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RESTAND
Research on Emotional effects of SeroTonin Agonism in Non-medicated Depression

PARTICIPANT INFORMATION SHEET

The effect of PF-04995274 on emotional processing in un-medicated depressed patients

We would like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information carefully, and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask us.

Thank you in advance for taking the time to read this.

What is the purpose of the study?

The purpose of this study is to investigate whether a drug which activates certain receptors in the brain changes how the brain deals with emotional information. Our research has previously shown that antidepressant drugs affect how people think about certain information, for example, by making them focus on positive facial expressions more than negative ones. These short-term effects have been found to predict whether the treatment will help people feel better in the long term.

Since currently available antidepressants do not always work on everyone or may sometimes cause unpleasant side effects, we are exploring potential mechanisms underlying antidepressant treatment that may allow for future development of antidepressants which are more effective and better tolerated for patients with depression. For this reason, we are recruiting participants who are currently suffering from depression/low mood.

The drug we are investigating is called PF-04995274. It is currently unlicensed, and like many established antidepressants, this drug affects a brain chemical messenger called serotonin but in a different way. We are going to test whether the mechanism by which PF-04995274 works on serotonin could lead to the development of more effective and faster acting treatments. In the study the effects of PF-04995274 will be compared with placebo (inactive drug) and with an established antidepressant, citalopram, which is a Selective Serotonin Reuptake Inhibitor (SSRI).

Why have I been invited?

We are sending you this information sheet because either a) you have shown interest in hearing more about this study, either by responding to an advertisement, responding to a letter from your GP practice, or having discussed it with your doctor, b) because you have previously expressed an interest in hearing about studies in the department (please do let us know if this is no longer the case), or c) your GP practice has signed up to help our study team and has identified you as a potentially eligible patient. You have been invited to take part because you have symptoms of depression, you are not receiving drug or face-to-face psychological treatment for the current episode of depression and you are aged 18-65. In total, we hope to include 75 volunteers with symptoms of depression.

Participating in research during the SARS-Cov-2 (Coronavirus; COVID-19) pandemic

We have taken a number of steps to minimize possible Covid-19 transmission in our research setting.

We will require all participants to follow our guidelines (outlined in the RESTART Study Participant Leaflet) to ensure the safety of our staff and other people using the Warneford Hospital site.

You will NOT be allowed to come on-site and take part in the study if you or a household member has any symptoms of Covid-19 either at the start of the study or in the last 2 weeks. If you develop Covid-19 symptoms during the study, you must let a member of the research team know as soon as possible.

Exclusion Criteria

You will NOT be able to take part in the study if you:

- Are not fluent in English;
- Have history of bipolar disorder, schizophrenia or eating disorders or any other conditions which may affect your safety in the study or the study results, at the discretion of the Investigator;
- Have received medication (such as antidepressants) or specific face-to-face psychological therapy for your current episode of depression;
- Are experiencing suicidal thoughts;
- Are currently using any medication that may interact with the study drugs or influence the fMRI scan (the research team will help you decide this);
- Have received electroconvulsive therapy for your current episode of depression;
- Are currently, or have previously been, dependent on drugs or alcohol;
- Have (or have had in the past) any medical conditions, which may affect your safety in the study or the study results (please discuss with the researchers if you think that this may be the case);
- Have abnormal values on the blood or urine tests that we do as part of our screening, which may compromise your safety in the study;
- Are currently pregnant or breastfeeding;
- Have participated in a research study involving the use of medication within the last 3 months;
- Have previously participated in a study using the same, or similar, emotional processing tasks;
- Have any known allergy or hypersensitivity to the medications used in this study (PF-04995274 or citalopram) (the research team will help you decide this);
- Are sexually active but not using a highly effective form of contraception;

- Smoke more than 10 cigarettes per day or similar levels of tobacco in other forms.
- Are not registered with a GP or if you are registered with a GP but do not consent for us to inform them of your participation.

If you have any contraindications to MRI scanning (e.g. certain metal objects in your body, pacemakers, significant claustrophobia) you will not be able to attend Research Visit One, but will be able to take part in the rest of the study.

During the screening visit we will ask you about your medical and psychological history and you will be able to discuss all these issues with a doctor.

Do I have to take part?

