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Original Article

Feasibility, acceptability, and preliminary efficacy of smartphone-based virtual reality relaxation in chemotherapy patients: A pilot study

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ABSTRACT

Background & Aim: While virtual reality holds promise for enhancing patient management and experience during chemotherapy, its use remains limited. The present study aimed to test the feasibility, acceptability, and preliminary efficacy of smartphone-based virtual reality relaxation (SVR) in chemotherapy patients.
Methods & Materials: In this pilot study, 29 participants were divided into two groups. The SVR group (n=14) experienced a 10-minute virtual reality intervention, while the control group (n=15) received standard care and guided imagery leaflets. Outcomes such as comfort, anxiety, pain, systolic blood pressure (SBP), diastolic blood pressure (DBP), and pulse rate were evaluated at baseline and post-chemotherapy. The Technology Acceptance Model (TAM) questionnaire and open-ended questions evaluated SVR's acceptability. Data was analyzed using descriptive statistics, non-parametric t-tests, and thematic analysis.
Results: The SVR intervention appears feasible, as evidenced by a high recruitment rate of 93.75% (30 out of 32 eligible patients) and a retention rate of 96.67% (29 out of 30 participants), despite one withdrawal. The SVR group showed significant comfort improvement (P=0.002), significant changes in pulse rate (P=0.047), and SBP (P=0.023) compared to the control group. Anxiety, pain, pulse rate, and DBP showed no significant differences. A significant TAM variable (P<0.001) confirmed the intervention's acceptability. Qualitative feedback showed no serious side effects and patients reported positive experiences.
Conclusion: The SVR intervention, feasible and acceptable, significantly improved comfort and altered pulse rate and SBP in chemotherapy patients. It shows potential as an oncology care strategy. Further validation is needed through large-scale trials.

Introduction

Cancer, a disease that tops the list of health issues in the world, is predicted to continue to increase and is projected to reach 28.4 million new cases in 2040, compared to 19.3 million new cases in 2020 (1). Regarding mortality, although cancer is currently the second-highest mortality leader after ischemic heart disease, it is likely to be the first by 2060 (2). Therefore, in order to reduce mortality, improve survival, and improve the quality of life of cancer patients, cancer modalities continue to be developed and explored (3). Of all the modality options, chemotherapy, as a traditional cancer treatment approach, is the most widely used and relied upon to date (4).

Chemotherapy modalities are beneficial in prolonging the lives of patients with cancer and improving their quality of life

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by inhibiting tumor cell proliferation and multiplication (5). However, along with healing, there are unwanted consequences due to side effects (e.g., pain, anxiety, nausea, fatigue, and depression) and varying treatment burdens (for instance, invasive procedures, exposure to chemotherapy environments, and treatment intervals) that trigger discomfort in patients with cancer (6). Discomfort is a multidimensional concept that encompasses physical, psychological, social, and spiritual aspects of human experience (7). A study reported that cancer patients experience high levels of discomfort during chemotherapy, which negatively affect their well-being, functioning, and satisfaction (8). In fact, fulfilling comfort is a basic need and one of the cornerstones of holistic nursing (9). Based on Kolcaba's theory, if cancer patients' comfort is fulfilled, it will have implications for treatment effectiveness and adherence (10). Therefore, it is important for oncology nurses to promote the comfort of patients with cancer, especially in the chemotherapy setting (8). Therapeutic interventions are needed to manage negative responses and symptoms that arise in patients undergoing chemotherapy.

Virtual reality (VR), a technology immersing user into a virtual, three-dimensional world, is known to be a widely used and growing therapeutic approach in healthcare. VR provides an immersive experience through visual and auditory stimulation in a virtual environment so as to be distracted from exposure to the real world (11). VR is one of the most recent non-pharmacological modalities to be demonstrated effective and offers a wide range of positive responses to cancer patients (12). Moreover, the integration of VR with smartphones, in particular, is on the rise (13). This form of VR is not only cost-effective, straightforward, portable, and immersive, but it also effectively enhances positive experiences, mitigates negative emotions, and manages pain in cancer patients (14). It helps alleviate anxiety and diverts patients' attention from pain by incorporating visual stimulation and soothing audio from smartphones or tablets (13).

