

Parental Information and Consent Form

Study Title: Saskatchewan Bone Strength Development Study (BSDS)

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INTRODUCTION

Your child is invited to take part in this research study because we want to assess bone properties, muscle strength, and physical activity in children with type 1 diabetes and typically developing (healthy) children. We are also studying how physical activity, nutritional and hormonal measures are associated to muscle and bone properties and development in children with type 1 diabetes and whether these relationships differ from those we observe in typically developing children.

Your child's participation is voluntary. It is up to you to decide whether or not you wish to have your child to participate. If you wish to have your child to participate, you will be asked to sign this form. If you decide to have your child to take part in this study, you are still free to withdraw your child at any time without giving any reason for your decision.

If you do not wish to have your child participate, you will not lose any benefits within the Health Authority or University of Saskatchewan to which you are entitled to or are presently receiving. It will not affect your relationship with your physician, researchers or anyone involved in the study.

Please take the time to read the following information carefully. You can ask the researcher to explain any words or information that you do not understand. You may ask as many questions as you need. Please feel free to discuss this with your family, friends or family physician before you decide.

WHO IS CONDUCTING THE STUDY?

Funding for this study comes from research grants. These grants will reimburse costs related to data collection and analysis. In addition, these grants will provide funds for small meals for participants. Neither the institution nor any of the investigators or staff will receive any financial benefit for conducting this study.

WHY IS THE STUDY BEING DONE?

This study is being done because we want to better understand the underlying reasons for higher fracture risk in children with type 1 diabetes compared to typically developing children. Previous research has demonstrated that children with type 1 diabetes have lower bone mineral density and muscle mass. However, it is poorly understood how physical activity levels, muscle force production as well as bone microarchitecture and metabolism in children with type 1 diabetes differ from typically developing children. This study will contribute to the understanding of bone and muscle health in children with type 1 diabetes.

Please note that the research sites, located at the University of Saskatchewan, Children's summer camp and the Diabetes Clinic, are under the jurisdiction of the Saskatchewan Health Authority. We are taking all safety precautions to reduce the risk of the spread of COVID-19 and expect you to follow public health directives as well.

WHO CAN PARTICIPATE IN THIS STUDY?

To be eligible to participate in this study your child needs to be between the ages of 6 and 15 years, either typically developing (healthy) or diagnosed with type 1 diabetes.

WHAT DOES THE STUDY INVOLVE?

The total time requirement for participation is 2 hours for the baseline measurement and 2 hours for the follow-up measurement after 1 year.

A. Testing Procedure:

1. You will receive two questionnaires in your recruitment package. These questionnaires are to be completed before your arrival, but can be completed after you arrive if necessary. The first questionnaire is a seven-day-recall, Physical Activity Questionnaire for Children that asks about your child's physical activity in the past seven days. In addition to the past seven days, you will be asked to specify the amount of participation (times per year) in activities/sports that load the forearm (such as gymnastics, wrestling, or baseball) our child has participated in. The second questionnaire is regarding background information, such as your child's sex, gender, handedness and fracture history. The questions related to musculoskeletal health (for example, previous fracture history, medication use, such as corticosteroids that may affect bone health, and other disease or drugs affecting bone and muscle health).
2. The two questionnaires will be collected at the time of data collection at the College of Kinesiology, University of Saskatchewan. In the event that a questionnaire(s) is (are) not returned or fully completed, a research assistant may contact you to conduct a phone interview. You are not required to answer any questions that you do not feel comfortable answering. Please see the contact information sheet at the end of this consent form.

Measurements at College of Kinesiology:

1. Your child can wear clean athletic shorts, t-shirt or tank top and running shoes during measurement session.
2. Your child's height, weight, and limb lengths will be measured upon arrival.
3. Your child's dominant forearm (the arm your child uses to perform daily tasks e.g. writing) will be scanned with peripheral Quantitative Computed Tomography (pQCT), a bone imaging tool, at two sites: one scan at the wrist and one scan from the forearm. Your child's dominant lower leg will be scanned at two sites: one scan at the ankle and one scan from the lower leg. A total of 4 scans (two sets) will be performed with pQCT with each scan set taking approximately 2-4 minutes.
4. Your child's dominant wrist and ankle will be scanned with a high-resolution pQCT (HR-pQCT). A total of two scans will be performed with HR-pQCT with each scan taking approximately 3 minutes for each site.
5. Your child's hand strength will be measured using a special device called a handheld dynamometer. Your child will be asked to squeeze this device for 3 seconds.
6. Your child's upper arm strength and endurance will be assessed by two push-up tests with their hands and toes using two different hand positions (four tests total).
 - a. Your child's movements during the push-ups will be recorded by a specialized motion capture system which tracks small plastic reflective spheres attached to your child's body using hypoallergenic tape. The acceleration of your child's movement will also be measured using accelerometers placed on their left forearm and right hip.
 - b. Your child will be instructed to perform as many push-ups as they can with their hands positioned on a special device designed to measure the force of each push-up (force plate) with two different hand positions.
 - c. Your child will also perform three maximal push-ups lowering themselves to the ground and pushing themselves back up as fast and as hard as they can with two different hand positions.
7. Your child's forearm strength will also be assessed using donkey kicks. Your child will be asked to start with both hands positioned on the force plate and to kick their legs as high as they can, similar to the starting movement of a handstand. Your child will be asked to perform this movement three times, with a short rest period between each trial.
8. Your child's leg strength and power will be measured using two jumping tests.
 - a. The first jumping test is a standing long jump, in which your child will be asked to jump as far forward as they can. Your child will be asked to perform this jump three times.