Taking part in the study is completely voluntary. If you do decide to take part in this study, we will ask you to sign a consent form but you can still withdraw at any time without giving a reason, and with no impact on your standard medical care. You will be able to ask any questions or express any concerns.

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

The study will involve 4 visits in total (Screening, First Dose Visit, Research Visit One and Research Visit Two), all taking place at the Warneford Hospital in Oxford. You will be assigned by chance to receive 7 days treatment with either PF-04995274 (the novel drug we are investigating) or a well-known drug called citalopram or placebo (the placebo looks like PF-04995274 and citalopram but has no drug in it). The treatment period might be extended to a maximum of 8-9 days if necessary to schedule the brain imaging scan. This will only happen with your consent.

Once the study period is finished, all study treatment will be discontinued in all cases.

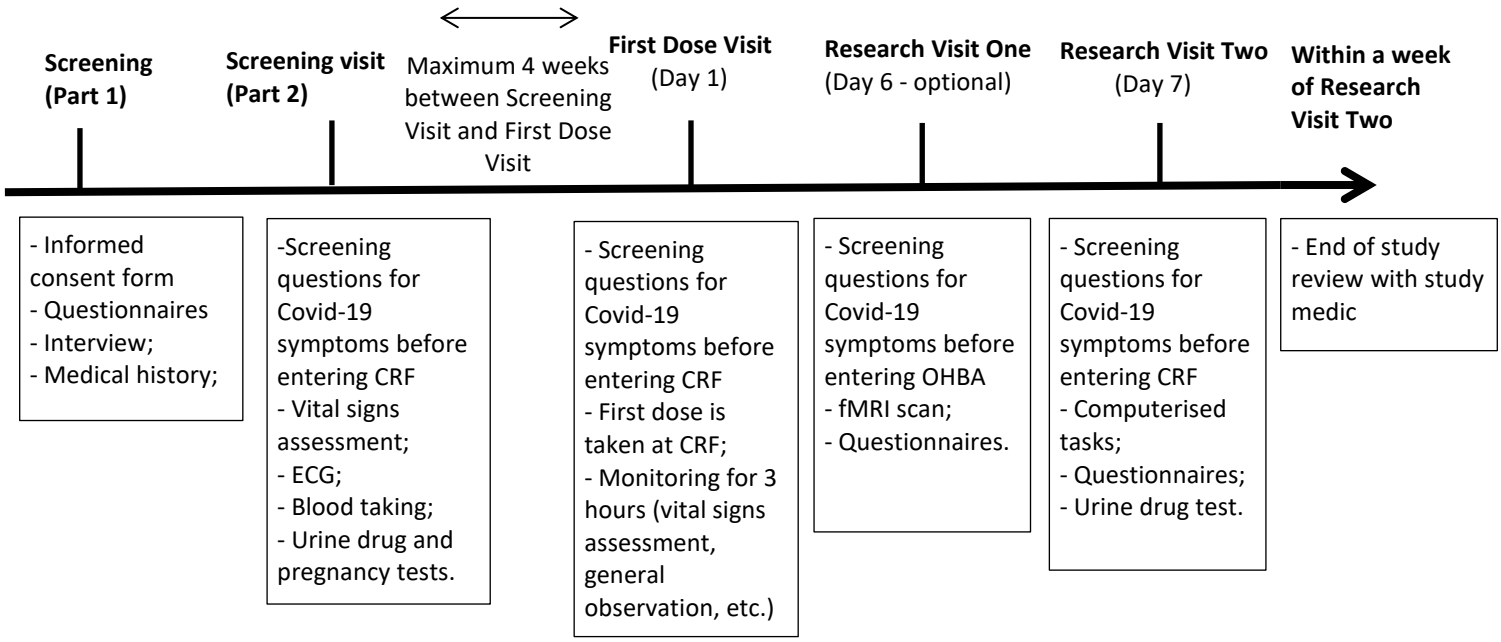

Figure 1: Study timeline

Screening

If you decide to take part, you will first be invited for a screening session (Part 1) which will be conducted either remotely by telephone call, completing online questionnaires (via Qualtrics), and a video call (using Microsoft Teams) or at the Clinical Research Facility (CRF) at the Warneford Hospital, dependent on current Covid-19 guidance. Screening (Part 1) will last approximately 90 minutes. We will ask you some detailed questions about your mental health, your previous history of treatment for depression, and ask you to fill in some questionnaires about your mood as well as a reading test. You will also be asked whether you or any household member have symptoms of Covid-19 or are at increased risk of severe Covid-19 disease.

