University of Liverpool
Institute of Population Health
NHS Alder Hey Children's NHS Foundation Trust
NHS The Walton Centre NHS Foundation Trust
Excellence in Neuroscience
thumbs up for Charlie
The Brain Tumour Charity
SIOPE SIOP Europe the European Society for Paediatric Oncology
Society of British Neurological Surgeons www.sbns.org.uk
BPNG British Paediatric Neurosurgery Group
BMA Foundation

THE COMBAT PROJECT

Core post operative morbidity set for paediatric brain tumours

Information sheet for adult whose child is participating in survey

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What is The COMBAT Project?

Harms or complications can occur after brain tumour surgery in children. The COMBAT project aims to improve how these are reported in research and clinical care.

Why is this project needed?

Brain tumours are one of the most common types of tumours in children. Children with brain tumours usually get surgery as their first type of treatment. All types of treatment have the risk of complications or harms. This is also true for surgery to remove brain tumours.

Different parts of the brain have different jobs to do. Some areas of the brain have more important jobs than others. If the tumour is in an area with an important job the complications or harms can be worse.

Research and clinical studies should record the results of treatment. We call these results outcomes and they can be both positive and unwanted. Unwanted outcomes include harms and complications. Outcomes aren't always measured and reported in the same way. This makes it difficult to compare or combine the results of research. Brain tumours in children are very rare. This means that it is very important we make the best use of existing and new research. By doing this we can improve treatment and care for children with brain tumours.

The COMBAT study will help us do this by agreeing which unwanted outcomes that studies must always report. We call this a "Core Outcome Set". You can watch a short video explaining this on the study website.

Various groups are affected by brain tumours in children. They need to agree on what the most important unwanted outcomes are. These groups include patients, their parents/carers, health professionals and researchers. Future research will measure and report these agreed outcomes. By doing this, we can improve the way we find out which treatments are best for children with brain tumours.

Why have you asked me to take part?

We have invited your child to take part because they have had surgery for a brain tumour. Their experiences are really important. We want to know what was important to your child after their operation, and what impact it has had on their life.

We have made a list of possible unwanted outcomes or unexpected effects of surgery. We would like your child to look at these and tell us which ones are the most important. The most important unwanted outcomes are the ones that future research will always report.

What will happen if I take part?

If you and your child agree to take part we will send you a link and instructions on how to do the survey. It will be online, you will need access to the internet through a phone, tablet or computer. There will be two surveys to complete in total. We expect each to take no more than 30 minutes.

We will ask you or your child to fill in some information about your child. We will also ask you complete a consent form to confirm that you are happy for them to take part. We will ask your child to complete an assent form to confirm they are happy to take part. We will ask you to countersign this form as well.

The survey will be a list of unwanted outcomes and we will ask your child to tell us how important it is to always measure and report each unwanted outcome. We will give you full instructions on how to complete the survey. If you need help or have questions you can contact us, and we can arrange a time to call you. Your child can complete the form by themselves or with your help.

Several different groups will take the survey. This includes children and young people who had the surgery as well as their carers, health professionals and researchers. Your child’s individual results will be confidential.

Survey 1

The survey will show a list of unwanted outcomes. We will ask your child to tell us how important they think it is to always measure and report each unwanted outcome.

We will keep survey 1 open for 4 weeks after sending you the invite. If they haven't completed the survey we will send you reminders by email.

At the end of survey 1 we will analyse everyone's responses. This usually takes a few weeks. When we've done this we will send you an invitation to survey 2.

Survey 2

We will show your child a chart in survey 2. It will have the ratings for each group that took part. We will also show their rating from survey 1. Only you and your child will be able to see your individual rating. No one else will be able to see anyone else individual score.

We will ask your child to consider the information from others and to rate how important each harm is again. They can change their rating or keep it the same. Their individual results will be confidential.

Survey 2 will be kept open for 4 weeks. At the end of survey 2 we will analyse the results. We will share and agree these results at a final meeting. In survey 2 you and your child will be able to tell us if they would like to attend this meeting or not.

If you or your child needs help to complete the surveys or have questions you can contact us, and we can arrange a time to call you.

It is important to complete both surveys even though they are similar. By completing both your child will help us to reach agreement on the most important unwanted outcomes to report.

What happens after the survey?

