

# Pilot study on the use of a Virtual Reality Tour to reduce anxiety in patients referred for PET/CT scans

<b>Submission date</b> 05/05/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 12/06/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 17/06/2024	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Every year a small percentage of patients that are referred for a PET/CT are unable to complete the procedure due to claustrophobia-induced and procedure-related anxiety. As PET/CT involves the use of a radioactive tracer, patients that have the injection but then fail to finish the scan due to anxiety will receive the radiation detriment for no benefit. The project proposed will investigate whether a virtual tour constructed from 360 videos of the PET suite, and procedures that the patient would undergo (Virtual Reality (VR) intervention), displayed on a VR Headset, could be used to reduce patient claustrophobia induced and procedure-related anxiety and improve the patient experience. The VR tour is very much like the virtual tours that estate agents use to showcase properties. This is a pilot study; therefore, the primary aim is to assess the acceptability and feasibility of the VR tour and collect data on anxiety measures for the intervention (VR) and comparator groups. This pilot will inform and appropriately power a larger trial and provide additional information to existing knowledge in the literature.

### Who can participate?

Adult patients attending a PET/CT scan

### What does the study involve?

Anxiety will be measured using two validated anxiety measures before and once again after the intervention or Comparator. The second measure will be taken before the patient's actual PET/CT scan. Anxious patients that are referred for PET/CT are given the opportunity to see the PET/CT scanner before their scan however this can be difficult to arrange due to clinical workload.

### What are the possible benefits and risks of participating?

We are conducting this trial to see if there is a potential benefit in reducing anxiety, with a focus on claustrophobia or anxiety directly regarding the scan. We do not know if the VRtour will reduce a patient's anxiety, which is why we are doing this study. We hope that the information we get from this study will help us to improve the care of people who are anxious about PET/CT scans.

It is very unlikely that a participant 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 them feel anxious. Motion Sickness from the VR tour is also a possibility, however, the tour has been designed to mitigate this risk and include mostly static viewpoints.

Where is the study run from?  
Churchill Hospital, Oxford (UK)

When is the study starting and how long is it expected to run for?  
August 2021 to June 2025

Who is funding the study?  
Oxford University Hospitals NHS Foundation Trust (UK)

Who is the main contact?  
Dr Michael Barnard, michael.barnard@ouh.nhs.uk

## Contact information

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number**

308656

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

16054, IRAS 308656

## Study information

**Scientific Title**

Pilot study on the use of a Virtual Reality Tour to reduce anxiety in patients referred for PET/CT scans

**Acronym**

PET-CT VR Tour

**Study objectives**

A virtual tour of the PET-CT pathway observed by patients before their actual first PET-CT procedure, reduces their anxiety more than the control (reading a PET-CT leaflet).

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 06/04/2022, London - Queen Square REC (HRA NRES Centre Bristol, 3rd floor, block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)2071048225, (0)2071048284; queensquare.rec@hra.nhs.uk), ref: 22/LO/0140

### **Study design**

Single-centre pilot study

### **Primary study design**

Interventional

### **Secondary study design**

Pilot study with randomised control design

### **Study setting(s)**

Hospital

### **Study type(s)**

Prevention

### **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

### **Health condition(s) or problem(s) studied**

Reduction of claustrophobia and procedural anxiety

### **Interventions**

Participants are randomised into the Intervention group or Control Group. Randomisation is completed using a web-based randomisation system using a simple computer-generated random number sequence list (sealedenvelope.com) for 20 patients, ensuring 10 participants in each group. Block randomisation will be used, and these blocks will consist of 4 participants. All participants are given a non-validated Anxiety Questionnaire after informed consent and eligibility. The Intervention group are given the virtual tour and their heart rate is measured during the intervention. 10 mins before their actual appointment time, the Anxiety questionnaire is completed again. Heart rate is monitored during the actual PET-CT scan. An interview is conducted after at least 1 day to gather information to improve the intervention. Control groups receive the anxiety questionnaire after consent and eligibility and are then asked to return to the waiting room with a PET-CT leaflet. 10 mins before their scan, they are asked to complete the anxiety questionnaire again. Heart rate is measured during the real PET-CT. No interview is required for the control group.

### **Intervention Type**

Behavioural

**Primary outcome measure**

1. Anxiety measured using Anxiety Questionnaire scoring at baseline and after the intervention (10 mins before PET-CT appointment time)
2. Acceptability and experience of the intervention measured using interviews from Day 2 onwards

**Secondary outcome measures**

Comparison of mean Heart Rate measurement measured using an optical sensor between virtual tour PET-CT bore experience and real PET-CT experience

**Overall study start date**

01/08/2021

**Completion date**

30/06/2025

**Eligibility****Key inclusion criteria**

1. Participants aged over 18 years old
2. Participant is willing and able to give informed consent for participation in the study
3. Participant has the required visual acuity to view the VR Tour
4. Participant has the manual dexterity to use the controller

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

20

**Key exclusion criteria**

1. Participant has received a PET/CT scan previously.
2. Participant has hearing impairment which means they cannot hear speech on the tour application.
3. Participant who are unable to communicate clearly in English over the telephone for 30 minutes.
4. Participant who are unable to understand written English.
5. Participant has limited mobility and is unable to position themselves with minimal assistance onto a bed.

**Date of first enrolment**

06/04/2022

**Date of final enrolment**

30/06/2023

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Oxford University Hospitals NHS Foundation Trust**

John Radcliffe Hospital

Headley Way

Headington

Oxford

United Kingdom

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## **Sponsor information**

**Organisation**

Oxford University Hospitals NHS Trust

**Sponsor details**

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**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.ouh.nhs.uk/>

**ROR**

<https://ror.org/03h2bh287>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

Oxford University Hospitals NHS Foundation Trust

**Alternative Name(s)**

Oxford University Hospitals National Health Service Trust, OUH

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Local government

**Location**

United Kingdom

## **Results and Publications**

**Publication and dissemination plan**

Planned publication in Virtual Reality and British Institute of Radiology journals.

**Intention to publish date**

31/12/2025

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are not expected to be made available. Data sharing is only available in the NHS Trust where the study is taking place and for the regulatory authorities.

**IPD sharing plan summary**

Not expected to be made available