If after Screening (Part 1) you fulfil our inclusion criteria, you will be invited for an on-site Screening Visit (Part 2) at the Clinical Research Facility (CRF), Warneford Hospital. This screening visit will last between 30-60 minutes. During this time we will give you a routine medical examination (medical history, blood pressure check, height and weight measurement, and ECG). We will take a urine sample to test for drugs such as cannabis (we can only recruit people who do not currently use street/recreational drugs). If the test results are positive, the team member who has conducted the test will discuss this with the medic or research staff member present and we will then inform you and provide any relevant advice. A positive result on the drug screen will mean you are unable to take part in this study. Results of the drug screen will remain confidential. For female participants we will also perform a pregnancy test; a positive result will again mean you are unable to take part in the study. We will similarly inform you of the results and keep all results confidential. We will also take a blood sample which we will then analyse to check your general health.

If you are eligible for the study and willing to proceed with it, we will write to your GP informing them of your participation.

First Dose Visit (Day 1)

If you meet the study criteria and want to continue, you will be asked to return again within the next four weeks, to the Clinical Research Facility (CRF) at the Warneford Hospital. Before being allowed into the CRF building you will be asked again whether you or any household member have symptoms of Covid-19. You will be randomly allocated into one of three groups (PF-04995274, citalopram or placebo). This means that you will take one of three sets of study medication but neither you, nor us will know which group you are allocated to. This is in order to prevent any effects that would be caused by treatment expectations. Information about your allocation will be stored securely during the study and unblinding (finding out which group you were in) will only be possible at the end of your participation in the study or if it is deemed necessary for medical reasons.

Whichever group you are in, you will need to take 3 tablets and one capsule each day, as explained in the table below. The reason for this is that we want the experience to be the same for all participants regardless of their allocation. It is important that you do not leave out a tablet or capsule.

PF-04995274 group	**Citalopram group**	**Placebo group**
3 Tablets containing **PF-04995274** (5 mg each, 15mg total)	**3 Tablets** containing **placebo**	**3 Tablets** containing **placebo**

1 placebo Capsule	**1 Capsule** with tablet containing **citalopram** (20 mg)	**1 placebo Capsule**

This visit will need to take place in the morning and will last about 4 hours in total. At the beginning of the session, we will briefly check that the inclusion/exclusion criteria are still met, and we will also ask you about any other medication you may have taken. You will then receive the first medication dose. After receiving the drug/placebo, we will ask you to wait for 3 hours in one of our quiet research rooms. During this period you are welcome to read or do some work. We will monitor you regularly and we will also assess your blood pressure and heart rate.

At the end of the visit, you will be given the study medication with full instructions of how to take them. You will also be given key details about the study and contact information for one of the researchers, who you can contact if you have any concerns about taking the study medication or if you're experiencing any side effects that are causing you concern.

Research Visit One (Day 6)

Please be aware that current NHS and government guidance on social distancing and use of PPE will also be followed at each visit to protect both participants and researchers from COVID-19 infection/transmission.

On the 6th day of taking the study medication, you will be asked to come in the morning to the Oxford Centre for Human Brain Activity (OHBA), also located in the Warneford Hospital, for a MRI brain imaging scan (see below for more details, under 'What is MRI Scanning?'). Before being allowed into the building you will be asked again whether you or any household member have symptoms of Covid-19. This visit will last about 2 hours. During the brain scan, you will be required to complete two simple tasks involving emotional stimuli (faces) and non-emotional cues (letters/numbers). During the scan there will also be periods of time when there will be no task to complete. During these periods we will use the scanner to measure other aspects of your brain structure and blood flow which will be helpful when we analyse the data. Additionally, we will measure your pulse, breathing rate, eye movements and skin conductance during the scan, which will also be helpful for analysing the data. This will involve wearing a thin strip of fabric around the waist and having some electrodes attached to your fingertips.

This visit is an optional visit. If you are unable to take part in an MRI scan or do not wish to take part in the MRI scan, you will still be able to take part in the rest of the study.

