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Neuroimaging investigation of brain mechanisms of attention and cognitive control

Adult Volunteer Panel Study Participant Information Sheet

Principal Investigator: Dr Alexandra Woolgar Study Title: Neuroimaging investigation of brain mechanisms of attention and cognitive control PRE/NRES Code: PRE.2018.101

You are being invited to take part in a research study. Before you decide whether or not to participate it is important that you understand why the research is being done, what it will involve and how the information collected from you is stored and used. Please take time to read the following information carefully and discuss it with others if you wish. 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 part.

What is the purpose of the study?

The aim of this study is to better understand how our brains support our ability to perceive, pay attention to, and respond to objects, sounds and words.

Who is organising and sponsoring this research?

Cambridge University is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this. Cambridge University will keep identifiable information about you for 1 year after the study has finished.

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 at:

https://www.medschl.cam.ac.uk/research/privacy-notice-how-we-use-yourresearch-data/

Has the study been approved?

This study has been reviewed and approved by an independent group of people, Cambridge Psychology Research Ethics Committee (CPREC), who have a duty to protect research volunteers' safety, rights, wellbeing and dignity.

Why have I been invited to take part?

You have been asked to participate either because you responded to an advertisement or because you previously volunteered to be a member of the Volunteer Panel at the Cognition & Brain Sciences Unit.

Do I have to take part?

It is up to you whether or not to take part. Before deciding you should read this information sheet and ask about anything that is not clear. If you decide to take part we will ask you to sign a form indicating that you have agreed (consent form). However, even after you have signed that form you can withdraw from the study without having to give us a reason.

You should be aware, however, that we aim to anonymise our results (separate and remove your personally identifying information) as soon as possible after data collection to protect your privacy. If you decide to withdraw some time after your participation it may therefore not be possible to identify and remove your specific results.

What will I be asked to do in the study?

Taking part requires you to visit the Cognition & Brain Sciences Unit for one or more sessions, or to complete a task online from wherever suits you. Sessions are typically 1-2 hours, but may be up to 3.5 hours; the researcher will explain this to you. You will be asked to do one or more computerised tasks. You may also be asked to perform these tasks within a brain scanner: either an MRI scanner or an MEG scanner, and/or with EEG recording (see below for the details of these techniques). The Researcher will explain which of these scans, if any, will take place during a given visit, and the length of time that you can expect to be with us.

We measure reaction time, accuracy or other aspects of task performance. Stimuli might include letters, written words, pictures, simple geometrical shapes, tones or other simple sounds, spoken words, sentences, or stories, presented at a comfortable level, or we might ask you to imagine stimuli like pictures, words or stories in your head. In speeded tasks, responses must be given as quickly as possible. In unspeeded tasks, you will just try to be as accurate as you can. Tasks are designed to test aspects of attention, perception, problem solving, mental speed etc. For example, you might be shown an object on a computer screen, and be asked to press a button to indicate what you see. Sometimes there is no 'correct' answer, we just want to know what you see or hear. All of the tasks will be explained in detail before you start and you will have the opportunity to practice them and ask any questions you may have.

Will video or audio recordings be made?

The study does not involve video or audio recording.

Will I be paid for taking part or have my expenses paid?

To thank you for your contribution to this study we will reimburse you at a rate of £12/hour for task-based fMRI, EEG, or MEG, with a guaranteed minimum of 2 hours (£24) for fMRI, £10/hour for purely behavioural assessments (without any brain imaging), and £12 for attending a session to have a structural MRI. We will also reimburse your travel expenses, up to a limit that you can discuss with the researcher. Online studies will be paid in increments of 15 minutes (i.e. £1.50), always rounding up to the next 15 minutes.

What is an MRI scan?

MRI stands for "magnetic resonance imaging." MRI uses a strong magnetic field to give us a 3D picture of your brain and allows us to see changes in the activity of different parts of your brain as you do tasks. MRI is a non-invasive technique (all the scanning equipment is outside of the body) that is used routinely in modern medicine. It has no known side effects. It does not involve injections or x-rays. Because of the strong magnetic field a qualified MRI operator will ask you to remove all metal belongings (which we will store safely) and check that you have no metal within your body. You remain clothed throughout and metal that is part of your clothes (jeans rivets etc.) is normally unproblematic. If the operator does not think it is safe we will not continue. They will also ask you questions to ensure that you will be comfortable in the scanner. If you are very uncomfortable in small, confined spaces you may not wish to participate. If it is safe and you are happy to proceed, during the session you will lie comfortably on a hospital-style bed with your head inside the MRI scanner whilst the scans are taken. It is a bit noisy and you will be asked to wear ear-plugs. You will be provided with a hand-held alarm that you can squeeze if you become uncomfortable or distressed at any time. This will alert the operator who will remove you from the scanner immediately. To collect good information it is important that you keep your head as still as possible when in the scanner. Scans typically last 30 to 60 minutes.

