

PARENT INFORMATION SHEET
Perth Children's Hospital

**Validation of Physical Activity Assessment Questionnaires for youth with
Type 1 Diabetes**

We know that exercise is beneficial for physical and mental health for all people, and this is especially true for people with Type 1 Diabetes (T1D). A key goal for us in the diabetes clinic is to be able to give the best guidance and support for our patients with T1D to exercise for health and fitness. But, first we need to know how to measure physical activity, and to do that we need a reliable tool, or questionnaire. There are questionnaires for general use, but we don't know if these are accurate in youth with T1D. Therefore, this study aims to identify a questionnaire that we can use in clinic to quantify and understand the types of activity our youth do. This will also help to generate a more complete picture of overall health. With this knowledge, we can also help our youth to increase activity and to do so safely. We would also like to explore to see if there are any relationships between amount of physical activity and blood glucose control.

Why are we contacting your child?

We are asking your child to take part in this study because they have T1D and are aged between 8 and 17 years old.

Who is carrying out the study?

This study is being run by Dr Craig Taplin of the Department of Endocrinology and Diabetes. He will be assisted in this study by research staff from both Perth Children's Hospital and the Telethon Kids Institute.

What will the study tell us?

This study will allow us to identify a standard, reliable questionnaire that can accurately identify and measure physical activity in youth with T1D.

Does your child have to take part in this study?

Participation is entirely optional. Your child's clinical care will remain the same whether they decide to participate or not. If they decide to take part and then change their mind, they are free to pull out at any time. Not doing this study will not affect their treatment by their clinic team, or any service at PCH.

What will your child be asked to do if they decide to take part in this study?

If your child chooses to do this study, you will be asked to meet with the study team twice. One of these times can be scheduled with a clinic visit. At the first visit the study team will set your child up with an accelerometer. The accelerometer is a small device that your child will wear on a strap around their waist to measure physical activity. Your child will need to wear the accelerometer for the next 7 days.

At the end of the 7 days your child will be asked to complete three different questionnaires regarding their physical activity and return the accelerometer to the study team. This visit should take no more than 15 minutes.

If your child is already wearing Continuous Glucose Monitors (CGM), we would also like to review their CGM data to explore if we can see any links between physical activity components, such as frequency, duration and intensity and blood glucose control. Your child does not need to do anything additional for this component of the study. We will only review data that is already being collected.

If we are unable to complete face to face visits, we will do this study remotely. This means, you will not need to come to PCH for visits. If your child chooses to do this study, we will arrange a time to speak with you both to talk through what your child will need to do in the study, and make sure we answer any questions you may have. Once this is done, we will send you a link to sign the consent form online and arrange to send the accelerometer to you – either by post, or a research team member may deliver it to your house. A follow-up phone call will be arranged with you to ensure that the accelerometer is fitted correctly on your child and for you to ask any questions. At the end of the seven-day wear, we will send you the links for your child to complete the questionnaires online. This should take no more than 15 minutes. We will also arrange for you to return the accelerometer, again either by post, or a research team member may collect it from your house.

Is there likely to be a benefit to your child?

A possible benefit is that this could increase your child's awareness of how active they usually are, and on which days/waking times they are most inactive.

Is there likely to be a benefit to other people in the future?

The results from this study will be important in identifying the best way of identifying and measuring physical activity levels in youth with T1D, without the use of physical activity tracking devices/apps. This will allow us to develop, together with the children/adolescents and their parents, education plans about exercising safely and optimally. This will play a role in improving the standard of care for patients with T1D and improving or maintaining their long-term health.

What are the possible risks and/or side effects?

There are no significant risks in your child being involved in this study. We will not be asking your child to do anything different for this study. They will continue with their usual activity and life-style, and their usual diabetes management. They may find wearing the accelerometer slightly inconvenient, but it is small and light and easy to wear.

What are the possible discomforts and/or inconveniences?

This study only involves the collection of levels and amounts of physical activity, by your child using an accelerometer and filling out questionnaires. Your child may find wearing the accelerometer inconvenient. They can withdraw from the study at any time within the seven day study period if they wish.

Where is my information kept?

Your child's study records will be kept in a locked cabinet in the Diabetes Service office at PCH, and on password-protected online hospital databases. Only the study team will have access to these records.

What about your child's privacy?

Your child's privacy will be maintained at all times. Any presentation or publications arising from this study will not identify your child by name. All data will be presented as unidentifiable grouped data.

Only the investigators and the study team will be able to link your results to your child. However, your child's involvement in this research study will be recorded in the clinic database, and their health records. This is a standard practice of the Diabetes Service.

Who has approved the study?

The Child and Adolescent Health Service Human Research Ethics Committee has approved this study. This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)* produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies

Who to contact for more information about this study?

If you would like any more information about this study, please contact:

Name: Dr Craig Taplin
Contact no: (08) 6456 5897
Email: diabetes.research@health.wa.gov.au

Who to contact if you have any concerns about the organisation or running of the study?

If you have any concerns or complaints regarding this study, you can contact the Executive Director of Medical Services at PCH (Telephone No: (08) 6456 2222). Your concerns will be drawn to the attention of the Ethics Committee who is monitoring the study.

What to do next if your child would like to take part in this research

Please sign the attached consent form, and contact either Dr Taplin (6456 5897; craig.taplin@health.wa.gov.au), or Dr Shaun Teo (PhD) (6456 8078; shaun.teo@health.wa.gov.au) to register your interest for the study.

THANK YOU FOR YOUR CONSIDERATION OF THIS STUDY

PARENT CONSENT FORM
Perth Children's Hospital

PLEASE NOTE THAT PARTICIPATION IN RESEARCH STUDIES IS VOLUNTARY AND SUBJECTS CAN WITHDRAW AT ANY TIME WITH NO IMPACT ON CURRENT OR FUTURE CARE.

I have read the information
Given Names Surname

explaining the study entitled:

Validation of Physical Activity Assessment Questionnaires for youth with Type 1 Diabetes

I have read the Parent Information for this study, and understood the information given to me. Any questions I have asked have been answered to my satisfaction.

I consent to my child's participation in this study.

I understand that my child may withdraw from the study at any stage.

I agree that research data gathered from the results of this study may be published, provided that my child is not identified by name.

I understand that some of the staff working on this study are employed by the Diabetes Research Team which is part of the Telethon Kids Institute and are not employed by the government of Western Australia. These staff are working with the approval of the Child and Adolescent Health Service (CAHS) and will follow all the required policies and procedures and will safeguard the confidentiality of the participant information.

Name of Parent (please print) _____

Name of Participant (please print) _____

Signature of Parent _____

Date _____

Declaration by consenting investigator

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of investigator (please print) _____

Signature _____

Date _____