We will adhere to contact tracing procedures (https://www.gov.uk/guidance/nhs-test-and-trace-how-it-works):

- A record of visiting research participants will be maintained (name and visit date)
- A researcher or a designated individual will inform you if any member of the team develops symptoms of, or tests positive for, COVID-19 within 2 weeks of your visit
- We expect you to notify the research team if you develop symptoms of, or test positive for, COVID-19 within 2 weeks of research participation. Please email restandstudy@psych.ox.ac.uk.

Research Visit Two (Day 7)

On the 7th day of taking the study medication, you will be asked to visit the Clinical Research Facility (CRF) at the Warneford Hospital again, in the morning. Before being allowed into the building you will be asked again whether you or any household member have symptoms of Covid-19. During this visit, lasting about 3.5 hours, we will ask you to complete simple computer-based tasks assessing emotional and non-emotional cognitive processing. The

tasks will require you to make a response on the keyboard to pictures (for example, identify peoples' facial expressions) or to positive and negative words presented on the screen. One task will involve choosing between shapes presented on a screen, some of which lead to winning money and some which lead to losing money; your aim is to win as much money as possible, and your winnings (up to £10) will be added to your reimbursement at the end of the study. You will also complete the emotion potentiated startle test (EPST) in which eye blink responses to loud noises are measured using recording electrodes. On the same day we will also ask you to complete some online questionnaires (via Qualtrics) measuring your mood. Possible side effects of the study medication will be monitored and we will take a final urine sample to test for drugs. At the end of this visit, we will ask you to try to guess which treatment you received.

During the treatment week

During this week, a researcher will phone you up on treatment day 2 and day 4 to check how you are feeling. We will particularly want to talk to you after your second dose of the drug to ensure you have no concerns. We will also send you a text message every day reminding you to take the pills. We will also give you a 24-hour contact phone number of a member of the study team; you can always call us if you have any concerns or queries during the study week. If there is any change in your health status or medication use during the week, please inform a member of the study team. It's very important to let the study team know as soon as possible if you develop any Covid-19 symptoms.

For further instructions/requirements/advice while involved in the study, see *What should I consider?,* below.

End of study review (Day 10-14)

After the study is finished, all study medications will be discontinued. Within a week of the final visit, one of the study Psychiatrists will meet with you for an end of study review to check how you are feeling and if you have any concerns– or, dependent on travel arrangements and your preference, they may call you instead. They will discuss potential options such as a referral back to their GP with advice about your potential diagnosis and further treatment (which could involve specialist services) or the option to have your clinical care transferred to one of the study psychiatrists for a period of time. If the latter, your GP will be informed about the transfer of care and any diagnosis or future care plan. All of this will be done in discussion with you to ensure you are happy with the outcome and happy with what information is shared with your GP. During this review you will have the opportunity to be "unblinded" – to find out whether you received PF-04995274, citalopram or placebo during the week of study medication.

Information about the study medications

PF-04995274 is a new, unlicensed, drug. Like many established antidepressants, this drug affects brain serotonin but in a different way. In human clinical trials, approximately 142 people have previously had the drug in Clinical Trials run by Pfizer: 94 participants received single doses and 48 had it for two weeks. Results from these studies suggest that PF-04995274 is safe and generally well tolerated with only mild side effects. When combined with another drug scopolamine (also known as hyoscine), 3 participants experienced more severe adverse reactions including mood alterations, drowsiness, weakness and dizziness. However, in the current study, PF-04995274 will not be given in combination with scopolamine.

Citalopram is a commonly prescribed antidepressant, used to treat depression.

The placebo is identical to the other two drugs, but has no active ingredients.

What is MRI scanning?

MRI scanning works by using powerful magnetic fields to examine the tissues of the body. It is used widely in medicine to provide images inside many different parts of the body to help doctors detect diseases or to guide treatments. MRI is a routine procedure which is safe, painless and involves no ionizing radiation. As well as MRI scans to obtain an image of your brain for research purposes only, we will be using a special method called functional MRI (fMRI) which is designed to measure the activity levels in different parts of the brain. Having an MRI scan involves simply lying still inside the scanner. During this time you will be made comfortable and you will be able to contact researchers at all times. You will not feel anything, although you will hear some quite loud noises. MRI and fMRI are both extremely safe procedures and thousands of people have such scans every year. However, because of the magnetic fields involved, some people are not suitable for MRI scanning (See *Are there any possible disadvantages or risks from taking part?* , below).

