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PATIENT PARTICIPANT INFORMATION SHEET

Study title: Research offering Seizure First Aid Training to people with epilepsy and their family and friends: A pilot trial (REC reference no: 5/NW/0225)

1. Invitation paragraph

You are being asked to take part in a research study. Before you decide whether you want to take part, it is important for you to know why the research is being done and what it will involve. Please read this information sheet carefully. If you wish to you can talk about it with your friends and relatives. Ask us if there is anything you do not understand or if you want more information. You can take time to decide whether you want to take part.

2. What is the reason for the study?

People with epilepsy need to know what to do when a seizure happens. They also need to be able to tell others what to do. This is also true for the friends and family of people with epilepsy. To feel confident to do these things, some people with epilepsy and family members have said they need more information about epilepsy and seizure first aid. They said they want to know more about the effects of seizures, how to deal with different types and know when they do and do not need emergency medical help. Therefore, together with the Epilepsy Society, we have made a short course on seizure first aid that people with epilepsy and their family and friends can go on. The course is called Seizure First Aid Training.

Ambulance staff, neurologists, nurses and emergency medicine doctors have helped us decide what information the course should give. The course takes 3 hours to do and people with epilepsy take it together with a family member or friend. It is a group based course so there are other people with epilepsy and their family and friends at the course. Our study is looking to see how helpful the Seizure First Aid Training course is. We want to know whether it helps people with epilepsy and their family and friends get the information they want and whether it makes them more confident managing seizures. We need to know this so the NHS can decide whether it should offer the course.

3. What type of study is it that you are doing?

The type of study we are doing is called a pilot randomised trial. In this sort of study, people taking part are put into one of two groups at random by a computer. The first group is called Group A and the second Group B. People who are put in Group A get the Seizure First Aid Training course straightaway and people in Group B continue to receive their normal medical care. The health of the people in the two groups is then compared to see if the Seizure First Aid Training was helpful or not.

After the two groups' health has been compared, people in Group B then get to go on a Seizure First Aid Training course if they want it. At the moment we do not know if the Seizure First Aid Training course is any more helpful

than the normal care people already receive from the NHS. This means a randomised trial is the most exact and fair way to see how helpful the course is. Each year thousands of people take part in randomised trials.

4. Why am I being asked to take part?

We are looking for people with epilepsy to take part in our study with a family member or friend. To take part in our study, people with epilepsy need to be aged 16 or over. They must have been diagnosed with epilepsy for 1 or more years and be prescribed anti-epileptic medication. They also need to have visited a hospital emergency department for epilepsy two or more times in the last 12 months. The person can have any type of epilepsy and their seizures can be of any severity. However, people cannot take part in the study if they experience non-epileptic seizures. The Seizure First Aid Training course is given in English. This means people can also only take part if they can speak, read and understand English well. You are being invited to take part because we believe you fit the above description.

5. Do I have to take part?

No. It is up to you. Even if you decide to take part, you are still free to change your mind at any time. You would not need to give a reason. A decision to not take part will not affect your medical care. No new information would be collected on you. However, any information that had already been collected would be kept.

6. What will happen to me if I take part?

If you want to take part, our researcher will arrange to see you at a time and place that is convenient for you. They could meet you at your home or our university offices. You will also be asked to choose a family member or friend to take part in the study with you. At the appointment, the researcher will explain the study to you and your family member or friend and answer any questions you have. You will be given this information sheet to keep and each asked to sign a consent form. You will then be asked to each fill in a questionnaire. It will ask your health, quality of life and how you manage seizures. The researcher will be on hand to help you if needed. The appointment will last about one hour. After the appointment, the researcher will use a computer programme to put you into either Group A or Group B. The group you are put in will decide when you and your family member or friend gets to go on the Seizure First Aid Training. You will not be able to choose which group you are put in and we will not make the decision ourselves. We will let you know which group you have been put in.

7. What will happen to me if I am put into Group A?

If you are put into Group A you will be asked to go on a Seizure First Aid Training course about a month after you signed the consent form. You will still continue to take your medications and see your doctors and nurses as normal.

After going on the course you will be asked to fill in a short questionnaire about your health three times. The first time will be three months after you joined the study. The researcher will telephone you and ask you the questions. It should take about 10 minutes. The second time will be six months after you joined the study. On

this occasion you will be sent the questionnaire in the post and asked to post it back to us when you have finished it. It should take you about 30 minutes to do.

The final time you will be asked to fill in the questionnaire will be about twelve months after you joined the study. You will do it during a face-to-face appointment with our researcher. This appointment will last about one hour and happen at a time and place that is convenient for you.

8. What will happen to me if I am put into Group B?

If you are put into Group B you will not get to go on the Seizure First Aid Training course straightway. Instead, you will continue to receive your normal medical care for the next 12 months and be asked to fill in a questionnaire on your health three times. The first time will be three months after you first filled it in. The researcher will telephone you and ask you the questions. It should take about 10 minutes. The second time will be six months after you first filled it in. On this occasion you will be sent the questionnaire in the post and asked to post it back to us when you have finished it. It should take you about 30 minutes to do.

The final time you will be asked to fill in the questionnaire will be about twelve months after you first filled it in. You will do it during a face-to-face appointment with our researcher. This appointment will last about one hour and happen at a time and place that is convenient for you. You will be able to go on a Seizure First Aid Training course after everyone in the study has completed their final questionnaire. This should mean your course will typically take place about six months after you filled in your final questionnaire.

