Public Participant Information Sheet

Title of Project: Virtual Reality as a tool for Emotional Control related to undergoing Magnetic Resonance Imaging.

Researcher Name: Darren Hudson.

Purpose of the research:
Anxiety is commonly associated with diagnostic imaging examinations, such as Magnetic Resonance Imaging (MRI). Commonly in MRI this presents as claustrophobia and fears related to the scanner itself. This can cause reduced image quality from patient movement or even failure to complete a scan.

Advances in scanner design and technology have improved the patient experience and shortened scan times. Some patients still find the experience difficult. There is benefit from support in managing this. A common approach is by suitably preparing patients beforehand. Knowing what to expect can remove fear of the unknown. A key aspect is how accurately any supplied resources represent what is involved. Another strategy is to visit a scanner in advance or spend time trying it out. This further reduces fears around what is involved.

Both approaches are used in practice. They come with challenges in how effective they are. Written or video information can only go so far in relaying what to expect. Time to explore the scan room takes up scanner time. A possible solution is the use of Virtual Reality (VR) in creating a virtual scan experience. VR uses computer technology to create a simulated environment. In this case an experience of having an MRI examination. This allows patients to more accurately experience the sights and sounds involved. Which in turn should replicate a response similar to that in reality. Use of a virtual environment frees up scanner time allowing patients to use the experience as much as needed. Coping strategies could also be taught within VR to support managing response to a scan.

The purpose of this study is to evaluate a VR tool of an MRI experience. To assess how the tool effects emotional response to MRI anxiety. Also its acceptability and use by members of the public to direct future development.

What would taking part involve?

On expressing interest to participate, you will first be asked to complete some initial questions. These check your suitability for the study. This data may be used to provide wider information around levels of perceived claustrophobia and anxiety.

Once accepted onto the study, you will be invited to attend a VR session at a suitable time for you. This session will introduce the VR tool and how it is used. Undergoing exposure to the VR tool involves the use of a head mounted device over your eyes. This displays the virtual experience in 3D. You are then able to safely explore and experience a virtual scan. An experienced MRI radiographer will be with you the whole time. They will guide you through the session.

During this session, you will be asked to use the virtual tool at least twice, up to a maximum of 5 times. Before, during and after each experience you will be asked a series of questions. These questions are used to monitor your response. At the end further feedback will be asked on your overall experience and usefulness of the tool itself.

Please expect the appointment to last from between 1.5-3hrs, depending on the number of exposures performed during the session.

Why have I been approached?
Following your expression of interest in the study, we are looking for participants aged 18years or above who have experienced undergoing an MRI scan before. In order to gauge response in advance, preference is for participants to have experienced a scan of the head/neck or chest areas with head first entry into the scanner. Based on the initial screening questions, you will need to not have any existing anxiety disorder, be taking medications for anxiety or depression, and have no significant impairment or disability which would affect your use of the head mounted device.

What are the possible disadvantages and risks of taking part?
The use of VR is increasing, both at home and in clinical use. Many people do not experience any side effects. The use of VR can cause feelings similar to motion sickness. These feelings can include nausea, dizziness, visual problems and disorientation. All of which are short lived, improve over repeated use and when removed from the virtual environment. Due to improvements in software design, it occurs far less than it used to be. Severe cases are reported in less than 5% of users.

Assessment of any symptoms is part of the study aims. This is to ensure potential for them is low. You will be asked whether you have any history of migraines or motion sickness. These can increase your potential to experience symptoms. You will also be asked not to drink any alcohol the night before. Please let us know if you have any cold or flu symptoms on the day of your appointment.

Feelings of being disconnected from yourself or reality can be enhanced through VR. This results from a sensory mismatch. It makes it difficult to interpret reality, causing feelings of disconnect. Part of the initial assessment is to check for any potential for this. To continue in the study, you will have scored low.

Should you having any problems whilst within the VR tool you can remove yourself at any time. This can be by letting the researcher know or by removing the head mounted device.

Feeling any of the above is reduced through limiting your time within the virtual environment. Each exposure will last no more than 20 minutes. Each exposure will be separated by a 15-minute gap. A maximum of five exposures will be carried out within the appointment.

What will happen if I don't want to carry on with the study?
You are completely in control at all times. You can remove yourself from the virtual experience or stop the session at any time without any consequence to yourself. Simply inform the researcher or carefully remove the head mounted device. Any data acquired up until that point will still be used. It will help in assessing acceptability of the tool. If you do not wish your data to be used it can be withdrawn at any time up until completion of the study.

How will my information be kept confidential?
The University of Exeter processes personal data for the purposes of carrying out research in the public interest. The University will endeavour to be transparent about its processing of your personal data and this information sheet should provide a clear explanation of this. If you do have any queries about the University's processing of your personal data that cannot be resolved by the research team, further information may be obtained from the University's Data Protection Officer by emailing informationgovernance@exeter.ac.uk. or at http://www.exeter.ac.uk/ig/

On participation into the study, you will be assigned a unique identification number. No personal information will be used during review of the data. Your name will only be accessible with your consent form and associated identifier via a secure server that only the lead researcher can access. Only your age and sex at birth will be used for analysis and any published outputs. On completion of the study and achievement of the qualification all records on file will be destroyed (approximately 2-3years time).

A recording of your experience within the MRI experience may also be captured for educational purposes. This is a copy of what you will have seen within the VR tool. It does not include audio footage or any direct video of yourself.

Will I receive any payment for taking part?

A £25 gift voucher will be given following participation in recognition for your time and involvement.

What will happen to the results of this study?

Results from the study will primarily be used to support attainment of an academic qualification. They will also help further development of the VR tool used. It is hoped that results will be of interest for publication in relevant peer-reviewed journals and presentation at professional conferences.

Who has reviewed this study?

The project has been reviewed by the Psychology Research Ethics Committee at the University of Exeter.

Further information and contact details.

The lead researcher can be contacted via research@inhealthgroup.com

Should you be unhappy or have any concerns about any aspect of this project and wish to complain, please contact the University of Exeter Research Ethics and Governance team via cgr-reg@exeter.ac.uk

Thank you for your interest in this project.