- b. The second jumping test is a countermovement jump test. Your child will be asked to jump up as high as possible using their whole body. Your child will be asked to perform this jump three times.
9. Your child will be fitted with an activity monitor (Actigraph accelerometer), which is a small device that is worn on your child's right hip for seven days. This monitor will record your child's physical activity levels during the week. An instruction/recording sheet will be sent home with each child. We ask you to mail the accelerometer and recording sheet seven days after the testing session (in the prepaid envelope provided to you).
10. Your child will also receive a third and final questionnaire, which details nutritional intake. Your child might require your help in filling out this questionnaire.

A small meal is provided from Subway during the course of this testing period. Please see the menu option form at the end of this questionnaire. As a thank you for participation, your child will receive a minimum of 5 tickets to Saskatoon Indoor Leisure Centres at the end of testing session. There is an optional photo taking for your children during this study for publication purpose. Your children's face will be censored and will not be recognized by public. You can opt in or out this option on attached consent and assent forms.

If your child wish to participate in study measures *at the Saskatchewan Children's Camp during the summer*, they will be the same as above with one exception. Bone scanning with high resolution of pQCT (#4 above) will not be performed at the camp. Participants will have an opportunity to have these two scans at the College of Kinesiology after the camp.

Measurements at the Diabetes Clinic:

As part of your standard of care you will visit the Diabetes Clinic to provide blood samples. The research team would like to collect 5 mL (1 tsp) of blood to evaluate your child's hormones and markers related to bone growth and development. The researchers will do their best to arrange this blood draw at the same time as your routine blood draw to eliminate the need for an additional needle poke. The researchers also ask for your permission to collect your child's records of height and weight from the Diabetes Clinic visits and any available glucose monitoring reports from the annual appointments since the initial visit.

You are welcome to attend and watch the testing sessions. However, it is not mandatory that you attend the testing with your child. Your child will always be accompanied by an adult research assistant until you come to pick up your child.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

If you choose to have your child participate in this study, they may not directly benefit. However, you will be provided with images of the bones and muscles scanned and results from the performance measures, should you request them. This information is used to

answer the research question and cannot be used for diagnostic purposes of bone or muscle health. Knowledge gained from this study may provide essential information that can be applied to the therapy of children with or without type 1 diabetes to optimize bone strength development and fracture prevention.

ARE THERE POSSIBLE RISKS AND DISCOMFORTS?

If you choose to have your child participate in this study, there is a minor risk that involves exposure to small amounts of radiation during the pQCT and HR-pQCT scans. The total amount of radiation your child will be exposed to is very low, an average less than 10 microSv total for both scanning methods. If we need to repeat a scan due to movement artifact we will do so only once. The maximum effective dose of radiation will be less than 15 microSv. This dose is comparable to the amount of background radiation a person receives in 1-2 days from naturally occurring sources in Saskatchewan. For reference, a cross-country flight could expose a person to about 30 microSv of radiation (<http://www.hc-sc.gc.ca/hc-ps/ed-ud/respond/nuclea/measurements-measures-eng.php>). There is also minor pain when completing the blood test. Finally, there is a risk of the inadvertent release of your personal health information. The researchers have taken measures to protect the privacy of your information and this risk is considered very small.

WHAT IF NEW INFORMATION BECOMES AVAILABLE THAT MAY AFFECT MY DECISION TO PARTICIPATE?

Researchers and research assistants will provide you with an image, description of your child's bone scans after measurement. If there is any information in the scan or other measures that warrants medical attention, study doctor (Dr. Nour) will contact your family physician.

WHAT HAPPENS IF I DECIDE TO WITHDRAW MY CHILD?

Your decision to have your child participate in this research is voluntary. You may withdraw your child from the study at any time. You do not have to provide a reason. There will be no penalty or loss of benefits if you choose to withdraw your child. Your future relationships within the Saskatchewan's Pediatric Endocrinology and Diabetes team, University of Saskatchewan and with your medical practitioner will not be affected.