What if the MRI scan suggests something unusual about my brain?

Like faces, brains come in all shapes and sizes, so that there are many normal variations of what the scan shows. The scan you will have is not intended to be part of your medical record or designed to diagnose any illness you might have. However, there is a chance of less than 1:100 that a significant abnormality, of which you are unaware, becomes apparent in the research scan. In such circumstances, we may contact you (and if you agree, your GP) to discuss with you what the scan shows and whether any further tests are required. Detection of such unexpected abnormalities may have the benefit of starting treatment early, but may also have detrimental implications for future employment and insurance. If you are not willing to be contacted in these circumstances, then we are unable to proceed with the scan. This does not affect your statutory rights.

What is an MEG scan?

MEG stands for "magnetoencephalography", which gives us recordings of the electrical activity from your brain as you do tasks. MEG has been used routinely in research for 20 years and has no known side effects. MEG is non-invasive (all the scanning equipment is outside of the body) and does not involve any injections or X-rays. You remain clothed throughout. MEG measures very weak magnetic fields produced by the brain's activity, so before the scan, a qualified MEG operator will ask you to remove all metal belongings (which we will store safely). A small number of electrodes will also be placed on your head, to record your head position and eye movements. This preparation period will take 15 to 45 minutes. After that be asked to sit underneath the MEG helmet that covers most of your head but not your face. MEG scans are not noisy and you will be able to talk with the Operator at any point if

you wish to stop. It is important that you keep your head as still as possible. The scan will typically last 30 to 60 minutes.

Our data acquisition and analysis are not optimized for diagnostic purposes, and we do not train our staff to use MEG data for any kind of medical purposes. However, it is possible that we see something that we consider abnormal, in which case, we may contact (and if you agree, your GP) to discuss with you what the data show and whether any further tests are required. Detection of such unexpected abnormalities may have the benefit of starting treatment early, but may also have detrimental implications for future employment and insurance. If you are not willing to be contacted in these circumstances, then we are unable to proceed with the scan. This does not affect your statutory rights.

What is an EEG scan?

EEG stands for "electroencephalography", which gives us recordings of the electrical activity from your brain as you do tasks. It has been safely and routinely used in research and hospitals for over 50 years and has no known side effects. EEG is noninvasive (all of the scanning equipment is outside of the body), does not involve any injections or X-rays and you remain clothed throughout. An elasticated cap is placed over the top of your head (not over your face). It has soft silicone (rubber like material) tips that rest gently against the skin on top of your head. To make these 'electrodes' they are then filled with salt-water (like seawater) paste. Once filled, they conduct the very weak electrical signals generated by the brain's activity that are then recorded by a computer. Getting a good, comfortable fit of the cap and then filling/testing the tips takes about 45 minutes during which you can relax, chat, watch a movie etc. Wearing the cap and the feel of the salt water against the skin is unusual to begin with but people often get used to it and stop noticing that it's there after a while. A second EEG recording device, which is a headset designed for playing video games, may also be fitted either on top of this cap, or on its own, and we will put cotton wool soaked in salt water between each electrode and your cap. Once everything is in place you will be asked to do the task that will usually take 30 to 60 minutes. When the task is finished the cap is removed and you can wash any remaining paste completely out of your hair. We have the necessary facilities (basin, hand-shower, towels, shampoo) near to the testing room. Sometimes, EEG will be recorded at the same time as MEG (see above). EEG scans are not noisy and you will be able to talk with the Operator at any point if you wish to stop.

Our data acquisition and analysis are not optimized for diagnostic purposes, and we do not train our staff to use EEG data for any kind of medical purposes. However, it is possible that we see something that we consider abnormal, in which case, we may contact (and if you agree, your GP) to discuss with you what the data show and whether any further tests are required. Detection of such unexpected abnormalities may have the benefit of starting treatment early, but may also have detrimental implications for future employment and insurance. If you are not willing to be contacted in these circumstances, then we are unable to proceed with the scan. This does not affect your statutory rights.

What are the possible risks/side effects of taking part?

There are no obvious risks from the computer tasks that you will be asked to complete. If you become tired or uncomfortable during any of the tasks please let us know and we can take a break or end the session. For online studies, we will include regular opportunities for breaks. Remember you can withdraw from the study at any time without needing to give us a reason.

With the appropriate safety checks in place MRI, MEG and EEG are safe, non-invasive imaging techniques, with no known side effects.

What happens to my personally identifiable information?