9. Where and how will the Seizure First Aid Training courses be run?

The courses will be run on weekdays at a hospital near to your home. For the course, you will need to go to the hospital just once. The courses will typically run from [INSERT TIME] until [INSERT TIME], with breaks included. The research team will speak with you to find a course that is convenient for you to go to.

Each course will be given by a specially trained health professional from the charity, the Epilepsy Society. These people are typically nurses and will be able to help should a seizure happen. About 10 people with epilepsy and their family and friends will be at each of the courses. During the course, the health professional will give lots of information about epilepsy and show some video clips. They will talk about things people with epilepsy and their family and friends have said they want to know more about. This includes giving information on:

- How common epilepsy is.
- Its causes and some myths about epilepsy.
- The tests doctors use to diagnose it.
- The different types of seizures and their effects.

- How to deal with different seizures, including when to call an ambulance and how to help paramedics help you.
- How to improve your confidence and tell others what to do to if a person with epilepsy has a seizure.

At the course, you can ask questions. If you want to, you can share your experiences with the other people taking the course. Everyone taking the course is given an information pack to keep. It includes all the things talked about on the course. It also gives the details of support organisations. If you agree, we will audio-record the Seizure First Aid Training course sessions. We want to do this to have a record how well the course was run by the health professional. If illness means you can only go to part of the course, we can arrange for you to finish the course on another day.

10. How long would I be involved in the study?

If you are put into Group A you will be in the study for about one year. If you are in Group B you will typically be involved with the study for about 18 months.

11. Expenses

We do not expect you will have any expenses from taking part in our study. If needed, we can pay for a taxi to take you and your family member or friend to and from the course. We will also provide refreshments for you. All participants will receive a £10 shopping voucher for each of the questionnaires they do by post or in person. This is to thank them for their time and effort. Therefore, each person who takes part in our study can get up to £30. If you decide to take time off work to go on the course, we will not be able to pay you or your employer.

12. Are there any benefits in taking part?

We hope you and your family member or friend will get helpful information on epilepsy and learn some things that may increase your confidence to deal with seizures. However, this cannot be guaranteed. The information we get from the study may help us better support people with epilepsy in the future.

13. Are there any risks in taking part?

There are no known disadvantages or risks of taking part. Taking part in the study will not change the care you get for epilepsy. Your medicines will stay the same and you will see your usual doctors and nurses as normal. The Seizure First Aid Training course and some of the questionnaires that we will ask you will involve thinking about your epilepsy and feelings. For some people, this may be upsetting. You can stop taking part in the course or doing the questionnaire at any time. This would not affect your medical care in any way.

If taking part in the course or answering the questionnaires makes you worried about your feelings, you can talk to your GP. You can also ask the health professional giving your course for advice. However, they would not be able to refer you to any NHS service themselves.

14. Will my taking part in this study be kept confidential?

Yes. All the information we collect on you during the study will be kept confidential. Only the research team will be able to see the information. This includes the audio recordings. Anything that we publish or pass on will have your name and address and any personal information removed so that you cannot be identified. All information will be stored on password protected computers at the University of Liverpool. Your participation will not affect your medical care.

With your permission, we would want to tell your GP/ hospital specialist about your taking part. We would also need to speak with them and possibly access your medical records if the health professional giving your course or our researcher becomes worried about your wellbeing. However, we would talk about this with you first.

The Seizure First Aid Training course is given to groups of about 10 people with epilepsy and their family and friends. Because of this, we cannot promise that other participants will not share information about one another outside of the group. To lower the chances of this happening, we will get all participants to sign a form. This will say that they agree that anything they hear about other participants should not be talked about outside of the group. The health professional giving the course will remind participants of this.

As part of the project we would like to see if being in the study helps you become more confident to deal with seizures. One way we would like to find this out is by seeing if your use of hospital emergency departments changes. Information on when you have visited hospital emergency departments is already stored by the Health and Social Care Information Centre. They are a public body, sponsored by the Department of Health. With your agreement, we would like to see information held by the Health and Social Care Information Centre on your visits to hospital emergency departments. To do this, we would send the Health and Social Care Information Centre your NHS number and ask them for information on how many times you used hospital emergency departments in the 12 months before coming into our study and then how many times you went whilst you are in the study. All information that will be sent between the Health and Social Care Information Centre and us would be done using secure methods.

15. What happens when the study stops?

You continue to receive your normal medical care.

16. What if something goes wrong?

The University of Liverpool has insurance cover just in case you experience a problem from taking part in the study. If you are worried about anything to do with the study, you should contact the research team. Their details are at the end of this sheet.

17. What will happen to the results of the study?

The results from this study will be published in scientific journals. You will not be identified in any publication. If you want a copy of the published results, you can ask for one by contacting the study team. All information generated by this study will be held on password secured computers at the University of Liverpool offices. In line with the university's policy, data will be archived at the University of Liverpool for of at least 10 years, longer if judged to be of historical significance. After this period the data will be destroyed.

18. Who is funding and organising the study?

The study is funded by the National Institute for Health Research. The study is being done by the Institute of Psychology, Health and Society, The Whelan Building, University of Liverpool, L69 3GL. The lead researcher is Dr Adam Noble.

19. Who has reviewed the study?

This study has been reviewed and approved by National Research Ethics Service Committee North West - Liverpool East (Reference: 15/NW/0225).

20. Contact for further information:

Should you need further information about the study you can contact the research team at any time:

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Email: Seizure_First_Aid_project@liv.ac.uk

You will be given a copy of this information sheet and a signed copy of your consent form to keep.

Thank you!