

The use of pre-operative virtual reality to reduce anxiety in women undergoing gynaecological surgeries: a prospective cohort study

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Abstract

Background: Pre-operative anxiety is common and is associated with negative surgical outcomes. Virtual reality (VR) is a promising new technology that offers opportunities to modulate patient experience and cognition and has been shown to be associated with lower levels of anxiety. In this study, we investigated changes in pre-operative anxiety levels before and after using VR in patients undergoing minor gynecological surgery.

Methods: Patients who underwent elective minor gynecological surgeries in KK Women's and Children's hospital, Singapore were recruited. The VR intervention consisted of 10-minute exposure via a headset loaded with sceneries, background meditation music and breathing exercises. For the primary outcome of pre-operative anxiety, patients were assessed at pre- and post-intervention using the Hospital Anxiety and Depression Scale (HADS). Secondary outcomes of self-reported satisfaction scores and EurQol 5-dimension 3-level (EQ-5D-3L) were also collected.

Results: Data analysis from 108 patients revealed that HADS anxiety scores were significantly reduced from 7.2 ± 3.3 pre-intervention to 4.6 ± 3.0 post-intervention ($p < 0.0001$). Furthermore, HADS depression scores were significantly reduced from 4.7 ± 3.3 pre-intervention to 2.9 ± 2.5 post-intervention ($p < 0.0001$). Eighty-two percent of the patients self-reported VR intervention as 'Good' or 'Excellent'. EQ-5D-3L showed no significant changes in dimensions of 'mobility' ($p = 0.32$) or 'self-care' ($p = \text{NA}$) but significant changes in dimensions of 'usual activities' ($p = 0.025$), 'pain/discomfort' ($p = 0.008$) and 'anxiety/ depression' ($p < 0.0001$).

Conclusions: For patients undergoing minor gynecological procedures, the VR intervention brought about a significant reduction in pre-operative anxiety. This finding may be clinically important to benefit patients with high pre-operative anxiety without the use of anxiolytics. Future studies could include large scale randomized controlled trials in multiple surgical populations.

Trial registration: This study was registered on clinicaltrials.gov registry (NCT03685422) on 26 Sep 2018.

Background

Anxiety can be defined as emotions of fear, tension or unease and is often encountered before surgery [1, 2]. Pre-operative anxiety has been shown to be correlated with acute and chronic post-surgical pain, increased use of post-operative analgesia and post-operative nausea and vomiting [3-5]. It also has significant impact on recovery, including longer post-operative hospital stay and even cognitive and behavioral ramifications [2-5]. It is especially pertinent for women undergoing gynecological procedures due to the nature of their treatment, and women often experiencing higher levels of pre-operative anxiety compared to men [2, 6, 7].

Pre-operative anxiety is mainly influenced by patient factors, psychological factors and surgical factors. Patient factors include demographic characteristics and personal medical history, while psychological

factors include personal stress threshold, perceived rapport with hospital personnel and trait-anxiety [2, 6]. Surgical factors such as the type of surgery, prior surgical experiences, willingness to undergo the proposed intervention, can also determine pre-operative anxiety [8-11]. By identifying high risk patients for pre-operative anxiety, adverse clinical outcomes can be then managed and alleviated [12].

While pharmacological interventions for pre-operative anxiety are available, reservations such as safety profile and cost often hinder physicians to fully utilize them. Therefore, non-pharmacological methods such as music and Virtual Reality (VR) are gradually growing in popularity to improve the overall patient surgical experience [13-17].

The use of VR therapy in various clinical settings is well documented, such as physical rehabilitation, pain distraction, overcoming phobias, anxiety disorders, and post-traumatic stress disorder (PTSD) [18, 19]. It is reported that VR therapy results in significantly reduced anxiety, persistent pain intensity, faster wound healing, and improved neurorehabilitation outcomes in patients with burns and complex regional pain syndrome [20, 21]. The technology usually consist of an audio system (earphones or headphones), a visual system (head-mounted displays) and an integrated set up (motion tracking systems) [22]. By providing multiple stimuli to the human senses, VR systems are able to allow the user an immersive experience and “presence” in the virtual world [22].

