Examination of brain plasticity through structural and functional MRI during audio-visual training in hemianopia patients with Virtual Reality
(Study to predict the outcome of an audio-visual training rehabilitation program)

Participant Information Sheet

You are being invited to participate in a research study. Before you decide whether to participate, 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 feel free to ask us if you would like more information or if there is anything that you do not understand.

Part 1 tells you the purpose of this study and what will happen to you if you take part.
Part 2 gives you more detailed information about the conduct of the study.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take a part.

Thank you for reading this.

Part 1

1. What is the purpose of the study?

Loss of vision in parts of the outer (peripheral) visual field occurs commonly in survivors of strokes that affect the visual system. One rehabilitation technique is 'visual search training'. This aims to help participants by teaching them to look around (scan) the environment to compensate for their visual field loss. It has been hypothesized that audio-visual stimuli can further enhance the visual loss compensation. While there is good evidence that the treatment technique works, the exact mechanisms are not well understood.

Part 2

2. What will happen if I take part?

Before we start:
Before taking part in this study the researcher will you meet with you for an online meeting to explain what the training involves and answer any questions you may have.
During the study we will take detailed images of your brain structure and measure which areas are active during audio-visual tasks.
Before we scan any participant, we must make sure that this is risk free; we will therefore informally discuss the requirements for scanning at this meeting. After our discussion you will have a time to consider participating in this study or not, you may wish to spend this time talking to family, friends or GP or your stroke physician about taking part in the study.

Taking part in the study:
You will be asked to take part in 'audio-visual training' at home for six weeks. The training, a video-game specifically developed to train you to scan your environment, will take around 30 minutes every day for five days per week. The training will use a Virtual Reality system that we will supply, and the researchers will support you to do the task easily at home.

Figure 1: an example VR system – participants will wear a viewing display and use two hand-held controllers to play a game designed for scanning training.

The VR system will automatically track usage when you play the game. You will also be asked to complete a diary recording what training you did over this period. We will call you weekly to monitor the training performance and check if you have any concern about the training.

Our main aim is to record changes to your brain while you perform the audio-visual training. We will therefore scan your brain two times: 1) directly before the training starts, 2) at the end of training period. This means that you will have to visit the Imaging Centre at The University of Liverpool two times. Each visit takes around 1 hour. We will arrange travel for you and pay for this.

3. What happens during the assessment?

- At each visit in the imaging centre the researcher will ask you to perform an audio-visual experiment using a VR system. The task will take around five minutes to complete and is very similar to the training task you perform at home. The researcher will explain exactly what you need to do at the time of the test.
- In addition, you will perform a search task (Bell task) which will be asked to find printed objects on a monochrome printed (A0 size) poster to provide a wide-field assessment.
- You will be asked to fill in a short questionnaire (25 questions) to measure the quality of life before and after the training, this will take approximately 10 minutes.
- We will scan your brain to measure a number of different things: Some scans will measure your **brain structure**, and you will be required to simply lie as still as you can in the scanner;
  Other scans will measure **brain function** while you do an audio-visual task. There are two audio-visual tasks in the scanner and each one will take 8 minutes. You will be asked to look for a visual target and press on the top button with your index finger to hit the target or the side button with you thumb to avoid the obstacle as soon as you see them. Total MRI scan time will be around 50 minutes.
- Before the scan you will be asked to fill in a short safety screening form to make sure there are no reasons why you would not be suitable for magnetic resonance scanning.

- Also, you will be asked to sign a consent form before starting the scanning. If you have difficulty writing, someone independent can witness your agreement to take part and sign the form instead.
- When we scan your brain, you will be asked to wear a hospital gown (changing rooms are provided) and remove items which are affected by the magnetic field (e.g. hearing aids, mobile phones, keys, coins, pens, credit cards - secure lockers are provided).
- Magnetic resonance scanning is noisy but causes no pain, harm or long-term effects. We will ask you to wear headphones, to make the scans more comfortable and to protect your hearing.
- If – for whatever reason - you feel uncomfortable during the scan, you will be able to notify us we will remove you from the scanner without delay.

- We will ask you not to speak during or between experiments, although we can hear you if necessary.

4. How will my data be used?

The University processes personal data as part of its research and teaching activities in accordance with the lawful basis of 'public task', and in accordance with the University's purpose of "advancing education, learning and research for the public benefit.

Under UK data protection legislation, the University acts as the Data Controller for personal data collected as part of the University's research. The researchers act as the Data Processor for this study, and any queries relating to the handling of your personal data can be sent to Dr Georg Meyer, (georg@liv.ac.uk, 0151 7942579).

Further information on how your data will be used can be found in the table below".

