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

Submission date
05/05/2023

Recruitment status
No longer recruiting

Registration date
12/06/2023

Overall study status
Completed

Last Edited
17/06/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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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Principal Investigator

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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
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United Kingdom
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Sponsor information

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Oxford University Hospitals NHS Trust

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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