Study Protocol

Title:

Integration of Virtual Reality as analgesia for outpatient flexible cystoscopy: a randomized prospective study

Scientific title:

Effect of Virtual Reality as analgesia for outpatient flexible cystoscopy on procedural discomfort: a randomized prospective study

Background:

Virtual reality has made an impact in areas of acute and chronic pain as an adjunct to standard analgesia regimes1. Research has already shown benefit in areas of paediatric procedures2, burn wound debridements3 and endoscopic gynaecological procedures4 to manage acute procedural pain. It appears subjective pain scores and anxiety levels may be reduced with this non-pharmacological approach1,2,3,4,5. This has not been introduced within the scope of urology procedures.

Flexible cystoscopy is commonly carried out in the outpatient clinic under local anaesthetic. There wide variation in patients experience with this procedure, with a large number tolerating it poorly, which can also detract from the accuracy of the procedure6,7. Integrating Virtual reality as an adjunct to analgesia for outpatient flexible cystoscopy may improve patient satisfaction outcomes, and reduce numbers of patients requiring cystoscopy under General Anaesthesia.

Aim:

To determine if virtual reality technology will act as an analgesic aid to improve patient satisfaction following outpatient flexible cystoscopy.

Hypothesis:

If virtual reality technology is used at the time of outpatient flexible cystoscopy, there will be an improved patient levels of pain, anxiety and overall satisfaction.

Method:

This will be a single-centre, open label, randomized prospective cohort study conducted within the Urology Department of Dunedin Hospital.

The Principal investigator will be Prof Amir Zarrabi (Urology Consultant). The Lead/Communicating investigator will be Thomas Clarkson (Urology Registrar).

Eligible participants will be patients who present for flexible cystoscopy in the outpatient setting. Exclusion criteria: Patients with vision impairment or significant cognitive impairment. Patients who do not have the capacity to provide independent informed consent and must be able to read and understand the participant information sheet and consent form.

Recruitment will be from the outpatient clinic over a 12-month period. Estimated sample size 200 patients.

Participants will be consented then randomly allocated to Virtual Reality (VR) intervention group or control group. Routine flexible cystoscopy under local anaesthetic will take place with no procedural change in the way samples are collected in both groups. However, the intervention group will wear a VR headset with distraction environment VR software. They will then watch a VR movie for the duration of the procedure. Prior to the procedure in each group, Participants will complete a standardized questionnaire about their expectations of the procedure. This will include questions relating to pain, anxiety and overall expectation. After the procedure, patients will complete the same questionnaire investigating their pain, anxiety, VR response (if applicable) and overall satisfaction. The headset will be cleaned between uses.

The primary outcome will be patients’ pain, anxiety and overall satisfaction scores. This will be collected on standardized questionnaires as guided by similar international studies3,5,8.

Data will be collected in a de-identified manner. Patients will be assigned a participant number when they consent for the study. This will determine whether they are in the intervention or control group and this will be stated on the questionnaire sheets along with ethnicity and age. De-identified data will be stored under password protection on the secure district health board computer system. It will be kept for 10 years.

Identifiable data (consent forms) will be stored in a locked room in the secure hospital building and will not be released to the public. Identifiable data will only be accessed by the investigators. It will be kept for 10 years. Please see the standalone data management plan for more information.

Data will then be analysed to see if there is correlation between VR and primary outcome scores. No further follow up is required.

References:

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