********

**Participant Information Sheet**

**Title of Project:** *Development and Evaluation of a Novel Treatment Intervention for People with Acquired Brain Injury*

1. **Invitation Paragraph**

You are being invited to take part in a research study. Before you decide to participate, it is important that you 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. If you would like more information on any aspect of the study, please ask us. Take as much time as you need to decide whether or not you wish to take part. If you decide you do wish to take part you will be asked to sign a form (consent form) confirming your willingness to participate and will also be provided with a copy of this form to keep.

1. **What is the purpose of this study?**

**Acquired brain injury (ABI), as a result of a stroke, head injury, tumour etc,** may cause difficulties with **memory, concentration, planning, and problem solving.** These difficulties sometimes cause problems with managing everyday tasks, particularly when they involve many steps (such as cooking a meal). Goal management training (GMT) involves teaching people mental strategies to improve their ability to remember the steps in a task, and to stay ‘on task’ and there is evidence that this can improve performance on complex everyday tasks**. Computerised memory training programmes** that adapt the difficulty level to the performance of the person being trained also hold some promise. **Working memory** is a mental process for keeping and **updating** information in mind, and this is important for planning ahead and solving problems. **Combining GMT and working memory updating (WMU)** training may increase the benefit that could be gained from either of these training programmes alone. We have developed a new combined intervention and want to see if it is acceptable to people with ABI. We also want to use a type of brain scanning, functional magnetic resonance imaging (fMRI), to explore the effect the combined intervention has on brain function. Our aim is to use our findings to **inform clinical treatments for people with ABI.**

1. **Why have I been invited to participate?**

You are being invited to take part because you have suffered an acquired brain injury (such as a head injury, stroke, or other type of brain injury) and have reported some difficulties with doing everyday tasks that may involve remembering to do things, planning or organisation.

1. **Do I have to take part?**

No, it is up to you to decide whether or not to take part. Even if you decide to take part, you are still free to withdraw at any time and without giving a reason.

1. **What will happen to me if I take part?**

We will access your medical records to obtain information about previous brain scans you might have had or details of your brain injury. However, your existing care will not be affected by your decision to take part in the study.

The study has 3 main components.

1. **Initial appointments**
2. *Initial neuropsychology assessment*

During your first visit we will ask you to perform some **pen and paper tests to assess memory, planning and problem-solving skills.** We will use a questionnaire to look at everyday functioning and we will also give you an introduction to the training programme. This visit will last approximately two and a half hours. This appointment can also be conducted remotely via a video-call using the internet as a way of mitigating **COVID-19** circumstances.

1. *Brain scan*

Following that, you will participate in your first brain scanning session, so we can study how your brain responds when you perform memory tasks inside the scanner. The brain scan will take about one and a half hours, although you will not actually be inside the scanner for more than 60 minutes of this time. If you have certain implants or devices in or on your body or certain tattoos (depending on size and location), then you will not be allowed to take part in this study. Additionally, if you suffer from claustrophobia (fear of enclosed spaces), then this study might not be right for you.

When you come for your brain scan, a member of the research team will take you through **a checklist** to make sure that it is safe for you to be scanned. You will then be asked to change into MR-safe clothing and taken into the MRI-room. Once in the MRI-room, you will be positioned on the scanner bed. You will be given earplugs or headphones to reduce the noise made by the scanner. It is important that you are able to stay still during your scan, but if you are uncomfortable, you can ask to stop at any time.

While you are in the scanner we will ask you to perform simple tasks **such as remembering locations of coloured dots or figures you see on a projection screen, and respond by pressing buttons with your fingers**. At all times you will remain in contact with us through the intercom and you will have a buzzer in your hand, in case you want us to stop the scan and come into the scanner room. At the end we will ask you to lie still for a further ten minutes while we acquire a **picture of your brain**.

After your scan, just as a precaution, we ask that study participants not drive for 15 minutes. You will be asked to remain in the Clinical Research Imaging Facility (CRIF), Queen Elizabeth University Hospital (QEUH) with a member of the research team for approximately 15 minutes. A refreshment may be offered while you wait.

Due to the ongoing situation involving **COVID-19** we understand some of you might feel uncomfortable with having a brain scan. Therefore, attending the brain scanning sessions will not be mandatory for entering the study although it is preferrable. Finally, if you intend to complete the brain scan sessions we will ensure that all necessary NHS approved measures and precautions are in place to minimise contact and adhere to social distancing rules.

1. **Intervention**

For the next eight weeks, you will be taking part in the **intervention part of the study**. There will be **8 weekly combined GMT and WMU training sessions**. Each GMT session will take two hours while the WMU session will last between one hour and one hour and fifteen minutes. There will be a break between the GMU and WMU training sessions allowing you to have a rest and relax. Sessions will be conducted in a group format – groups will contain two to six participants. If it is not possible for you to complete both training sessions on the same day, alternative options will be offered, i.e. completing the WMU session from home or attending on a different day in the same week. In between the training sessions you will be asked to complete some homework and relaxation exercises. Participants will be offered the option of conducting the **GMT and WMU training sessions remotely via a video-call using the internet** to mitigate **COVID-19** circumstances**.** The **GMT** sessions will continue to be in a group format, while the **WMU** sessions can be completed at one’s own time at home.

1. **Follow-up appointments**

At the end of the eight-week intervention you will be asked to complete the same pen and paper tests you completed at your initial appointment. This will allow us to assess changes in your performance as a result of the intervention. You will also be asked to undergo a **second brain scan** which will be the same as the first scan you underwent. This appointment can also be conducted remotely via a video-call as a way of mitigating **COVID-19** circumstances.