In the gynecological population, limited evidence has been reported on the use of VR therapy for postoperative care and management. In a non-randomized controlled study recruiting patients undergoing colposcopy (cervical examination), Vasquez et al. showed that patients assigned to VR group reported reduced pain scores post-VR intervention [23]. Another prospective randomized controlled trial in an outpatient hysteroscopy setting showed that the use of VR during the procedure resulted in significantly decreased average pain score and anxiety when compared to controls [24]. Nevertheless, there are limited studies conducted in a gynecological population, and no formal sample size calculations were performed to study the expected clinical effect size related to pre-operative anxiety.

There are also few or no studies investigating the effectiveness of VR during the pre-operative period in Singapore. In view of the potential clinical benefits of VR, our study aimed to assess pre-operative anxiety (primary outcome) and self-reported satisfaction of VR and EQ-5D-3L (secondary outcomes) in women undergoing minor gynecological procedures

Methods

This prospective cohort study measured the efficacy of immersive VR in reducing pre-operative anxiety in patients undergoing elective gynecological surgery between March 2019 and January 2020 at KK Women’s and Children’s Hospital, Singapore. The study protocol adhered to the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) guidelines, and was approved by the SingHealth Centralized Institutional Review Board, Singapore (SingHealth CIRB Ref: 2018/2200), and registered on Clinicaltrials.gov (ID: NCT03685422).

Inclusion and Exclusion Criteria

Women aged 21 – 70 years old, American Society of Anesthesiologist (ASA) physical status I or II, with no visual or mental impairment and undergoing gynecological surgery were included in this study. Patients with severe motion sickness, significant respiratory disease or obstructive sleep apnea, oncological gynecology and obstetrics patients were excluded. Women who were unable to communicate in English or unable to understand the administered questionnaires were also excluded from this study.

Psychometric Assessment Tools Used

The State-Trait Anxiety Inventory (STAI) designed by Spielberger et al. has been used extensively in research and clinical settings [25]. It has been used to measure the presence and severity of current symptoms of anxiety and a generalized propensity to be anxious. The tool consists of 40 items, 20 allocated each to state-anxiety and trait-anxiety. Test-retest reliability coefficients on initial development ranged from 0.31 to 0.86, with intervals ranging from 1 hour to 104 days.

The Hospital Anxiety and Depression Scale (HADS) is commonly used to assess the patients' level of anxiety and depression during their hospitalization and is preferentially used as an indicator for global psychological distress [26]. Each item on the questionnaire is scored from 0 to 3, thus a patient may have a total score from 0 to 21 for the anxiety and depression subscales, respectively. A score of 0-7 indicates normal level of anxiety/depression while 8-10 indicates borderline abnormal and 11-21 indicates abnormal. Validity of the HADS was deemed "good" to "very good", with comparable sensitivity and specificity of longer scales including the STAI and the Symptom Checklist-90 anxiety scales [27]. HADS has been validated in gynecological populations undergoing procedures, achieving good levels of internal consistency with Cronbach's α of 0.78 and 0.84 for anxiety and depression subscales, respectively, and 0.88 for the whole instrument [28]. As compared with conventional instruments that measure anxiety (e.g. STAI), the shorter HADS provides increased convenience for patients and allows for multiple measurements at different time points pre and post intervention.

The EuroQol 5-dimension 3-level (EQ-5D-3L) questionnaire [29] is one of the most widely used instruments for measuring health-related quality of life. It consists of a descriptive system comprising 5 dimensions with 3 levels of self-reporting in each dimension. For measuring patient satisfaction with regards to the VR intervention, a self-reported 4-point Likert scale with the following items: "Poor", "Fair", "Good" and "Excellent" was used. Pain scores at rest was scored using a 0-10 Numerical Rating Scale (NRS).

Patient Recruitment

Patients presenting to the day surgery service for a variety of minor gynecological procedures were initially screened by study investigators using the operative room surgical listing schedule. The investigators then evaluated the patient's medical records to determine her eligibility. Patients meeting

inclusion criteria were approached in a pre-operative holding area. Risks and benefits of the study were explained, and informed consent was obtained. No patient remuneration was provided in this study.

