CORE-KDT

Core Outcomes in Refractory Epilepsy with Ketogenic Diet Therapy

PARENT INFORMATION SHEET
Interview and/or Delphi Survey

Project title: Core Outcomes in Refractory childhood Epilepsy treated with Ketogenic Diet Therapy (The CORE-KDT study)

Thank you for expressing an interest in our research study. We are recruiting parents of children with refractory (difficult to manage) epilepsy currently treated with ketogenic diet therapy or who have been in the past year. Please read the following information carefully to help guide your decision to take part or not. We will be happy to answer any questions you may have.

What is the purpose of the study?

Research often uses seizure control and the side effects of a ketogenic diet as the main way of assessing ketogenic diet therapy (these are known as 'outcomes'). However, we think it is important to also consider other outcomes that address physical health, mental health and quality of life to name a few. It is essential we involve parents and carers in this research to identify the outcomes of importance to them. We will also seek the views of healthcare professionals' (for example paediatric neurologists, ketogenic dietitians and epilepsy nurses). Together this will guide the development of an agreed list of outcomes (also known as a 'core outcome set') that should be measured for children who are following a ketogenic diet. The Chief investigator (Jen Carroll) is undertaking this research as part of her PhD studies.

Why have I been invited?

You have been invited to participate because you are a parent or carer to a child aged 18 or under with epilepsy who is being treated with a ketogenic diet or has weaned from the diet in the past year. Your views are very important to us, particularly in relation to managing the ketogenic diet and the outcomes you feel we should be assessing for children with epilepsy treated with ketogenic diet.

Do I have to take part?

Taking part in the study is completely voluntary; you don't have to take part if you don't want to. Your choice to take part or not will not impact on your child's care. If you decide to take part and change your mind you are free to withdraw at any time, without giving a reason.

Can my child take part?

No, this study is assessing parents and carers views.

What will taking part involve?

This study has two phases where we would welcome your involvement and you may choose to take part in one or both phases.

Phase 1 Interview: One interview with a researcher (Jen Carroll) to explore the outcomes of importance to you and your child's experiences of epilepsy and the ketogenic diet. The interview will take approximately 60 minutes. This can be done in person, via telephone or audio/video call using Skype; whichever you prefer. If you would prefer to meet in person, Jen will arrange to meet you at a time that is convenient for you which might be a forthcoming hospital appointment or your own home if preferred. The interviews will be audio recorded.

Phase 2 online Delphi survey: Completion of an online survey called a 'Delphi Survey' in which you will be asked to score the importance of a range of outcomes. Delphi surveys are used to reach consensus on a topic of interest. Parents, healthcare professionals and researchers will all be invited to score the same list of outcomes over two rounds. Each round of the survey will take approximately 20 minutes to complete. The online link to the survey will be sent to your email address.

Round 1: you will be presented with a list of outcomes that have been identified from past research studies of childhood epilepsy treated with ketogenic therapy and the interviews undertaken with parents in phase 1. You will be asked to rate how important you think the outcomes are on a scale of 1 (not important) to 9 (critically important). You will have an opportunity to add comments or any outcomes you think are missing.

Round 2: approximately 3 weeks after completing round 1, you will receive an email asking you to complete round 2 of the Delphi survey. The questions will be identical to round 1 and you will again be asked to rate the outcomes on a scale of 1-9. However, you will be able to see your round 1 answer and the anonymous scores of the other groups involved in round 1; parents, healthcare professionals and researchers. You can amend any of your scores in light of this information or keep it the same. This method helps us achieve consensus on the core outcomes of importance.

If you volunteer to take part in the Delphi survey, it is important that you complete both rounds to enable us to gather meaningful data.

How will we use information about you?

We will need to use information from you for this research project. This information will include your:

- name
- contact details.

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.
Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our (University of Plymouth) website www.plymouth.ac.uk/students-and-family/governance/information-governance
- by asking one of the research team
- by sending an email to our Data Protection Officer dpo@plymouth.ac.uk
- by ringing us on 01752 588826

What will happen to the information that I give?

