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Virtual Reality as a Distraction Tool in Outpatient Colposcopy: A Randomized Controlled Trial

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Abstract

Background: Colposcopy is an outpatient gynaecological procedure associated with pain and anxiety. Virtual reality (VR) has been used to reduce these in various clinical settings; however, its application in gynaecology remains limited.

Aims: This study evaluated whether VR use during outpatient colposcopy reduces patient anxiety and pain and assessed its efficacy and feasibility.

Materials and Methods: This single-centre randomised controlled trial at a gynaecological oncology outpatient clinic included patients undergoing their first colposcopy. Participants were randomised 1:1 to standard care or VR-assisted colposcopy. The standard group could view the procedure on a screen; the VR group wore a headset. Both groups had background music and could hear instructions. Participants completed questionnaires on baseline data, anxiety (STAI), and pain (1-10), with VR group also reporting on effectiveness and side effects. Outcomes were analysed per protocol.

Results: From January 2020 to December 2021, 124 patients consented; 116 were analysed (58 per group). The target sam-

ple of 200 was not met. Interim analysis due to slow recruitment showed no differences in anxiety change (-6 vs -7; p=0.6) or pain (2 vs 2; p=0.4). Recruitment ceased given slow accrual and no observed benefit. VR was well tolerated (0.09% side effects) and acceptable, with 86% willing to reuse it.

Conclusion: VR did not reduce pain or anxiety during colposcopy compared with standard care. It was well accepted, with minimal side effects, and is a feasible distraction tool; however, larger studies also show no benefit. Comparable anxiety reductions suggest current reassurance and distraction strategies are effective.

Keywords: Colposcopy, Anxiety, Virtual Reality, Patient Satisfaction, Outpatients

Introduction

Colposcopy is recommended as further investigation following an abnormal cervical screening test or for further evaluation of abnormal vaginal bleeding. Colposcopy can cause patient anxiety for many reasons including anticipation of the discomfort involved, intrusiveness of the procedure and possible results including a cancer diagnosis [1]. A Cochrane review comparing the efficacy of various interventions aimed at reducing anxiety during colposcopy, reported that colposcopy was associated with high levels of anxiety, higher than those found in women pre-operatively and similar to those following an abnormal screening test for foetal abnormalities [2]. Furthermore, high levels of anxiety before and during colposcopy can have psychological consequences including pain, discomfort and failure to return for follow-up [2].

Many methods have been used previously to decrease anxiety during colposcopy, including increasing patient information pre-procedure with brochures, the use of music in the background during the procedure and the use of local anaesthetic for more extensive procedures during colposcopy such as insertion of intra-uterine devices or local large loop excisions with electro-cautery [1].

Virtual reality (VR) technology can be used to visually distract patients through an immersive and calming, three-dimensional environment helping to modify their lived experience. The VR device is a headset with audio that allows users to explore a 360 degree virtual landscape by turning their head, enhancing the sense of immersion. VR devices have been used as a distraction tool to reduce anxiety or pain during various medical procedures, including hospital-based needle procedures, dental and periodontal procedures, and urological endoscopy [3]. More recently, they have been applied in gynaecological settings, including outpatient hysteroscopy and embryo transfer procedures [3,5]. A previous trial assessing the effect of VR in an outpatient colposcopy setting included only 44 participants, did not report details regarding randomisation, and focused primarily on pain as the outcome, measured using a subjective pain score [4]. Since conducting our trial there has been one other randomized controlled trial published assessing the use of virtual reality to decrease anxiety in outpatient colposcopy [5]. This trial, conducted in Germany, compared anxiety scores among patients undergoing standard colposcopy, VR prior to colposcopy and VR both prior to and during colposcopy. No differences in anxiety were seen between the groups [5].

Aims

This trial was designed to prospectively evaluate the efficacy and feasibility of a VR device in reducing anxiety among women undergoing outpatient colposcopy following an abnormal cervical screening test. We conducted a randomized controlled trial in a single center tertiary institution's outpatient colposcopy clinic. Participants were randomly allocated 1:1 to either the standard procedure (colposcopy without the VR device) or the intervention arm, in which patients wore the VR device for the duration of the colposcopy. The primary endpoint was the difference in reduction of state anxiety scores between the two groups, measured using pre- and post-procedure STAI state anxiety scores. Secondary endpoints included differences in self-reported pain scores, rated on a 0 to 10 scale.

