Easy read participant information sheet

Developing a preconception care pathway for women with epilepsy

Invitation and summary

We want to invite you to take part in this study. This study aims to develop a care pathway for women with epilepsy.

A 'care pathway' is a guide for healthcare professionals to help in the care and treatment of a person. It is a way of ensuring that each person gets the best care and treatment to meet their individual needs.

The care pathway we want to develop will help all women with epilepsy prepare for pregnancy. This will include getting access to the best care and information before they get pregnant.

We invite you to take part in the online survey.

This study has involved two stages. Women with epilepsy, their partner, spouse, and families have participated in focus groups or interviews (study stage 1 completed). The results have helped develop the online survey.

Online survey (study stage 2):

We will invite you to complete two online surveys. Each survey will ask for your opinion. The survey will ask what is essential for women with epilepsy when they are preparing for pregnancy.

If you take part in the surveys, we will invite you to join a meeting at the end of the study. It is up to you if you choose to do this.

Why have I been asked to take part?

We believe that as a person living with epilepsy, you are an 'expert' patient. We think you can help us by sharing your experiences. Your input will help us find out what is essential for women with epilepsy. Before you decide whether you would like to take part, please consider,

1. Why the research is being done, and

2. What it will involve

The research team can help go through this information sheet with you. You don't have to read all the information. You can ask for support reading it. The research team can help. They can help you decide whether you would like to take part.

The information sheet is in two parts:

Part 1. Tells you about the study and what will happen to you if you take part.

Part 2. Gives you more detailed information about how the study will be carried out. This includes information about consent, and how to complain.

Do ask if anything is unclear.

Part 1: About this study.

Why are we doing this research?

We want to improve preconception care for women with epilepsy. We want to find ways to improve the care for all women with epilepsy.

Preconception care means taking steps to improve a woman's health before she gets pregnant.

Preconception care is vital because epilepsy and epilepsy drugs can increase the risk of problems for mother and baby. These include:

- Risks of seizures getting out of control. This could increase the chance of injury or even death in epilepsy.
- Risks of birth defects in the baby and learning problems as they develop.

Preconception care offers the chance to avoid some of these risks. But some women struggle to plan pregnancy. And some women miss out and don't get this care. We are not sure why this happens.

This study will listen to people with experience. This includes people living with epilepsy, health professionals who work with people with epilepsy and those who provide help and support. This type of research is called a 'Delphi' study. This study method brings experts together to agree on areas of concern, which in this case is preconception care.

The results of this study will be used to:

- Identify what support is essential for women with epilepsy (interventions)
- Develop a care pathway, to help healthcare professionals offer the right support at the right time for women with epilepsy, and
- Develop a patient-reported outcome measure. This will measure how the care pathway has had an impact on care for women with epilepsy. It can also be used for future research.