Several studies in cancer populations have shown that VR is effective in reducing the pain and anxiety of patients with cancer due to medical procedures (13,15). VR, which is easily accessible to patients, presents relaxation, entertainment, and calming content using devices such as VR glasses, head-mounted displays (HMDs), or VR headsets. These devices come in various brands and levels of sophistication and immersive capabilities (16). However, the findings of meta-analyses examining the application and research of VR in the context of chemotherapy remain inconclusive and unclear (13). Despite the ambiguity of the results, VR research in these settings still has the potential for further testing with a variety of VR methods and content (11,13). Thus, the commencement of suitable testing begins with pilot studies, which lay the groundwork for larger randomized controlled trials (RCTs). However, the scope of these initial pilot tests, particularly those exploring the use of VR in cancer patients undergoing chemotherapy, remains limited. This highlights the need for further investigation in this area. Therefore, the present study was initiated in recognition of the potential applications of VR in the context of chemotherapy. This pilot study was required as a precursor to the primary randomized controlled trial in order to assess the feasibility, acceptability, and preliminary efficacy of Smartphone-based Virtual Reality Relaxation (SVR) on aspects such as comfort, pain, anxiety, and vital signs in patients undergoing chemotherapy. We hypothesized that SVR is feasible, safe, and readily accepted, and it significantly influences the study outcomes.

Methods

Study design

This pilot study was a parallel randomised controlled trial (RCT) with blinded outcome assessors and a sealed envelope for the random allocation of participants. The study aimed to test the preliminary efficacy, acceptability, and

feasibility of SVR interventions for cancer patients undergoing chemotherapy. This pilot study was a precursor to the main registered protocol on ClinicalTrial.gov (NCT05756465). The study protocol adhered to the Consolidated Standard of Reporting Trial (CONSORT) statement reporting guideline (17).

Participants

The study population consisted of cancer patients who received chemotherapy at One Day Chemotherapy of Dr Sardjito General Hospital Yogyakarta, Indonesia, during March 2023. Inclusion criteria for this study involved cancer patients who received chemotherapy in all cycles, were at least 18 years old, had performance status (ECOG score) ≤ 2, and were able to understand and sign the informed consent form. Exclusion criteria included a history of skull structure or cervical spine disorders that would make it difficult to use the VR device; cognitive, visual, and auditory impairments; wearing minus or plus glasses and using a chemo port; having a history of seizures, dizziness, or visual-induced motion sickness.

Sample size

We deemed a total sample size of 20 to 30 patients as appropriate. We planned for each group to comprise a minimum of 10 to 15 participants, maintaining a 1:1 ratio. Finally, the SVR group comprised 14 participants (following one dropout), while the control group consisted of 15 participants.

Randomization and blinding

Allocation sequence generation was achieved using simple randomization, which was implemented through a formula from Microsoft Excel (the 'rand between' function). To ensure allocation sequence concealment, we employed a two-step process. First, the generated random sequences were printed and placed inside individual opaque, sealed envelopes. These envelopes were then mixed and numbered sequentially. When a participant was enrolled in the study, the next envelope in the sequence was opened to reveal the participant's group allocation. Due to the characteristics of the VR intervention, blinding was not possible for participants; however, to reduce measurement bias, we blinded the outcome assessor and data analyst regarding the allocation of intervention and control groups. We used a curtained partition during the intervention to minimize contamination and knowledge sharing between participants.

