**WP2 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 neurological 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 interventions are beneficial for reducing anxiety, depression and other behaviour problems in children and young people with epilepsy.

This study is the second 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 this second stage of the larger research project, we want to see how the treatment works with the epilepsy-specific material in it, and we want to know what families think of the treatment. So, we are giving the treatment to families and asking families to tell us what they think about it.

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

We are inviting 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 want your child and you to join the study, and both you and your child need to agree to take part. 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. You 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 happen to my child and me if I take part?**

If you and your child are interested in taking part, you will be asked to complete a brief questionnaire designed to identify any problems with anxiety, mood or behaviour that your child might be experiencing (Strengths and Difficulties Questionnaire) and a longer questionnaire at home. This will take about 45 minutes, depending on your answers to the questions. Someone will give you a password and username so that you can complete the questionnaire on a computer at home, or maybe at the hospital if you prefer this.

You and your child will be invited to attend an assessment in person where a therapist will discuss the specific emotional or behavioural difficulties identified in the questionnaires with you in further detail. They will also ask you and/or your child about what support you want for your child’s emotional and/or behavioural needs and whether the study intervention may be able to meet those needs. The assessment will take about one hour and will be audio/video recorded. If you, your child and the researcher think that the intervention may be helpful, then you will be offered this. If your family is not offered the intervention, we will discuss other alternatives with you and if appropriate, we will support you to access other services.

If you do have the treatment, the 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 practicing strategies at home. Completing the worksheets will take approximately 5 minutes each week.

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. The sessions (including any face-to-face or over the phone or Skype) will be video or audio recorded – the purpose is to ensure that therapists are delivering sessions in the same way.

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

You and/or your child will be invited for interviews during and after the intervention, to provide us with feedback about the therapy. These interviews (including any in person or over the phone or Skype) will also be video or audio recorded and we will use your feedback to help further develop the treatment. These interviews will take about 45 minutes.

You and/or your child will be asked to complete the same questionnaires that you completed at the start of the study, 6 months after beginning the study so that we can track your child’s progress. These questionnaires can be completed at home and they will take about 45 minutes.

All audio and video recordings made during the study will be transcribed by a transcription service and any information that would make your or your child identifiable from the transcriptions would be removed. The recordings and the transcriptions will be kept confidential and will be stored and accessed as described in the ‘*Will my / my child’s 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 data protection policies.

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 or young people will be deprived of an intervention 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 we can signpost or refer you to other sources of support if appropriate.

**Will taking part help my child?**

We cannot guarantee that the study will help your child, but treatments like this one have helped children and young people in the past. Additionally, 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.

**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 records and the data collected for the study will be looked at by authorised persons from the research or clinical teams 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 as a research participant 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 other relevant health professionals, as appropriate, to let them know that your child is taking part in the study and the result of the screening questionnaires. We will also write a short assessment and outcome letter resulting from the intervention to your child’s 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 do withdraw from the study, the information from the questionnaire and other measures 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 researcher/ therapist know.

We would also ask you to complete the follow up-measures (questionnaires) 6 months after the start of the study, even if you did not complete the intervention. You do not have to complete these measures 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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