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Title Page

Virtual Reality for Acute Pain in Outpatient Hysteroscopy: A Randomised Controlled Trial

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Short running title – Virtual Reality for Pain Management

Abstract

Objective: To evaluate the effectiveness of virtual reality as a distraction technique in the management of acute pain and anxiety during outpatient hysteroscopy.

Design: Parallel group, prospective randomised controlled trial.

Setting: UK University Hospital

Methods: Forty consenting, eligible women were randomised to virtual reality intervention (immersive video content as a distraction method) or standard care during outpatient hysteroscopy from August to October 2018.

Main Outcome Measures: Pain and anxiety outcomes were measured as a numeric rating score (scale of 0-10).

Results: Compared to standard care, women with virtual reality intervention experienced less average pain (score 6.0 vs. 3.7, mean difference 2.3, 95% CI 0.61-3.99, p=0.009) and anxiety (score 5.45 vs. 3.3, mean difference 2.15, 95% CI 0.38-3.92, p=0.02).

Conclusion: Virtual Reality was effective in reducing pain and anxiety during outpatient hysteroscopy in a mixed-methods randomised control trial. Its wide potential role in ambulatory gynaecologic procedures needs further evaluation. **Funding:** Supported by NIHR Patient safety Translational Research Centre funding.

Keywords: Virtual reality, outpatient hysteroscopy, pain, anxiety, Randomised Controlled Trial.

Trial Registration: The trial is registered at the US National Institutes of Health (ClinicalTrials.gov) #NCT03699280 https://clinicaltrials.gov/ct2/show/NCT03699280 https://clinicaltrials.gov/ct2/show/NCT03699280

Tweetable abstract: Virtual Reality can be used as a part of a multimodal strategy to reduce acute pain and anxiety in patients undergoing outpatient hysteroscopy.

Introduction

Performance of diagnostic and operative procedures for gynaecological conditions in the consultation room setting, is becoming increasingly commonplace in order to reduce risks of general anaesthetic, decrease health care costs and increase convenience for both patient and provider[1]. Such procedures are usually well tolerated[2] but can be associated with acute pain and anxiety [3],[4] [5] [6]. Pain relief options include sedation, local anaesthetic, analgesics and distraction techniques, though no consistent good quality evidence exists to underpin practice[7] [8] [9] [10] [11] [12].

Virtual reality (VR), a relatively new intervention, has been studied as a distraction technique for non-pharmacological pain relief. It is a computer-generated representation of an immersive environment viewed through a headset [13]. The cost, quality and accessibility of virtual reality devices has significantly improved in recent years and offered novel application in the medical field. Virtual reality for managing pain has been studied in paediatrics, dentistry, burns treatment, chronic pain, labour, episiotomy and phobias [14–22] [23] [24]. Although a metaanalysis suggested that VR may have a role in reducing pain scores in acutely painful procedures, it was found to be effective only in needles and burns physical therapy. The studies of VR on pain and anxiety however were limited by clinical and statistical heterogeneity[14] [25] Nonpharmacological options of pain relief have not explored the role of virtual reality in reducing pain and improving patient experience in outpatient hysteroscopy [26]. To our knowledge, there are no publications studying the effects of Virtual Reality in the management of pain during office gynaecological procedures [7]

We conducted a randomised controlled trial of virtual reality intervention as a distraction technique, versus standard care, in managing acute pain and anxiety during outpatient hysteroscopy.

Methods

Study design and setting

The study was a single centre, parallel group, prospective randomised controlled trial conducted at a large University hospital in London UK from August 2018 to October 2018

(Whipps Cross University Hospital). The study was approved by the National Research Ethics Committee, Health Research Authority and registered as a clinical trial. (ClinicalTrials.gov Identifier: NCT03699280). The study was supported by NIHR Patient safety Translational Research Centre funding.

Study participants and eligibility criteria

Consecutive women scheduled to undergo an outpatient hysteroscopy were invited to participate in the trial. Eligibility criteria included all consenting women 18 – 70 years of age with a planned outpatient hysteroscopy. Excluded were any women with hearing or visual impairment, or any known anatomical characteristics that makes performing the office procedure difficult, e.g. cervical conization, amputation.

