PARENT/GUARDIAN INFORMATION SHEET

Working Memory in Children and Adolescents with an Acquired Brain Injury
Researchers: Dr Anna Adlam and research team

We would like to invite you and your child to take part in a research study evaluating a computerised working memory training programme. Before you decide if to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please do not hesitate to contact us if there is anything that is not clear or if you would like more information (contact details can be found at the bottom of this sheet). Thank you for reading this.

What is this study about?
An acquired brain injury (ABI) in childhood can lead to problems with working memory (i.e., the ability to hold information in our mind when doing things like trying to solve a problem or learn something new). This can cause further difficulties with learning, academic achievement, behaviour, and social functioning. Such difficulties can result in problems in everyday life, including school, which can impact on the quality of young people’s lives and that of their families.

This study is evaluating a computerised working memory training programme with young people who have survived an ABI, and their families. We are interested in finding out what young people and their families think about the computerised training programme (e.g., how easy is it to use?) and whether the training programme helps with memory, attention, numeracy, and literacy. This study will also investigate how young people who have survived an ABI compare with age- sex- and IQ-matched individuals, who have not experienced an ABI, on measures of general cognitive function, memory, and attention.

Why has my child been invited?
We are hoping to recruit children between the ages of 8 and 16 years, who have survived a brain injury and have difficulties with working memory. We would like to invite your child to take part because of his or her age and history of a brain injury. We will check if your child has difficulties with working memory (by completing a brief screening assessment) before asking him or her to take part in the whole study. If your child does not have working memory difficulties or more children and families express an interest in taking part than we are able to see, then we will let you know about other research studies that we are conducting in case these are also of interest to you.

Does my child have to take part?
No, it is up to you and your child to decide whether you wish to take part. If you decide not to take part we will respect your decision, and it will not affect any healthcare that your child may receive. If you and your child do decide to take part, we will ask you first to sign a consent form and your child to give assent before he/she begins the study. We will give you a copy of the forms and this information sheet to keep. You are free to change your minds and you can withdraw from the study at any time without giving reason.

What will happen if my child takes part in the study?
If you and your child wish to participate, and you give consent/assent, then we will ask you to be involved in the study for about 6 months in total.

First, we will arrange a convenient time to meet with you and your child to explain the study in detail. We will then ask you and your child to complete a consent/assent form to indicate your agreement to participate in the study. During this session we will ask your child to complete a brief assessment of working memory and some other brief measures. This appointment will take about 45-minutes in total at your home. If we find that your child does not have working memory difficulties, then we will not continue with the study. If this happens, then we will let you know about other research studies that we are conducting in case these are also of interest to you.

If we find that you child does have working memory difficulties, then we will arrange to meet with your child again, within a week, to complete further assessments of general cognitive function, memory, and
attention, and some questionnaires. This will take approximately 2-3 hours (two to three separate sessions of 60-minutes each). We will also invite you and your child’s teacher (with your permission) to complete some study questionnaires.

A researcher (a ‘coach’) will then visit you and your child to introduce the computerised working memory training programme. We will invite your child to use it for up to five weeks, approximately 35 minutes per session. These sessions will be completed by your child and we will ask you to support your child if they have any questions when using the programme. We will teach you and your child how to use the programme.

There are two different types of this computerised programme – one aims to train working memory, and the other does not. All children participating in the research will be randomly assigned to the ‘training programme’ or the ‘non-training programme’. We will not know which version of the programme your child will be given, until we reach the end of the study. At the end of the study, if your child used the non-training programme, then we will offer you and your child the opportunity to use the ‘training programme’ in your own time separately from the research study.

At the end of the training we will ask you, and your child’s teacher, to complete some further questionnaires and we will invite your child to complete some assessment measures. This will take place at your home, over two to three sessions, each lasting approximately 1-hour.

With your permission, we would like to visit you and your child again 6 months after completing the computerised memory training and to repeat the questionnaires and cognitive measures. This will take place at your home, over two to three sessions, each lasting approximately 1-hour. We will also ask you and your child’s teacher (with your permission) to complete further questionnaires.

