CORE-KDT

Core Outcomes in Refractory Epilepsy with Ketogenic Diet Therapy

PROFESSIONAL INFORMATION SHEET
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 health care professionals and researchers who have experience working with refractory childhood epilepsy treated with ketogenic diet (KD) therapy. 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?

Our aim is to establish consensus among parents, carers, healthcare professionals and researchers on a core set of outcomes for refractory childhood epilepsy treated with KD therapy. The primary outcomes in clinical effectiveness trials tend to address seizure control and the side effects of KD therapy. 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, healthcare professionals and researchers working with this patient group to identify the outcomes of importance to them. Together this will guide the development of a core set of outcomes that should be measured in future clinical trials and may benefit clinical practice too. The chief investigator (Jen Carroll) is undertaking this study as part of her PhD studies.

What healthcare professionals can take part?

We are seeking the opinions of healthcare professionals and researchers who work with children with refractory epilepsy treated with KD therapy. For example, but not limited to; paediatric neurologists, ketogenic dietitians and epilepsy specialist nurses. If your profession isn't listed but you work with this patient group, please do get in contact with the researchers. Please feel free to share the study information with any other relevant professionals within your team that might like to take part.

What will taking part involve?

You are invited to take part in 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 anonymously 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 a scoping review of research studies (from 2008 to 2018) of childhood epilepsy treated with KD therapy and interviews undertaken with parents earlier in this study. 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 two 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.

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. If you decide to take part and change your mind you are free to withdraw at any time, without giving a reason. Completing the survey will be regarded as your implied consent to take part, that is the assumption that a person has knowingly agreed to participate in the research by performing a research activity or task.

What are the risks and benefits of taking part?

The survey is very low risk. There will be no direct benefits to you but the information you give may guide future research into childhood epilepsy treated with KD therapy and influence the routine monitoring of this patient group.

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

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 Research ethics committee (19/LO/1680, date 14/11/19) and supported by the Faculty Research Ethics and Integrity Committee on 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. Please feel free to share information about the study with other professionals. 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 entirely voluntary and will be held at a meeting or conference where healthcare professionals are in attendance. More information about this meeting will be sent to you after round 2 of the survey.

Questions?

If you have any questions, 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 the 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
Ethical approval has been granted by London-Surrey Research ethics committee (19/LO/1680, date 14/11/19) and supported by the Faculty Research Ethics and Integrity Committee on 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.