Recruitment, randomisation and follow up

After written informed consent, eligible women were randomly allocated using sealed envelopes to either the virtual reality intervention or standard care. Using a secure online system, a randomisation scheme based on permuted block of random block sizes (2, 4) and stratified by parity (nulliparous, multiparous) and menopausal status (premenopausal, post- menopausal), created the allocation sequence. Due to the nature of the intervention, blinding of participants, care providers and outcome assessors was not possible, but allocation remained concealed until randomisation.

The intervention group received the virtual reality device with immersive video content for the use during their outpatient hysteroscopy as a distraction method. The VR headset was shown to the patient after confirming eligibility and prior to recruiting. They were given the option of trying the headset on, however the video was played only at the start of the procedure.

In the standard care group, women underwent their outpatient hysteroscopy as a routine procedure without offering the virtual reality intervention. Patient follow up was clinically indicated, not arranged for the purpose of the trial.

Outpatient hysteroscopy (standard care)

All procedures were performed in the office setting using a 3.2 mm rigid hysteroscope (Stortz Versascope) using normal saline as distension medium. A vaginoscopic technique was utilised unless it failed and dilatation was necessary. Patients were instructed to self administer analgesics prior to the procedure (either paracetamol or non steroidal anti-inflammatory drugs). Depending on the indications and findings of the hysteroscopy, additional procedures like pipelle biopsies, endometrial biopsies using biopsy forceps, polypectomies, Mirena coil insertions or removals were recorded. Intracervical local anaesthetic infiltration was administered where necessary in the form of rescue analgesia.

Virtual reality during hysteroscopy (intervention)

Immersive and interactive video content was delivered to patients randomised to the virtual reality intervention using an portable, standalone VR headset called Oculus Go with a head mounted display with built in audio drivers and cleaned with wipes between patients. Disposable hygeine masks were used as an underlay below the headset.
The guided relaxation experience included viewing an 8-minute video called 'Forest of Serenity' commissioned by St. Giles Hospice, developed by Holosphere and narrated by Sir David Attenborough[27]. The immersive video simulated a calming rainforest and a lake setting with animated wildlife, which could be explored by using the headtracker. The video played was one with minimal movement and a familiar voice to achieve maximal desired effect. The video was played for the duration of the procedure and replayed when the procedure exceeded 8 minutes. Patients were allowed to stop viewing the video or remove the headset at their own discretion or in the event of side effects. There was no screening for infectious diseases as a part of the protocol over and above the standard infection control procedures clinically required in the NHS.

Outcomes and measurements

Primary outcome measurements were worst and average pain, based on numeric rating scores (11-point scale from 0 to 10; 0 representing 'no pain/anxiety' and 10 representing 'worst imaginable pain/anxiety') along with anxiety, recorded pre-procedurally (as

‘anticipated’ prior to the procedure) and that ‘experienced' during the procedure [28], [29,30]. ‘Worst pain scores’ indicated the most pain experienced during the procedure, even if momentary. Data was collected immediately before and after the procedure. Data on the proportion of patients eligible, stratification factors (menopausal status and parity) consented and randomised, reasons for non-participation, and acceptability of the trial and intervention to participants and healthcare providers, were collected. The perception of the clinician performing the procedure and the nursing staff regarding feasibility of using the virtual reality equipment for each patient who had the intervention was assessed through questionnaires. Semi-structured interviews were conducted with women who received the virtual reality intervention within 30 minutes of the procedure and were recorded on a digital voice recorder. The questions focused on the patient’s experience of the hysteroscopy and the intervention, pain and anxiety perceived and also any other aspects that they felt were relevant to hospital care. The interviews allowed for all participants to be asked similar questions within a flexible framework.[31]
Interviews continued until no new information was being obtained and theoretical saturation point was reached.[32]

Sample size and statistical analysis

The target sample size for this trial was 40 (20 per group), based on the weekly number of women attending who could be approached (15) and an estimated 60% participation rate. There were no prior estimates of standard deviations available for power estimation. All data was entered into a secure database and anonymised using participant codes at the point of data entry.

Statistical analysis was by intention-to-treat including all randomised participants, using R software Version 3.5.1 (Feather Spray). Continuous data were summarised as mean and standard deviation, and categorical data as counts and percentages. Between-group differences were reported with 95% confidence intervals (CI) and p-value (using t test to compare normally distributed data). Cohen’s d, difference in scores measured on a standard deviation scale, was used to determine effect size with values above 0.7 considered to be large[33]. Linear regression was used to estimate difference in continuous outcomes between groups post-procedure, adjusting for

stratification factors (of menopausal status and parity). Bonferroni correction was applied for multiple testing.

