



Parent Information Sheet

Perth Children's Hospital

Title	What do children and adolescents with Type 1 and Type 2 Diabetes in Western Australia eat?
Short Title	Dietary Audit: Children with T1D and T2D
HREC Number	RGS0000003979
Coordinating Principal Investigator	Dr. Amelia Harray
Location	Perth Children's Hospital

1 Introduction

You and your child are invited to take part in a research project. The research is for young people with type 1 diabetes (T1D) and type 2 diabetes (T2D). The aim of the research is to identify the types of foods children and adolescents with T1D or T2D are eating. This information will allow dietitians working within the Diabetes Department at Perth Children's Hospital to reflect on how current practices, support and nutritional guidelines are provided to young people living with T1D and T2D.

As part of this study you will receive a summary of your child's dietary intake.

This participation information sheet tells you about the research. It explains what you and your child will be asked to do. Please read this information. Then ask questions about anything you want to know about the research.

2 Why are we doing the research?

Nutritional management is essential to achieve best possible glycaemic control which is linked with reducing complications for people with T1D and T2D. Internationally, nutritional recommendations for children and adolescents with diabetes are based on healthy eating guidelines that are suitable for all children. In Australia these are based on the Australian Guidelines to Healthy Eating for Children and Adolescents.

However, the ability to follow dietary advice has been reported to be one of the more difficult aspects of Diabetes management. In addition to dietary education and advice provided by PCH clinical dietitians, families also access information from alternative sources. Despite 3 monthly clinic appointments at PCH, we don't know the types and amounts of foods eaten by children and adolescents with T1D and T2D in Western Australia.

A recent study from Royal Children's Hospital in Melbourne, used the same questionnaire that we are using in this project which will allow us to see how the dietary intake of children in Western Australia differs from another population of children in Australia.

We hope that by doing this research we can see if children and adolescents with T1D and T2D in WA are meeting current recommendations and assist in identifying areas that can be improved in clinic to better support families and improve nutritional outcomes. This will also provide researchers with knowledge to help guide future research studies.



3 What will my child be asked to do if they choose to take part in the research?

After reading this information sheet, if you and your child decide to participate you will be asked to provide electronic consent. In order to receive the survey, we are also requesting permission to add your child in the Australian Eating Survey® website by adding your email address and your child's first and last name. Once these details are entered, you will receive an email from info@australianeatingsurvey.com.au with a link to complete the Australian Child and Adolescent Eating Survey Food Frequency Questionnaire online. This link will take you to a website outlining that the survey responses are confidential and all information will not be shared or sold. The questionnaire takes approximately 20 minutes to complete online. Once you have completed the survey, an individual report is generated and emailed to you outlining your child's dietary intake. This report will also be available to the research team and results will be stored in a password protected document on a secure network at Perth Children's Hospital.

This questionnaire is hosted on a secure server by the University of Newcastle. They collect Australian Nutrition Surveys through an online application. If your child is between 2-11 years, you will be asked to fill in the questionnaire for them. If your child is older than 12 years, they can fill in the survey but may need your help. The questionnaire will take approximately 20 minutes to complete.

We are also requesting your permission to access information about your child and their diabetes management from the Western Australian Children's Diabetes Database. Each time you attend clinic the information that is collected such as age, diabetes duration, insulin regimen, total insulin requirements, HbA1c, height and weight, and any other diagnosis is recorded into this database. We would like to look at this information to see if there are any similarities in the types of foods children eat and their clinical characteristics and diabetes management. The data we are interested in listed above, would be copied from the database and linked with your questionnaire responses by a unique study id given to your child once you sign the consent. This id is used so that your child's name is not recorded on the data sheets and remains confidential.

4 Who is carrying out the research?

The researchers from the Children's Diabetes Centre at Perth Children's Hospital and Telethon Kids Institute are working together to do this research. Funding for the research has been provided by the Children's Diabetes Centre.

5 Does my child have to take part in this research?

You and your child do not have to be part of the research. If you say no, your child will still be looked after by their diabetes team. If you say yes, you will be asked to sign an e-consent form. By signing it you are telling us that you:

- Understand what you have read
- Consent to your child to take part in the research project
- Consent to the use of your child's personal and health information as described.

If you and your child decide to take part and then change your mind, you are free to pull out at any time. If you decide you don't want to be part of the research anymore then please let us know. If you withdraw, your child's de-identified data will be included in the study unless you ask for it to be removed. This will not affect how you and your child are looked after by the diabetes team at the hospital.



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

Your child's dietary intake report will outline all the macronutrients (protein, fat and carbohydrates) and micronutrients your child consumes. The report will also compare this to current Australian guidelines.

We cannot promise that you will benefit directly from being part of the research. However, if there are changes to current practice, or teaching in the clinic due to this study, your child may receive some benefit in the future.

7 What are the possible risks or side effects?

As this is a low risk study with no interventions or invasive procedures, there are no known or foreseeable risks, harm or discomforts associated with participating in this study. This study involves the voluntary disclosure of dietary intake of a child with T1D or T2D. Participating does not mean you must alter your current dietary intake.

We are using a questionnaire that has been used by other groups previously without any issues arising. However, if any of the questions asked, raises any concern, you can contact the research team, your clinic team or HeadSpace which operates after-hours psychological assistance in the community.

8 What will happen to my information?

At consent, your child will be allocated a unique identifier, this will be used on study documents in place of your child's name. Any paper documents will be stored in a locked cupboard. Electronic files will be password-protected and stored on a computer that only the research team can access. You have the right to ask to see the information that has been collected about your child as part of this research.

At the completion of the study, de-identified files will be archived and retained for at least fifteen years. Data will then be disposed of in accordance with Department of Health Patient Information Retention and Disposal Schedule.

The results of this research may be presented at conferences or published in professional journals. Personal information will not be identifiable in any results that are published or presented.

9 Who has approved the study?

All research in Australia that involves humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). This research project 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)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

10 Who to contact if you have any complaints about the project or the way it is being conducted

If you have any concerns about the rights of your child as a participant in the study or you have a complaint about how the research is carried out, you can contact an independent person, the Executive Director Medical Services at Perth Children's Hospital (Telephone No:



6456 2222). Your concerns will be drawn to the attention of the Ethics Committee who is monitoring the study.

If your child suffers any injuries or complications because of this research project, you should contact the study team as soon as possible and we will help arrange medical treatment.

11 Who to contact for more information about this study

If you would like any more information about this study, please do not hesitate to contact the research team. We are very happy to answer your questions.

Contact person for the research team

Name	Dr. Sabrina Binkowski
Position	Research Officer
Telephone	08 6456 4617
Email	Sabrina.Binkowski@health.wa.gov.au



Parent Electronic Consent Form

Perth Children's Hospital

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Declaration by parent

I have read the Participant Information Sheet, or someone has read it to me in a language that I understand.

I understand the purpose, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I provide permission to exchange personal, identifiable information (my child's full name and email address) with the Australian Eating Survey® website for participation in this study.

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.

I freely agree for my child to participate in this research project as described and understand that I am free to withdraw my child at any time during the project without affecting their future health care.

Full name of Child	_____
Full name of Parent/Guardian	_____
Signature _____	Date _____

I certify that all the information in the document above is correct, and I understand that signing this form electronically is the equivalent of signing a physical document.