after treatment. Again, if there are any symptoms that are worse than this, participants will be referred to Dr. Silva and her medical colleagues for evaluation.
3. Rare risks of chiropractic treatment: In adults, there is a risk of rib fracture or herniated disc from chiropractic manipulation. These results of chiropractic care have rarely if ever been reported in children, and in the cases where they did occur, it was concluded in research that the child had some pre-existing condition that made them more vulnerable to these risks such as reduced bone density. The manipulation procedures performed in this study will be delivered very gently, so such risks would be expected to be very rare.
4. Unknown risks or side effects: There is always a chance that any medical treatment can harm you. The research procedures in this study are no different. In addition to risks described in this consent, you may experience a previously unknown risk or side effect.
5. Risk of a data breach: There is always a chance that there could be a data breach even with all of the precautions we are taking. Your records are being kept in secure systems, and the data collected for the study for analysis will be coded when it is stored, so the data cannot be connected to you even if this system were breached. There is, however, no way to bring the risk of a data breach to zero.
6. Risk of embarrassment: It is possible that it will be embarrassing to you to answer questions about your pain and your quality of life. Hopefully the knowledge that your participation may help others will offset any discomfort or embarrassment you may feel.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

We do not know if you will get any benefit from participating in this study. However, some people have experienced decrease of curvature or reduction of rib prominence from the care procedures used in this study. But if you take part in this study, information learned may help others with your condition.

WHAT WILL IT COST YOU TO PARTICIPATE?

The cost of care procedures that the active treatment group will receive will be borne by the study. Exercise equipment and heel lifts, arch supports, and buttock supports, if indicated, will also be provided free of charge. Arch supports work best in supportive footwear and parents will be encouraged to provide such footwear. The doorway bar for partial hanging only works well when the participant's feet easily touch the floor in the doorway. For shorter participants, parents will need to provide some suitable platform. The step platforms used when performing step exercises are one alternative, but there are various ways to provide a safe platform and the costs will vary.

Subjects may incur costs for transportation, parking, and data charges for mobile devices. The study will reimburse for mileage at $.20/mile to offset the expenses for travel to the active treatment visits (not the examination visits at Carrie Tingley Orthopaedic Clinic that can often be combined with x-ray visits).

You and/or your insurance company, Medicare, or Medicaid will be responsible for the costs of all care and treatment that you would normally receive for any conditions you may have. These are costs that are considered medically necessary and will be part of the care you receive even if you do not take part in this study.

The University of New Mexico is not allowed to bill your insurance company, Medicare, or Medicaid for the medical procedures done strictly for research. For this reason, the cost of care procedures will be borne by the study and the heel lifts, arch supports, butt lifts if necessary and the exercise equipment will be provided free of charge.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

How will my information be kept confidential?

Your name and other identifying information will be maintained in locked files, available only to authorized members of the research team, for the duration of the study. For any information entered into a computer, the only identifier will be a unique study identification (ID) number. Any research records including personal identifying information and any record linking that information to study ID numbers will be retained until the participant reaches age 22 and then will be destroyed. Information resulting from this study will be used for research purposes and may be published; however, you will not be identified by name or any other identifying information in any publications.

Dr. Whyte Ferguson will be keeping regular treatment notes in her secure medical records system during the active treatment intervention period and, after the study is completed, she will transfer these notes to participants' secure UNM medical record.

Information from your participation in this study may be reviewed by CTSC for the Pilot Project, federal and state regulatory agencies, and by the UNM Human Research Review Committee (HRRC) which provides regulatory and ethical oversight of human research. There may be times when we are required by law to share your information. However, your name will not be used in any published reports about this study.

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave information, or what the information is. The REDCap system will be used for electronically share the data with the Biostatistician who will analyze the data. REDCap is a secure, web-based program to capture and store data at the University of New Mexico. Please be aware, while we make every effort to safeguard your data once received on servers via REDCap, given the nature of online surveys, as with anything involving the internet, we can never guarantee the confidentiality of the data while still en route to the server.

You should know there are some circumstances in which we may have to show your information to other people because of legal requirements. For example, the law may require us to share your information with the following agencies and for the following reasons:

- The law requires us to share your information with authorities if you report information about a child being abused
- If you pose a danger to yourself or someone else.
- A court or agencies, if you have a reportable disease or condition.

Authorities, if you report information about a child being abused, if you pose a danger to yourself or someone else. Dr. Silva, the Principal Investigator, is planning to obtain a Certificate of Confidentiality. We expect that a Certificate of Confidentiality from the National Institutes of Health will cover this research. The researchers with this Certificate of Confidentiality may not disclose or use the information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by the Certificate of Confidentiality cannot be disclosed to anyone who is not connected to the research. Except if there is a federal, state, or local law that requires disclosure, (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment, or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate of Confidentiality cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by University of New Mexico CTSC Pilot Awards Program which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study.

If you choose to leave the study early, data collected until that point will ordinarily remain in the study database and is not identified with you in any way in that database. You may, however, request that your data be removed from the database and it will be removed.

