

**Project Title:** Neuromuscular control of upright posture in adolescents with and without idiopathic scoliosis

**HREC Number:** HREC/20/QCHQ/61556

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Your child has been invited to be in this research study because they have been identified as an **adolescent without scoliosis**.

Thank you for taking the time to read this **Parent/Guardian Information Statement and Consent Form**. We would like to ask your child to participate in a **research project** that is explained below.

**It is ok to say, "no thanks, I don't want to be involved"**

### **What is an Information Statement?**

These pages tell you about all the steps and procedures of the project, so that you can decide whether you would like your child to take part. Before you decide, you can ask any questions you have about the project. You may want to talk about the project with your family, friends or health care worker.

### **Important things to know**

- It is your choice whether or not your child can take part in the research. You do not have to agree if you do not want to.
- If you decide you do not want your child to take part, it will not affect the treatment and care your child receives through Children's Health Queensland

If you would like your child to take part in the research project, please sign the consent form provided by the Researcher. By signing the consent form, you are telling us that you:

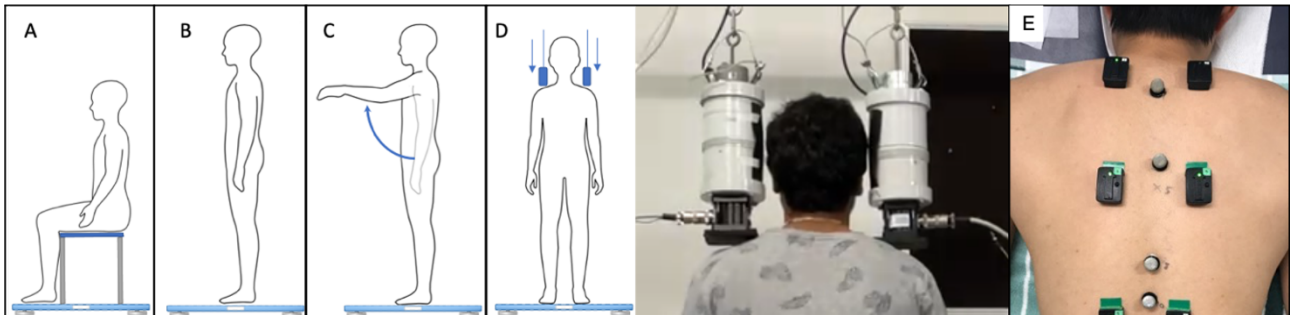
- understand what you have read
- had a chance to ask questions and received satisfactory answers
- consent to your child taking part in the project

We will give you a copy of this information and consent form to keep.

### **1. What is the research project about?**

This study will compare the postural control of the spine in teenagers with and without idiopathic scoliosis (sideways curve of the spine). The first part of the study focuses on how the back and muscles of the spine respond when performing a variety of simple movement tasks. The second part of the study looks at how their muscle responses change after the posture of their shoulders, trunk and hips has been adjusted by the lead researcher. The third part of the study allows us to determine if the size and quality of the muscles that control the spine are altered in teenagers with scoliosis. This involves our participants having an MRI (a scan of the back muscles).

**For Part 1 and 2:** The simple movement tasks that will be performed are: A) quiet sitting, B) quiet standing, C) raising both arms quickly and D) sudden loading onto the shoulders of small weights. While your child completes these tasks, a 3-D motion camera will be tracking the movement of reflective markers adhered to your child's back and hips (grey circles in E). Recording electrodes will also be placed on their back, abdomen and hips to record muscle activity (black boxes in E). Neither the reflective markers nor surface electrodes provide any *stimulus*, they are just like applying a sticker to the body. This allows us to measure how far the participant moves, how stiff their body is through the movement(s), as well as the timing and amplitude of their muscle activity.



Your child will need to attend one or two testing session, that will last approximately 3 hours. Tests will be conducted at The University of Queensland, St Lucia Campus, at the Laboratory for Motor Control and Pain Research in the School of Biomedical Sciences: Otto Hirschfield Building, Room 307.

For **Part 3:** A Magnetic Resonance Image (MRI) scan, which has no ionising radiation and uses a powerful magnet and radio waves, will take clear and detailed pictures of the participant's back to enable us to measure muscle volume and quality. The MRI will also be done at The University of Queensland, St Lucia Campus, and should take less than 1 hour. This facility is very close to the lab where the other measures will be taken. A researcher will take you there before the lab testing.



A map with directions will be provided for your convenience.

## 2. What does this research project involve?

- For participants without scoliosis, we will be asking some basic information regarding their general health, including pain and physical activity.
- For the MRI procedure, participants will be asked to change into a gown and cotton trousers (keeping on underwear). All jewellery and body piercings are required to be removed for the scan. Participants will need to lie still on their back during the scan. You will be able to see your child through a window and talk to them through a speaker.
- The MRI scan is pain-free but does produce loud, knocking noises during the scan. It is important to note that some people are scared of being in small places (claustrophobia). If you think your child might be claustrophobic, the MRI part of the study may not be suitable. It may be possible to still take part in all other aspects of the study, excluding the MRI. Please discuss this with the researchers.
- Participants will need to be dressed in clothing such as athletic shorts and non-racerback sports bra/crop tops (for females) for the movement testing tasks as their back will need to be exposed for the marker/electrode placement and to allow observation of the spine. The lab space will be enclosed with curtains for privacy. It is ideal if sports/crop tops contain no metal hooks or loops so that they may be worn inside the MRI scan also.
- Ultrasound imaging will be used to accurately locate the positions for the reflective markers and recording electrodes. There is no sensation felt from ultrasound (except that the contact gel used can be a little cold). The reflective markers and surface electrodes (image E) are applied with double sided tape, which is easily removed afterwards.