Pre-VR intervention assessments included demographic data, pain scores and psychometric questionnaires (STAI, HADS and EQ-5D-3L; Figure 1). Patients were then given a Samsung Gear VR3 (Samsung Co. Ltd) headset and audio earpieces, fitted with a Samsung 8 smartphone (Figure 2A) running 'Oculus Relax VR' program (Figure 2C) [30]. Disposable sanitary covers and earbuds were provided, that were discarded and replaced between each user (Figure 2B). Patients were given 11 immersive scenarios to choose from, and the experience was integrated with background meditation music and breathing exercises. The 11 scenarios included sceneries from a tropical beach in the Philippines, a rice terrace in the Philippines, wine glass bay beach in Australia, 12 Apostles in Australia, Fern Bern in New Zealand, a forest creek in Germany, a daisy garden in Germany, the Grand Canyon in the (United States of America) USA, watching northern lights in the USA, floating in the sky in clouds and being on the moon in outer space. The VR intervention was conducted with patients lying in bed in the fowler's position with knees straight, in a quiet pre-operative waiting area. Patients were able to move their body freely in bed while on the headsets and were also instructed to discontinue the VR intervention if they experienced any side effects such as motion sickness or dizziness.

After the VR intervention, pain scores, satisfaction scores and psychometric assessments (HADS, EQ-5D-3L) were performed and collected. The VR intervention lasted for 10 minutes, with pre- and post-intervention surveys all done 1-2 hours before surgery. The patients subsequently underwent their intended surgical procedure under general anesthesia. Intra- and post-operative care provided adhered to standard hospital protocol. Data on intra- and post-operative analgesic use was also collected. Patients were all admitted to the day surgery unit in the hospital post-operatively before being further assessed to be discharged or for longer hospital stay. Data on analgesic use and pain scores were also collected post-operatively in the recovery area.

The primary outcome for this study was the change in pre-operative anxiety as quantified by the HADS scale. The HADS anxiety scores pre- and post-VR were compared for data analysis. For secondary outcomes, EQ-5D-3L and patient satisfaction of the VR intervention were targeted and used for data analysis of the patient's health state and anxiety levels.

Sample size calculation and statistical analysis

Tan et al. [31] reported difference in mean (SD) HADs anxiety between pre- and post-intervention in music experiences as 4.61 (4.08). The calculated sample size of 70 was based on the following assumptions: considering a conservative mean (SD) HADS difference of 2.0 (8.0), level of significance as 5% and power as 90%. After adjusting for 40% loss to follow up, ineligibility and withdrawal, a recruitment goal of 110 patients was targeted.

Categorical and continuous variables were summarized as frequency (proportion) and mean \pm standard deviation (SD) respectively. Difference between pre- and post-VR experiences were compared using paired

t – test and McNemar test for paired continuous and paired categorical data respectively. P-value < 0.05 was considered as statistical significance and all the tests were two – sided. Analyses were done using SAS version 9.4 software (SAS Institute; Cary, North Carolina, USA).

Results

A total of 110 patients aged 24 – 59 years old were recruited but only 108 patients' data were analyzed as 2 patients withdrew prior to the intervention. Table 1 shows the demographic data for the patients. Majority of the patients were of Chinese ethnicity (70.37%), ASA 1 status (72.22%) and underwent dilatation, curettage and hysteroscopy (82.41%) (Table 1). No adverse events were reported during and post VR intervention. Pre-operative HADS scores compared between types of surgery showed no significant difference ($p = 0.4879$).

Table 1 Patient Demographics

Characteristics	Mean \pm SD/ n (%)
Age (years)	43.56 \pm 6.68
Race	
Chinese	76 (70.37)
Malay	15 (13.89)
Indian	4 (3.70)
Others	13 (12.04)
ASA status	
Class 1	78 (72.22)
Class 2	30 (27.78)
Weight (kg)	64.60 \pm 12.54
Height (cm)	158.56 \pm 5.97
Duration of surgery (min)	26.43 \pm 41.86
Type of surgery	
Dilatation and Curettage, Hysteroscopy	89 (82.41)
Others	19 (17.59)

Values are represented as mean \pm standard deviation (SD) or number (%).

Pre- and post-VR psychological outcomes are displayed in Table 2. Importantly, for our primary outcome, there were significant reduction in anxiety and depression using HADS ($p < 0.0001$). Furthermore, for our secondary outcome, anxiety/depression ($p < 0.0001$), self-reported perception of pain and discomfort ($p = 0.0073$) and perceived health states ($p < 0.0001$) in EQ-5D-3L also showed significant improvements post-VR intervention pre-operatively.

