Local Header

COMPARING THE EFFECTIVENESS OF DIFFERENT TREATMENTS IN REDUCING DISSOCIATIVE SEIZURE OCCURRENCE

(LREC 13/LO/1595)

###### **PARTICIPANT INFORMATION SHEET**

You are being invited to take part in a research study. Here is information to help you decide. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Do please take time to decide whether or not you wish to take part

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

We are undertaking a study to look at treatments for dissociative seizures. At this stage of the study we wish to see whether people who are given a diagnosis of dissociative seizures and an information leaflet about dissociative seizures by a neurologist/epilepsy specialist, carry on having seizures or not. If people carry on having their seizures and are seen by a psychiatrist who may be able to understand other factors that contribute to their seizures, we will then want to investigate whether a ‘talking treatment’ known as Cognitive Behavioural Therapy is more effective in helping people control their seizures and improve other aspects of their lives, than is the medical care that people receive from their neurologist/epilepsy specialist and / or from a psychiatrist. We would do this as part of what is called a randomised controlled trial and, if you were still having seizures, we would ask you if you were interested in taking part in that part of the study.

## 2. Why have I been invited to take part?

We are approaching you because we know from the neurologist/epilepsy specialist who recently saw you that you have been given a diagnosis of dissociative seizures. In addition to this, we are inviting people who are aged 18 or older, who we believe would be willing to continue to complete seizure diaries and able to complete questionnaires, who would be willing to see a psychiatrist about their seizures, who have no record of having any intellectual disabilities and who do not have any current seizures thought to be due to epilepsy or any problems with drugs or alcohol. We are inviting you because we believe that you fit this description.

## 4. Do I have to take part?

No. It is up to you to decide whether or not to take part. If you are interested in taking part then you will be given the opportunity to discuss the trial with a research nurse and/or with a member of our research team who will be helping to run the study for us.

If you decide to take part, you are still free to withdraw at any time and without giving a reason. If at any time you decide to withdraw from the study, or decide not to take part, this will not affect the standard of care you receive now or in the future. We would not collect any new information on you. However, any information that we had already collected would be kept by the study team.

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

If you decide to take part then a research worker or nurse will arrange to meet with you at a time that is convenient for you. At the appointment the research worker or nurse will explain the study to you in more detail and answer any questions that you may have. We will give you another copy of this Information Sheet to keep and ask you to sign a consent form.

The research worker will then ask you to continue to complete diaries relating to the how often you have the different types of your seizures. The study’s research worker will go through how to do this with you. We will ask you to keep these detailed records at least until you are seen by the psychiatrist. The research worker will be in contact with you regularly, every couple of weeks, to find out how many seizures you have been having and answer any questions you may have. We will also check when you are due to see the psychiatrist and where.

The researcher will also collect some simple information on things such as your age, previous medical history and employment history.

When you are seen by the psychiatrist, they will also ask you about your seizures. They will go over the points covered by the neurologist at diagnosis and will give you another leaflet on dissociative seizures. They will undertake an assessment of any psychological problems that you may have and will explain how treatment might help you. If you have continued to have your seizures they will also explain the treatment study we are undertaking and ask you if you want to take part. It may sometimes be the case that the psychiatrist will discuss with you whether additional assessment is needed before we confirm that you can enter the trial, or determine that you might not be able to be enter the trial. They will also give you some practical tips for dealing with your seizures and everyday problems.

If you join our study, we will ask if we can use your (English) NHS number or your (Scottish) CHI to register you with the (English) Office for National Statistics or the (Scottish) Information and Statistics Division. Having this NHS or CHI number will help us contact you, perhaps through your GP, if you move house during our study.

With your permission, we will write to your GP to let them know that you are taking part in this study.

**6. What do I have to do?**

If you decide to take part in the study, we will ask you to continue to keep records of your seizures and to agree to be seen by a psychiatrist with expertise in dissociative seizures after 3 months.

**7. How long will I be in the study?**

If you agree to take part in this part of the study it will take about 3 months. If you become involved in the later treatment study this will be for about a further year.

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

Keeping records of your seizures and being seen by a psychiatrist can make you think and talk about your feelings and things that have happened to you and about your seizures. For some people, this may be upsetting. Psychiatrists are, however, used to helping people in distress so they may be able to help reduce your distress. You can, however, withdraw from the study at any time. You would not need to give a reason for doing so and this will not affect the quality of medical care you receive.

If as a result of taking part in the study you become concerned about your feelings you can talk to your GP. You can of course also raise this with the medical specialists you are seeing as part of the study.

## 9. What are the possible benefits of taking part?

By taking part in this part of the study you will help us understand more about the pattern of what happens to people’s dissociative seizures when they have been given their diagnosis. We hope, however, that you will also get some helpful information during the study about your condition.

## 10. Are their any restrictions on what I can do?

There will be no restrictions on your diet or lifestyle during the study. The doctors you see will make any changes to your medication that they feel are necessary for you.

