



THE COMBAT PROJECT

Core post operative morbidity set for paediatric brain tumours

Information sheet for adult whose child is participating in interview

Contents

What is The COMBAT Project?	1
Why is this project needed?	1
Why have you asked me to take part?	2
What will happen if I take part?	2
What happens after the interview?	2
Do I have to take part?	2
Will my data be kept confidential?	3
What if I change my mind?	3
Are there any risks in taking part?	3
Are there any benefits in taking part?	3
Will I get paid for taking part?	4
Who is running the study?	4
Next steps	4
Additional information	4

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 Project 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 would like to interview your child about your child's experiences after surgery. By doing this we can make sure that their views are included when deciding what unwanted outcomes are most important. The most important unwanted outcomes are the ones that future research will always report.

What will happen if I take part?

We will conduct the interviews online on Microsoft Teams. To take part you and your child will need access to the internet through a phone, tablet or computer. Each interview will take 45-60mins. We will audio and video record the interview to make sure we have correctly documented what your child has said. This will be carried out using Microsoft Teams and checked by the lead investigator. We will be using the NHS or University of Liverpool Microsoft Teams accounts, both of which are secure. We will then transcribe the interviews. We will delete your child's interview recording as soon as we have finished analysing the data from the interviews.

Before the interview we will organise a short meeting online or over the phone. This will be to check you have understood this information sheet and if you have any questions. We will ask you to fill in a form with some information about your child. We will also ask you complete a consent form to confirm that you are happy to take part. We will also ask your child to sign an assent form which confirms they are happy to take part. We will ask you to countersign this form as well.

What happens after the interview?

After the interview we will analyse what your child has said. We will use the outcomes they have said to make a survey. We will ask several groups to take this survey to say what outcomes they think are the most important. These groups include children and young people, their carers, healthcare professionals and researchers. You and your child can take the survey too. The most important outcomes will be included in future research.

We will also look at the outcomes that were most important to your child. We will compare these to what other patients and carers that we have interviewed have said. We will look for any common themes. We may publish this with some quotes from your child's interview. We will make sure anything we use is anonymous, and that your child can't be identified from it.

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 and your child if they want to take part. This study is completely separate from the care your child receives from their medical team. We will not tell your medical team if they 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 interview' 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.

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.

You or your child can withdraw their interview for up to 1 week after it. After that any anonymous data until your 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 your operation can be upsetting. Your child can take break or stop taking part at any time. Your child can do the interview alone, or if you and they would prefer you can be present for the interview. You can also feedback to us on any concerns about the interview.

If you are worried about your child's health you can contact their 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?

Your participation is greatly appreciated. We will be offering £25 vouchers for your time. Amazon, Love2Shop, Tesco, Asda or Sainsburys vouchers will be available. You will receive the voucher even if your child has to stop the interview early or withdraw from the study after the interview.

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 steps

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-interview>

If you 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 interview' option on the form.

If we haven't heard from you after 3 weeks we will contact you. We will call to confirm if you want to take part in the study.

We will contact you by email to organise a time convenient for you if you want to ask any further questions. If you have said you would like to be involved we will email you to organise a convenient time for the first meeting. This first meeting will be to go through the information sheet and consent form. We will organise a time for the interview during the first meeting.

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=Vll6V1MgZgY>