**WP3 Information about the project for parents and carers**

**Project title: Mental health in children with epilepsy trial**

We work at Great Ormond Street Hospital and the Institute of Child Health. We would like to invite you and your child to take part in a research study. Before you decide if you would like to take part, it is important for you to understand why the research is being done and what it will involve for you and your child.

Please read through the following information carefully and discuss it with others if you wish. Take your time to decide whether or not you wish to take part.

Please ask us if there is anything that is not clear or if you would like more information.

**What is this project and why are we doing it?**

We know that children and young people who have problems like epilepsy are more likely to have other difficulties like anxiety, low mood or behavioural problems, which can affect the young person’s overall health. We want to find the best way of treating such problems. The purpose of this study is to investigate whether psychological treatments are beneficial for reducing anxiety, depression and other behaviour problems in children and young people with epilepsy.

This study is the third stage of a larger research project on this topic. In the first stage of this larger research project, a psychological treatment for children and young people was developed. This was done by using an existing treatment that has been shown to work in children and young people (but not those with epilepsy specifically) and adding some epilepsy-specific materials to it to make it more relevant to children and young people with epilepsy and their families. In the treatment, therapy based on cognitive behavioural therapy (“CBT” – a type of therapy which aims to help you with your difficulties by looking at the link between your behaviour, thoughts, emotions and physical sensations) or behavioural strategies is provided. It includes strategies that research has shown to be helpful in reducing symptoms of anxiety, mood or behavioural problems in children and young people. The treatment is given to parents/carers and/or their child (depending on the child’s age, abilities and specific difficulties). The researcher can tell you about what the therapies involve in more detail.

In the second stage of the larger research project, we wanted to see how the treatment worked with the epilepsy-specific material in it and we wanted to know what families thought of it. So, we gave the treatment to families and asked them for their opinion on it.

Now, in the third stage of the project, we want to find out if giving the new treatment to families is helpful to them. We will do this by comparing the outcome of two groups of families: one group (group A) that does get the new treatment and one group (group B) that does not get the new treatment.

**Why have my child and I been asked to take part?**

We are contacting children and young people aged 3-18, who have epilepsy and who are attending an epilepsy clinic at [site name] and receiving or waiting to receive assessment or treatment, who may benefit from support for emotional or behavioural difficulties.

**Do my child and I have to take part?**

No. It is up to you and your child whether you and your child want to join the study. We will describe the study and go through this information sheet with you. If you wish to participate in the study, we will ask you to provide your consent to taking part. Your child also needs to be happy to take part in the study. You and your child are free to withdraw at any time, without giving a reason. This would not affect the standard of care your child receives or how quickly your child receives the care.

**What will my child and I be asked to do if we take part?**

Questionnaire

If you are interested in taking part, we will ask you and/or your child some brief questions, and depending on your answers to these, you and/or your child will be asked to complete a questionnaire (the Development and Wellbeing Assessment). Someone will give you a password and username so that you can complete the questionnaire on a computer at home or possibly at the hospital, and it can also be completed over the telephone. Depending on your answers to this questionnaire, you and/or your child may be invited to take part in the next stage of the study.

Allocation to a group

In this next stage of the study, a computer will allocate you and/or your child by chance (randomly) into either group A (the group that does get the new treatment) or group B (the group that does not get the new treatment). So you will have a 50/50 chance of either receiving the new treatment or not receiving it. Whether you are allocated to Group A or Group B you will still get your usual standard clinical care treatment.

After the computer allocates you and/or your child to a group, we will invite you to answer some further questions about you and your child.

*Group A*

If you are put into group A, you will be offered the new treatment.

Before you start the new treatment, you and/or your child will be invited to attend an in-person assessment, where the therapist will discuss the specific emotional or behavioural difficulties identified in the questionnaire with you further in detail. The assessment will take about one hour and will be video/audio recorded.

Once you start the new treatment, a therapist will guide you and/or your child through it. This will involve speaking with the therapist over the telephone once a week for around 30-50 minutes, completing worksheets and applying practices at home. Completing the worksheets will take approximately 5 minutes each week. The meetings (including any in person over the phone or Skype) will be video or audio recorded for quality purposes – the purpose is to ensure that therapists are delivering sessions in the same way.

In total, you may have up to 22 sessions, but the average number is 16 and the number depends on your specific goals for treatment.

If you are put into group A, before and after the new treatment takes place, a researcher may ask you and/or your child some more questions about their epilepsy and their experience of issues such as anxiety and depression. These interviews would be audio/video recorded and would last about 45 minutes.

*Group B*

If you are put in group B, you will not be offered the new treatment.