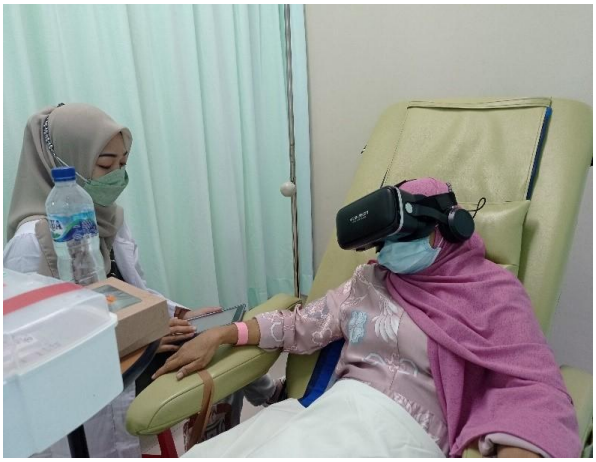
Procedure

Consecutive sampling, a non-probability sampling method, was used. This involved selecting all subjects meeting the inclusion criteria within a specific intervention period. The research team consisted of one clinical oncology nurse, two research nurses as outcome assessors (OA), and three trained nurses as intervention providers (IP). Data collection was conducted on a per-individual basis. Data collection was conducted before pre-medication chemotherapy and after one cycle of chemotherapy was completed. Baseline data collection began after patients completed standardized pre-chemotherapy screening (upon entering the chemotherapy room). If patients agreed to join the study, they signed an informed consent form. Outcome assessors reviewed the baseline and evaluated the outcomes completed independently by the participants with the assistance of the OA. After the patient started the first chemotherapy regimen, the IP gave a brief briefing regarding the VR intervention tools and objectives for 5 minutes, after which the intervention continued for approximately 10 minutes. The 360^{o} video content selection was adjusted to the patient's preference (Figure 1). After the patient completed one session of the chemotherapy cycle, quantitative data collection and a 10- to 15-minute semi-structured interview were conducted for qualitative evaluation of the intervention.

360° Video: Pine Forest and Waterfall in Yogyakarta, Indonesia

360° Video: Daan Park in Taipei City, Taiwan

360° Video: Wisdom Park and Natural Pond in Yogyakarta, Indonesia



The patients used the VR device accompanied by the intervention provider

Figure 1. 360-degree videos as SVR content and Participants while using VR

Intervention

This study involved an immersive virtual reality approach using a smartphone and a Shinecon 6.0 VR Box (virtual reality glasses with headphones). The VR device was paired with a smartphone device that uses the Android or iOS operating system, had a minimum screen size of 5.5 inches and a maximum of 6.0 inches, and had a minimum screen resolution of 1080 x 1920 pixels to provide the best image quality. It was connected to WIFI or the internet to access 360-degree videos loaded on the researcher's YouTube channel. The SVR content, which utilized 360-degree videos, was produced by researchers using video editing software and had a duration of approximately 10 minutes. The duration was determined based on previous research by Fabi et al,(18) where this duration may be effective in anticipating patient saturation with the content and preventing visual-induced motion sickness. The 360-degree videos that we produced consisted of 3 options, namely Wisata Mangunan Pine Forest, Yoygyakarta, Indonesia, Wisdom Park and Kedung Pedut, Yogyakarta, Indonesia, and Daan Park, Taipei City, Taiwan. Researchers used a 360-degree video with a natural panoramic background and combined with relaxation music that refers to previous studies (Figure 1) (11).

Outcome measurement

This study primarily assessed comfort, with secondary outcomes including anxiety, pain, pulse, and blood pressure. The study's feasibility and acceptability were evaluated using a Technology Acceptance Model (TAM) questionnaire and open-ended questions.

Comfort was assessed using the Shortened General Comfort Questionnaire (SGCQ) by Kolcaba et al. (9). The Indonesian version of the SGCQ, validated by Artanti et al. (19), demonstrated a high level of content validity, with an Item-CVI score of 1 and a Scale-level CVI score of 1, indicating that each item's relevance, accuracy, clarity, credibility, and

equality were accepted. The instrument also showed good reliability, with a Cronbach's alpha score of 0.769, falling within the acceptable range of 0.7–0.95. Higher scores indicated greater comfort.

Anxiety was evaluated using the Visual Analogue Scale for Anxiety (VAS-A), with higher scores indicating increased current anxiety. A study has demonstrated test-retest reliability (r=0.44, P<0.001) and convergent validity with the State-Trait Anxiety Inventory's state subscale (STAI-State; r=0.60, P<0.001)(37) and VAS was an adequate predictor of STAI score, with a correlation of 0.78, indicating that VAS is a valid measure of anxiety (20).

Pain in chemotherapy patients was quantified using the Numeric Rating Scale (NRS). The NRS showed high construct validity (correlations with the VAS ranging from 0.86 to 0.95) and excellent test–retest reliability (r= 0.96) (21). Pulse rate and blood pressure were objectively measured using a digital sphygmomanometer (OMRON Brachial Sphygmomanometer HEM-7120).