How will my data be collected?	The data will be saved on password protected LiMRIC MRI workstation and on anonymous CD for data analysis
How will my data be stored?	On password protected LiMRIC MRI workstation and University computers
How long will my data be stored for?	It will be stored for 10 years
What measures are in place to protect the security and confidentiality of my data?	All information will be kept private, confidential and secure.
Will my data be anonymised?	No, but during the data analysis, your data will be identified by the date and the experimental type, so it will not be presented by your name.
How will my data be used?	It will be presented as part of a PhD thesis, used for the research study, presented at research meetings and published in scientific literature, so that other researchers can also benefit from the sharing of information.
Who will have access to my data?	Only people involved in this study or in making sure it runs correctly will be able to look at your data (the researcher, the supervisors, and the MRI staff in the Liverpool University MRI Centre).Also, clinical team will have access to medical history to check the eligibility criteria.

Will my data be archived for use in other research projects in the future?	No
How will my data be destroyed?	It will be deleted and destroyed after 10 years

5. Expenses and / or payments

The study will cover the costs for all visits.

6. Are there any risks in taking part?

The magnetic resonance scanning:

There are no known risks in properly conducted magnetic resonance scanning. MRI scanning, in contrast to X-rays or CT-scans, does not involve ionising radiation.

MRI is noisy: High quality ear-plus and headphones will be provided to protect your hearing.

MRI uses a strong magnetic field: This means we cannot scan you if you are fitted with a any device that provides electrical stimulation, for example a heart pacemaker, mini-defibrillator etc); We will also not scan you if there are certain metal objects in your body, for example surgical clips in your head; any metal particles that may have remained in your eye or head after accidents, or if you have an artificial heart valve. The radiologist will discuss your medical history to ensure you can be scanned safely before the first scan.

Occasionally research studies using magnetic resonance imaging reveal significant unexpected abnormalities that require medical follow-up, either for further investigation or (more rarely) treatment. The scans we do are for research purposes, but we review them carefully to avoid missing such an abnormality. We will spend a few extra minutes taking high-quality images that will be reviewed by a consultant physician. Your scans will be assessed by specialists at the Liverpool University Hospitals Foundation Trust stroke unit, who already have your medical history. Please note that this is not a substitute for a 'medical' magnetic resonance scan that a doctor might order for diagnostic purposes. It should therefore not be considered a 'health check'.

The Virtual reality headset:

There are no known risks related to the audio-visual training that you will be asked to do during the study. Most people enjoy playing the VR game. Some people may, however, find the VR headset uncomfortable or find that it induces a headache or eye-strain (simulator sickness) when it used for a long time. We ask you not to use it for more than about 30 minutes per day and to remove the VR headset immediately if you experience any discomfort. You can take

breaks as required when you do the training. No long-term adverse effects that stem from VR system usage are documented.

Some instructions should be followed during the home training with the VR headset. Wearing the VR will take you to a new 3-dimensional environment that is separate from the real space that surrounds you. The game is designed to be played while you are sitting comfortably. You should ensure that you play in a clear, open space free from any dangers (e.g. sharp objects, glasses, stairs, other people ...etc).
We will provide the valuable VR kit for the six weeks of training at home. It will be cleaned and disinfected before delivery. The game will be installed and you will be trained how to start and use it. We ask you to use the VR kit responsibly and not to download or try any other games or applications as well as keeping the VR kit safe, away from liquids, direct sun light or heat.

7. Are there any benefits in taking part?

Your participation as hemianopia voluntary is helpful to build a better understanding about this rehabilitation technique which may become a useful part of improving the visual function for stroke patients.

8. What will happen to the results of the study?

The results of the research study will be presented at research meetings and published in scientific literature. The study will take at least three months to conduct and longer to analyse fully, we are happy to supply you with our results after the analysis is complete.

9. What will happen if I want to stop taking part?

During the study, you are able to withdraw at any time without explanation. Your data up to the period of withdrawal may be used, if you are happy for this to be done. Otherwise, you may request that it is destroyed and that no further use is made of it.

10. What if I am unhappy or if there is a problem?

If you are unhappy, or if there is a problem, please feel free to let us know by contacting Dr Georg Meyer, (georg@liverpool.ac.uk, 0151 7942579) and we will try to help. If you remain unhappy or have a complaint that you feel you cannot come to us with, then you should contact the Research Governance Officer on 0151-794-8290 (ethics@liv.ac.uk). When contacting the

Research Governance Officer, please provide details of the name or description of the study (so that it can be identified), the researcher(s) involved, and the details of the complaint you wish to make.

11. Who can I contact if I have further questions?

If you wish to take part in this study or if you require more information, please contact the **Principal Investigator**:

Dr. Georg Meyer,
Department of Engineering, Digital Innovation Facility Building, University of Liverpool, Liverpool L69 3GL
Telephone: 0151 7942579
Email: georg@liverpool.ac.uk

Or you may contact:

Prof Fiona Rowe,
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