In between appointments you will receive phone-calls, texts or emails, according to your preference, as reminders of your next sessions.

1. **What are the possible benefits of taking part?**

We will reimburse you for your travel to the training sessions, and your participation will help us develop a better understanding of the relationship between brain and behaviour. You may also find that the combined training has a positive effect on your thinking skills.

1. **Will my GP be informed?**

Yes, we will send **a letter to your GP** informing them of your participation and enclosing further information about the study. The **anatomical MRI brain scans** will be transferred to NHS systems and be linked to your **medical file.** Your scans will then be reviewed by a neuroradiologist who will write a report. In the unlikely event that an abnormal finding extending beyond the existing brain injury is detected, we will contact your GP and you will be referred to an appropriate clinician for further investigations. You should be aware that you may then have to disclose such findings in future applications for health-related insurance.

**Are there compensation arrangements if something goes wrong?**

In the unlikely event of anything untoward happening, NHS insurance applies to the management and conduct of the study. The design of the research will be indemnified by the University of Glasgow. If for any reason you would like to raise a complaint you can contact the NHS Greater Glasgow & Clyde (GG&C) complaints office at: **complaints@ggc.scot.nhs.uk****.**

1. **Will my taking part in this study be kept confidential and what will happen to my data?**

All information that is collected about you during the course of the research will be kept **strictly confidential.** We will be collecting and storing identifiable information from you (such as name and contact details) in order to undertake this study. **This identifiable data will remain on NHS systems** and thus the **NHS GG&C** is responsible for looking after your information and using it properly. **NHS R&D staff may** also require access to the data for **auditing purposes**. Your personal data (name, data collected for safety checks) will be held separately from your brain image data, and your images will be referred to by a code. All images collected from the fMRI scans will be anonymised before any analysis is carried out on them, therefore it will not be possible to identify you from the images in any way. **The anonymised data will be stored on a secure university network.** It is possible that the anonymised data may be used by researchers working within the university for other similar ethically approved research protocols, where the same standards of confidentiality will apply. In all cases your **name will not be used** and your data will be identified only by a digit code.

We will keep personal information about you (and the code) until the project has finished and will not pass this information to a third party without your expressed permission. Should you choose to withdraw from the study, which you are free to do at any time, your data may still be used up until the point of your withdrawal. **The anonymised data will be stored for up to 10 years in University archiving facilities** in accordance with relevant Data Protection policies and regulations.

We will inform you when the study results are published, and the journal article will be shared with you. A summary for readers who are not scientists will also be provided together with the article. In addition, the study findings will be shared with individuals with ABI and their families via local networks. No personally identifiable information about you will be included in these reports and presentations.

1. **Who is organising and funding the research?**

The research will be organized by **Katerina Pappa, a PhD Candidate** in Psychological Medicine. She is supervised by **Professor Jonathan Evans** and **Dr Satu Baylan,** Institute of Mental Health & Wellbeing, and **Dr Kristin Flegal,** Institute of Neuroscience and Psychology**.** This research is jointly funded by the Neurosciences Foundation and Sackler Foundation.

1. **Who has reviewed the study?**

The South East Scotland Research Ethics Committee gave the study a favourable ethical opinion. The MRI research environment is overseen by **Tracey Hopkins,** Lead Research Radiographer, CRIF, QEUH.

1. **Open Brain Data**

We will give public access to all the data from this project through an open online database to allow other researchers to check our analyses, or apply their own. The data we share publicly will not have your name on it, only a code number, so people will not know your name or which data is yours. We will not share any other information that we think might identify you. If you change your mind and withdraw your consent to participate in this study, we will not collect any additional data about you. We will delete your data if you withdraw before it is deposited in the database. However, any data and research results already shared with other investigators cannot be destroyed, withdrawn or recalled. Letting us use and share your data is voluntary. However, you must be willing to share your data in this way to participate in this study.

If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified. However, by using additional data linked to your name (for example brain scans obtained from your medical records), one could potentially associate your images or other information in our database back to you. In addition, a security breach (break in or cyber-attack) might lead to someone being able to link you to your data. This risk is very low because your data are stored in a secure database, and the information about your identity is stored separately from the data themselves, linked only through a code.

1. **Data Protection Declaration**

**NHS GG&C is the sponsor for this study based in Scotland, UK.** We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. NHS GG&C will keep identifiable information about you for ten years after the study has finished, until 2031. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information: https://www.nhsggc.org.uk/patients-and-visitors/faqs/data-protection-privacy/.

1. **Contact for Further Information**

**Miss Katerina Pappa,** *PhD Candidate in Psychological Medicine.*

**Tel:** 0141 451 6863, **Email:** a.pappa.1@research.gla.ac.uk

Institute of Mental Health and Wellbeing, School of Medical Veterinary & Life Sciences.

2nd floor, Imaging Centre of Excellence,

Queen Elizabeth University Hospital, Glasgow, G51 4TF.

**Supervisory Team:**

**Prof Jonathan Evans:** **Tel:** 01412113978, **Email:** jonathan.evans@glasgow.ac.uk

**Dr Kristin Flegal**: **Tel:** 01414516841, **Email:** kristin.flegal@glasgow.ac.uk

**Dr Satu Baylan:** **Tel:** 01414515879, **Email:** satu.baylan@glasgow.ac.uk

Thank you for taking the time to read this information sheet. If you have any questions or would like some more information, please feel free to contact a member of the research team and discuss it with them.

If you would like to discuss the study with an independent member outside of the research team please contact:

**Dr Breda Cullen: Tel:** 01412113912 **Email:** Breda.Cullen@glasgow.ac.uk

*Senior Lecturer in Clinical Psychology,* Institute of Mental Health & Wellbeing