Virtual reality for acute pain in outpatient hysteroscopy: a randomised controlled trial

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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 0–10).

Results Compared with standard care, women with virtual reality intervention experienced less average pain (score 6.0 versus 3.7, mean difference 2.3, 95% CI 0.61–3.99, P = 0.009) and anxiety (score 5.45 versus 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 gynaecological procedures needs further evaluation.

Keywords Anxiety, outpatient hysteroscopy, pain, randomised controlled trial, virtual reality.

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.

Linked article This article is commented on by TJ Clark, p. 96 in this issue. To view this mini commentary visit https://doi.org/10.1111/1471-0528.16391.

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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 anaesthesia, decrease healthcare costs and increase convenience for both patient and provider.¹ Such procedures are usually well tolerated² but can be associated with acute pain and anxiety.³–⁶ Pain relief options include sedation, local anaesthetic, analgesics and distraction techniques, though no consistent good quality evidence exists to underpin practice.⁷–¹²

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 have significantly improved in recent years and offer 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.¹⁴–²⁴ Although a meta-analysis 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 heterogeneity¹⁴,²⁵ Nonpharmacological options of pain relief have not explored the role of virtual reality in reducing pain and
improving patient experience in outpatient hysteroscopy.\textsuperscript{26} To our knowledge, there are no publications studying the effects of virtual reality in the management of pain during office gynaecological procedures.\textsuperscript{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 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 make performing the office procedure difficult, e.g. cervical conisation, 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 (Gynecare Alphascope, Ethicon, Somerville, NJ, USA) using normal saline as distension medium. A vaginoscopic technique was utilised unless it failed and dilation was necessary. Patients were instructed to self-administer analgesia prior to the procedure (either paracetamol or non-steroidal anti-inflammatory drugs). Depending on the indications and findings of the hysteroscopy, additional procedures such as 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 a portable, standalone VR headset called Oculus Go with a head-mounted display with built-in audio drivers that was cleaned with wipes between patients. Disposable hygiene 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.\textsuperscript{27} The immersive video simulated a calming rainforest and a lake setting with animated wildlife, which could be explored using the headtracker. The video played was one with minimal movement and a familiar voice to achieve the 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.\textsuperscript{28,29} ‘Worst pain scores’ indicated the most pain experienced during the procedure, even if momentary. Data were 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 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 immediately before and after the procedure.
providers, were collected. The perception of the clinician performing the procedure and the nursing staff regarding the 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.30

Interviews continued until no new information was being obtained and a theoretical saturation point was reached.31

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 were 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 (Microsoft, Redmond, WA, USA). 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.32 Linear regression was used to estimate the 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 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, eight declined to participate and five did not meet eligibility criteria. Finally, 40 of 48 (83%) women agreed to participate and were randomised (Figure 1). Reasons for exclusion of the five patients included four patients being over the age of 70, of which one patient had hearing difficulty and one patient did not need a hysteroscopy. Eight patients declined to participate: two wanted to see the procedure, two patients had used virtual reality before for gaming and were queasy, two patients were very anxious about the procedure and declined participation, one patient could not wait for the procedure as there were delays in the clinic and one 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 were 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 four clinicians of consultant grade and a nurse and a healthcare assistant supported the clinics. A 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. Of the patients, 18% (7/40) had had an experience of an outpatient hysteroscopy in the past, this 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 and 0.85 minutes, and that in the standard care group 3.8 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 a previous history of claustrophobia and decided to remove the headset when the procedure started as she felt claustrophobic.
Pain and anxiety
Compared with standard care, the virtual reality intervention had a large effect reducing worst pain with a 2.2 score difference (28% reduction, score 7.85 versus 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 versus 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 versus 3.3, 95% CI 0.38–3.92, \( P = 0.024 \), Cohen’s \( d \) 0.73) (Table 2, Appendix S1).

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, while controlling for anticipated pain and anxiety scores, parity, menopausal condition and cervical stenosis (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 (\( P = 0.011 \); \( R^2 = 0.24 \)) after controlling for covariates. For average pain scores, a 2.28-point decrease in experienced pain was observed (\( P = 0.01 \); \( R^2 = 0.24 \)) and for anxiety scores, a 2.13-point decrease (\( P = 0.024 \); \( R^2 = 0.16 \)) was associated with the VR condition compared with the 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 and anxiety scores, parity, menopausal condition and cervical stenosis (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 (\( P = 0.011 \); \( R^2 = 0.24 \)) after controlling for covariates. For average pain scores, a 2.28-point decrease in experienced pain was observed (\( P = 0.01 \); \( R^2 = 0.24 \)) and for anxiety scores, a 2.13-point decrease (\( P = 0.024 \); \( R^2 = 0.16 \)) was associated with the VR condition compared with the control. After applying Bonferroni correction for multiple testing, our findings regarding pain and anxiety remain significant.