Table 2 Pre-Virtual Reality and Post-Virtual Reality psychological outcomes

Variables	Pre-VR	Post-VR	P value
STAI S-anxiety score	39.59 ± 11.14	--	--
STAI T-anxiety score	40.10 ± 9.07	--	--
STAI total score	79.69 ± 18.78	--	--
HADS score			
Anxiety	7.23 ± 3.27	4.62 ± 3.03	<0.0001
Depression	4.12 ± 3.34	2.92 ± 2.51	<0.0001
EQ-5D-3L dimensions anxiety/ depression			<0.0001
Not anxious/ depressed	62 (57.41)	90 (83.33)	
Having anxious/ depressed	46 (42.59)	18 (16.67)	
EQ-5D-3L dimensions Pain/ Discomfort			0.0073
No pain/discomfort	72 (66.67)	84 (77.78)	
Having pain/discomfort	36 (33.33)	24 (22.22)	
EQ-5D-3L health state	71.57 ± 17.75	76.05 ± 15.07	<0.0001

Values are represented as mean ± standard deviation (SD) or number (%)

HADS Hospital Anxiety and Depression Scale, *STAI* State-Trait Anxiety Inventory, *VR* Virtual reality

Table 3 displays values of EQ-5D-3L for all 5 dimensions and 3 levels in detail, with the number of patients reporting each level within each dimension pre-VR and post-VR intervention. Table 4 shows the pain and satisfaction scores collected. Notably, pain scores collected pre- and post-VR intervention did not reveal any significantly changes ($p = 0.2178$). Intra- and post-operative pharmacological information, including type, dosage and route of analgesia, are displayed in Table 4. Significantly, for the secondary

outcome of patient satisfaction of the VR intervention, 82.41% of the participants rated the experience as 'Good' or 'Excellent' (Table 4).

Table 3 EQ-5D-3L individual dimensions

	Mobility		Self-care		Usual Activities		Pain/ Discomfort		Anxiety/ Depression	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Level 1	106 (98.15)	107 (99.07)	108 (100.00)	108 (100.00)	102 (94.44)	107 (99.07)	72 (66.67)	84 (77.78)	62 (57.41)	90 (83.33)
Level 2	1 (0.93)	1 (0.93)	0 (0.00)	0 (0.00)	6 (5.56)	1 (0.93)	36 (33.33)	24 (22.22)	46 (42.59)	18 (16.67)
Level 3	1 (0.93)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
P value	0.3170		-		0.0250		0.007		<0.0001	

Values are represented as number (%)

Table 4 Pain and Satisfaction Scores

Characteristics	Mean \pm SD/ n (%)
Pre-operative pain score pre-VR	0.44 \pm 1.24
Pre-operative pain score post-VR	0.60 \pm 1.21
Patient satisfaction on VR experience	
Excellent	35 (32.41)
Good	54 (50.00)
Fair	17 (15.74)
Poor	2 (1.85)
Maximum pain scores post-operative in recovery	2.22 \pm 2.41
Mean dose of Fentanyl used intra-operatively (mcg)	84.55 \pm 19.49
Mean dose of Morphine used intra-operatively (mg)	5.79 \pm 2.72
Paracetamol use intra-operatively	56 (51.85)
Duration of stay in the recovery unit (min)	64.50 \pm 31.89
Fentanyl use in the recovery unit	16 (14.81)
Morphine use in the recovery unit	6 (5.56)
Paracetamol use in the recovery unit	9 (8.33)

Values are represented as mean \pm standard deviation (SD) or number (%).

VR Virtual Reality

In terms of immersive VR scenario selection, majority of the participants (24, 22.22%) selected Wine Glass Bay Beach, Australia, followed by Northern Lights, USA (20, 18.51%), Tropical beach, Philippines (19, 17.59%), Daisy Garden, Germany (15, 13.89%), 12 Apostles, Australia (9, 8.33%), Fern Bern, New Zealand (6, 5.56%) and Forest Creek, Germany (6, 5.56%).

Discussion

To our best knowledge, this is the first VR study investigating pre-operative anxiety conducted for patients undergoing minor gynecological procedures in Singapore. For the primary outcome, we found that the use of a 10-minute VR intervention resulted in a significant reduction of pre-operative anxiety as measured using the HADS. These findings are in congruence with other studies using HADS to measure changes in pre-operative anxiety for VR interventions in oncology patients [32, 33] and patients in

intensive care [34]. Taken together, it might suggest that VR could have a role to play alleviating pre-operative anxiety.