Patient and public engagement

Prior to the study, the development of the research question was informed by patient's priorities and preferences. Staff and patients were involved in the planning of the study and in designing the intervention including the selection of videos for viewing. Patients and public representatives were not involved in the recruitment or the conduct of the study. Interviews and focus group discussions gathering information on the implementation, acceptability and content of the virtual reality videos viewed with clinical staff, was done to get an understanding of factors that might influence participation in a definitive trial.

Results

Patient recruitment and characteristics

A total of 53 women were approached for 6 weeks between August 2018 and October 2018. Of these, 8 declined to participate and 5 did not meet eligibility criteria. Finally, forty of 48 (83%) women agreed to participate and were randomised. (Figure 1). Reasons for exclusion of the 5 patients included 4 patients being over the age of 70, of which one patient had hearing difficulty and 1 patient did not need a hysteroscopy. Eight patients declined to participate of which 2 patients wanted to see the procedure, 2 patients had used virtual reality before for gaming and were queasy, 2 patients were very anxious about the procedure and declined participation, 1 patient couldn't wait for the procedure as there were delays in the clinic and 1 patient had brought her own headphones with an audio track to keep herself distracted. All patients completed the procedure except one having standard care who did not tolerate the procedure and needed to be booked for an outpatient hysteroscopy under general anaesthetic. Data for all 40 patients was considered for statistical analysis.

Baseline characteristics (Table 1) show that groups were balanced for features including age, parity, menopausal status, previous experience of outpatient hysteroscopy, anticipated pain and anxiety scores, and analgesic intake prior to the procedure. Before

the procedure, the mean pain and anxiety scores anticipated by the patient during the procedure were 6.7 and 5.98 respectively and there were no significant differences in either score between standard care and virtual reality groups. The procedures were performed in a single centre by 4 clinicians of consultant grade and a nurse and a healthcare assistant supported the clinics. Vaginoscopic approach was possible in 90% (36/40) of all the procedures (19/20 in the VR group and 17/20 in the standard care group). In the VR group, 2/20 had cervical stenosis and needed rescue local anaesthetic versus 4/20 receiving standard care. Eighteen percentage of the patients (7/40) had an experience of an outpatient hysteroscopy in the past and was comparable in the two groups. The mean duration of the outpatient hysteroscopy and additional procedures performed in the VR group procedure was 3.25 minutes and 0.85min respectively and that in the standard care group was 3.8 minutes and 1.75 minutes respectively.

Nausea was experienced by one patient in the virtual reality intervention arm, however she kept the headset on until the end of the procedure; one patient had previous history of claustrophobia and decided to removed the headset when the procedure started as she felt claustrophobic.

Pain and anxiety

Compared to standard care, the virtual reality intervention had a large effect reducing worst pain with a 2.2 score difference (28% reduction, score 7.85 vs. 5.65, 95% CI 3.79 – 3.79, p=0.011, Cohen's d 0.82), average pain with a 2.3 difference (38% reduction, score 6.0 vs. 3.7, 95% CI 0.61-3.99, p=0.009, Cohen's d 0.81), and anxiety with a 2.15 difference (39% reduction, scores 5.45 vs. 3.3, 95% CI 0.38-3.92, p=0.024, Cohen's d 0.73)[14] (Table 2, Appendix S1).

In order to examine whether the observed effects of virtual reality were robust, multiple regression models were fitted for each pain and anxiety outcome, to estimate the effect of the virtual reality condition, whilst controlling for anticipated pain and anxiety scores, parity, menopausal condition and cervical stenosis (Table 3; Appendix S1). For worst pain scores, the virtual reality condition accounted for a 2.11-point decrease in

experienced pain, compared with the control group (p=0.011; R2=0.24), after controlling for covariates. For average pain scores, a 2.28-point decrease in experienced pain was observed (p=0.01; R2=0.24) and for anxiety scores, a 2.13-point decrease (p=0.024; R2=0.16) associated with the VR condition compared with control. After applying Bonferroni correction for multiple testing, our findings regarding pain and anxiety remain significant.

Follow up questionnaire results revealed that all (100%) of the women who received the virtual reality intervention were happy to have the procedure again in the outpatient setting. Fifteen percent (6/40) women receiving standard care expressed their views that they would have liked to have the procedure done under general anaesthetic instead of the outpatient setting.