Materials and Methods

Prior to commencing the trial, a feasibility study was performed with 22 patients, using VR while having colposcopy. There was a reduction in anxiety in 91% of participants, the device was widely accepted by participants and there were no reported side-effects.

Participants were enrolled in the RCT between January 2020 and December 2021. Eligible patients were aged 18 years or older, required colposcopy with a possible minor cervical procedure, and had no prior history of colposcopy. Participants were excluded if they were pregnant, were on psychotropic medications, had uncorrected visual impairment, history of seizures or severe motion sickness, or could not understand written and spoken English.

Following standard pre-procedure counselling including the indication for colposcopy and procedure details, eligible participants were informed about the trial and consent obtained. Participants completed a pre-procedure questionnaire which documented baseline data; age, parity, previous experiences which may make colposcopy traumatic for them and previous VR experience. Anxiety was assessed using the Spielberger State-Trait Anxiety Inventory (STAI), a well-established and validated questionnaire used to assess baseline (trait) anxiety and situational (state) anxiety. This consists of a 4-point Likert scale with 20 questions for both trait and state anxiety. Scores range from 20 to 80, with higher scores reflecting either higher state or trait anxiety. The difference in state anxiety was measured by the difference in the state anxiety score before and after the colposcopy.

Participants were randomly allocated 1:1 using computer-generated randomisation. The standard arm underwent colposcopy as per usual clinical practice, including background music and the option to view the procedure live on a screen. Participants in the intervention arm wore a VR headset during the procedure. All participants were informed they could discontinue VR at any time if uncomfortable or experiencing side effects.

The VR device displayed a relaxing video (bears in a river or pandas playing) without audio. In both groups, participants were counselled throughout the procedure and could hear instructions from the colposcopist. A nurse was present in both settings to provide reassurance and assist with the procedure.

All participants completed a post-procedure questionnaire including the STAI, a pain score (1–10), and, for the intervention arm, additional questions on device satisfaction.

Statistical Analysis

At the time of study design, no randomised controlled trials had evaluated VR for anxiety reduction during colposcopy, and no established minimal clinically important difference for STAI scores was available. The closest comparable study assessed music during colposcopy and reported a reduction in state anxiety scores (mean difference -4.8 ± 12.3 SD) [1]. Based on this, a sample size of 104 participants per arm was calculated.

The trial was approved by the Royal Prince Alfred Hospital Human Research Ethics Committee of the Sydney Local Health District (HREC/17/RPAH/134-X17-0090) and retrospectively registered on 3 June 2025 with the Australian New Zealand Clinical Trials Registry, ACTRN12625000566437.

https://anzctr.org.au/Trial/Registration/TrialReview.aspx?id=389094&isReview=true

Results

Between January 2020 and December 2021, a total of 157 patients were approached to participate in the study. A total of 124 patients consented to participate in the study. Eight were excluded from data analysis due to issues with documented consent. Of the remaining 116 participants, 58 were allocated to the control group and 58 to the VR group. Anxiety scores could not be compared for eight participants due to incomplete data; five did not complete the STAI questionnaire, and three removed the VR device due to technical issues. Participant flow through the study is shown in Figure 1. Baseline characteristics of each group are presented in Table 1. An interim analysis demonstrated no significant difference between the intervention and control groups. Due to slow recruitment and the absence of a dis-

cernible benefit, further recruitment was discontinued.

