

PARENT INFORMATION SHEET

Perth Children´s Hospital

**The effect of different exercise intensities in improving glycaemic control in individuals with impaired hypoglycaemia awareness**

**Why are we asking you?**

We are asking your child to take part in this study because your child has type 1 diabetes, is aged between 14 and 18 years, and has impaired awareness of hypoglycaemia.

**Why are we doing the study?**

Usually people with type 1 diabetes (T1D) know when they are going low by showing symptoms like becoming pale and shaky. This is called hypoglycaemia awareness. However, some people with T1D are not able to feel their hypoglycaemia symptoms and so they may be at a higher risk of having a severe hypo. Avoiding hypos for several weeks can improve hypoglycaemia awareness in these people, but this often means running blood glucose levels quite high for a while which is not an ideal solution.

Exercise has significant benefits in people with diabetes in improving fitness, bone health, and wellbeing, and has also been found to be useful in improving glucose levels. This study is investigating the effect of two different exercise programs on their glucose levels and overall glucose control.

**What will the study tell us?**

We want to see if introducing a home-based, 4-week program of exercise (either continuous low-intensity, or intermittent high-intensity cycling) is practical, and if it improves hypoglycaemia awareness, time spent in target range (3.9 to 10 mmol/L) and reduces hypoglycaemia in individuals with T1D.

**Who is carrying out the study?**

The study is being carried out by Dr Mary Abraham and Professor Tim Jones, together with the Research Team at Perth Children´s Hospital and Telethon Kids Institute.

**Does my child have to take part?**

No, your child does not have to take part in this study. However, if the study interests your child, talk it over before you decide whether they will take part in it. If they decide to take part and then later change their mind, that is ok. They can pull out at any time and it will not change the way they are treated by their clinic team.

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

If your child is interested and eligible to take part in this study, please read the information below before you decide whether or not you would like your child to participate.

**Study outline:**

This study involves a screening visit followed by 8 study visits over a 20-week period. These are described below.

**Screening visit: Phone, Face to Face or Email:**

A member of the research team will check to determine that your child meets the inclusion criteria for this study. Your child will also be asked to complete a hypoglycaemia awareness questionnaire to confirm their eligibility for the study.

**Week 1: Face-to-face familiarisation session:**

The first visit will be a familiarisation visit, where you will meet the study team in the research facility. You have the opportunity to ask any questions about the study to make sure that you know exactly what is involved and you are happy for your child to participate. If you and your child agree to take part, we will ask you to both to sign a consent form. We will then collect some baseline details about your child’s diabetes, ask them to complete another hypoglycaemia awareness questionnaire and a physical activity record, and familiarise your child with the exercise bike that will be used for the study. Your child will be asked to sprint on this exercise bike as hard as they can for 10 seconds to determine their maximal power output, as this will be used to determine how intense they should exercise for their exercise sessions at home. If they are not already on a continuous glucose monitoring system (CGMS), they will be provided with a Dexcom G5 CGMS to use during the study period. This system will monitor your child’s tissue glucose levels and provide you/your child with glucose readings every 5 minutes which will be available real-time on your phone. Your child will receive education about how to use it from a certified diabetes educator. Lastly, your child will be provided with a hypoglycaemia symptom diary to record their hypoglycaemia, and hypoglycaemic symptoms and treatments over the next two weeks.

**Week 3:** **Home-visit, set-up of ergometer at home, randomisation:**

We will visit you at home to set up and install the same exercise bike from Week 1, and also provide your child with an activity-monitoring watch (Garmin Forerunner) which will also measure their heart rate. Your child will be trained by a member of the research team on the use of the exercise bike, and we will also help them with the setup and use of the activity monitoring watch which will allow the research team to view their completed exercise sessions through Garmin’s online platform (Garmin Connect).

Your child will then be randomly assigned to complete *low-intensity* exercise or *high-intensity* exercise 3 times a week for 4 weeks. The exercise sessions should be done at the same time of the day during the study. The preferred sessions timings are either in the morning before breakfast or at least 3 hours after your child’s last insulin bolus (before their evening meal), as below:

*Low-intensity exercise:* Continuous cycling for 16 minutes at 5% of their peak power output achieved at the week 1 session.

*High-intensity exercise:* 2 minutes of cycling at 5% of their peak power output, followed by four 15-second maximal sprint efforts each separated by 4 minutes of cycling at 5% of their peak power, finishing with 2 minutes of cycling at 5% of their peak power (16 minutes total).

The visiting researcher will assist in helping your child become familiar with both exercise formats, and the activity-monitoring watch will be programmed to alert them when they need to start and stop with the repeated sprints. Your child will also be advised to eat a meal rich in carbohydrates and proteins following exercise (for example, spaghetti bolognese).

We will also collect their hypoglycaemia symptom diary from week 1, and provide them with a new hypoglycaemia symptom diary which they will be asked to complete from week 5 to week 7.