What should I consider?

Covid-19 risk

We have carefully considered resuming this study in light of the current Covid-19 situation. In our view the anticipated benefits of conducting this study outweigh the risks of Covid-19 transmission. However it is entirely up to you whether you want to take part and you may withdraw at any time. We have taken a number of precautionary steps to lower the risk of possible Covid-19 transmission during this study. We have reduced the number of on-site visits as far as is practically possible and where integrity of the study data isn't compromised.

All on-site visits take place at the Warneford Hospital site, either in the CRF facility or the University's Department of Psychiatry buildings. Covid-19 risk reduction measures have been put in place that follow NHS and/or National guidelines; examples include mandatory face coverings, social distancing, enhanced cleaning regimes and screening everyone that enters the building for Covid-19 symptoms, including having their temperatures taken.

We provide all study participants with a Study Participant Leaflet which gives more detail about what we are doing to protect you, and what we expect of participants in order to protect others.

Birth control requirements

The effects of the study drug when given to a pregnant woman or an unborn baby have not been fully investigated. Therefore, pregnant women or women planning a pregnancy during the study must not take part. During the study you and any sexual partner must use a highly effective method of contraception if engaging in sex with risk of pregnancy, starting from Visit 1 (Screening) until 30 days after receiving study treatment. Female participants must not breastfeed, and male participants must not donate sperm.

Acceptable methods of contraception include:

- Combined (estrogen and progestogen containing) or progestogen-only hormonal contraception; the contraceptive pill, patch, vaginal ring, injection, or implant.
- Intrauterine device or hormone-releasing system (the coil/IUD/IUS)
- Bilateral tubal occlusion, vasectomy (or vasectomised partner)
- Sexual abstinence

Please note: Periodic abstinence (the rhythm method, and other fertility awareness methods), withdrawal, and use of spermicides only are not acceptable methods of contraception.

Advice for the week of the study

After the end of your First Dose Visit we advise you to not drive, cycle, or operate machinery, in case you experience any side effects from the study medication. To ensure you get home safely after the visit, we will either arrange a taxi or travel expenses (e.g. bus tickets) for the journey home will be reimbursed.

During the week of drug/placebo administration, we advise you not to drink alcohol and not to carry out activities requiring full alertness in case you notice any impairment.

Future research participation

We will ask you if you would like to be contacted about future research participation in the future; this is completely optional and does not affect your involvement in the current research project. Agreeing to be contacted does not oblige you to take part in any future studies.

Are there any possible disadvantages or risks from taking part?

Sometimes clinical interviews and psychological questionnaires can ask for information that might be potentially upsetting (for example, information about your mood). All clinical assessments will be administered by a qualified professional who can provide adequate information and treat any sensitive issues with care. You are under no obligation to answer the questions if they make you uncomfortable. We will also do our best to make you feel as comfortable as possible throughout the whole study. The tasks of emotional processing have been extensively used in multiple previous studies with no adverse effects. There is potential that you may find some of the tasks distressing but this is unlikely given the benign nature of the stimuli. You can however cease testing at any time if you do find it unpleasant.

Although taking blood is a very safe procedure, it can sometimes be uncomfortable and may result in localised bruising. Only trained staff members will take blood, and pressure will be applied afterwards to minimise any bruising.

Side effects will be monitored throughout the treatment. Side effects that have been reported with PF-04995274 are headaches, nausea, abdominal pain, back pain, diarrhoea, flatulence and cardiac changes (including hypotension). Side effects that have been reported with citalopram are abdominal pain, constipation, diarrhoea, dyspepsia (indigestion), gastro-intestinal disturbances, nausea and vomiting. The purpose of the medical screening at the start of the study is to make sure that it is safe for you to take the study medication. If you experience any negative side effects during the course of the study you should contact the research team (you will be given contact details) or your GP immediately.