Table 1: Baseline Data for Control and VR groups

	Control (58)	VR (58)
Age (years; mean (SD))	35 (10)	32 (8)
Nulliparous (%)	84	86
Previous VR experience: Yes (n (%))No (n (%))	34	40
Previous Traumatic experience (%)YesNoNot willing to disclose	<1	<1
Mean Trait Anxiety Score (score (no. analysed))	37 (55)	41 (50)
Mean Pre-procedure State Anxiety Score (score (no. analysed))	41 (55)	42 (50)

Table 2: Change in Pre and Post Anxiety Score in Patients having Standard Colposcopy vs VR

	Standard Colposcopy (n=55)			VR used for colposcopy(n=50)			Difference in change of median scores (p value)
	Pre-colposcopy(median ((IQR))	Post-Colposcopy (median, ((IQR))	Change in score (median, ((IQR))	Pre-colposcopy(median, (IQR))	Post-Colposcopy (median, (IQR))	Change in score (median, ((IQR))	
STAI State Anxiety Score	41 (34, 47)	33 (25,40)	-6 (1,12)	42 (34,49)	34 (28,41)	-7 (2,15)	1 (0.6)

Table 3: Median Pain Score during Colposcopy in Patients having Standard Colposcopy vs VR

	Standard Colposcopy (n=55)	VR used for colposcopy(n=50)	p value
Pain score during colposcopy(median (IQR))	2 (1,3)	2 (1,3)	0.4

Tables 2 and 3 compare the primary endpoints between groups. State anxiety scores decreased in both groups (-6 vs -7; p=0.6), with the 1-point difference not clinically significant. Pain scores were identical (2/10; p=0.4). Subgroup analyses showed no significant differences by age, parity, prior VR experience, prior traumatic experience, colposcopist experience, or biopsy status.

Seven of the 58 participants who used the VR device discontinued its use partway through the procedure. In most cases (5 of 7), this was due to technical issues, primarily the device not being adequately charged. Another participant stopped the VR as only part of the image was being projected. The reason for stopping the VR was not recorded for one participant; however, no side-effects were reported.

Fifty-four participants out of the 58 answered the question regarding whether they experienced any side-effects. Five of these participants reported side-effects (dizziness, vertigo and/or nausea). No other side-effects were reported.

Eighty-six percent of participants who completed the question on willingness to reuse the VR device answered yes (50 out of 54). None of those unwilling to use it again reported side-effects; however, they did report low entertainment and immersion with the device.

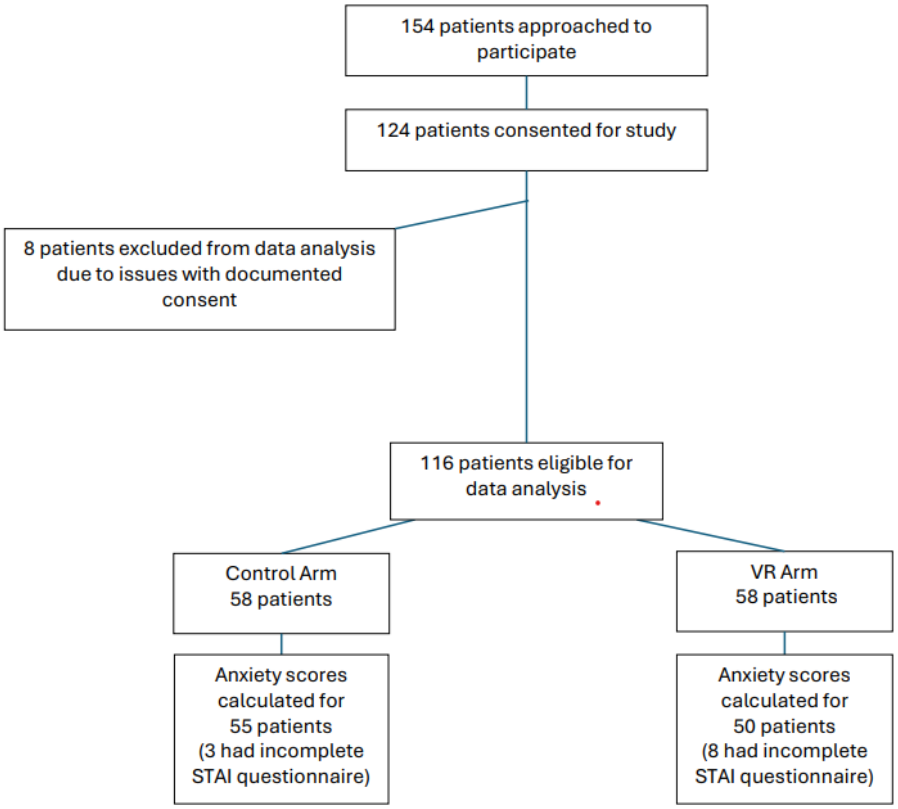

Figure 1: Participant involvement in the study

Discussion

Restricting recruitment to patients with no prior colposcopy extended the recruitment period but reduced potential bias associated with previous colposcopy experience. Randomisation further reduced bias by facilitating the equal distribution of potential confounding factors between groups.