This study revealed that there is significant preoperative anxiety amongst the gynecological patients recruited, with the STAI measure showing moderate anxiety for both state and trait anxiety. Surgery is a daunting experience that comes with emotional vulnerabilities. These emotions are often intensified moments before surgery, causing overwhelming anxiety and even depressive moods [10]. Increased preoperative anxiety is associated with postponement or even cancellation of planned surgeries, increase in anesthetic requirements, prolonged hospital stay and poorer overall patient satisfaction [35, 36].

Patient-centric outcomes were investigated as part of our secondary outcomes in this study using the EQ-5D-3L. This provided other insights into patients' health conditions, baseline functional status and quality of life. In this study, EQ-5D-3L assessment showed significant improvement on self-reported pain/ discomfort and anxiety/ depression dimensions before gynecological surgery when VR was used. In addition, self-reported perception of 'usual activities' dimension also showed significant improvement post-VR. Furthermore, patients had overall positive self-reported satisfaction for the VR experience prior to their scheduled gynecological procedure.

In previous studies, patients who received VR treatment reported a reduction in pain and anxiety [21], faster wound healing [37], decreased chronic pain intensity [20] and other neuro-rehabilitation improvements [38]. These results largely corroborated with our findings, which showed reduction in anxiety. While the exact neurobiological mechanistic theory behind VR's action remain unclear, it is generally suggested that VR acts as a distraction by rendering several possible mechanisms by: i) engaging different senses simultaneously and inducing a sense of presence in the virtual environment, thus diverting one's attention from painful stimuli and other negative emotions such as stress and anxiety [39]; ii) employing attentional resources in immersive and interactive virtual environments to modulate ascending nociceptive stimuli and thus reduce pain experience [40]; iii) isolating the user both visually and acoustically from the actual environment to escape from the painful world cognitively [41]. VR could serve as a non-pharmacological intervention in clinical settings to modulate emotional affective, emotion-based cognitive and attentional processes [42]. Interestingly, although the mean pain scores pre- and post-VR intervention were not statistically significant, there was a significant improvement of self-reported perception in the dimension of 'pain/discomfort' in the EQ-5D-3L. The pain score changes could be attributed to pre-surgical administration of vaginal or oral prostaglandins for cervical softening.

Study limitations

There were several limitations in our study. Firstly, the instruments used for assessment of anxiety were dependent on self-reported psychometric questionnaires. Although these psychometric tools have been validated in previous studies with similar target populations, there might be still variable reliability in our study's setting. Therefore, to mitigate this limitation, multiple psychometric measures were utilized to provide a more comprehensive assessment of pre-operative anxiety and any changes after VR intervention. Secondly, the patient population selected has to have the ability to read and understand

English, which might limit the number of participants. To mitigate this limitation, our patient recruitment target was maximized and achieved for this study.

Thirdly, multiple factors unrelated to surgery could influence pre-operative anxiety. For example, we did not investigate interactions between study team investigator and the patient. Non-study team members and the surrounding environment may also affect the patient's mood and anxiety. The effects of different scenarios on anxiety scores were also not studied due to an unequal distribution of scenarios that were chosen by patients. Finally, there was a lack of a control group to compare anxiety scores without VR intervention, making it difficult to assess the true effect of VR on pre-operative anxiety. Future randomized controlled trials are needed to validate our findings in this study.

Conclusions

VR relaxation technique is a promising method for anxiety alleviation that could be extended for hospital use (rehabilitation, outpatient procedures, diagnostic scanning and perioperative period). This strategy may potentially increase patient satisfaction while providing non-pharmacological anxiolytic effects with minimal side effects. Larger scale randomized studies are required to validate these findings.

List Of Abbreviations

ASA: American Society of Anesthesiologists; HADS: Hospital Anxiety and Depression Scale; SD: standard deviation; STAI: State-Trait Anxiety Inventory; STROBE: Strengthening the Reporting of Observational studies in Epidemiology; VR: virtual reality

Declarations

Ethics approval and consent to participate

The study was approved by the SingHealth Centralized Institutional Review Board, Singapore (SingHealth CIRB Ref: 2018/2200), and registered on Clinicaltrials.gov (NCT03685422). The authors declare that all the recruited patients provided informed consent, and that this work was conducted in accordance with the Declaration of Helsinki.

Consent for publication

All patients provided informed consent on the use of their de-identified data for publication purpose.

Availability of data and materials

The datasets generated and analyzed in this work are available for anyone who wishes to access the data by contacting the corresponding author.