At the end of the second survey we will analyse the results. Then we will invite a group of children/young people who have had a brain tumour, their carers, health professionals and researchers to a meeting. This meeting will be online. The purpose of the meeting will be to discuss the results and agree the final core outcome set.

It won't be possible for everyone who completes the surveys to attend the meeting. If you and your child would like them to attend, you can tell us by answering a question at the end of survey 2. If you say you would like to take part we will send you and your child more information about the meeting.

We will keep you up to date with how the project is going through project summary sheets.

Do I have to take part?

No. It is entirely up to you if you want to take part. This study is completely separate from the care your child receives from their medical team. We will not tell their medical team if you decide to take part or not.

If you do not want to take part, choose the ‘I/my child DO NOT want to take part in the survey’ option on expression of interest form. We will not contact you again.

Will my child’s data be kept confidential?

We will need to use information from you and your child’s medical records for this research project.

This information will include your name and contact details, as well as details about your child’s name, brain tumour and surgery. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your or your child’s name or contact details. Your data will have a code number instead.

The program we use to do the survey automatically collects your computer or device's IP address. An IP address is a unique number for your computer or device, like a digital home address. We will not routinely use this information in our research. We only need to check it if we think someone is submitting the survey more than once, as this can affect our results.

Alder Hey Children’s Hospital is the sponsor of this research and is responsible for looking after your information. We will keep all information about you safe and secure by following all privacy rules. The study's information will be stored on password-protected files. They will be on a secure University of Liverpool network. It will not be accessible to anyone apart from the study team. Any quotes we use will be anonymous and you and your child will not be able to be identified from them.

Once we have finished the study we will keep some of the data for at least 10 years after the study on a secure network. This may be longer if the data has historical value. All the data stored will only have the code number attached to it - any identifying data will be destroyed. This follows Alder Hey Children's Hospital and University of Liverpool guidelines. After this time it will be destroyed. Your child's data will not be shared outside the UK.

What if I change my mind?

You or your child can stop being part of the study at any time, without giving a reason, but we will keep information about them that we already have.

You and your child have the right to ask us to remove, change or delete data we hold about them for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

If you do stop being part of the study, any anonymous data until their withdrawal will be kept in the study. This is because it will be difficult to separate from other data.

Are there any risks in taking part?

We do not expect any major risks of taking part. Sometimes talking about when they had their operation can be upsetting. They can take break or stop taking part at any time. You can also feedback to us on any concerns about the survey. If you are worried about your child's health you can contact your medical team for advice.

Are there any benefits in taking part?

There are no direct benefits of taking part but we hope they will enjoy participating. Taking part will help improve how we do research. In the future, it will also help improve the care offered to children with brain tumours.

Will I get paid for taking part?

This is a volunteer opportunity and their participation is greatly appreciated. We can't offer payment but we hope they will enjoy taking part in this study.

Who is running the study?

Doctors and researchers at the University of Liverpool, Alder Hey Children's Hospital and The Walton Centre are running this study. Dr Sandhya Trichinopoly Krishna is leading this project. She is a doctor at Alder Hey Children's

Hospital. She is doing this project for her PhD at the University of Liverpool. She will be the person who contacts you and carries out the interviews.

If you have any concerns about the study please contact the study team – alternatively you can contact the research sponsor at research@alderhey.nhs.uk or Alder Hey PALS department at PALS@alderhey.nhs.uk.

Next step

If you and your child would like to take part please fill in the following expression of interest form:

https://app.onlinesurveys.jisc.ac.uk/s/liverpool/expression-of-interest-form-survey

If you or your child do not want to take part or be contacted by us then please choose the 'I/my child DO NOT want to take part in the survey' option on the form.

We will contact you if you have indicated you would like us to call you to answer any questions.

If you have said you would like to take part we will email you details about how to fill in the survey. You will be asked to complete a consent form at the start of the survey stating you are happy to participate.

Additional information

The study website can be found at www.thecombatproject.org

It contains videos and further information about the project.

The study team can be contacted through this email address: thecombatproject@alderhey.nhs.uk

Please use the above address for more information or support with the survey, or to report any problems with it.

If you have more questions about how we use your data you can contact the study team, or the Research Sponsor Data Protection Officer at dpo@alderhey.nhs.uk.

You can find out more about how we use your information from:

https://www.hra.nhs.uk/information-about-patients/

There is an animated video on youtube about how we use your information:

What is GDPR - https://www.youtube.com/watch?v=VlI6V1MgZgY