The use of the STAI questionnaire, a validated questionnaire for assessing state and trait anxiety allowed an accurate and objective measurement of anxiety in this patient population.

Although not the primary objective of the study, a previous trial found music to be an effective intervention for reducing anxiety, demonstrating a 6.45-point difference in change scores between groups ($p < 0.0002$) [1]. In contrast, our study demonstrated only a 1-point difference between the intervention and control groups. However, both groups in our trial showed a reduction in anxiety scores of at least 6 points, which may explain the absence of a statistically significant difference between groups. Similarly, in another study investigating classical music during colposcopy, no difference was observed between groups, yet both experienced a clinically meaningful reduction in anxiety of at least 7 points [8]. In our study, both arms were counselled by the proceduralist before, during and after the procedure. It is difficult to determine how much impact this counselling may have had. Counseling and reassurance may have acted as confounders and could be more influential in decreasing pain and anxiety than visual or auditory distraction. The decrease in both groups may also be due to the relief from completing the procedure and/or finding out the provisional results, which is part of the standard counseling.

Despite being a negative trial there was widespread acceptability of the device with 86% of participants (50/54) reporting they would be willing to use it again dur-

ing colposcopy. Side-effects were minimal, and all participants who experienced them indicated a willingness to use the device again. It is difficult to determine whether the reported side effects were attributable to the VR device or the colposcopy itself, which is known to cause similar symptoms, including nausea and vasovagal responses.

In the control arm, patients were able to watch the procedure on a colposcopy screen. This enabled the colposcopist to show findings in real time, explain areas that may require treatment or biopsy, and facilitate teaching for junior doctors or medical students present during the procedure. While this may represent a potential confounding factor, it was not appropriate to exclude it from the control arm, as it reflects routine practice within our institution.

Another limitation of this study was the inclusion of only English-speaking participants, as the questionnaires required proficiency in written English. This restricts the generalisability of the findings to non-English speaking populations. Further research is warranted to explore the effectiveness of visual distraction interventions in patients with limited English proficiency. The use of the written questionnaire also carried a risk of transcribing error as participants were required to complete sixty items in the inventory which required circling an answer for each of the items. Five of the patients did not answer all the questions in the questionnaire. This could be secondary to not understanding the question or missing it due to the large number of questions in the inventory. While the use of a different tool to assess anxiety such as VAS was considered due to its user efficiency, the STAI questionnaire is reported as a much more reliable tool.

Recruitment for the trial took much longer than initially anticipated due to the COVID-19 pandemic necessitating the cancellation of many lower-risk, first time colposcopy patients. Recruitment was also paused for a period of five months while a method for sterilising the devices to prevent aerosol-based infection was developed and subsequently approved by the hospital executive.

This study demonstrated no statistically significant difference in pain or anxiety scores with the use of virtual reality during colposcopy compared with standard care. While the VR device was well accepted, associated with minimal side effects, and appeared to be a feasible distraction tool during outpatient colposcopy, both groups demonstrated similar reductions in anxiety, suggesting that current methods of distraction and reassurance may be sufficient. Larger studies performed since this study also show no benefit of virtual reality during colposcopy.

Clinical Trials Registration

The trial was retrospectively registered on 3 June 2025 with the Australian New Zealand Clinical Trials Registry, ACTRN12625000566437

https://anzctr.org.au/Trial/Registration/TrialReview.aspx?id=389094&isReview=true

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State-Trait Anxiety Inventory for Adults: (S-TAI-AD): **License to Administer was purchased for this study.**

Conflicts of Interest

The authors have no conflicts of interest to declare.

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