Participant Information Sheet for Delphi Survey and Consensus Meeting [Professional]

Study Title: Developing a preconception care pathway for women with epilepsy in the UK: Identifying key interventions and patient-reported outcomes using a mixed-methods Delphi consensus approach

Invitation and summary

We would like to invite you to take part in a study to help develop a care pathway for women with epilepsy preparing for pregnancy.
Preconception care is advised for women with epilepsy. It involves taking steps to make sure a woman's epilepsy and health are at the best possible before getting pregnant. This is vital because epilepsy and epilepsy drugs can increase the risk of problems for mother and baby. These include:

- Risks of worsening seizure control, if a woman stops taking her epilepsy drugs for fear of harm to the baby. This could increase the chance of injury or even death in epilepsy.
- Risks of birth defects in the baby, if the mother is not taking the best type and dose of an epilepsy drug.
  This includes valproate (Epilim).

Preconception care offers the chance to avoid some of these risks. However, it is unclear why some women do not receive preconception care and struggle to plan pregnancy. In the absence of evidence, we believe we need to bring together people living with epilepsy and professionals who work with and provide services for people with epilepsy, to agree what works best. One such method, called a 'Delphi' study brings 'experts' together to agree on areas of concern.

Why have I been asked to take part?

You have been invited to consider taking part in this study as we believe you are an expert. This Delphi study will involve collecting feedback from experts, which will be shared and reviewed over a series of stages known as 'rounds' until an agreement is made. We believe you have professional experience in supporting women living with epilepsy.

We invited people with personal experience of living with epilepsy to take part in this study. The first stage of the study focused on the personal experiences of women living with epilepsy, their partner, spouse, family, friends and carers. The second stage of this study will involve anyone with a vested interest to improve preconception care for women with epilepsy; this will involve:

- People with personal experience of living with epilepsy
- Health professionals with expertise in preconception care and care of women with epilepsy
- Members of voluntary organisations supporting women with epilepsy, and
- Researchers with expertise in preconception care and care of women with epilepsy

Before you decide whether or not you would like to take part, you need to consider why the research is being done and what it will involve. We will provide contact details of the research team who can go through this information sheet with you, to help you decide whether or not you would like to take

part. They can also answer any questions you might have. Please read this information sheet carefully, and feel free to talk to others about the study if you wish.

The first part of the Participant Information Sheet tells you the purpose of the study and what will happen to you if you take part. Then we give you more detailed information about how the study will be carried out. The final part will involve you providing consent to take part, and will require your signature.

Do ask if anything is unclear. This information is available in an easy-read format.

Part 1: Purpose of the study and what will happen if I take part

Why are we doing this research?

This study aims to address the need to reduce the variation in preconception care that different women with epilepsy receive. We want to find ways to improve the opportunity for all women with epilepsy to have the best possible care before any pregnancy. This is especially important for women who, at the moment, are being missed.
Results will be used to:
- Identify essential support (interventions)
- Develop a pathway of stages for stepping in to support women, and
- Develop a patient-reported outcome, to measure impact in service and in future research

What will it involve? (See also, study flow chart, page 3)

