

# PARTICIPANT INFORMATION SHEET

## **Study title: Research offering people with epilepsy a course to help them get the information they want and improve their quality of life: a randomised trial**

(REC reference no: 12/LO/1962)

### **Invitation paragraph**

You are being asked to take part in a research study. Here is some information to help you decide if you want to. Please take time to read it carefully. If you wish to you can talk about it with friends, relatives and your GP. 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.

### **1. What is the purpose of the study?**

People with epilepsy need to do things to lower their chances of having seizures and to reduce the effect epilepsy has on their lives. They may need to take medicines every day and learn to stay away from triggers for seizures. They need to learn first aid for epilepsy and tell others what to do if a seizure happens.

To feel confident in doing these things, some people with epilepsy say they want more information about epilepsy. Therefore, we are bringing an information course to England for people with epilepsy. The course is already given to people with epilepsy in other countries and has been found to help them. After taking the course, people there know more about epilepsy, feel more confident in dealing with epilepsy and have fewer seizures.

The course is called MOSES. This stands for Modular Service Package Epilepsy. It was designed with the help of people who have epilepsy themselves. The course takes two days to do and patients take it together with other people with epilepsy. If they want, patients can take a family member or friend to the course with them. Two health professionals run each course.

Our study is going to test the MOSES course in England. We want to see if it can help people with epilepsy here get the information they want and improve their quality of life.

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

The type of study we are doing is called a 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 get put in Group A get the MOSES 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 MOSES was helpful or not. After the two

groups' health has been compared, people in Group B then get to go on a MOSES course if they want it.

At the moment we do not know if the MOSES course is any more helpful than the normal medical care people already receive from the NHS. This means a randomised trial is the most exact and fair way to test how helpful MOSES is. Each year thousands of people take part in randomised trials.

#### **4. Why am I being invited to take part?**

We are looking for people with epilepsy to take part in our study. To take part in our study, people need to be aged 16 or over. They must have been diagnosed with epilepsy and have had two or more epileptic seizures in the last 12 months. The seizures can be of any type. The 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 this 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 has already been collected would be kept.

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

If you want to take part, a 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. At the appointment, the researcher will explain the study to you some more and answer any questions you have. You will be given this information sheet to keep and be asked to sign a consent form. You will then be asked to fill in a questionnaire about your epilepsy. It will ask you about your seizures and what affect they have on your life. The researcher will be on hand to help you with the questionnaire 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 get to go on the MOSES course. 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 MOSES course about a month after you signed the consent form.

After going on the MOSES course you will be asked to fill in the questionnaire about your epilepsy two more times. You will be asked to complete it by post six months after you first filled it in. Then again during a face-to-face appointment with a

researcher one year after you first completed it. This appointment will last about one hour and take place at a time and place that is convenient for you.

After filling in the questionnaire for the last time you may be asked by the research team if you want to take part in an extra face-to-face interview. We are doing these interviews with a small number of participants from Group A so we can hear their views of the course. If you are invited to be interviewed, it is up to you if you take part. If you do, it will last about one hour and take place at a time and place convenient for you. With your permission, the interview will be audio-recorded to provide an accurate record of the conversation. The recording will be destroyed once the research team have listened to it and typed it up.

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

If you are put into Group B you will continue to receive your normal medical care for the next 12 months, and be asked to fill in the questionnaire on your epilepsy two more times. You will be asked to complete it by post six months after you first filled it in. Then again during a face-to-face appointment with a researcher about one year after you first completed it. This last appointment with the researcher will last about one hour and take place at a time and location that is convenient for you.

You will be able to go on a MOSES course after everyone in the study has completed their final questionnaire. This should mean your MOSES course will typically take place about six months after you fill in your final questionnaire.

## **9. Where and how will the MOSES courses be run?**

The courses will be run at a hospital near to your home. For the course you will need to go to the hospital two days in a row. The course will run from 9 o'clock in the morning until half past five in the evening on both days, with breaks included. Some courses will run at weekdays and some at weekends. The research team will speak with you to find a course that is convenient for you to attend.

You will take the course with about 10 other people with epilepsy. If you want them to, there will be some space for a family member or friend of yours to take the course with you.

The course will be led by two health professionals, such as epilepsy nurse specialists. At least one of the people running the course will have a medical or nursing background in case a seizure happens.

During the course, the health professionals will give lots of information about epilepsy. They will talk about things people with epilepsy have said they want to know more about. This includes giving information on:

- how common epilepsy is
- its causes
- the different types of epilepsy
- the emotional side of having epilepsy
- the tests doctors use to diagnose it
- how epilepsy is treated and ways to remember to take medicines

- how to spot triggers for seizures
- the chances of becoming seizure-free
- the rights of people with epilepsy
- how to improve your confidence and tell others what to do to if you have a seizure.

At the course, you can ask questions. If you want to, you can also share your own experiences with the other people taking the course.

Everyone taking the course is given an information book to keep. This book has been designed with the help of people with epilepsy. 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 MOSES course sessions. We want to do this to provide a record of how well the course was run by the health professionals.

If illness means you can only go to one day of the course, we can arrange for you to finish the course on another day somewhere else.

#### **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, or slightly longer if you take part in an interview about the course. If you are in Group B you will be in 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 to and from the course. We will also provide lunch and drinks for you. If you decide to take time off work to go on the course, we will not be able to pay you or your employer. All participants will receive a £20 shopping voucher on return of their final questionnaire to thank them for their time and effort.

#### **12. What are the possible benefits of taking part?**

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

#### **13. Are there any restrictions on what I can do?**

No. There will be no restrictions in terms of your lifestyle when taking part in this study. Your medicines will not be altered in anyway. You will still see your usual doctors and/or nurses as normal.

#### **14. What are the possible disadvantages and risks of taking part?**

There are no known disadvantages or risks of taking part. The course is routinely given to people with epilepsy in other countries. However, the course and some of the questionnaires involve thinking about your epilepsy and feelings. For some people, this can be upsetting. You can stop taking part in the course or doing the questionnaire at any time. This would not affect your medical care.

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 professionals giving your MOSES course for advice. However, they would not be able to refer you to any NHS service themselves.

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

All the information we collect on you during the study will be kept confidential. This includes the audio recordings. Only the research team will be able to see the information. 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 King's College London. Your participation will not affect your medical care.

With your permission, we would want to tell your GP about your taking part and see your medical file. We would also need to tell your GP if one of the health professionals giving your MOSES course or our researchers becomes worried about your well-being. However, we would discuss this with you first.

The MOSES course is given to groups of about 10 people at a time. Because of this, we cannot promise that other participants will not share information about one another outside of the group. To lower the chance 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 discussed outside of the group. The health professionals giving the course will remind participants of this at the start of the course.

**16. What happens when the study stops?**

You continue to receive your normal medical care.

**17. What if something goes wrong?**

King's College London provides 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 study manager. Their details are at the end of this sheet.

**18. 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.

**19. 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 Clinical Neuroscience Department, PO 57, King's College London, Denmark Hill Campus, London, SE5 8AF. The lead researchers are Professor Leone Ridsdale and Professor Laura Goldstein.

**20. Who has reviewed the study?**

This study has been reviewed and approved by NRES London – Fulham Research Ethics Committee.

**21. Contact for further information:**

Should you need further information about the study you can contact the study manager at any time (*contact details removed for this report*)

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