**11. Expenses**

If you take part in the study and see the research worker, we will offer you up to a maximum of £25 towards your travel for each visit to the hospital/out-patient clinic that is necessary as part of the study to give us information. However, if you take time off work to attend the study appointments we cannot pay you or your employer for this.

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

## All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you will have your name and address removed so that you cannot be recognised from it. We will not identify you in our computers or publications by name, and will only refer to you by participant number, which will be used in place of your name on any future publications. All information will be stored on password protected computers. Your participation will have no influence on your medical care.

With your agreement we would inform your GP that you are taking part in the study and look at your medical file. We would also need to inform your GP or other professionals if one of the health professionals or research workers in the study became concerned about your well-being or about the implications of what you tell us for someone else’s well-being. We would of course discuss this with you.

## 13. What will happen if new information becomes available?

Sometimes during the course of a study new information might become available about the treatment that is being tested. If this happens, either your medical doctor (neurologist/epilepsy specialist/psychiatrist) or a member of the research team will contact you and arrange to talk to you about this and discuss with you whether you want to continue. If you decide to withdraw from the study your doctor will make arrangements for your care to continue. If you decide to continue in the study you may be asked to sign an updated consent form.

## 14. What happens when the study is over?

Once the trial is over, we will see describe what has happened to the seizures of people initially given their diagnosis and an information leaflet. If your seizures have continued we will ask you whether you want to take part in the next phase of the study which will compare CBT with standard medical care for treating dissociative seizures.

## 15. What happens if something goes wrong?

We do not expect there to be any adverse effects from taking part in this study, however if you are harmed during the study and this is due to someone’s negligence, then you may have grounds for legal action for compensation against the NHS but you may have to pay your legal costs. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms should be available to you.

King’s College London holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study you may be eligible to claim compensation without having to prove that King’s College London is at fault. This does not affect your legal rights to seek compensation.

If for any reason your seizures get much worse during the study, then you will be able to talk to your medical specialist or any of us who are involved in the study and discuss what you want to do.

## 16. What happens to the results of the research study?

We will publish the results of the research in scientific journals and we will present the results at scientific meetings. In addition we will talk to service providers about the results of our research. You will not be identified in any report/publication. If you would like a copy of the published results, we can provide this at the end of the study.

**17. Discontinuation of the study by the investigators**

We will need to contact you at different stages of the study to ask for information and will give you two reminders to let us have this information. If at any particular stage you change your mind about taking part in the study and we do not hear from you at all, we will contact you on only one further occasion to discuss the study. If we cannot discuss this with you we will assume you have chosen to leave the study. We can reassure you that you will not be contacted repeatedly if you decide you no longer wish to be part of the study. If you then change your mind about letting us have the information we asked for, you can contact us by phone, letter or email to then re-join the study if you wish.

At any time during the study, the investigators have the right to end your participation in the study for any reason. If later on in the study it is concluded that you no longer have capacity to consent to participating we would like to be able to continue to use any data that we have already collected, in an anonymised form.

**18. Withdrawal from the study**

Taking part in this study is entirely voluntary. You can stop taking part in the study at any time without giving a reason and without this affecting your care in any way, now or in the future.

**19. Who is organising and funding the research?**

The study is being funded by the National Institute for Health Research. The study is being organised by researchers at the Institute of Psychiatry (King's College London), the South London and Maudsley NHS Foundation Trust, the University of Sheffield, the University of Edinburgh and Brighton and Sussex Medical School. Members of the research team include Professor L. Goldstein, Dr J. Mellers, Professor T. Chalder, Professor M. Richardson, Professor M. Reuber, Dr A. Carson, Dr J. Stone and Dr N. Medford, as well as several other colleagues who work with them.

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

This study has been granted ethics approval by the London - Camberwell and St Giles Research Ethics Committee. The study has also been reviewed by the National Institute for Health Research Health Technology Assessment programme.

**21. Contact for further information**?

If you wish to discuss the study in greater detail then please contact one of the following people:

(TBC- Trial manager)

Dept of Psychology

PO 77

The Henry Wellcome Building

Institute of Psychiatry

King's College London

De Crespigny Park

London SE5 8AF

Tel…..

Name and contact details of local Site PI

Other contacts

Professor Laura Goldstein, Professor of Clinical Neuropsychology and Hon Consultant Clinical Psychologist; Dept of Psychology, Institute of Psychiatry (tel …..)

Dr John Mellers, Consultant Neuropsychiatrist, Maudsley Hospital, London

 (tel …..)

Professor Markus Reuber, Department of Neurology, Royal Hallamshire Hospital, Sheffield (tel: …..)

Dr Jon Stone, Consultant Neurologist, Western General Hospital, Edinburgh

(tel: …..)

If you would like any independent advice about taking part in a research study please contact the Patient Advice and Liaison Service (tel: XXXXXXXXXXXXX)

Thank you for reading this information sheet. You will be given a copy to keep. If you have understood the contents of this sheet and wish to take part, please complete the consent sheet. If you have any questions please feel free to ask them now.