Competing interests

Ban Leong Sng is an associate editor of BMC Anesthesiology. All other authors report no conflicts of interest in this work.

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Authors' contributions

JJI Chan reviewed the literature, planned the study, oversaw patient recruitment, data analysis and interpretation, and wrote the manuscript. YCT reviewed the literature, helped in patient recruitment, managed the raw data, helped in data analysis and interpretation. KHM helped in patient recruitment, data management, data analysis and interpretation. CW reviewed the literature, helped in funding, oversaw data management, data analysis and interpretation. SR reviewed the literature, helped in the study design, performed data analysis and interpretation. SATH reviewed the literature, helped in the study design, and reviewed the data analysis and interpretation. SBL reviewed the literature, planned the study, and oversaw the study including the design, data analysis and interpretation. All authors approved the final version of the manuscript and agree to be accountable for all aspects of this work.

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Figures

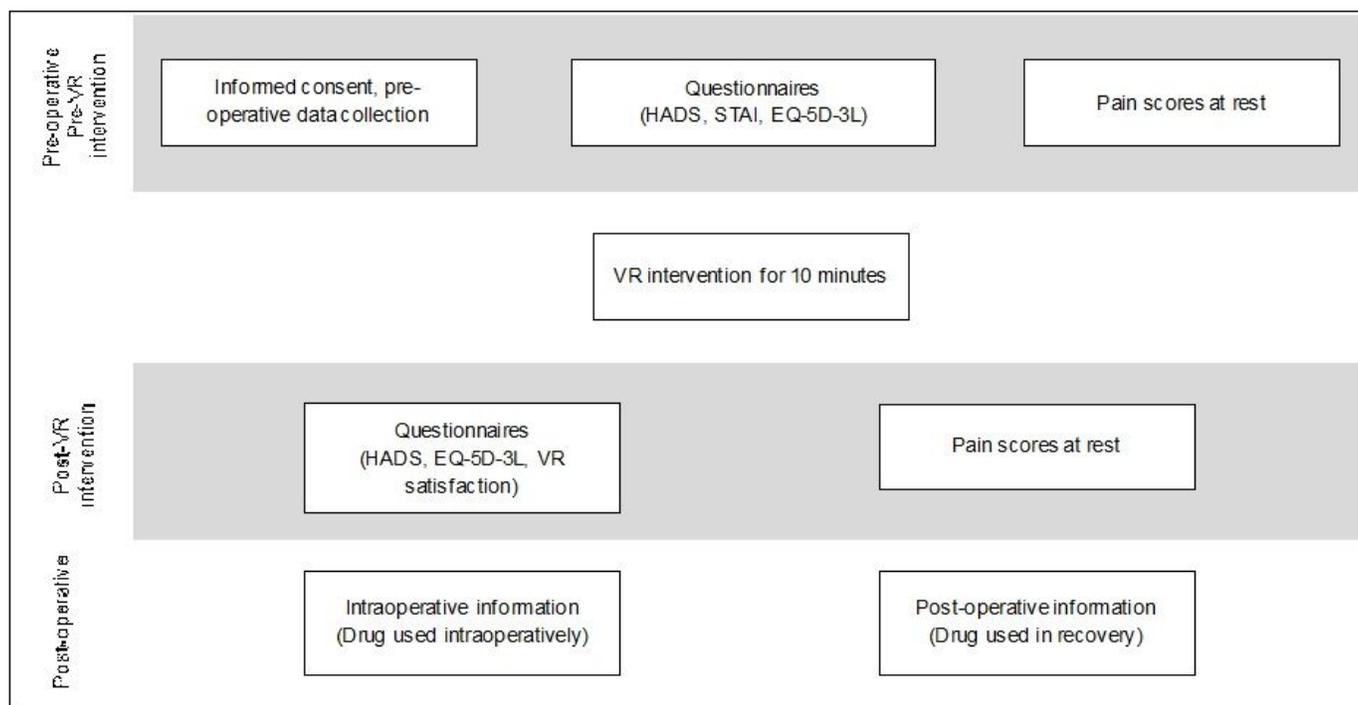


Figure 1

Study flowchart



Figure 2

The setting of VR intervention. (A) The Samsung 8 smartphone for attaching onto a Samsung Gear VR 3; (B) Disposable sanitary covers and earbuds were provided for each use; and (C) A screenshot of menus of Relax VR. Used with permission from Relax VR [30].

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [CONSORTChecklistVR.doc](#)
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