You have provided us with two types of information. *Personal data* includes your name, address and date of birth – information from which you could be identified and that we use to contact you, calculate your age and so on. *Research data* includes information like the buttons you pushed on a computer task, information from a brain scan and your answers on a questionnaire; in other words, information from which it would not be possible, or would be very difficult, to identify you personally.

We separate your personal data and your research data, and treat these two types of information very differently.

The University of Cambridge Data Protection Officer is the Data Controller for any personal data that you have given us. Contact details: The Old Schools, Trinity Lane, Cambridge CB2 1TN data.protection@admin.cam.ac.uk.

Electronic personal data are either entered directly into a secure area of our computer system or transferred there as soon as possible after collection. Personal data on paper records is kept in a locked filing cabinet within a secured building. Personal data are treated with strict confidentiality and in line with the UK general Data Protection Regulation, which regulates the collection, storage, processing and disclosure of such information. This information is held very securely and only for as long as is necessary (e.g. for contacting you and for the management of the research). Retention of these data is necessary for the management of our volunteer panels, payments to volunteers and for procedures in the case of unusual findings of potential relevance to participants' health.

If you have taken part in a brain scanning study, the scanner operator will have been through a safety-screening sheet with you. This is an important record that safety procedures were followed. This sheet includes your name, address and date of birth and the name and address of your General Practitioner (GP). The scanner operators keep a secure copy of this sheet for 10 years in case of safety audit, even if you stop participating in studies here. After 10 years this record will be deleted.

If you have questions about how long and for what reasons your Personally Identifiable Information is held, please ask the researcher.

What happens to my research data?

Your research data, typically combined with similar information from other volunteers, will be used for scientific research. The results are typically presented in scientific papers and talks, in teaching and in explaining our science to health professionals, school groups and the public in general. We take great care to ensure that individuals cannot be identified from our research outputs.

Undertaking scientific studies is expensive and relies on the generous contribution of time from volunteers. To make the most of your research data we plan to look after it for the long term and may use it to answer research questions beyond those for which it was originally collected. This may include combining research data from this study with data from other studies in the CBU in which you have been involved. In addition to our own analyses, we agree with the principle that research data, often collected with public money, are a public good, produced in the public interest, which should be made openly available with as few restrictions as possible in a timely and responsible manner. Many of the bodies that fund our research insist that we follow this principle. In line with this we may also share research data with other researchers in the UK and around the world, free of charge. This is important for the scientific process, so that other researchers have the opportunity to check our results, or conduct new analyses. It also helps avoid research duplication.

We are aware that, very rarely, research data could be used to identify an individual (for example, questionnaire responses about life events could identify a particular person to someone who knows him or her; or the precise shape of your brain could be used to identify you in the unlikely event that someone else already had another scan of your brain). In such cases, we take great care to reduce the chances of such identification by omitting critical details, such as removing the face from an MRI scan. Moreover, in most cases, we will require people who access research data to agree to a "data usage agreement", where they agree not to try to identify anyone, and not share the data will anyone else. However, on occasion, there is a need to make the data fully "open". If research data are made open, then we have no control over how that information is used.

You should only agree to participate in this study if you have understood and consent to this re-use and sharing of research data.

If you change your mind and later withdraw your consent to participate in this study (you can call Alexandra Woolgar at 01223 767704 to do this), and we will not collect any additional data about you. We will delete your data if you withdraw before the study was published or shared with others. However, any research data already published or shared with other investigators cannot be destroyed, withdrawn or recalled.

Can I get access to my results from the study?

It is important that, as researchers, we minimise potential harm to volunteers in our studies. We often use new techniques and interpreting research data can be complicated and has the potential to cause undue concern. For this reason we do not divulge individual results (with the exception of abnormalities detected on MRI

scans, see above). If you have concerns about your performance please discuss these with the researcher.

Are there compensation arrangements if something goes wrong?

Adequate provision is made for insurance or indemnity to cover liabilities which may arise in relation to the design, management and conduct of the research project.

What should I do if I have a complaint about the study?

We are keen that volunteers feel informed and well treated when they take part in our research. If you have a complaint about this study please contact the Principle Investigator listed at the end of this information sheet in the first instance. If you are not happy with the response, please contact the Director of the Cognition and Brain Sciences Unit (director@mrc-cbu.cam.ac.uk). Further steps can be taken through the University of Cambridge if necessary.

Thank you for considering taking part in this study. Our research depends entirely on the goodwill of potential volunteers such as you. If you require any further information, we will be pleased to help you in any way we can.

Further information and contact details

If you require more information, please contact:

Dr Alexandra Woolgar

MRC Cognition & Brain Sciences Unit

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Email: Alexandra.woolgar@mrc-cbu.cam.ac.uk