Oxford University Hospitals
NHS Foundation Trust

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PARTICIPANT INFORMATION SHEET

Feasibility study on the acceptability of a Virtual Reality Tour for patients referred for their first PET-CT scan

We'd 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, 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.*

What is the purpose of the study?

We know that a lot of people are anxious about having a PET-CT scan. We want to test whether a Virtual Reality (VR) tour of a PET-CT suite, which includes footage from inside the scanner bore, could help with this anxiety. The VR tour is created using 360 degree videos which contain audio and a specialised tour program, very much like the virtual tours estate agents use to showcase properties, and is displayed on a VR headset for patients to see before their booked PET-CT scan.

This is the VR Headset that is used in the trial, a Meta Quest 2.

An example of a section of the VR Tour (PET-CT scan room)

The best way to test the effectiveness of the VR tour is by a larger trial. Before we carry out a larger trial, we need to gather information, such as what people think of the VR tour and how useful it is to them. So, we are carrying out a smaller version of the trial, called a pilot study. The pilot study forms part of the professional doctorate for a member of the study team.

Why have I been invited to take part?

You have been invited to take part because you have been referred for your first PET-CT scan. We are intending to recruit about 20 patients.

Do I have to take part?

No. Taking part in this study is entirely voluntary. If you decide to take part, you are free to withdraw from the study at any time and without giving a reason. Deciding not to take part or withdrawing will not affect the standard of care you receive in any way.

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

When you spoke to the booking team for your PET-CT scan you gave permission for us to contact you to answer any questions you might have and check that the study is appropriate for you.

If you decide to take part, we will ask you to attend the hospital either 1 hour before you are due for your PET appointment or on a day and time before that's convenient for you. When you arrive, a member of the research team will check whether you have any further questions about the study and will ask you to sign a consent form.

You will be asked if you wish to complete an Anxiety Questionnaire (optional) to assess your current state of anxiety regarding the PET-CT procedure. This will be completed on the researcher's laptop. Then the researcher will give you a VR headset and a controller to hold in either hand and they will show you how these work. During the VR tour, you will see what it will be like to go for your scan – the tour will simulate the different parts of the scanning procedure, such as the radioactive tracer injection and lying

inside the scanner for a reduced amount of time as you would for the real scan. During the tour you will also have your heart rate measured via a sensor placed around one of your calves. The tour should last approximately 20 minutes. At the relevant section of the tour, you will be asked to lie down on a bed. A member of the research team will help you into this position. This can be done by pausing the tour first before getting into position. Once complete you will be asked to return to the waiting room.

We will ask everybody who completed the anxiety questionnaire to do so again approximately ten minutes before their scan appointment. During your PET appointment, you will continue to wear the heart rate monitor so that we can see what sections of the PET procedure may cause more anxiety. No information regarding the scan result will be used but we will ask you whether we can use your PET image data to analyse your motion during the scan. This may provide a quantitative measurement on anxiety during the scan, with the hypothesis that anxious patients will move and fidget more than calm patients.

A member of the research team will telephone you a day or so after your scan at a time that is convenient for you, to ask you some questions about your experience. The telephone call will last around half an hour. This information will be used to improve the VR Tour for future studies, and you will also be asked to score the tour in terms of how much you felt it benefitted you on a scale of 1 to 10.

What should I consider?

We will ask you to participate in this study if you are aged 18 or older and you have not had a PET-CT scan before.

Are there any possible disadvantages or risks from taking part?

It is very unlikely that you would be harmed by taking part in this research. As the VR tour simulates the PET-CT experience, it is possible that it may make you feel anxious. If this is the case and you are unable to continue, the tour will be stopped, and the researcher will make sure that the Radiographers who conduct your scan know so that they can help and advise you.

VR experiences can cause dizziness, nausea, and motion sickness. For this particular VR Tour the risk from these effects will be small. The VR Tour is designed in a way to minimise these effects as much as possible, for all apart from one of the VR viewpoints are static, i.e. you do not move around the VR environment.

What are the possible benefits of taking part?

We are conducting this trial to see whether the VR intervention is acceptable to patients and if there is a potential benefit to anxious patients. We hope that the information we get from this study will help us to improve the care and experience of patients referred for PET-CT scans.

