Acceptability of a virtual reality tour for patients referred for their first PET-CT scan

Submission date	Recruitment status No longer recruiting	Prospectively registered		
02/08/2023		Protocol		
Registration date	Overall study status Completed Condition category Other	Statistical analysis plan		
04/09/2023		Results		
Last Edited		[] Individual participant data		
18/06/2024		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. Most patients will have some form of anxiety when having their first PET-CT scan and so an intervention that would help alleviate procedural anxiety and improve the patient experience is welcomed. 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 procedure-related anxiety and improve the patient experience. The Virtual Tour (VT) is very much like the VTs 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 VT tour for any patient having their first PET-CT and collect data on anxiety before and after the VT. This pilot will inform and appropriately power a larger trial (multicentre) 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 a non-validated anxiety measure before and once again after the intervention. The second measure will be taken before the patient's actual PET/CT scan. Heart rate will also be measured during the VT and during the actual PET-CT scan. These will be compared to see if the mean heart rate is reduced when compared to the VT mean heart rate. An interview is conducted a day or two after the PET-CT scan to gather information on the participant's experience, which will be used to further improve the VT.

What are the possible benefits and risks of participating?

The researchers are conducting this trial to see if our current prototype is acceptable and if there is a potential benefit in reducing anxiety directly regarding the scan. They do not know if the VT will reduce a patient's anxiety, which is why they are doing this study. It is hoped that the information from this study will help 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 VT 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 (UK)

When is the study starting and how long is it expected to run for? December 2022 to June 2023

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

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

Contact information

Type(s)

Principal Investigator

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Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

318986

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

IRAS 318986, CPMS 55006

Study information

Scientific Title

Feasibility study on the acceptability of a virtual reality tour for patients referred for their first PET-CT scan

Acronym

PET-CT VR Tour HR

Study objectives

That the current prototype virtual tour is acceptable to patients. A virtual tour of the PET-CT pathway observed by patients before their actual first PET-CT, reduces their heart rate during the real PET-CT compared with their heart rate during the virtual tour PET-CT.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 27/02/2023, London - Dulwich REC (HRA, Skipton House, 80 London Road, London, SE1 6LH, United Kingdom; +44 (0)2071048094; dulwich.rec@hra.nhs.uk), ref: 23/LO/0050

Study design

Single-centre pilot study

Primary study design

Interventional

Secondary study design

Feasibility study

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

See study outputs table

Health condition(s) or problem(s) studied

Reduction of procedural anxiety

Interventions

All participants have the Virtual Tour (VT). All participants are given a non-validated Anxiety Questionnaire after informed consent and eligibility. During the VT their heart rate is measured. 10 minutes before their actual appointment time, the Anxiety questionnaire is completed again. Heart rate is monitored also during the actual PET-CT scan. An interview is conducted after at least 1 day to gather information to improve the intervention.

Intervention Type

Behavioural

Primary outcome measure

- 1. Heart rate measured using an optical sensor during virtual tour PET-CT bore experience and real PET-CT experience
- 2. Acceptability and experience of the intervention measured using interviews from Day 2 onwards

Secondary outcome measures

1. Anxiety measured using Anxiety Questionnaire scoring at baseline and after the intervention (10 min before PET-CT appointment time)

Overall study start date

01/12/2022

Completion date

30/06/2023

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

Lower age limit

18 Years

Sex

Both

Target number of participants

20

Total final enrolment

20

Key exclusion criteria

- 1. Participant has received a PET/CT scan previously
- 2. Participant has a hearing impairment which means they cannot hear speech on the tour application
- 3. Participants who are unable to communicate clearly in English over the telephone for 30 minutes
- 4. Participants 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

27/02/2023

Date of final enrolment

28/06/2023

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 OX3 9DU

Sponsor information

Organisation

Oxford University Hospitals NHS Trust

Sponsor details

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OUH Cowley
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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 European Radiology and appropriate conferences.

Intention to publish date

31/12/2024

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.1	01/01/2023	02/08/2023	No	Yes