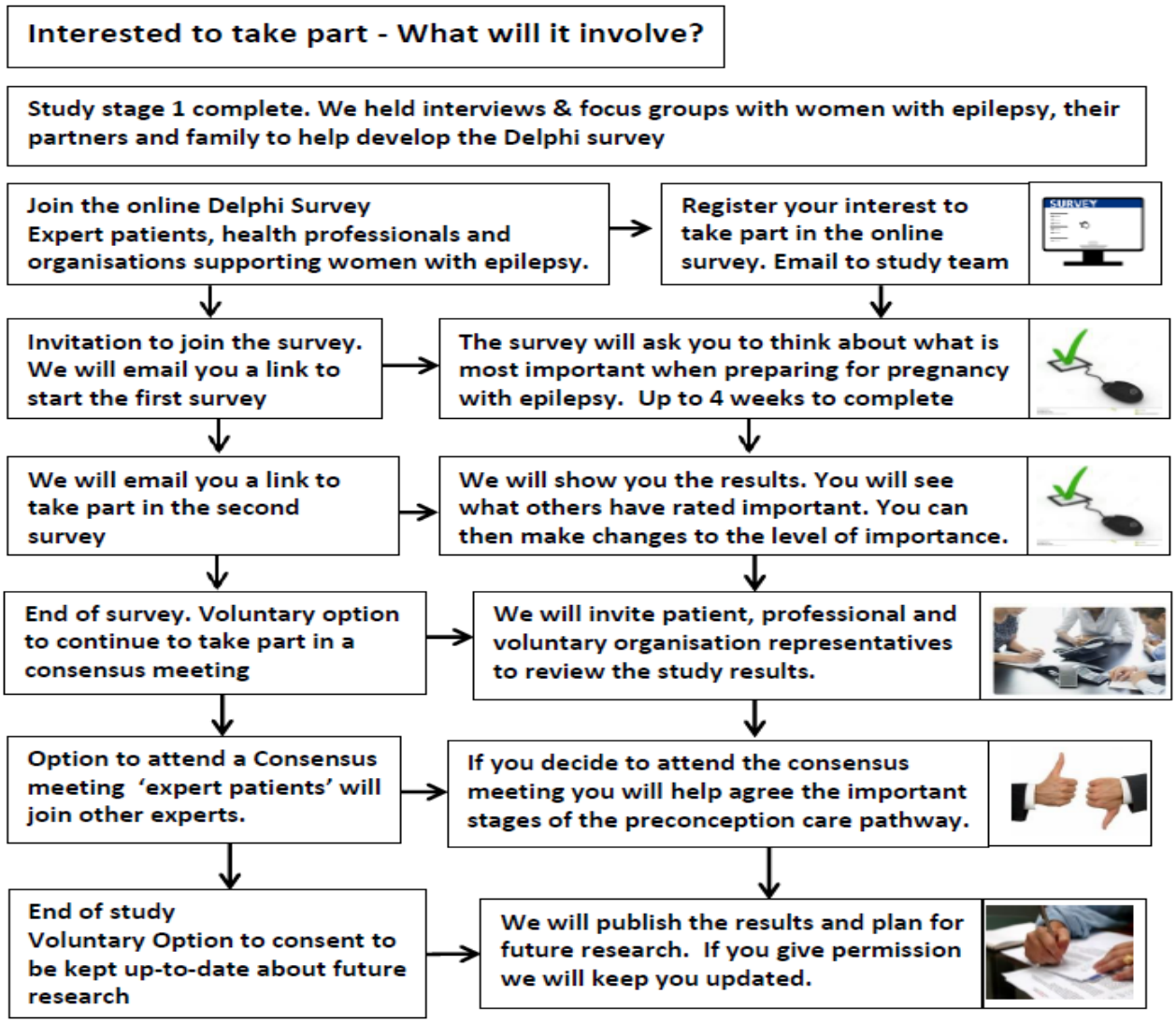
Taking part in two online surveys. We are inviting 'experts' to complete two surveys. We define experts as those engaged in providing preconception care/ counselling and support for women with epilepsy.

Online survey – If you agree to take part in the survey, we ask you to register your interest to take part and provide your email.

When the survey is due to open, you will be sent an email and ask you to log-on and complete the survey. At log-in, we will ask you to confirm which group best describes you, e.g. member of a voluntary organisation or healthcare professional. We will ask you to tell us about the organisation you represent and your profession. We will ask you to confirm you have read the participant information and had any questions answered. You are required to confirm your agreement by ticking the econsent box to proceed to the survey. The survey starts with an opening page and then goes through a series of web pages with questions. The questions will ask you to rank what you feel is important from a list of options relating to preconception care. The online survey will take between 10-20 minutes to complete. You can take as many breaks as you need, by saving the page and returning later to complete the survey. At the end of the first survey, you will be given the option to attend a consensus meeting. We will ask you to tick a box on the consent form and provide your preferred contact details.

Consensus meeting – This stage of the study is optional. We plan to bring a group of participants (patients and healthcare professionals) together to agree on the final results. The meeting will involve ou casting your vote on the final content of the care pathway. We will help arrange your travel and accommodation as needed. The format of the meeting, venue and location will conform to safe conduct of research guidelines and NHS Public Health guidance, to maintain your safety.

Study flow chart – what will I have to do if I take part?



Will participation in this study affect me in any way?

This study involves no procedures, and you won't be asked to take any medicines. For patient-participants taking part in this study will not affect your clinical care.

Are there any benefits to taking part in the study?

There will be no direct benefit to you from participating in this study. However, the information you provide will help guide healthcare providers, future researchers and policy-makers focus on what is important to women with epilepsy preparing for pregnancy.

Are there any risks from being in the study?

This is a very low-risk study. We are gathering information by survey responses. We will ask your permission on the electronic consent form (tick a box). All information you provide will be treated in the strictest confidence, and prevent your involvement in the study being known. We will remove all names and personal identifying information.
Detailed information on this is given in Part 2.

We recognise that being asked views about pregnancy may be upsetting. The research team have experience in researching this topic, and should you feel upset or distressed at any point or wish to terminate the survey for any reason, you will be free to do so. The research team can also refer you to an appropriate counselling service if you wish.