Will I be paid for taking part?

You will be reimbursed for reasonable parking expenses incurred for your appointment as you will need to be at the hospital for the VR experience or possibly longer than your normal appointment due to the trial.

Will my taking part in the study be kept confidential?

If you agree to take part, the information that we obtain whilst you are in the study will be kept strictly confidential within the research team. The information will be held securely and electronically at Oxford University Hospitals NHS Foundation Trust (OUH). Electronic files will be stored on a secure OUH managed server. Any paper sheets and forms with data will be stored in a locked file cabinet within the Imaging Section of the Medical Physics and Clinical Engineering (MPCE) department at the OUH. The MPCE department is only accessible with an OUH ID card and is always locked. Your name will not be passed to anyone else outside the research team or the Sponsor (Oxford University Hospitals NHS Foundation Trust). You will be allocated a study number which will be used as a code to identify you on any relevant forms.

Responsible members of the Oxford University Hospitals NHS Foundation Trust may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

What will happen to my data?

We will be using information from you to undertake this study. Research is a task that we perform in the public interest. Oxford University Hospitals NHS Foundation Trust, as sponsor, is the data controller. This means that we, as Oxford University Hospitals NHS Foundation Trust researchers, are responsible for looking after your information and using it properly. We will use the minimum personally identifiable information possible. We will store the anonymised research data and consent forms, securely at Oxford University Hospitals NHS Foundation Trust for 12 months after the end of the study.

The research team will use your personal details, e.g. name, and telephone contact details, to contact you to explain the trial and for the telephone interview a day or so after your scan. We will keep this identifiable information about you for a maximum of 12 months after the study has finished.

Your rights to access, change, or move your personal information may be limited, as we need to manage your information in specific ways for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at:
https://www.ouh.nhs.uk/privacy/default.aspx

You can find out more about how we use your information by contacting the Chief Investigator (daniel.mcgowan@ouh.nhs.uk).

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

You are free to withdraw at any time without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive in any way. If you withdraw from this study, we will no longer contact you or collect any further data from you but will use the data already collected from you.

What will happen to the results of this study?

We intend to publish and present the results of this study in scientific journals and conferences. In all cases, the information will be provided in such a way that you cannot be identified. The results will also contribute to the fulfilment of an educational requirement, which is a study team members professional doctoral thesis. If you would like a summary of the study results, please let a member of the research team know.

What if there is a problem?

If you wish to complain or have any concerns about any aspect of the way you have been approached or treated during this study, you should contact Dr Daniel McGowan daniel.mcgowan@ouh.nhs.uk. You may also contact the Patient Advice and Liaison Service (PALS) (01865 221473).

There are no special compensation arrangements. Oxford University Hospitals NHS Foundation Trust will provide indemnity for this study. If you are harmed due to someone's negligence, then you may have grounds for legal action, but you may have to pay for it.

NHS bodies are legally liable for the negligent acts and omissions of their employees. If you are harmed whilst taking part in a clinical trial as a result of negligence on the part of a member of the study team this liability cover would apply.

Non-negligent harm is not covered by the NHS indemnity scheme. The Oxford University Hospitals NHS Foundation Trust, therefore, cannot agree in advance to pay compensation in these circumstances. In exceptional circumstances an ex-gratia payment may be offered.

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

Patients have provided advice on the design of this information sheet.

If you would like more general information about taking part in research, you may find the following links useful:

www.crn.nihr.ac.uk/can-help/patients-carers-public/how-to-take-part-in-a-study/

www.nhs.uk/Conditions/Clinical-trials/Pages/Introduction.aspx

Who is organising and funding the study?

This research is being organised and sponsored by the Oxford University Hospitals NHS Foundation Trust. Funding for this study is provided by the MPCE department at the OUH.

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 favourable opinion by the ### Research Ethics Committee.

Participation in future research:

You will not be contacted to take part in any other future research.

Further information and contact details:

Please contact:

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Position: Chief Investigator

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Thank you for reading this information sheet and for considering taking part.

APPENDIX A: STUDY FLOW CHART