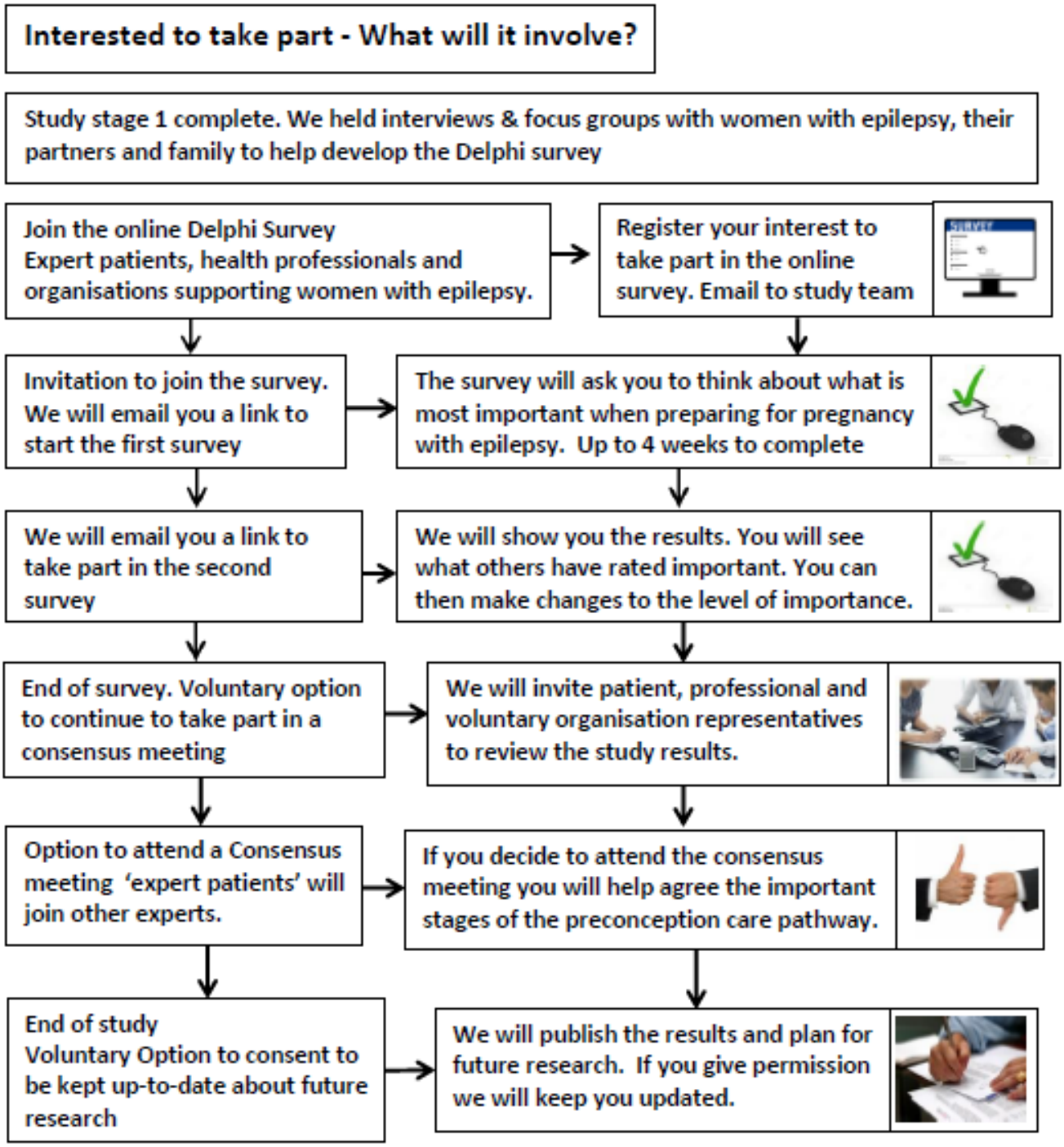
Is this study for me?

You can take part if you are a:

- Women with epilepsy, their partner, spouse, family, friend or carer
- Health professionals who work with women with epilepsy
- Commissioner of services for women with epilepsy
- Researcher
- A person involved in providing help and support for women with epilepsy

Taking part is voluntary.

What will taking part involve?



Are there any benefits of taking part in the study?

There are no direct benefits to you. The information you provide will help guide healthcare providers and future research focus on what is important for women with epilepsy.

Are there any risks from taking part in the study?

This is a low-risk study. We will ask you to think about your experiences when completing the survey.

There is a chance you might get upset. Talking about your pregnancy experience may be upsetting. The research team have experience in research on this topic. You can take a break from questions if you feel upset or distressed. You can end the interview, focus group, meeting or survey. For any reason, and you are free to do so. The research team can 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. We will pay travel costs for attending meetings. We will pay fuel costs if using your vehicle. We will pay out-of-pocket costs, such as childcare, data charges, call-time minutes. We will ask you to give us your receipts before we can agree on the payment.

Who can answer my questions about the research study?

The research team will answer any questions. They can discuss any concerns you have about this study.

How to contact the research team:

If you have any questions about this study

Principle Investigator at the Walton Centre is Janine Winterbottom can be contacted via the research team

You can request contact

Contact details of the Research team: Telephone: 0151 556 3721

Study website: https://tinyurl.com/epilepsypreconceptionstudy

Email: preconceptionstudy@thewaltoncentre.nhs.uk

Part 2: Details about the conduct of the study

Who is running this study?

The Neuroscience Research Centre at The Walton Centre NHS Foundation Trust is running this study. We will provide you with details, for information or if you need to make a complaint.

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.
- 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.
- 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 about your health and care 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.

Giving consent to participate in the study

Taking part in this study is voluntary. You have the right to say no, and you don't need to give a reason. This will not affect the treatment or care you receive in any way.

We will ask for your consent before you start the survey. At the end of the survey, we will ask if you would like to consider taking part in a meeting. This is optional.

If you change your mind, you can withdraw your consent at any time, without giving a reason.

We will ask if you want to be kept up-to-date about the results of this study.

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 any concerns, ask to speak with one of the research team members. They will do their best to answer your questions.

You can complain.

You can do this by contacting local Patient Advice and Liaison Services (PALS) available at the The Walton Centre NHS Foundation Trust, by contacting the Patient and Family Experience Team for assistance (tel: 0151 556 3090 or 0151 556 3091; email: PatientExperienceTeam@thewaltoncentre.nhs.uk.

Members of your local hospital team can also help provide this information for you.

If you are still unhappy, you can 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.

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