**What else will my child and I be asked to do if I take part?**

6 and 12 months after beginning the study we will invite you and/or your child to answer some questions (face-to-face, over the telephone or over skype) that we asked you at around the time the study started, so that we can track your progress. This will also be video/audio recorded.

We also ask that you allow us to access your hospital and educational records, as this will help us to assess if the new treatment has helped families.

We will cover travel expenses for families who make additional visits to sites to take part in the research.

**Is there anything to be worried about if my child and I take part?**

There are no specific risks from taking part in the study. No children will be deprived of any treatment that they would otherwise have received had they not been a part of the study. It is possible that thinking about their life and the effect of having epilepsy could be upsetting for you and/or your child. It is possible that the questionnaires and interviews may cause distress as they address sensitive issues. If you or your child feel any distress, please let us know so that we can offer support and think about what further help is needed, for example you may wish to be referred to services of support.

**Will taking part help my child and me?**

Not all families will get the new treatment. If you and/or your child do get the new treatment, we cannot guarantee that it will help you and/or your child, but the information we get from this study will help improve the treatment of children with anxiety, low mood or behavioural problems in the context of a neurological illness like epilepsy.

**What will happen to the recordings?**

All audio and video recordings made at any time during the study will be transcribed by a transcription service and any information that would make you or your child identifiable from them would be removed. The recordings and the transcriptions will be kept confidential and will be stored and accessed as described in the ‘*Will my taking part in the study be kept confidential?*’ section below. All recordings and transcriptions will be stored and accessed for less than 3 months after the study has ended, after which they will be destroyed confidentially in keeping with University College London and Great Ormond Street Hospital data protection policies.

**Will my / my child’s taking part in the study be kept confidential?**

If you and your child join the study, some parts of their medical and other records and the data collected for the study will be looked at by authorised persons from research or clinical team at the UCL Institute of Child Health and Great Ormond Street Hospital. This information will be transferred securely and entered onto a confidential database stored in the UCL data safe haven and a Great Ormond Street Hospital confidential database. It may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you and your child as research participants and will do their best to meet this duty. Please note that in the event that you or your child disclose any information that suggests a risk of harm to you, your child or others, we have a legal duty to disclose this information to the relevant bodies.

All your and your child’s personal data will be stored and accessed for less than 3 months after the study has ended, after which time it will be destroyed. Your and your child’s personal data – which includes your audio and video recordings – will only be accessible to the research team, although in the event of a sponsor-led audit or inspection, the individual carrying out this audit or inspection would also require access to your personal data in the course of their duties.

In order for you and your child to join the study, we must inform your child’s GP and other relevant health professionals that you wish to do this. We will write to your child’s GP, and any other involved health professionals, as appropriate, to let them know that your child is taking part in the study, and the result of the initial assessment(s). We will also write a short assessment and outcome letter resulting from the intervention to the health care team, so that your child’s health care is appropriately monitored and coordinated. Depending on the age of your child, we may also write a brief summary letter for them too. You will get a copy of these letters.

**What will happen if my child or I don’t want to carry on with the study?**

You and your child are free to withdraw from the study at any time. Your care will not be affected.

If you and your child do withdraw from the study, the information from the questionnaires, interviews and assessments that you have completed up to that point will be used in the analysis of the study results. If you prefer for this data not to be used, please let the therapist/researcher know.

We would also ask you to answer the follow-up questions 6 and 12 months after the start of the study, even if you did not complete the study. You do not have to do this if you do not want to.

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

We will write to you to let you know the overall findings of the study. We hope to publish the findings of the study. No names or other identifiable information will be used in any reports or publications. Direct quotes will be anonymised, however confidentiality cannot be guaranteed.

**Who has approved the research?**

All research in the NHS is looked at by a Research Ethics Committee. This project has been checked by the South Central – Oxford A Research Ethics Committee.

**Who do I speak to if I have more questions or worries?**

If you would like further information please contact:

Contact: Professor Roz Shafran

Address: UCL Great Ormond Street Institute of Child Health, 30 Guilford Street, London, WC1N 1EH

Email: gos-tr.mice@nhs.net

Telephone: 0207 905 2232

**What if there is a problem?**

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 you remain unhappy and wish to complain formally, you can do this by contacting the Patient Advice and Liaison Service (PALS) Office at ENTER SITE PALS DETAILS (telephone or email ).

If you or your child suffer an injury and you suspect that itis the result of the Sponsor’s (Great Ormond Street Hospital) negligence then you may be able to claim compensation, please discuss this further with the research team. Cover for negligent harm will be provided by the Great Ormond Street Hospital for Children NHS Foundation Trust through the Clinical Negligent Scheme for Trusts (CNST) and University College London.

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