- Sitting on a wooden stool, 10% of body weight will be in light contact at each shoulder, then suddenly released to fully rest on the participant's shoulders. This will be repeated 20-30 times with a short rest between each repetition.
- ~~While standing on a wide metal plate, 10% of body weight will be in light contact at each shoulder, then suddenly released to fully rest on the participant's shoulders. This will be repeated 20-30 times with a short rest between each repetition.~~
- The lead researcher will guide the participants to adjust the posture of the shoulders, trunk and hips. After which, the weight will again be slowly lowered or suddenly released to fully rest on the participant's shoulders again around 20-30 times, with a short rest break between each repetition.
- Activity of the muscle will be also be recorded during the following tasks: (i) quiet standing, (ii) quiet sitting, and (iii) doing a quick arm raise in standing.
- Photos and videos will be taken during testing which may be used in presentations and/or publications about this research project. Any identifying features will be appropriately blurred/blacked-out or cropped from images.
- The participants will perform three to five repetitions of short (3-5 seconds) maximal contractions of their shoulder, back, abdomen and hip muscles. These contractions should feel like they require a lot of effort but should cause no discomfort. Straps may be used to support the body region(s) during these contractions. Verbal encouragement may also be used (like at a sporting event – go, go, go, hard as you can!).
- A part of the project involves some of our participants undergoing the test procedures again on a separate day to see if the data is repeatable. If you and your child have volunteered for a second testing session, you will be required to return within two weeks.

### **3. What are the possible benefits for my child and other people in the future?**

This research project is not a treatment program, so there is not expected to be any direct benefit to the participants from their involvement. However, on completion of this study we expect the following benefits:

- Improved understanding of the how the muscular control of people with scoliosis differs from those without scoliosis
- Better understanding of how scoliosis affects postural balance and postural responses

### **4. What are the possible risks, side-effects, discomforts and/or inconveniences?**

The studies are designed to expose your child to the minimum possible risk, inconvenience and discomfort.

- There is no ionizing radiation used for MRI. It uses a powerful magnet, so you will need to complete an MRI Safety Questionnaire prior to the scan to ensure that the scan will be performed safely (dental braces are OK).
- The adhesive used for the markers and electrodes is hypoallergenic, but if any discomfort occurs, it can be removed immediately. Please tell the researchers if you believe that your child has an allergy to tapes/bandaids etc.
- The small load released onto the shoulders is controlled and is not expected to cause any discomfort.
- The maximum contraction of muscles may cause some feelings of stiffness/muscle soreness either after the test, or the following day. This is normal and is commonly experienced after a bout of unaccustomed exercise (i.e. after the first game of football for the season), and will subside without treatment.
- The estimated duration of a testing of movement control tasks session is 3 hours. The participant is allowed to take as many rest breaks as needed during this time.

### **5. What if I wish to withdraw from the research project?**

Your decision whether or not your child will participate will not prejudice their future relations with the Queensland Children's Hospital, Brisbane. If you decide your child will participate, you are free to withdraw your consent and to discontinue participation at any time. The decision to withdraw from the study will not affect your child's medical treatment or their relationship with the people treating them.

If you do decide to withdraw your child from this study, we would like to use any data already collected in our analyses. However, you may request to have their data withdrawn from the project altogether by contacting the researchers. Their data will be withdrawn from the study on request up until the data has been submitted for publication.

**6. What will be done to make sure my child's information is confidential?**

Your child's records relating to this study and any other information received will be kept strictly confidential. Medical information will not be divulged to any third parties. Any publications will not allow identification of any individual, and data will be identified and stored under a numerical code. All electronic files that contain personal information will be password protected. Your signed consent form will be kept in a locked cabinet (Otto Hirschfield Building, University of Queensland).

**7. How can I obtain the results of this study?**

You may obtain outcome information (such as journal publication) if you indicate that you would like to receive this, and provide your email address on the Participant Consent Form.

**8. What happens if there is an unintentional discovery of a health-related problem?**

There is almost no chance that there will be any clinical finding that could be considered actionable, but should this occur, we are unable to provide any medical treatment or advice. You will be referred to your General Practitioner.

**9. Consent**

After reading and understanding this Information Sheet and having any questions answered to your satisfaction, please sign the attached Consent Form. All study participants will be provided with a signed and dated copy of the Participant Information Sheet and Consent Form for their personal records.

**10. Who should I contact for more information?**

If you would like more information about the project or if you need to speak to a member of the research team, please contact:

**A/Prof Kylie Tucker**, email: [k.tucker1@uq.edu.au](mailto:k.tucker1@uq.edu.au) or mobile: 0414 839 402

**Ms Phoebe Ng**, email: [phoebe.ng@uqconnect.edu.au](mailto:phoebe.ng@uqconnect.edu.au)

**HREC Information:**

The Children's Health Queensland Hospital and Health Service Human Research Ethics Committee (HREC) has approved this study.

If you have any concerns and/or complaints about the project, the way it is being conducted or your child's rights as a research participant, and would like to speak to someone independent of the project, please contact the CHQ HREC Coordinator by phone: **3069 7002** or email: [chqethics@health.qld.gov.au](mailto:chqethics@health.qld.gov.au).

Alternatively, you may contact the University of Queensland HREC Coordinator by phone: **3443 1656** or email: [humanethics@research.uq.edu.au](mailto:humanethics@research.uq.edu.au).