

How does virtual reality affect patients' experience when undergoing awake surgery?

Submission date 21/06/2018	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 08/01/2020	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 28/08/2020	Condition category Surgery	☐ Individual participant data

Plain English summary of protocol

Background and study aims

It is common for people undergoing arm surgery to have it done under local or regional anaesthetic and remain fully awake. This type of anaesthesia is commonly known as a 'block'. The block is performed with ultrasound guidance by an experienced anaesthetist. In recent years, virtual reality (VR) headsets have become increasingly affordable and accessible. People are becoming increasingly comfortable with and enjoying using new technology. The aim of this study is to see how the use of virtual reality affects patients' experience under regional or local anaesthesia.

Who can participate?

Patients aged over 18 undergoing upper limb surgery under local or regional anaesthetic

What does the study involve?

Participants are randomly allocated into one of two groups. One group receives a virtual reality headset and headphones for the duration of the surgical procedure and one group (the control group) do not receive a virtual reality headset and headphones but are still asked to complete some questionnaires on their experience. All participants receive the usual anaesthetic technique. This involves the use of local anaesthetic to numb the area where they are having their operation. It is called a block or regional anaesthetic. Participants' experiences during the procedure are collected using questionnaires.

What are the possible benefits and risks of participating?

What are the possible benefits and risks of participating? Taking part does not change the care participants receive. Participants still have a block performed with ultrasound guidance by an experienced anaesthetist. For some people, motion sickness can be a problem with virtual reality headsets. In the clear majority of cases this is only slight. If this occurs participants can tell the anaesthetist, who will be present and monitoring them throughout, and they can either give them some medicine to help with the sickness or remove the headset. They can ask for the headset to be removed at any time without this affecting the care they receive. Very rarely people find the experience of being awake for the procedure difficult. If this is due to pain or

discomfort they can have further local anaesthetic or pain medications through a drip that will be placed in a vein before the block is performed. If this doesn't help they may receive a sedating medication via the drip or a general anaesthetic if this is safe.

Where is the study run from?
Royal United Hospital, Bath (UK)

When is the study starting and how long is it expected to run for?
November 2017 to September 2018

Who is funding the study?
Clinical Society of Bath (UK)

Who is the main contact?
Dr Richard Edwards
Richard.edwards16@nhs.net

Contact information

Type(s)
Public

Contact name
Dr Richard Edwards

Contact details
Royal United Hospital
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Bath
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Additional identifiers

Integrated Research Application System (IRAS)
201443

Study information

Scientific Title
Does immersive virtual reality reduce procedural anxiety in patients undergoing awake surgery?

Study objectives
Virtual reality headsets reduce patient anxiety when undergoing awake upper limb surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 14/05/2018, HSC REC B (Office for Research Ethics Committees Northern Ireland (ORECNI), Customer Care & Performance Directorate, Lissue Industrial Estate West, 5 Rathdown Walk, Moira Road, Lisburn, BT28 2RF; +44 (0)28 9536 1400; no email provided), ref: 18/NI/0081

Primary study design

Interventional

Study design

Single-centre interventional randomised controlled trial with participant blinding to outcome measures

Study type(s)

Other

Health condition(s) or problem(s) studied

Patients undergoing upper limb surgery under regional or local anaesthesia

Interventions

Method of Randomisation

The randomization process will be undertaken by a person who will not play any other part in the research project. It will be done using the web (pseudo)randomization service: <https://www.randomizer.org/>.

There will be a block randomisation of two groups of 20 to yield even numbers in each group. A series of numbered, sealed packages will be produced with individual numbers written on them, which must be opened in numerical order.

Participants will be randomised on the day of surgery by the opening of an opaque envelope determining their group allocation. They will be assigned to one of two groups: a control group or an intervention group. In addition to any intervention, both groups will receive care-as-usual (CAU).

