Understanding Side Effects of Antiseizure Medication: The Impact of Medication Type, Personal Background, and Thinking Style

PARTICIPANT INFORMATION SHEET

You are being invited to take part in a research study on behalf of the University of Liverpool and Epilepsy Research Institute. Before you decide, please take this opportunity to read through this information sheet and discuss it with friends.

This study is being conducted by Liam Jarvis, a PhD student in a joint partnership between the University of Liverpool and Epilepsy Research Institute UK, supervised by Dr Adam Noble.

What is the purpose of this study?

In the UK, the most common treatment for epilepsy is antiseizure medication. However, some people can experience unpleasant side effects, which can reduce quality of life and how satisfied people are with their treatment. It is unclear why some people experience side effects whilst other do not. Our study is going to try and find some answers to this question, by investigating a range of factors including epilepsy background, medication type and strength as well as psychological factors that are involved in the experience of side effects, in addition to epilepsy type and medications.

Why have I been invited?

We are looking for people with epilepsy and the significant others of people with epilepsy (e.g., partner, family member or friend). Along with being able to independently complete online questionnaires in English, eligible participants must meet the criteria stated below.

People with epilepsy taking part would need to:

- Be aged 18 years or over and living in the UK
- Report a formal diagnosis of epilepsy
- Be prescribed at least one daily antiseizure medication

People taking part as a significant other of someone with epilepsy would need to be:

- Aged 18 or over and living in the UK
- Be a family member or friend of someone formally diagnosed with epilepsy who is prescribed at least one daily antiseizure medication (the person with epilepsy they know can be of any age)

Please note people with epilepsy can take part with or without a significant other taking part, similarly significant others can take part with or without a person with epilepsy they know taking part.

Unfortunately, people who have a terminal health condition and/or severe psychiatric condition (e.g., active psychosis) cannot take part.

What does taking part involve?

If you decide to take part in this study, you will be asked to complete questionnaires at three time points over a 9-month period. All questionnaires will be completed online and all information will be kept confidential.

The questionnaires include questions about your or your significant other's epilepsy and treatment, experiences of side effects, healthcare use, mental wellbeing, and beliefs about thinking style.

Timing:

- Time 1: Straight away after you agree to take part
- Time 2: Approximately 3 months later
- Time 3: Approximately 9 months after you first joined the study

To make sure taking part is as easy as possible we shall send you the surveys when they are due and offer you reminders. To help us do this you will be asked to provide your preferred method of contact and one backup method.

What are the potential risks and benefits of taking part?

There will be no direct benefit to the healthcare for people with epilepsy who take part (or anyone they know). However, it is our hope that taking part will help us further understand how side effects from antiseizure medication are experienced. This may help inform future research and possibly reduce side effects for people in the future.

Every participant - both those with epilepsy and significant others - will receive a thank-you acknowledgement for their time and effort in taking part. For each survey a person is sent and fully completes they will get a £5 "love2shop" voucher. This means, if someone takes part in the entire study they will receive a total of £15 in shopping vouchers. On top of this, there we shall also run an extra prize draw after each round of surveys to win another "love2shop" voucher to the value of £50 (the chances of a person winning a prize draw is about 1 in 500).

There are minimal risks to you from taking part in this study. However, some of the questions will ask you to think about your epilepsy (or the epilepsy of the person you know). It is possible that this may be upsetting for some people. Please remember you can stop doing the survey at any time without giving a reason.

Should you have any concerns having completed the survey, please do get in contact with your care provider. We will also provide the details of some potentially helpful organisations with free helplines. Please also let us know so we can improve the quality of future research. Contact details for the principal study investigator will also be provided.

How will we use information about you?

We will need to use information from you and, if taking part as a significant other, from the person you know with epilepsy (whether they are participating or not) for this research project.

This information will include your name and contact details, which includes:

- Email address
- Telephone number
- Postal address

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.

The University of Liverpool is the sponsor of this research and are responsible for looking after your information. We will not share your information related to this research project with any other organisations.

We will keep all information about you safe and secure by:

- Storing your data on a secure system certified by Cyber Essentials

- Identifiable information for the purpose of notifying you when it's time to complete the 2nd or 3rd surveys will be stored in a password-protected file and replaced with a participant ID number
- Ensuring all personally identifiable participant information will be stripped from the data and not included in the analysed dataset

International transfers

Your data will not be shared outside the UK.

How will we use information about you after the study ends?

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.

We will keep your study data for a maximum of 10 years. The study data will remain fully anonymised and securely archived or destroyed.

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.

You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

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

You can find out more about how we use your information: https://www.liverpool.ac.uk/legal/data_protection/

Do I have to take part?

No. Participation is voluntary. A decision to take part will not affect your medical care or that of anyone else you know.

What should I do if I want to take part?

If you are interested in taking part, please click next and read through the consent form. Should you have any questions, please contact the Principal Investigator (contact details below). After completing the consent form, the main study questionnaires follow. We estimate it will take you about 20 minutes to complete the Time 1 survey, 5 minutes to complete the Time 2 survey, and approximately 12 minutes to complete the Time 3 survey. There are no right or wrong responses to the survey questions. The

number of participants we can include in this study is limited by the available funding for participant reimbursement.

What if I change my mind?

You are free to change your mind at any point during the research process, including during or after completing the online questionnaire. You would not need to give a reason, and this would not affect the medical care you or anyone you know gets.

You can request your study data be deleted up until the point of anonymisation, after which it will not be possible to identify you. Data will be fully anonymised after Time 3.

If you want to stop taking part, no more information will be collected from you. Your rights to access, change or move the information that had already been collected though are limited, as we need to manage your information for the research to be reliable and accurate. If you choose to stop taking part in the study, we will keep the information about you that we have already. However, you do have the right to request that your data is deleted, up until complete anonymisation, by emailing the study team. We anticipate complete data anonymisation to occur in June 2027. To protect your rights, we will use the minimum amount of personal information possible.

What will happen to the results of the study?

The results from this study will be published in scientific journals and other forums. You will not be identified in any publication. If you want a copy of the published results, please contact us via email.

Who is funding the study?

The study is jointly funded by the Epilepsy Research Institute and the University of Liverpool.

What if something goes wrong?

If you are worried about anything to do with the study, please contact the Principal Investigator Dr Adam Noble. If you feel you cannot come to us, then you should contact the University of Liverpool's Research Governance Officer (Tel: 0151 794 8290; email ethics@liv.ac.uk).

The University maintains the highest standards when processing your data. However, if you have any concerns about the way in which the University handles your personal data, then you have the right to lodge a complaint with the Information Commissioner's Office by calling 0303 123 1113.

Who has reviewed the study?

This study has been reviewed and approved by the Health Research Authority (HRA) and the northwest NHS Research Ethics Committee.

Contact for further information:

Should you need further information about the study or if you would like a copy of the study results you can contact the research team at any time:

Study team coordinator

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Thank you for taking the time to read through this information sheet