After the interviews, we will listen to the recordings to help understand parents and carers experiences of living with childhood epilepsy, the ketogenic diet and their views on outcomes. The interviews will be typed and anonymised. Your personal details will be kept confidential and will not be shared. Once the results of the interviews are analysed, we will make them available to interview participants to review and welcome any further feedback. The research team may present the data at relevant conferences or in journals read by health care professionals. We may use some direct quotes from the interview. If we do this, we will be very careful to make sure that neither you nor anyone you talk about can be identified. The results of the Delphi survey will be analysed with the aim of reaching consensus on the most important outcomes to measure in future. Your results will be completely anonymous.

What are the advantages of taking part?

There will be no direct benefits to you, but you may find completing the interview and/or Delphi survey interesting and even enjoyable. It is hoped the information you provide will guide and influence the way children on a ketogenic diet are monitored.

What are the possible disadvantages and risks of taking part?

You will not be exposed to any risk of physical harm associated with the interview or completion of the Delphi survey and you don't have to answer any questions that you don't want to. Understandably, it is possible that talking about your experiences might be upsetting, if this happens you can stop at any time.

Will my taking part in the study be kept confidential?

We will protect the confidentiality and anonymity of all participants and their data at all times. We will anonymise anything you say that might identify you or others when we write up the results. All the data from the study will be stored on the University of Plymouth secure network drives. Ethical approval has been granted by London-Surrey REC (19/LO/1680, date: 14/11/19) and supported by the University of Plymouth Faculty Research Ethics and Integrity Committee (FREIC ref 19/20-1197, date: 05/12/19).
It is possible that some of the data collected will be looked at by authorised persons from the University of Plymouth to check that the study is being carried out correctly. Anyone who has access to the records will also be governed by the same rules of confidentiality.

How long will the data be kept for?

The University of Plymouth is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Plymouth will keep identifiable information about you for 10 years after the study has finished.

What happens next?

If you wish to take part and haven't already registered your interest, then please do so via the study website https://www.plymouth.ac.uk/core-kdt where you will be asked to provide your contact details. If preferred, please contact the researchers directly using the contact details below. They will be more than happy to answer any further questions you might have. Parents and carers are encouraged to take part individually of each other as they may have differing opinions. Please feel free to share information about the study with other parents or carers of a child with epilepsy treated with ketogenic diet therapy. If they would like to take part, they will need to register separately from you.

What happens after the survey?

When the two rounds of Delphi survey are complete, you will be asked if you would be interested in attending a consensus group meeting with representatives from all groups. Again, this is voluntary and travel expenses will be reimbursed.

Questions?

If you have any questions about the study, interviews or Delphi survey, please don't hesitate to contact one of our research team.

Jen Carroll 01752 588826 (University Lecturer, Dietitian, PhD student and Chief Investigator) Jennifer.carroll@plymouth.ac.uk **Avril Collinson 01752588848** (University Lecturer, Dietitian and Director of Studies) Avril.collinson@plymouth.ac.uk	**Our address:** Institute of Health and Community, School of Health Professions, University of Plymouth, Plymouth, PL6 8BH.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to someone from the research team (Jen Carroll or Avril Collinson) who will do their best to answer your questions. If you have a minor complaint or concern then you need to contact the researchers in the first instance.

Formal Complaints

If you wish to make a formal complaint or if you are not satisfied with the response you have gained from the researcher(s) in the first instance then please contact:

Administrator to Faculty Research Ethics and Integrity Committee
Faculty of Health and Human Sciences,
University of Plymouth,
4th Floor Rolle Building, Drake Circus,
Plymouth, PL4 8AA
Tel: 01752 586992

Who is funding the research?

This study is sponsored by the University of Plymouth and The British Dietetic Association General and Education Trust Fund.

Who has reviewed the study?

This study has been reviewed and approved by London-Surrey Research Ethics Committee (19/LO/1680, date: 14/11/19) and supported by University of Plymouth Faculty Research Ethics and Integrity Committee (FREIC ref 19/20-1197, date: 05/12/19)

Thank you for taking the time to read the information sheet. If you decide to participate you will be given a copy of the information sheet to keep and your consent will be sought.