If you choose to have your child enter the study and then decide to withdraw your child later, all data collected about your child during enrolment will be retained for analysis.

WILL I BE INFORMED OF THE RESULTS OF THIS STUDY?

After your child's participation, you will receive the images of your child's bones and muscles and the results of your child's grip strength and jump tests in comparison to reference data will be emailed to you if you wish to receive this information. Reports addressing study objectives will also be emailed to you if you wish to receive this information.

WHAT WILL THIS STUDY COST ME?

You will not be charged for any research-related procedures. You will not be paid for participating in this study. You will not receive any financial benefits for being in this study, or as a result of data obtained from research conducted under this study. Your parking during the measurements will be covered and your child will receive a small meal from Subway and minimum of 5 tickets to Saskatoon Indoor Leisure Centres.

WHAT HAPPENS IF SOMETHING GOES WRONG?

If an adverse event related to the study occurs, trained staff will be available throughout the conduct of the study and will respond immediately. Necessary medical treatment will be made available at no additional cost to you. By signing this document, you do not waive any of your legal rights.

WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?

In Saskatchewan, The *Health Information Protection Act (HIPA)* defines how the privacy of your child's personal health information must be maintained so that their privacy will be respected. Your child's confidentiality will be respected. No information that discloses your child's identity will be released or published without your specific consent to the disclosure. A special number (which will not include their initials, date of birth, name or address) will be used. The same number will be used for labeling all forms and tubes related to blood collection, analysis and storage. Blood samples will be analyzed and stored at the Western College of Veterinary Medicine (Dr. Unniappan Lab) for 5 years. Your child's study records, including their questionnaires and scan information will be kept for 5 years in a locked cabinet in the testing labs with restricted access at University of Saskatchewan. Your child's information and results of the study will also be recorded in a computer database. Only the investigators and research assistants will have access to these study records. However, research records, including history of diagnosis of type 1 diabetes, bone fracture, disease or medication which influence bone or joint health, identifying your child may be inspected in the presence of Dr. Kontulainen or her designate by a representative of the University of Saskatchewan Research Ethics Board for the purpose of monitoring the research. However, no records, which identify your child by name or initials, will be allowed to leave Dr. Kontulainen's research lab. The results of this study may be published or presented in a scientific meeting, but your child's identity will not be disclosed.

WHO DO I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?

If you have any questions or desire further information about this study before or during participation, you can contact Dr. Saija Kontulainen at (306) 966-1077 or by e-mail at saija.kontulainen@usask.ca.

If you have any concerns about your child's right as a research participant and/or your experiences while participating in this study, contact the Chair of the University of Saskatchewan Research Ethics Board, at (306) 966-2975 (out of town calls 1-888-966-2975). The Research Ethics Board is a group of individuals (scientists, physicians, ethicists, lawyers, and members of the community) that provide an independent review of human research studies. This study has been reviewed and approved on ethical grounds by the University of Saskatchewan Research Ethics Board.

ARE THERE ADDITIONAL TESTING OPPORTUNITIES?

Your child is also invited to participate in the one-year follow-up portion of this study, which is also one-time visit. What this means is that we require some participants to return to the College of Kinesiology one year after the original testing date to repeat the testing procedure so that we can assess muscle and bone growth and development in one year and compare with typically developing children. All testing procedures will be the same as the original baseline testing, which will take about 2 hours. Please indicate your interest in the one-year follow-up of the study on the attached consent and assent forms.

CONSENT TO PARTICIPATE

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- I have read (or someone has read to me) the information in this consent form
- I understand the purpose, procedures and possible risks and benefits of the study
- I was given sufficient time to think about it
- I had the opportunity to ask questions and have received satisfactory answers
- I understand that I am free to withdraw my child from this study at any time for any reason and the decision to stop taking part will not affect my future relationships
- I give permission to the use and disclosure of my child's de-identified information collected for the research purposes described in this form
- I understand that by signing this document I do not waive any of mine or my child's legal rights
- I will be given a signed copy of this consent form

I agree to have my child participate in this study.

Printed Name of Child Participant: _____

Printed Name of Parent/Guardian: _____

Signature of Parent/Guardian: _____

Date: (DD/MM/YY): ____/____/____

Printed Name of Person Obtaining Consent: _____

Signature of Person Obtaining Consent: _____

Date: (DD/MM/YY): ____/____/____

I agree to have my child's photo taken for the purpose of being published with the data collected. My child's face will be censored and unrecognizable to the public.

Yes

No

I would like to receive the results of my child's results and study findings.

Yes, email: _____

No

My child has read and understands the assent form.

Yes

No