MRI is safe and non-invasive and does not involve any ionising radiation (x-rays). However, because they use a large magnet to work, MRI scans are not suitable for everybody. Because of this, you will be asked pre-screening safety questions to help determine if you are able to take part. For example, if you suffer from claustrophobia, you could not be scanned. Normally, MRI scanning for research purposes would not be performed without

further investigation if you have a heart pacemaker, mechanical heart valve, mechanical implant such as an aneurysm clip, hip replacement, or if you carry other pieces of metal that have accidentally entered your body. While there is no evidence to suggest that MRI is harmful to unborn babies, as a precaution, the Department of Health advises against scanning pregnant women unless there is a clinical benefit; a pregnancy test will be done during your Screening Visit. If you think you might be claustrophobic, please discuss this in advance with the researcher, or let the radiographer or operator know before your scan. As some of the scans are noisy, we would give you earplugs to make this quieter for you. It is important that these are fitted correctly as they are designed to protect your hearing.

In preparation for your scan and for your comfort and safety we may ask you to change into pocket less and metal free "pyjama-style" top and trousers, which are available in a range of sizes. You may keep your underwear and socks on but we would ask ladies to remove underwired bras, if you have a suitable non-wired bra you may wear this instead. Please avoid any fabrics that contain metallic threads or have been silver impregnated (often marketed as anti-microbial/bacterial or anti-odour/stink). Metal jewellery including body piercing must also be removed. Eye shadow and mascara must also be avoided, since some types contain materials that can interact with the magnetic field. If you wish to wear eye makeup to your scan we can provide makeup removal wipes but you are advised to bring your own makeup to reapply. Lockers are provided to secure your personal belongings and clothing. Participants will be introduced carefully to the scanner and allowed to leave at any stage. Whilst in the scanner participants have easy access to a call button should they wish to stop the scan or speak with the radiographer or operator.

It is important to note that we do not carry out scans for diagnostic purposes, only for research. Our scans are not routinely looked at by a doctor and are therefore not a substitute for a doctor's appointment. Occasionally, however, a possible abnormality may be detected. In this case, we would have the scan checked by a doctor. If the doctor felt that the abnormality was medically important, you would be contacted directly and recommended to have a hospital (NHS) diagnostic scan arranged. You would not be informed unless the doctor considers the finding has clear implications for your current or future health. All information about you is kept strictly confidential.

What are the possible benefits of taking part?

Due to the short-term nature of the study, we do not expect participants to benefit significantly from the medications used here. This study will nonetheless give you an opportunity to discuss your feelings and concerns with a trained staff member as part of the screening session. By participating you are also contributing to the possible future development of safer and more effective antidepressant medications.

Will my General Practitioner/family doctor (GP) be informed of my participation?

After the screening session we will contact your GP to inform him/her that you are taking part in the study and to provide them with contact details in case they know of any reason why you should not complete the study; this is to help ensure your safety and well-being.

Additionally, any relevant medical information identified during the study procedures which requires follow up will be passed on to your GP, only after discussion with you and if you give permission. Similarly, after the end-of-study review, we will contact your GP to inform them about any outcomes which may require follow-up to ensure your safety and wellbeing after your contact with the research team has ended - including any advice for future management or referral, potential diagnosis, and if there has been transfer of care and a future care plan

developed. This will be done in discussion with you to ensure you are happy with the outcomes and the information shared.

Will my taking part in the study/data be kept confidential?

Yes. All the information about your participation in this study will be kept strictly confidential. Your results will be anonymised at the point of data collection (coded with a participant number) and no personal information will be attached to the research data. Data will be stored on a university computer for 10 years, while personal details will be stored separately in a locked filing cabinet. The only people who will have access to this data are the named researchers on this project and responsible members of the University of Oxford [and the relevant NHS Trust(s)] who will have access to the data for monitoring and/or audit of the study to ensure that we comply with applicable regulations.

Your personal information (email, telephone number, medical history) will be stored securely in a locked filing cabinet in a room that is locked when unoccupied. It will be accessible by named researchers only. It will be destroyed after the end of the study.

If you agree to be contacted about future research participation, we will store your personal contact details on an encrypted hard drive. This will also be stored securely in a locked filing cabinet in a room that is locked when unoccupied and will be accessible by named researchers only. Your personal data will be destroyed 10 years after the end of the study.