The gynaecologists performing the procedure reported that the intervention was feasible in 90% (18/20) and thought to be helpful for the particular patient in 85%(17/20) of cases. The staff nurses assisting the procedure reported that the intervention was feasible in 85% (17/20) and thought to be helpful for the particular patient in 85%(17/20) of cases

Patient and staff experience

Semi-structured interviews were conducted with patients (16 who received virtual reality intervention and 12 patients who had standard care), 2 clinical staff and 3 nursing staff (Appendix S2). Thematic analysis of interview transcripts provided rich insights into patients' experience of the VR intervention. A range of representative quotes from patients (Appendix S2) illustrates the possible mechanisms by which virtual reality immersion was reported to influence the experience of pain and anxiety. Positive experiences included a sense of relaxation that distracted from pain, as a result of calming visual imagery, environmental immersion and narrated soothing metaphors about pain control and deflection. Some patients appreciated the fact that the VR headset blocked sight of doctors and equipment that they found particularly anxiety provoking. Although patients generally reported that the VR did not remove their pain entirely, they reported that the distraction element helped control pain and immediate recovery from instances of sharp pain during the procedure. In contrast, some patients reported no effect of the VR technology on experienced levels of pain or that it was only

effective during low to moderate pain. Views were mixed on whether the lack of situational awareness of the consultation room was of benefit and some patients preferred to be more aware of the procedure or be able to talk unimpeded with the doctor. Qualitative analysis suggested that most patients found the headset to be comfortable. A minority of patients reported wearing the VR headset to be uncomfortable and claustrophobic, or that the sense of motion in the VR environment induced nausea but despite these limitations, the intervention was found to be effective in analysis.. One patient in the intervention arm experienced nausea, however she managed to keep the headset on till the end suggesting that the symptoms wasn't severe. Two patients declined to participate in the study as they had used VR for gaming and had experienced nausea. However the nature of the video used in the intervention was very different from the one used in gaming and the fact that the patient is lying down is likely to reduce the incidence of nausea whilst viewing the contents on the video. The qualitative analysis suggested patient feedback with a suggestion to have a range of videos or a video of a virtual hysteroscopy which would educate the patient about the procedure and introduce them to the intervention.

Discussion

Main findings

Compared to standard care, the virtual reality pain management intervention had a large effect in reducing pain and anxiety in outpatient hysteroscopy. This effect was robust, after controlling for baseline pain and anxiety expectations and a range of patient covariates. Staff and majority of the patients found the procedure to be both feasible and acceptable and patients reported a range of experiences, suggestive of the mechanisms by which VR technology may influence pain and anxiety via immersion, relaxation, distraction and imagery. Qualitative analysis suggested that the headsets were reasonably comfortable.

The study additionally demonstrated willingness of patients to participate and identified barriers to recruitment, non–participation, compliance or standardisation of healthcare providers care pathways through a mixed methods approach using qualitative data to draw useful insights complementing the findings from the quantitative analysis, in order to support future research and development in this area. Insights generated from the

themes suggested offering a multimodal pain relief strategy to improve experience at outpatient hysteroscopy. Qualitative analysis suggested patient profiling based on history, taking into consideration patient preferences by offering a variety of distraction techniques with a range of videos to choose from were they to choose virtual reality as a distraction technique. The analysis offered key insights into patient expectations concerning the degree of pain relief possible with virtual reality technology and implementation strategies to facilitate around transfer of research finding into clinical setting.

Strengths and weaknesses

The topic of pain control in gynaecological procedures is a difficult topic to study and a significant strength of this study lies in the parallel qualitative investigation of patient attitudes and experiences. The experimental arm of this study achieved a 100% follow-up rate from baseline and was strengthened through the use of standard methods of control, including randomisation, stratification and minimisation techniques ensured comparability at baseline and minimising selection bias. Numeric Rating Scale is known to be a validated measure of pain, is easy to use, has high compliance rates and detects meaningful changes in pain and anxiety[25].

One limitation of the intervention was that the video was made from a standing rather than prone perspective; the field of vision during hysteroscopy was such that the entire content of the virtual environment could not be explored and this might be addressed by development in the VR technology. Restriction of movement of the patient whilst engaging with the video in light of the nature of the diagnostic procedure could also limit the degree of immersion. The duration of the video was shorter than the length of the procedure for two patients, requiring the video to be restarted. This disrupted the immersion experience and required the health care assistant to keep a watch on when the video finished. Despite these limitations, the intervention was found to be effective in analysis.

