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# Sheffield Teaching Hospitals NHS Foundation TrustPARTICIPANT INFORMATION SHEET

**Title of Project: Developing a writing intervention for patients with seizures (a home-based study)**

**Name of Researchers: Gregg Rawlings, Prof Markus Reuber, Prof Brendan Stone & Dr Ian Brown**

*We would like to invite you to take part in a research study. Before you decide whether to take part, you should understand why the research is being done and what it would involve for you. Please read the following information carefully and talk to others about the study if you wish. Please contact us if there is anything that is not clear or if you would like more information. Please take time to decide whether or not you wish to take part. Thank you for reading this.*

**Background**

Epilepsy and non-epileptic attack disorder (NEAD) are chronic, disabling conditions that are characterised by seizures. People living with these disorders are also at an increased risk of developing other symptoms such as depression, anxiety and pain such as headaches. Research has shown in patients with other chronic conditions (such as arthritis and asthma), that writing may help to reduce symptoms and improve physical and psychological health. Although writing is a simple and easy form of therapy, the health benefits have yet to be investigated in patients with seizures.

This study is being carried out as part of a PhD research project based at the University of Sheffield.

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

The purpose of the study is to test whether a writing intervention can help reduce symptoms of epilepsy and NEAD including seizure frequency and severity, quality of life, anxiety, depression and illness perception. We are also interested in what you write about in the hope it will generate deeper insights and understanding of living with a seizure disorder.

**Why have I been asked to take part?**

We are approaching people who are over the age of 18 years old, who have a medical diagnosis of either epilepsy or NEAD (psychogenic nonepileptic / dissociative seizures) or both epilepsy and NEAD, who are literate in English, able to write and complete a series of questionnaires without any assistance, and who can provide informed consent.

If you agree to take part, we will ask for your consent for us to contact your doctor as we may need to confirm your medical diagnosis.

**Do I have to take part?**

It is your decision whether or not to take part. If you have any questions about this study you can contact us on the contact details provided at the end of the Participant Information Sheet. If you do decide to take part you are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive in any way.

**What will happen to me if I take part?**

You will be asked to sign a consent form to record your agreement to take part. You will also be asked to complete a set of questionnaires. This should take no longer than 15 minutes.

You can take part in the study in two ways: option 1 is if you would like to handwrite, option 2 is if you would like to type using a computer. You will receive both sets of material so you can decide which option is best for you at a later date.

**Option 1 (handwriting)**

You will receive four writing booklets. Each booklet will contain a topic (question) you should write about, space for you to write and a short questionnaire. You will be asked to complete one booklet each day at home, making sure all four are completed within two weeks. We ask that you spend at least 20 minutes writing about the topic.

Once you have finished each booklet, you will be asked to complete a short questionnaire asking how you felt the writing went. Once all four booklets are complete you will be asked to place the booklets back in the free post envelope that we will provide and send them back to us.

We will also provide a set of instructions containing important contact details and guidance to help you with your writing.

**Option 2 (computer typing)**

You will receive an information sheet with the details of a website address. When you access the webpage you will see four webpage links that will take you to a writing session. Each session will contain a topic (question) you should write about, space for you to write and a short questionnaire. You will be asked to complete one session each day at home, making sure all four are completed within two weeks. We ask that you spend at least 20 minutes writing about the topic.

Once you have finished writing you will be asked to complete a short questionnaire at the bottom of the page asking how you felt the writing went, and then press submit.

We will also provide a set of instructions containing important contact details and guidance to help you with your writing.

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You will also be provided with a writing session timetable asking you to record the time, date and location that you intend to complete the four individual writing sessions/booklets at home.

As part of the study, one month and three months after completing the last writing session we will send you a set of follow-up questionnaires.

**What are the possible benefits of this study?**

This study will help us evaluate the benefits of a writing intervention for improving the quality of life and reducing symptoms associated with seizure disorders. Also, the knowledge gained from patient’s writings will further contribute to a better understanding of what it is like to live with the individual conditions. We hope that the study proves that the writing is helpful and if so, it could be made available to other people experiencing seizures.

**What are the possible risks of taking part in this study?**

There are no significant risks associated with taking part in the study. Although we will provide you with details of services and organisations you can contact for further support. If you feel distressed or anxious during writing you can stop at any time.

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

All the information that is collected about you during this study will be kept strictly confidential. We will keep your personal details, such as name, address and telephone number, separate and locked in a secure location. This means that your identity will be kept private. Any personal details held by us will be destroyed once the study has finished.

**What will happen to the results of the study?**

The results of this study will contribute to a PhD Thesis. We will also publish the results of the study in a scientific journal. You will not be identified individually in the write-up. If any of your writings are published they will be done so under a pseudo (fake) name and any names or locations will be changed. If you would like a summary of the results of the study once it is complete, please let us know.

As part of this study, you will be asked to complete some short screening questionnaires about anxiety and depression. If you reported high levels of symptoms of anxiety or depression on these questionnaires, we will inform your GP about these findings so they can be addressed if this seems necessary and appropriate.

**What if I change my mind?**

You do not have to take part in this study. If you have agreed to take part, you can stop at any time without giving your reasons. This will have no effect on any services you are receiving.

**Who should I contact if I have a question or need more information?**

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**What if something goes wrong?**

If you have a concern about any aspect of this study, you should ask to speak to the
researchers who will do their best to answer your questions. If they are unable to
resolve your concern or you wish to make a complaint regarding the study, please contact Sheffield Patient Services Team (previously known as PALS) on 0114 2712400 or Dr Philip Harvey (Registrar and Secretary, University of Sheffield) on registrar@sheffield.ac.uk or 0114 222 1101.