You may be removed from the study if (very unlikely):

- They find that your participation in the study is more risk than benefit to you.
- The agency paying for the study chooses to stop the study early for a number of scientific reasons.

IF YOU DON'T' WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

You may wish to seek other chiropractic services and other massage services, other than those employed in this study, to address pain associated with scoliosis and to see if these therapies can help the condition in other ways. Swimming and yoga may also be of some help. Using bracing to control progression of scoliosis has been proved helpful, and physical therapy exercise programs have also been shown to be of some help.

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEACH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

Because this study is of moderate risk, there is no reason that you cannot participate in another research study. You should, however, inform and discuss such participation with Dr. Silva and/or Dr. Whyte Ferguson.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call Dr. Silva or seek emergency care immediately. You should also call Dr. Silva or seek emergency care if you get hurt or sick during the period of this study, whether or not you think that your illness or pain is due to the study. Dr. Silva is providing medical oversight of this research and will determine what type of treatment, if any, is best for you at that time.

Your need of medical care due to this study is very unlikely due to the minor risk associated with study procedures.

It is important for you to understand that the University of New Mexico does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of New Mexico will not pay for any wages you may lose if you are harmed by this study.

WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?

For those in the control group, there will be $50 compensation for completing both the beginning and ending evaluations (questionnaires and rib prominence assessments), total compensation: $50 per person. The compensation will be in the form of a merchandise card. Travel will not be re-imbursed because it is assumed that these evaluations will be performed at the time of the regular 6-month visits where x-rays will likely also be performed, and these visits are part of the participants' regular care.

For those in the active treatment group, there will be a $100 compensation for completing the initial 3 months of care including the intake questionnaires and rib deformity measurements, and there will be another $100 compensation for completing the second 3 months of care including the final assessments which include the questionnaires and the rib prominence measurement (maximum total compensation: $200 per participant. The compensation will be in the form of merchandise cards. There will also be $.20/mile re-imbursement for travel expense for traveling to the treatment visits. Travel will not be re-imbursed for the initial and ending assessments that include the questionnaires and rib prominence measurements, because it is assumed that these assessments will be performed at the regular 6 month visits that are part of the standard care for scoliosis patients.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

You will be informed if the investigators learn new information that could change your mind about staying in the study. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESEARCH TESTS?

You can be given feedback about the results from your rib prominence measurements and questionnaire results done for purposes of this research, if you let the examiner know at the time that these measurements and questionnaires are administered. If you are in the active treatment group, Dr. Whyte Ferguson will be monitoring the changes in the degree of rib prominence as part of management of your care and planning your future care. After the study is completed and after data is entered and all blinded functions are complete, this information will transferred from Dr. Whyte Ferguson's clinical notes into your UNM medical record.

A description of this clinical trial will be available on Clinical Trials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WHAT ELSE DO YOU NEED TO KNOW?

If you volunteer to take part in this study, you will be one of about 56 people to do so.

Your information will NOT be used or shared for future research studies, even if we remove the identifiable information like your name, medical record number, or date of birth. **HIPAA AUTHORIZATION: Protected Health Information (PHI), health information connected to your identifying information is being used in the screening process.** Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for other research for which the use or disclosure of protected health information for which an authorization or opportunity to agree or object is not required by 45 CFR 164.512. If you become pregnant anytime during the study, you must inform the study doctor because x-rays cannot be performed during your pregnancy. Chiropractic care and soft tissue release techniques pose no known risk to the fetus.

You may not be allowed to participate in the research study if you do not sign this form. If you decide not to sign this form it will not affect your:

- Current or future healthcare at the University of New Mexico;
- Current or future payments to the University of New Mexico;
- Ability to enroll in any health plans (if applicable); or
- Eligibility for benefits (if applicable).

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of New Mexico Health Sciences Privacy Officer between the business hours of 8am and 5pm Mountain Standard Time, Monday-Friday at (505) 272-1493.

INFORMED CONSENT SIGNATURE PAGE

You are participating or are authorized to act on behalf of the participant. This consent includes the following:

- Key Information Page
- Detailed Consent

You will receive a copy of this consent form after it has been signed.

_____ _____

Signature of Parent/Legal Guardian **Date**

_____

Printed name of Parent/Legal Guardian

_____ _____

_____

Signature of other Parent/Legal Guardian **Date**

Name of Child Participant if age 10-11

I have witnessed the informed consent process. This informed consent form was verbally reviewed with the subject.

_____ _____

Printed name of [authorized] person obtaining informed consent/HIPAA Authorization

Date

_____

Signature of [authorized] person obtaining informed consent/HIPAA Authorization

---

Child Assent (12-15 years old)
You are making a decision whether to participate (or to have your child participate) in this study.

_____
Name of Child Participant Date

_____
Signature of Child Participant

_____
Name of Parent or Child's Legal Guardian Date

_____
Signature of Parent or Child's Legal Guardian