**Are there any risks to my child?**

The study involves completing paper and pencil assessments, and training sessions using the computer, and we are asking you and your child to commit to the study for about 6 months in total. Although this is quite a lot of work, the time involved each day during the computerised training programme may typically be quite small, approximately 35 minutes. Each training session can be saved and completed in several attempts if needed (i.e., over a few days). Also, training sessions will be arranged by you at times that are convenient for you and your child. Your child might become tired during the assessments or training sessions. To minimise the risk of becoming tired, the assessments will be conducted over two to three relatively short sessions of 60-minutes each, and regular breaks for a rest will be included. In the unlikely event, that your child becomes stressed or upset in any way, the assessments will be stopped immediately and reasons for distress will be explored.

**What are the potential benefits?**

By participating in this study, you will be contributing to research investigating working memory and attention in children who have survived an ABI. You will also be helping us to evaluate the effectiveness of a computerised working memory training programme in children who have survived an ABI.

**Will my child’s information be kept confidential?**

Information collected about your child during the study will be kept anonymous and safe. This means we will not write your name or your child’s name or address on any questionnaires or score sheets. Information will be stored by the researcher in a locked filing cabinet or on a password protected computer. When the study is finished all information collected from questionnaires and other study measures will be stored in a locked drawer, at the University of East Anglia, for a minimum of 5 years and up to a maximum of 10 years. It will then be destroyed. If you agree to have your contact details added on to the Volunteer Register we will contact you before 5 years elapses to ask if you wish to remain on the Register.

At the end of each ‘training session’ the anonymised data will be automatically and electronically uploaded to a server via the internet. The company who own the training programme (and the server) may use the data for research purposes.

With your permission we will let your child’s GP know that s/he is participating in this study. This is in case you would like to discuss the study with the GP. However, no results will be shared with the GP without your permission. The only time we would disclose any of the information that you or your child
has given us, would be if criminal or other potentially harmful behaviour was made known. We would, however, aim to discuss this with you first.

**What will happen to the results of the study?**
The results will be submitted to peer-reviewed journals and presented at conferences and meetings. Yours and your child’s names will not be included on any research outputs, and all data will be presented anonymously.

If you would like to know how your child performed on the standardised measures of general cognitive function, memory, and attention then we can give you a brief report summarising this. This report will be written under the supervision of Dr Anna Adlam (Clinical Psychologist), and you can give a copy of the report to your child’s school, GP, or other health professionals working with your child. We can also give you an overall summary of the study findings for your information.

**Who is organising the research?**
This study is partly funded by the British Academy (Dr Anna Adlam, Dr Joni Holmes, and Professor Sue Gathercole) and Action Medical Research (Dr Anna Adlam, Dr Joni Holmes, Dr Fergus Gracey, Mr Edward Wilson, Professor Sue Gathercole, Professor Lee Shepstone). The research is in collaboration with the University of East Anglia, the MRC-Cognition and Brain Sciences Unit, and the Cambridge Centre for Paediatric Neuropsychological Rehabilitation.

**Who has reviewed the study?**
To protect your interests, before any research starts it needs to be checked that it is fair. This study has been reviewed and given a favourable opinion by the Local NHS Research Ethics Committee – Cambridge South (LREC ref. 11/EE/0434).

**What if there is a problem?**
If you have any questions or experience any difficulties then please contact a member of the research team. If you would like to make a complaint, please contact Dr Anna Adlam (contact details are below). For independent information and advice about participating in research, please contact the Patient Advice Liaison Service (PALS), 0800 376 09775 or pals@cpft.nhs.uk.

**What to do if you would like to take part?**
Enclosed is a consent form to share contact details for you to complete if you would like to take part in the study. You need to fill in the form, initial all the boxes, sign and send it back to us using the Freepost envelope provided or give it to the clinician who alerted you about our study. We will then telephone you to arrange the first meeting. We can only contact you if you return the consent to share your contact details form to us.

**Further information and contact details**
For further information about the project please contact Dr Anna Adlam (a.adlam@uea.ac.uk) at the University of East Anglia, Department of Psychological Sciences, Norwich Medical School, Elizabeth Fry Building, Norwich, NR4 7TJ, Telephone: 01603 59 1507 (office telephone). We will be happy to answer any questions that you might have.

Thank you for reading this information sheet.