

Participant Information Sheet

Title of study: Understanding how brain injury affects development.

Researcher: Beverley Garrigan

We would like to invite you to take part in our research study. Before you decide whether to take part we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have.

What is the purpose of the study?

This study is part of a PhD project. The purpose of the study is to look at how young people with a brain injury develop compared to people of the same age who do not have a brain injury. We want to look at how healthy young people develop and change as they get older, and investigate whether this is different for young people with a brain injury. Damage to the brain can affect various aspects of peoples' lives and the more we know about this, the better we will be able to help young people who have a brain injury.

Why have I been invited to take part?

You have been invited to take part in this study because you are aged between 16 and 21 and have a brain injury. We want to compare a group of people your age with a brain injury to a group of young people without a brain injury to investigate the effects of damage to the brain on different aspects of peoples' lives.

Do I have to take part?

It is up to you to decide to join the study. We will describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time, without giving a reason.

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

If you decide to take part you there will be two sessions. The first session will take about two hours in total. The second session will be two weeks after the first and will only take about 45 minutes.

In the session you will be asked to complete a range of tasks. You will first be asked some questions which measure how you think and solve problems. This part will take about one hour.

You will also be given a couple of short questionnaires to fill out which ask about different things such as how you behave and some questions about your family.

You will be shown some pictures which tell a story and you will be asked to make a decision about what you would do in that situation. The researcher will also ask you some questions and ask you to explain your answers. The researcher will record your answers using an audio recorder and will later use this recording to transcribe your answers. Only the researcher will listen to and transcribe your answers and the recording will be deleted at the end of the study. Your answers will be anonymised and some of them will be sent to a research group in Canada for them to process. This group won't know your name.

Two weeks after completing the first session you will be asked to complete some of the questions again, but not all of them. This second session will only take about 30 minutes.

Your parent or caregiver will also be asked to answer a short questionnaire about you and your behaviour which they can post back to the researcher.

As part of this study the researchers would like to look at your NHS Trust and GP records. This is to get details about your brain injury. If you decide to take part in the study you will be asked if you agree to the researchers looking at these records. If you agree, you will be asked for details of your GP practice.

Some of the tasks you will be asked to complete as part of this study may be tasks you have completed before with a clinician. You will be asked if you agree for the research team to access the scores to these tasks via your NHS Trust records. If you have completed these tasks in the past year and the research team can access your scores, you will not be asked to complete these tasks again in this study.

You will be asked questions about any police contact that you may have had. If you disclose any information about a crime which has not been reported to the police, or for which you are currently under investigation, the researcher may have to pass this information onto the relevant authorities.

Will my data be confidential?

All the information collected about you will be confidential. Your responses will be kept under a number not your name and your consent form containing your name will be kept separately to your responses. All your responses will be confidential unless you disclose information which suggests you are at risk of harm, in which case the researcher will have to pass on the information to the relevant people.

Expenses and payment

When you have completed both sessions you will be paid £5 for your time.

What are the risks of taking part?

The first session may last up to two hours so you may get tired or need a break. If you feel you would like a break at any time just let the researcher know. If you find any of the questions upsetting to answer, we can take a break and discuss this if you wish.

What are the benefits of taking part?

This study aims to add to our understanding of how young people develop after a brain injury. The research may not benefit you directly but you will be contributing to our knowledge, which could potentially help people with a brain injury.

What happens when the research stops?

The data collected in this study will be analysed and a report detailing the findings will be produced. Your data will be kept in secure storage for 5 years and then destroyed.

If you would like to know how you performed on the standardised measures then we can give you a brief report summarising your performance, and you can give a copy of this report to your school, GP, or other health professionals working with you. We can also give you an overall summary of the study findings for your information.

You will be asked if you agree to be contacted directly by the researcher, Beverley Garrigan, about future studies conducted as part of her PhD. If you agree to be contacted about these studies you are not agreeing to take part in any further studies, you are just agreeing to be contacted with information about them.

You will be asked if you would like to be added to a Research Volunteer Register hosted by Dr Anna Adlam (Clinical Senior Lecturer) at the University of East Anglia to inform you of opportunities to participate in ethically approved studies conducted by her and her team. This is voluntary and you can withdraw this consent at any time.

Further information and contact details

If you would like any further information about the study please contact Beverley Garrigan (email: B.Garrigan@uea.ac.uk).

If you would like to discuss this study with someone who is not involved in the research then you can contact the Norfolk Community Health and Care NHS Trust Patient Advice and Liaison Services (PALS) on 0800 088 4449.