Are there any costs to me personally from taking part in this study? Will I be paid for taking part?

You will not be paid to take part in this study, it is voluntary. However, all travel costs for meetings will be paid or reimbursed if using your vehicle. Any out-of-pocket costs, such as childcare, data charges, call time minutes will be paid or reimbursed on production of a receipt.

What happens if I change my mind?

If at any point you decide to stop taking part in the study, we will stop making contact with you. Information on how we handle your information is detailed in Part 2 of this information sheet.

What happens when the study stops?

It is intended that the results of the study will be presented at conferences and published in medical journals so that we can explain to the medical community what our research results have shown. Your views may be presented as direct quotes used to illustrate an experience of someone with personal experience of living with epilepsy. Confidentiality will be ensured at all times and you will not be identified in any publication.

It is hoped the results will influence service developments to be incorporated into the National Institute of Clinical Excellence Epilepsies guidelines.

Who can answer my questions about the research study?

You can contact the research team about any questions or concerns you have about this study using the contact details provided. A member of the research team will call you back or email (at your preference) to answer any concerns or provide further details. Detailed information on this is given in Part 2 What if there is a problem.

Giving consent to participate in the study

Participation in this study is voluntary. You have the right to decline to participate without penalty. If you agree to take part in the online survey, we will require your consent before you start to survey. All participants will need to access the study website and will be asked to tick the box to confirm they have read the information sheet.

We will ask your agreement to receive further details of this project and future research, by placing your initials in the box next to the statement on the consent form. This is voluntary.

You will have a chance to withdraw your consent if you change your mind for any reason. Any data (information you have provided) up to the date of withdrawal will be retained. Detailed information on this is given in Part 2.

Part 2: Detailed Information about the conduct of the study

Who is running this study?

The Neuroscience Research Centre, The Walton Centre NHS Foundation Trust is the study sponsor. The sponsor is who is responsible for running the study. They have asked local NHS hospitals in England, Northern Ireland, Scotland, and Wales to identify participants into study stage 2. They have asked The University of Liverpool to help in the day-to-day running of the Delphi survey.

The project has been reviewed by the Health Research Authority (HRA) and the National Research Ethics Service Committee (REC) to make sure that the study is scientifically and ethically acceptable.

This study is funded by the National Institute for Health Research (NIHR) Research for Patient Benefit (RfPB) Programme.

The study is also registered on the NIHR Portfolio and is eligible for Clinical Research Network support.

How will we use information about you?

We will need to use information from you for this research project.

This information will include your:

- Initials
- 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.

The University of Liverpool runs the Delphi survey; they will only keep hold of your email contact details for three months after you complete the survey, and then they will be permanently deleted. They must both follow the rules about keeping your information safe.

Once we have finished the study, we will keep the data for a maximum of 25 years 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.
- Your email and contact details will be deleted if you choose to withdraw from the survey.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. [**Your data will be stored locked securely in the Neuroscience Research Centre, The Walton Centre NHS Foundation Trust**]

Information sharing and other research

When you agree to take part in a research study, the information you provide may be beneficial to researchers running other studies in this organisation and other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research, or equivalent standards.

If you agree to take part in this study, you will have the option to take part in future research using data saved from this study. We will ask you to initial your agreement on the consent form if you wish to consent for information sharing and other research.

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/
- at The Walton Centre NHS Foundation Trust website (https://www.thewaltoncentre.nhs.uk)
- **at www.hra.nhs.uk/patientdataandresearch**
- By contacting The Walton Centre NHS Foundation Trust Data Protection Officer at DPO@thewaltoncentre.nhs.uk

- by asking one of the research team
- by sending an email to preconceptionstudy@thewaltoncentre.nhs.uk , or
- by ringing us on 0151 556 3721

What if there is a problem or something goes wrong?

If you have a concern about any aspect of the study, you should ask to speak with one of the research team members, who will do their best to answer your questions.

If you remain unhappy and wish to complain formally, you can do this by contacting The Walton Centre NHS Foundation Trust, Patient and Family Experience Team for assistance [tel: 0151 556 3091; email: PatientExperienceTeam@thewaltoncentre.nhs.uk]. Members of your local hospital team should also be able to provide this information for you.

If you are still unhappy and wish to complain formally, you can find more information on the NHS complaints procedure here: http://www.nhs.uk/NHSEngland/complaints-and-feedback/Pages/nhs-complaints.aspx.

Thank you for your time to read and consider this information sheet.

Should you decide to take part in this study, we will give you a copy of the information sheet and a signed consent form to keep.