**Week 5:** **Phone call to commence record of symptom diary**

We will contact you to remind your child to begin recording their hypoglycaemic events over the next two weeks in their symptom diary.

**Week 7:** **Face-to-face hospital or home visit, and end of first exercise program**

Your child will be asked to complete questionnaires on hypoglycaemia awareness and on their enjoyment of physical activity, and return their hypoglycaemia symptom diary. If your child was randomised to the high-intensity exercise program, they will be asked to complete a short semi-structured interview with one of our research team, which we will record with their permission, to assess how practical and achievable the exercise program was. We will also collect their symptom diary, and provide them with a new symptom diary and supply of continuous glucose sensors. This visit also marks the start of the 8-week washout or ‘break’ period from any study-related exercise.

**Week 13: Phone** **call to commence record of symptom diary**

We will contact you to remind your child to begin recording their hypoglycaemic events over the next two weeks in their symptom diary.

**Week 15: Home visit and start of second exercise program**

If your child began the study with the low-intensity exercise program, they will now change over to the high-intensity program, and vice-versa. The visiting researcher will help your child become familiar with the new program. Your child will also be asked to complete two questionnaires on hypoglycaemia awareness. We will collect their symptom diary, and provide them with a new symptom diary and supply of glucose sensors.

**Week 17: Phone call to commence record of symptom diary**

We will contact you to remind your child to begin recording their hypoglycaemic events over the next two weeks in their symptom diary.

**Week 19: Face-to-face hospital or home visit, and end of second exercise program**

Your child will be asked to complete questionnaires on hypoglycaemia awareness and on their enjoyment of physical activity, and return their hypoglycaemia symptom diary. If your child had just completed the high-intensity exercise program, they will be asked to complete a short semi-structured interview with one of our research team, which we will record with their permission, to assess how practical and achievable the exercise program was. Lastly, we will arrange to collect the exercise bike, activity-monitoring watch, and remaining glucose sensors.

**Is there likely to be a benefit to my child?**

There may be no immediate benefit to your child, but if the exercise programs are practical and show that they may improve hypoglycaemia awareness, we will conduct larger studies to see if exercise may be used as a treatment approach in people with T1D.

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

Clinical guidelines for diabetes encourage people with T1D to have a healthier lifestyle by increasing their exercise levels. The community could benefit in the long run through developing and testing home-based low and high intensity exercise programs which could be incorporated into your child’s daily routine.

**What are the possible risks and/or side effects?**

There is a risk of having low blood glucose levels during and after exercise. Your child will be required to wear a glucose sensor which will alert them when their blood glucose levels are falling, and so they can prevent hypoglycaemia by eating carbohydrates when they get the alert.

**What are the possible discomforts and/or inconveniences?**

Your child may experience a local skin reaction or infection at the insertion site of the sensor ﴾reddened skin, itching﴿, but this is rare. Sensors are treated with antibacterial substances and your child will be encouraged to clean their skin prior to insertion to minimise this risk.

**Where is my child’s information kept?**

All information that can identify your child by name will be treated as confidential and stored safely, so that only the research team can see that information. Electronic study data will be saved on the secure Telethon Kids Institute RedCap server and stored in a password protected database at Perth Children’s Hospital. Garmin activity watch and Dexcom glucose monitoring data will be saved on their company’s online platforms before being transferred to a password protected database at Perth Children’s Hospital. No personal information will be used in this process.

**What about my child’s privacy?**

Your child’s data will be coded and stored on secure PCH computers. Only the investigators and the research team will be able to link your results to you. All data published and/or presented from this study will not identify you by name. Your child’s involvement in this study will be recorded in the clinic database, and your child’s health records.

**Who has approved the study?**

This study has been approved by the Child and Adolescent Health Service Human Research Ethics Committee. 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 Mary Abraham**

Telephone contact: **08 6456 5027**
Email: Mary.Abraham@health.wa.gov.au

Name: **Dr Wayne Soon**

Telephone contact: **08 6456 4532**
Email: Wayne.Soon@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 about this study, you or your parent can contact the Executive Director of Medical Services at PCH (Telephone No: (08 64562222). 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:**

If your child would like to take part in this research study, please contact Dr Mary Abraham to make an appointment.

**THANK YOU FOR YOUR TIME**



**FORM OF CONSENT**

**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

 Given Names Surname

the information explaining the study entitled

**The effect of different exercise intensities in improving glycaemic control in individuals with impaired hypoglycaemia awareness**

I have read and understood the information given to me. Any questions I have asked have been answered to my satisfaction.

I agree to allow

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(full name of participant and relationship of participant to signatory)

to participate in the study.

I understand that my child can withdraw from the study at any stage and this will not affect his/her care at Perth Children’s Hospital.

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

Dated ................................. day of ............................................................ 20 ..........

Signature .........................................................................

I, ........................................................................... have explained the above to the

 (Researcher’s full name)

signatory who stated that he/she understood the same.

Signature ...............................................................................................

Date………………………….