Care-As-Usual

For these procedures, the patients' anaesthetic treatment options are discussed by the surgeon at the time of being listed for surgery. If the patient chooses to have awake surgery under a regional anaesthesia block then they are listed on specific theatre sessions.

Sedation and general anaesthesia are not routinely used during these sessions as it creates organisational problems. Sedation is not offered pre-operatively again, however if sometimes be accommodated. Patients will be invited to take part in the study after they have made their anaesthetic treatment choice and have been listed on a 'regional block list'. If the participant requests sedation during the study, this will be recorded and the participant withdrawn from the remainder of the intervention period. Data collected up to the point of withdrawal will be included for analysis.

No formal distraction method will be offered to the control group (e.g. music/TV). However, it is inevitable that 'Care As Usual' (and therefore the Control arm) will involve the participants interacting with the theatre staff. This, in itself, is a form of distraction which cannot be withheld. We will note the degree of interaction with theatre staff (e.g. "None", "During part of the procedure", "During most of the procedure") in order to discuss any null findings should they occur.

- Full physiological monitoring, according to the Association of Anaesthetists of Great Britain and Ireland (AAGBI) standards, for regional or local procedures as applicable.
- Regional or local (field infiltration) anaesthesia. The specific choice will be determined by the surgeon and anaesthetist, based upon the patient and procedural factors, on the day of surgery.
- Regional anaesthesia techniques will be performed by one of three nominated senior anaesthetists, experienced in upper limb regional anaesthesia. This will be performed in a dedicated anaesthetic room with AAGBI-compliant monitoring standards.
- Regional techniques include ultrasound-guided interscalene, supraclavicular, infraclavicular, axillary and/or median, radial, ulnar nerve blockade.
- The exact technique will be at the discretion of the anaesthetist, based on patient and operative factors.
- Local (field infiltration) anaesthesia will be administered in theatre by the surgeon performing the procedure.
- Local anaesthesia is targeted to the operative site and is performed immediately prior to the start of surgery.

Intervention Group

Within the intervention group, participants will receive a VR headset and headphones with a pre-programmed 'scene', for the duration of the procedure.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

'Oculus Go' VR Headset, Oculus VR

Primary outcome(s)

Patient anxiety, measured by STAI-S score before and during awake surgery at KTS, after 15 minutes following KTS and after 10 minutes in recovery

Key secondary outcome(s)

1. Patient satisfaction, measured by the Bauer patient satisfaction tool via a telephone call at 48 hours after discharge
2. Physiological parameters which are potential indicators of patient anxiety (heart rate and blood pressure) at KTS, 15 minutes after KTS and after 10 minutes in recovery

Completion date

25/10/2019

Eligibility

Key inclusion criteria

Study population:

1. Aged older than 18 years
2. Presenting at the Royal United Hospital, Bath for upper limb surgery
3. Undergoing upper limb surgery under local or regional anaesthesia alone

Inclusion criteria:

1. Scheduled for elective upper limb surgery
2. Intended anaesthetic technique to be regional or local anaesthesia alone
3. Body mass index 18-40 kg/m²
4. American Society of Anaesthetists (ASA) grade I-III

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Less than 18 years old
2. ASA grade IV
3. Unable to give informed consent
4. Patient refusal
5. Hearing or visually impaired
6. Inability to cooperate
7. Inability to read, speak and understand English
8. History of severe motion sickness
9. Patients scheduled to receive general anaesthesia at booking

Date of first enrolment

23/07/2018

Date of final enrolment

17/06/2019

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Royal United Hospital
Combe Park

Bath
United Kingdom
BA1 3NG

Sponsor information

Organisation

Royal United Hospitals Bath NHS Foundation Trust

ROR

<https://ror.org/058x7dy48>

Funder(s)

Funder type

Charity

Funder Name

Clinical Society of Bath (prize award)

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Kelly Spencer (kelly.spencer@nhs.net).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		27/08/2020	28/08/2020	No	No
HRA research summary			28/06/2023	No	No