MATURE MINOR PARTICIPANT INFORMATION AND CONSENT FORM
Perth Children´s Hospital

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

Why are we doing the study?
We know that exercise is good for both physical and mental health for people living with Type 1 diabetes (T1D). The diabetes clinic wants to give the best guidance and support for our patients with T1D to exercise for fitness and health. But, we first need to know how much activity and what type of activity youth do. To do that we need a reliable method of measuring physical activity, and so this study aims to identify a questionnaire that we can use regularly in clinic to accurately measure and understand the types of activity youth do. With this knowledge, we can then help our youth to increase their activity (if it is low), and know who to help with education around exercising safely with diabetes. 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 you?
We are asking you to take part in this study because you 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 valid questionnaire that can accurately identify and measure physical activity in youth with T1D.

Do you have to take part in this study?
You do not have to take part– it is entirely optional. If you decide to take part and then change your mind, you are free to pull out at any time. Not doing this study will not affect your treatment by your clinic team, or any service at PCH.

What will you be asked to do if you decide to take part in this study?
If you choose 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 you up with an accelerometer. The accelerometer is a small device that you will wear on a strap around your waist to measure physical activity. You will need to wear the accelerometer for the next 7 days.

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

If you are already wearing Continuous Glucose Monitors (CGM), we would also like to review your CGM data to explore if we can see any links between physical activity components, such as frequency, duration and intensity and blood glucose control. You do 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 you choose to do this study, we will arrange a time to speak with you to talk through what you 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 make sure the accelerometer is fitted correctly and for you to ask any questions. At the end of the seven-day wear, we will send you the links 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 you?
A possible benefit is that this could increase your awareness of how active you usually are, and on which days/waking times you 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 measuring physical activity levels in children and adolescents with T1D, without the use of physical activity tracking devices which are expensive. This will allow us to develop, together with the youth and their parents, education plans about exercising safely. 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 risks in you being involved in this study. We will not be asking you to do anything different for this study. You will continue with your usual activity and life-style, and your usual diabetes management.

What are the possible discomforts and/or inconveniences?
This study only involves the collection of information on your physical activity, by using a small wearable accelerometer as described earlier, and filling out questionaries. You may find wearing the accelerometer a bit inconvenient. You can withdraw from this study at any time within the seven day study period.

Where is my information kept?

Your 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 privacy?

Your privacy will be maintained at all times. Any presentation or publications arising from this study will not identify you by name. All data will be presented as grouped data without any names. Only the investigators and the study team will be able to link your results to you. Your involvement in this study will be recorded in the clinic database, and your 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/your parent 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 you 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 Teo (6456 8078; shaun.teo@health.wa.gov.au), to register your interest for the study.

THANK YOU FOR YOUR CONSIDERATION OF THIS STUDY

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PLEASE NOTE THAT PARTICIPATION IN RESEARCH STUDIES IS VOLUNTARY AND YOU 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 Mature Minor 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 participating in this study.

I understand that I 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 I am 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 Participant (please print) _____

Signature _____ 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 _____