

Parent/Caregiver Participation Information Sheet

Title	Low carbohydrate diets in the management of type 1 diabetes in Western Australian children: a qualitative study
Short Title	Low CHO Diet in T1D: Qualitative Study
Protocol Number	RGS0000003967 V2 17.07.2020
Coordinating Principal Investigator	Dr Amelia Harray
Location	Telethon Kids Institute

What is the purpose of this research?

An increasing number of families with children with type 1 diabetes (T1D) are reporting following a low carbohydrate (CHO) diet to try and control their child's blood glucose levels. We would like to understand the benefits and obstacles they encounter.

What will the study tell us?

By listening to the personal experiences of our parents/caregivers of children with T1D, we hope to get an understanding of why some families are using these low CHO diets to manage their child's T1D and how it is working for them and their children.

Is there likely to be a benefit to you?

We cannot guarantee you will receive any direct benefits from this research; however, possible benefits may include connection with other parents of children with T1D and the opportunity to talk about your experiences with managing this condition. By participating in this research, you will also be helping build evidence related to this dietary pattern.

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

The findings from this qualitative study will help inform a larger study where we will assess the health outcomes associated with varying levels of CHO intake and review dietary recommendations for children with T1D. This information could be used to update resources and advice for parents to support implementation of the recommendations.

Why are we doing the study?

We are aware that many families of children with T1D are implementing low CHO diets, and by obtaining real experiences about why and how families are doing will help inform future nutrition research projects to help children with T1D and assist health professionals to support families, to make more informed dietary decisions.

Who is organising and funding the research?

This research project is being conducted by the Children's Diabetes Centre at Telethon Kids Institute and was funded by a Children's Diabetes Centre Seeding Grant.

Who can be involved?

Parents/caregivers of children aged 10 years or younger with T1D who are currently, or have been in the last 6 months, trying to restrict the amount of CHO containing foods they give their child to manage his/her T1D. Participants will need to have access to the internet.

Do you have to take part?

Participation in any research project is voluntary. We will respect your decision whichever choice you make. If you decide to take part and then later have a change of mind, then that is ok, and you can withdraw from the study at any stage. If you decide that you will take part in this project, we invite you to sign the consent form attached. Your decision whether you take part or not take part, or to take part and then withdraw, will not affect your child's routine treatment, relationship with those treating them, or relationship with the Telethon Kids Institute or Perth Children's Hospital.

What will you need to do to take part in this study?

If you decide to take part in this study, you will firstly be asked to complete a short online survey designed to gather some background information. You will then be asked to participate in an online focus group with other parents of children with T1D. Due to the nature of online video platforms, there will be a maximum of three individuals attending each of the online focus groups. This may include a spouse or someone you know or a parent you may not know.

During the focus groups you will be asked questions, for example, 'Can you tell us any benefits you have noticed for your child having been on a low CHO diet?' and 'Where do you get your information/advice regarding low CHO diets?'. We will discuss possible and convenient times for the online focus group on recruitment. We expect the online focus group to take no longer than an hour.

The online focus groups video and audio will be recorded, and these recordings will only be accessible by the research team. You will receive a reimbursement for your time on completion of the online focus group.

What are the possible risks and/or side effects?

This is a low risk study, meaning we do not anticipate any risks from being involved in this project. In the unlikely event that you become upset or distressed because of participation in the research, we will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff and will be provided free of charge. Although each participant will be asked to sign that they will treat anything said in the online focus group as confidential, there is always a risk that this may not be the case.

What if you want to withdraw from this study?

Participation in this study is voluntary; therefore, you can withdraw from the study at any point during the project. Withdrawal will not affect your relationship with the researchers or the Children's Diabetes Research Centre. Information collected up to the point of withdrawal will be deleted from the project if that is your wish unless data is collected in the online focus groups. Individual data cannot be identified from online focus group data.

Where will the collected information be kept?

All information collected for this research project will be treated as confidential and securely stored. All data including electronic records and video and audio recordings will be stored on password protected computers accessible only by the diabetes research team. All written data will be kept in a locked cabinet in a restricted access area within the Telethon Kids Institute. At the completion of the study, de-identified files will be archived and retained for at least fifteen years.

What about your privacy?

In most situations, we will treat what you say as being private and confidential. Information obtained during the research project may be reviewed by authorised representatives of the study Sponsor (Telethon Kids Institute), the approving authority or as required by law for the purpose of verifying the procedures and the data.

As soon as the information collected is collated it will be de-identified, that is, names will be removed, and the information coded so that no one can associate what has been said with anyone. Any data that is published and/or presented will be provided in such a way that individuals cannot be identified.

What happens when the study ends?

You will receive a summary of the results of the project by email approximately 3 months after the project is completed.

Who has approved the study?

The ethical aspects of this research project have 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 do you contact for more information about this study?

If you would like any more information about this study, please do not hesitate to contact Dr Amelia Harray on 6456 5882. She will be happy to answer your questions. You are entitled to retain a copy of the project's Participant Information and Consent Form.

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

If you have any concerns or complaints about the way we ran this study, you can contact the Executive Director of Medical Services at Perth Children's Hospital (Telephone No. (08) 6456 2222). Your concerns will be drawn to the attention of the Ethics Committee who monitors the study.

What do you do next if you would like your child to take part in this research If you would like to take part in this research study, please contact Amelia on 6456 5882 or email Amelia.Harray@telethonkids.org.au

Thank you for your time.

FORM OF CONSENT

Parent/Caregiver

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

Ihave read
Given Names Surname

the information explaining the study entitled

Low carbohydrate diets in the management of Type 1 Diabetes in Western Australian children: a qualitative study

Any questions I have asked have been answered to my satisfaction.

I agree that I..... can participate in the study.

I understand that the online focus group video and audio will be recorded.

I understand I may withdraw from the study at any stage of the project.

I agree that research data gathered from this study may be published and that no names will be used.

I understand that I am required to treat the online focus group discussion as confidential.

Participant Signature.....Date.....

I, have explained the above to the
(Investigator's full name)
signatory who stated that he/she understood the same.

Signature of Investigator.....Date.....