The effect of the intervention is likely to depend on the nature of the video as are the side effects like movement induced nausea. The video in the intervention was in a familiar voice and was designed to alleviate pain, which may have contributed to the results.

Although the groups were comparable, there were higher number of patients of cervical

stenosis in the standard care group (4/20) when compared to the VR group (2/20) which may have influenced the outcome.

The intervention, due to its nature, could not be blinded from the participants, so a placebo effect related to self-reporting of outcome scores may have influenced the results. Non-blinding of the participants could have resulted in patients receiving the VR intervention underreporting the pain and anxiety scores and those patients not receiving the intervention to have over-reported the scores. Additionally, the pain and anxiety scores were measured within 10 minutes of the intervention and were therefore subject to a degree of recall bias. As prior estimates of standard deviation were not available, powering the study for any expected effect size was not possible. No formal power calculation was performed. However, we detected a relatively large significant difference between groups and therefore avoided the risk of a type 2 error. Our findings will inform sample size calculations for a future full-scale trial.

To our knowledge, this is the first randomised evaluation of feasibility, effectiveness and acceptability of a virtual reality intervention in gynaecology. However, a trial protocol has been published for a randomised controlled trial for VR analgesia for women during hysterosalpingograms and results will be forthcoming.[34]

Interpretation of findings

Ensuring adequate pain relief and allaying anxiety during outpatient hysteroscopy can be challenging and can impact women's satisfaction with the experience. Appropriate patient selection, counselling and adequate pain management during the procedure can improve patient experience, reduce the number of failed procedures, and improve safety, accuracy and effectiveness of the procedure.

There is a lack of consensus on the choice of analgesia for outpatient hysteroscopy [9] with a recent metaanalysis and systematic review suggesting oral NSAIDS and TENS for pain relief.[35] Despite this, there has been limited research into the role of distraction techniques in the management of pain and anxiety in ambulatory gynaecological procedures with no published studies on virtual reality as a pain relief modality.[26] Nonpharmacological options of pain relief at outpatient hysteroscopy include music [36,37],

hypnosis, vaginoscopic methods of hysteroscopy,[38] adjusting the temperature and pressure of distension medium, stretching of the uterus with a full bladder and electricity via TENS [26] watching the screen[39] , conversation with positive suggestion and guided imagery. Our study provides new evidence that VR distraction techniques could be used in future to enhance the range of pain relief options.

Our qualitative findings are suggestive of the psychological mechanisms by which VR reduces pain but further research is needed in this area. Interaction with VR uses a substantial amount of the patient's limited controlled attentional resources.[40]. [41] [42]. By virtue of spending lesser time thinking about the procedure by distracting the patients, the intervention may operate to reduce pain scores.

From a service implementation perspective, insights generated from the themes suggested offering a multimodal pain relief strategy to improve experience at outpatient hysteroscopy. Qualitative analysis suggested patient profiling based on history, taking into consideration patient preferences by offering a variety of distraction techniques with a range of videos to choose from were they to choose virtual reality as a distraction technique. The analysis offered key insights around managing patient expectations around the degree of pain relief with virtual reality and implementation strategies around transferring research finding into clinical setting.

The study showed a large sized reduction in scores in pain or anxiety with virtual reality, even though it is unlikely to eliminate pain completely. The intervention was well tolerated with no serious side effects. It would be useful to compile core outcome sets based on patient reported outcomes for pain and anxiety towards future research in ambulatory gynaecological procedures. Algorithmic prediction of the types of patients who would benefit most from the intervention should also be modelled in future trials based on patient characteristics, baseline pain and anxiety scores and a past history of claustrophobia for planning a multimodal analgesic strategy.

The type of VR equipment and the degree of interaction with the video is likely to effect the analgesic effectiveness.[19] Virtual reality is an evolving technology and designing appropriate content of the video with adequate duration, headsets and hygiene masks to comply with infection control protocols and also have affordances and good aesthetics

that make it comfortable to wear would be paramount prior to clinical adoption, which would need codesign with patients and manufacturers. It would be appropriate to have a range of videos for the patient to choose from, which might be with our without narration. Other avenues include using virtual reality for patient education for familiarisation with the procedure and using it as a triage prior to offering it as an intervention for pain relief.