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were happy to have the procedure again in the outpatient setting. In all, 15% of the women (6/40) receiving standard care expressed that they would have liked to have had the procedure done under general anaesthetic instead in the outpatient setting.

The gynaecologists performing the procedure reported that the intervention was feasible in 90% (18/20) and was 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 was 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), two clinical staff and three 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, which 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 were not 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 is 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 while viewing the contents on the video.

| Table 1. Baseline characteristics of participants in standard care and virtual reality |
|--------------------------------------|----------------|----------------|
| Characteristic                       | Standard care  | Virtual reality |
|                                     | (n = 20) Mean (SD) or n (%) | (n = 20) Mean (SD) or n (%) |
| Age (years)                          | 31.3 (5.2)     | 31.1 (5.4)     |
| Parity, n                            | 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 hysterectomy        | 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 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               | 0.008   |
| Virtual reality            | 20  | 5.65 (2.41)| 4.52–6.78               | 0.008   |
| Difference                 | 2.20| 0.61–3.79 |                         |         |
| Average pain scores        |     |           |                         |         |
| Standard care              | 20  | 6 (2.62)  | 4.78–7.22               | 0.009   |
| Virtual reality            | 20  | 3.7 (2.66) | 2.46–4.94               | 0.009   |
| Difference                 | 2.3 | 0.61–3.99 |                         |         |
| Anxiety scores             |     |           |                         |         |
| Standard care              | 20  | 5.45 (3.35)| 3.88–7.02               | 0.019   |
| Virtual reality            | 20  | 3.3 (2.03) | 2.35–4.25               | 0.019   |
| Difference                 | 2.15| 0.38–3.92 |                         |         |

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The qualitative analysis suggested from patient feedback having 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 with 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 the 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 the 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, should 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 by the use of standard methods of control, including randomisation, stratification and minimisation techniques, which ensured comparability at baseline and minimising selection bias. The 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.35 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; this might be addressed by developments in VR technology. Restriction of movement of the patient while engaging with the video in light of the nature of the diagnostic procedure could also limit the degree of immersion. The length of the video was shorter than the procedure for two patients, requiring the video to be restarted. This disrupted the immersion experience and required the healthcare 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 such as 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 with the VR group (2/20), which may have influenced the outcome.

Due to its nature, the intervention 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 who received the VR intervention under-reporting the pain and anxiety scores and in those patients who did not receive the intervention over-reporting 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.33

**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,
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 maintain affordability and good aesthetics that make them comfortable to wear would be paramount prior to clinical adoption, which would need co-design these with patients and manufacturers. It would be appropriate to have a range of videos for the patient to choose from, which might be with or without narration. Other avenues include using virtual reality for patient education for familiarisation with the procedure and 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 to the clinical setting needs to be evaluated by future trials and economic evaluations of additional costs of equipment and training.

**Disclosure of interests**

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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 meta-analysis and systematic review suggesting oral nonsteroidal anti-inflammatory drugs and transcutaneous electrical nerve stimulation (TENS) for pain relief.^34^ Despite this, there has been limited research on the role of distraction techniques in the management of pain and anxiety in ambulatory gynaecological procedures and no published studies on virtual reality as a pain relief modality.26 Non-pharmacological options of pain relief at outpatient hysteroscopy include music, hypnosis, vaginoscopic methods of hysteroscopy, adjusting the temperature and pressure of distension medium, stretching of the uterus with a full bladder and electricity via TENS watching the screen, conversation with positive suggestion and guided imagery. Our study provides new evidence that VR distraction techniques could be used in the future to enhance the range of pain relief options.

Our qualitative findings indicate 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.39–41 By virtue of spending less time thinking about the procedure because they are distracted, the intervention may operate to reduce patient pain scores.

From a service implementation perspective, insights generated from the themes suggest offering a multimodal pain relief strategy to improve the 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, should 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 reduction in scores in pain or anxiety with virtual reality, even though VR 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 for 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 to plan a multimodal analgesic strategy.

The type of VR equipment and the degree of interaction with the video is likely to affect the analgesic effectiveness.19
Hologic, Viforpharma, Preglem/Quintiles. ND, JA, FJGC, JM and GF have nothing to disclose. Completed disclosure of interest forms are available to view online as supporting information.

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 was involved in the study design and write up of the study protocol.

Details of ethics approval
Newcastle and North Tyneside 1 National Research Ethics Committee. United Kingdom. Approval Date–29/5/2018. Reference 18/NE/0165.

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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.

Supporting Information
Additional supporting information may be found online in the Supporting Information section at the end of the article.

Appendix S1. Multiple regression analysis of clinical outcomes in the trial: full model parameters.

Appendix S2. Patients’ experiences of undergoing the VR distraction technique: Representative perspectives based upon example quotations from qualitative data.

Appendix S3. Healthcare staff feedback of administering the VR intervention: representative perspectives based upon example quotations from qualitative data.

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