Data which has been made fully anonymous may be shared with other academic and commercial organisations in the future, including those outside of the EU, for future research projects. Those future projects can focus on any topic that might be unrelated to the goals of this study. Sharing anonymous MRI data aims to encourage transparency of scientific studies and accelerate the progress of research by enabling other researchers to do extra analysis on the data or combine data from numerous smaller studies. Once this data has been shared with other organisations, it cannot be destroyed, withdrawn or recalled. By agreeing to share your data, you will be making a free and generous gift for research that might help others. It is possible that some of the research conducted using your information eventually could lead to the development of new methods for studying brain, new diagnostic tests, new drugs or other commercial products. Should this occur, it is important that you understand you will not receive any part of the profits generated from such products and you will not have any ownership rights in the products.

Will I be reimbursed for taking part?

Upon completion of the study you will receive £200 for your participation in the research (or £170 if you do not take part in the MRI scan). Additionally, you will be able to win up to £10 while completing one of the study tasks. Reasonable travel expenses will also be reimbursed on production of receipts, or a mileage allowance provided as appropriate.

What happens to the blood and urine samples I provide?

Blood samples taken during the Screening Visit will be sent on the same day using the interhospital blood transport system to the pathology labs of the John Radcliffe Hospital, where tests of general health will be performed. Following this, the blood samples will be disposed of by the laboratory.

Urine samples will be used for drug screening and pregnancy tests by a trained staff member using dipstick tests. After the results are obtained the sample will be disposed of.

What will happen to my data?

Data protection regulation requires that we the state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the data controller and is responsible for looking after your information and using it properly.

We will be using information given by you and will use the minimum personally-identifiable information possible. We will store the de-identified research data and any research documents with personal information, such as consent forms, securely at the University of Oxford for 10 years after the end of the study. If you agree to be contacted about further research, we will keep your contact details securely at the University of Oxford for 10 years after the end of the study, unless you ask for their removal earlier. We will keep any other identifiable information about you for 12 months after the study has finished.

Oxford Health NHS Trust will use your name and date of birth to track your involvement in the study, and may use your contact details and NHS number to make sure that relevant information about the study is recorded for your care. They will keep identifiable information about you from this study for 12 months after the study has finished.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at: https://compliance.web.ox.ac.uk/individual-rights

You can find out more about how we use your information by contacting catherine.harmer@psych.ox.ac.uk

Please refer to the above section on confidentiality for further details – this includes the possibility of sharing anonymised data with other academic and commercial organisations in the future, including those outside of the EU, for future research projects.

What will happen if I don't want to carry on with the study?

You can withdraw from this study at any time, without explanation. If you do withdraw from the study, we would like to keep your data so that we can analyse them. However, if you do not want us to, you can request that we destroy the data. Withdrawing from the study will not have any impact on your standard medical care.

What will happen to the results of the research study?

Some of the results of this study may be published in a scientific journal. However, no information which could be used to identify any individual participant will be published. If you are interested in finding out about the overall results of this research, please let us know, and we will make arrangements to inform you once the study is completed.

What will happen if new information becomes available during the course of the study?

In the unlikely event that new information, relevant to your continuation in the study, becomes available, we will contact you to discuss this as soon as possible.

What if there is a problem?

You will be given the phone number of one of the researchers for the duration of your involvement in the study. You will be able to contact them if you have any concerns.

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact Prof. Catherine Harmer at the address above or email catherine.harmer@psych.ox.ac.uk or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 572224 or the head of CTRG, email ctrg@admin.ox.ac.uk.

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study.

In addition, Patient Advice and Liaison Service (PALS) is a free and confidential service which is completely independent of the study and can provide help and advice if you have comments, concerns, compliments, or complaints. They can be contacted on 0800 328 7971, via email PALS@oxfordhealth.nhs.uk or at their office based in the main building of the Warneford Hospital.

How have patients and the public been involved in this study?

Potential participants were involved in reviewing all aspects of the Participant Information Sheet.

Who is organising and funding the research?

The study is sponsored by Oxford University and is funded by a grant from the Medical Research Council. The researchers are not being paid specifically for including you in this study.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given a favourable opinion by Oxford B Research Ethics Committee.

Contact details

If you would like any further information on this study, or if you have any concerns, please contact either our recruitment team (Email: restandstudy@psych.ox.ac.uk or telephone: 07775 007621) or Professor Catherine Harmer (Email: catherine.harmer@psych.ox.ac.uk or telephone: 01865 618 326).

Thank you for considering taking part.