Conclusions

Immersive virtual reality intervention is feasible, effective and acceptable in a clinical setting as a distraction technique for the management of pain and anxiety in patients undergoing outpatient hysteroscopy. This study demonstrated a robust effect for VR technology in this application, within a relatively small-scale trial. Future development of VR technologies for this application, coupled with larger-scale trials, would strengthen the evidence-base for alternative pain management interventions in ambulatory gynaecology. Transferability of these findings into the clinical setting needs to be evaluated by future trials and economic evaluations of additional costs of equipment and training.

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KSK has provided expert reports for medical negligence cases for which fee is paid by instructing solicitors. Public bodies and Charities in the UK and European Union largely fund his research. He has occasionally participated in research projects where pharmaceuticals (e.g. Ferring Pharmaceuticals, GSK) have contributed a grant. He has received honoraria for speaking at meetings by Ferring Pharmaceuticals; Olympus; various Colleges, Universities and Societies.and royalty on books from publishers - Taylor and Francis, Hodder Arnold and Huber. He has been an editor of medical Journals including BJOG, EBM-BMJ, BMC Med Edu; and is also a partner/director in a Partnership/Company where he offers advice on several matters including matters within medical research and scientific editing. His institution has received sponsorship for organizing educational meetings from Ferring Pharmaceuticals; Leo-Pharma; Alere; Ethicon; Hologic; Viforpharma; Preglem/Quintiles.

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Contribution to authorship:

The study was a part of a Dissertation for ND, for an MSc In Health Care and Design, Imperial College London. ND was involved in the writing of the drafts of the study protocol and manuscripts, data collection and was the outcome assessor. JB was the study supervisor and was involved in the writing of the drafts of the study protocol and manuscript, reviewing the draft of the statistical analysis plans and interpretation of results. KSK was involved in the study set up and writing of the draft of the manuscript and interpretation of results. JM was involved in collation of the data. JA was involved in the set up of the study and randomisation and reviewed the draft of the manuscript. FJGC was involved in the final data analysis. GF was a study supervisor and involved in the study design and write up of the study protocol.

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Data Access and Responsibility: The principal investigator, Nandita Deo, had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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Table 1. Baseline characteristics of participants in standard care and virtual reality

Characteristic	Standard care (n = 20) Mean (SD) or n (%)	Virtual reality (n = 20) Mean (SD) or n (%)
Age (years)	31.3 (5.2)	31.1 (5.4)
Parity (No.)	2.2 (1.9)	2.4 (1.7)
Nulliparous	4 (20)	4 (20)

Multiparous	16 (80)	16 (80)
Ethnicity		
White	8 (40)	9 (45)
Black	4 (20)	3 (15)
Asian	5 (25)	8 (40)
Mixed	3 (15)	0 (0)
Menopausal status		
Pre-menopausal	7 (35)	7 (35)
Post-menopausal	13(65)	13(65)
Prior outpatient hysteroscopy	3 (15)	4 (20)
Hysteroscopy indication		
Heavy Menstrual Bleeding	5 (25)	6 (30)
Incidental finding	2 (10)	5 (25)
Postmenopausal bleeding	11 (55)	8 (40)
Lost coil thread	2 (10)	0 (0)
Recurrent postcoital bleeding	0 (0)	1 (5)
Pain killers taken before procedure	12 (60)	13(65)
Pain score anticipated by patient	6.5 (2.0)	7.0 (2.2)
Anxiety score anticipated by the patient	5.6 (3.1)	6.4 (2.9)

Table 2. Comparison of experienced pain and anxiety between standard care and virtual reality intervention in the Trial

Group	n	Mean (SD)	95% Confidence Interval		p-value
Worst Pain Scores					
Standard Care	20	7.85 (2.56)	6.65 ,9.05		
Virtual Reality	20	5.65 (2.41)	4.52, 6.78		
Difference		2.20	3.79	0.01	0.008
Average Pain Scores					
Standard Care	20	6 (2.62)	4.78, 7.22		
Virtual Reality	20	3.7 (2.66)	2.46, 4.94		
Difference		2.3	0.61, 3.99	0.01	0.009
Anxiety Scores					
Standard Care	20	5.45 (3.35)	3.88, 7.02		
Virtual Reality	20	3.3 (2.03)	2.35, 4.25		
Difference		2.15	0.38, 3.92	0.02	0.019

Figure 1: Patient recruitment in the trial.