The feasibility of the SVR intervention was evaluated by calculating recruitment and retention rates, which represent the number of eligible patients who enrolled in the study and those who completed the entire course, respectively. The acceptability of SVR was evaluated using a mixed-methods approach that combined both quantitative and qualitative techniques.

The quantitative assessment was based on the TAM, which includes three key variables: Perceived Usefulness (PU), Perceived Ease of Use (PEOU), and Acceptance of IT. Each of these variables was assessed using a questionnaire consisting of 7 items, totaling 21 items across all variables. The PU questionnaire gauges the perceived utility of the SVR intervention, while the PEOU questionnaire measures how easy the SVR device is to use. The Acceptance of IT questionnaire, on the other hand, is designed to capture user attitudes towards the acceptance of technology. The SVR intervention is deemed useful, easy to use, and acceptable if the average scores for PU, PEOU, and Acceptance of IT exceed 3, respectively.

Qualitatively, open-ended questions were asked to participants to explore the evaluation and acceptance of SVR through a semi-structured interview method. Questions included: How would you describe the experience during and after using the VR device? What duration of 360-degree video content do you feel comfortable with? Did you feel any discomfort from the VR content and tools? What needs to be improved? And what is your preference for being calm and relaxed during chemotherapy?

Ethical considerations

This study has obtained ethical clearance from the Ethics Committee of the Faculty of Medicine, Public Health, and Nursing, Universitas Gadjah Mada (approval number: KE/FK/0301/EC/2023). All participants provided written informed consent at the start of the study. We provided subject information outlining the study objectives, intervention procedures, data use, benefits, compensation, and principles of anonymization and confidentiality of information. To ensure patient anonymity and confidentiality, all patient identifiers were coded before data analysis. The key linking codes to patient identifiers was securely stored and only accessible to the principal investigator. All data were reported in aggregate, ensuring individual patient data could not be discerned.

Statistical analysis

Statistical analyses were performed using SPSS version 24 for Windows (SPSS Inc., Chicago, IL, USA). Descriptive statistical tests were used to describe demographic data, baseline variables, primary outcomes (acceptability by TAM model evaluation), which were presented as means and standard deviations. We analyzed by using Fischer exact test and Mann-Whitney U test statistics to describe and compare baseline demographic characteristics and secondary outcomes (comfort, pain, anxiety, pulse rate, systolic blood pressure, diastolic blood pressure) between the intervention and control groups. Differences within groups and between two groups were examined through Wilcoxon t-tests and Mann-

Whitney U-test. A two-sided P value of less than 0.05 was considered statistically significant with a 95% confidence interval. Effect size calculations used Cohen's d to assess the effect of the intervention through comparison of the SVR and control groups by dividing the mean standardized difference by the pooled standard deviation (large effect size, d= 0.80; medium effect size, d= 0.50; and small effect size, d= 0.20) (22). Qualitative data were collected through audio-recorded, semi-structured interviews to extract relevant information supporting the acceptability of the intervention. These interviews were transcribed immediately following their conclusion. The qualitative data were then analyzed thematically, with participants' quotes presented to illustrate key themes. In cases of differing interpretations, qualitative results were reviewed with other researchers to reach a consensus. This process ensured a comprehensive and accurate representation of the qualitative findings.

Results

Feasibility of recruitment and baseline characteristics

The recruitment process for this study is illustrated in Diagram 1. Out of 32 eligible cancer patients, two declined to participate, with one citing a lack of interest and the other providing no clear explanation. As a result, a total of 30 participants were included and randomized into the SVR group (n=15) and control group (n=15), resulting in a recruitment rate of 93.75%. One participant withdrew early in the SVR group (n=14) due to feeling sleepy, leaving 29 participants who received the intervention and completed the post-intervention assessment, resulting in a retention rate of 96.67%. Characteristics of cancer patients in each group who completed the intervention are presented in Table 1. The participants had a mean age of 52.8 years (SD= 12.0), with the majority being female (82.8%), unemployed (72%), earning less than the average monthly income (72.4%), married (82.8%), accompanied during chemotherapy (86%), having an ECOG score of 0 (86%), and having no comorbidities (72.4%). There were significant differences in SBP and DBP between groups at baseline, while the ECOG score was imbalanced. However, no significant differences were observed in other baseline characteristics and outcomes (P>0.05).

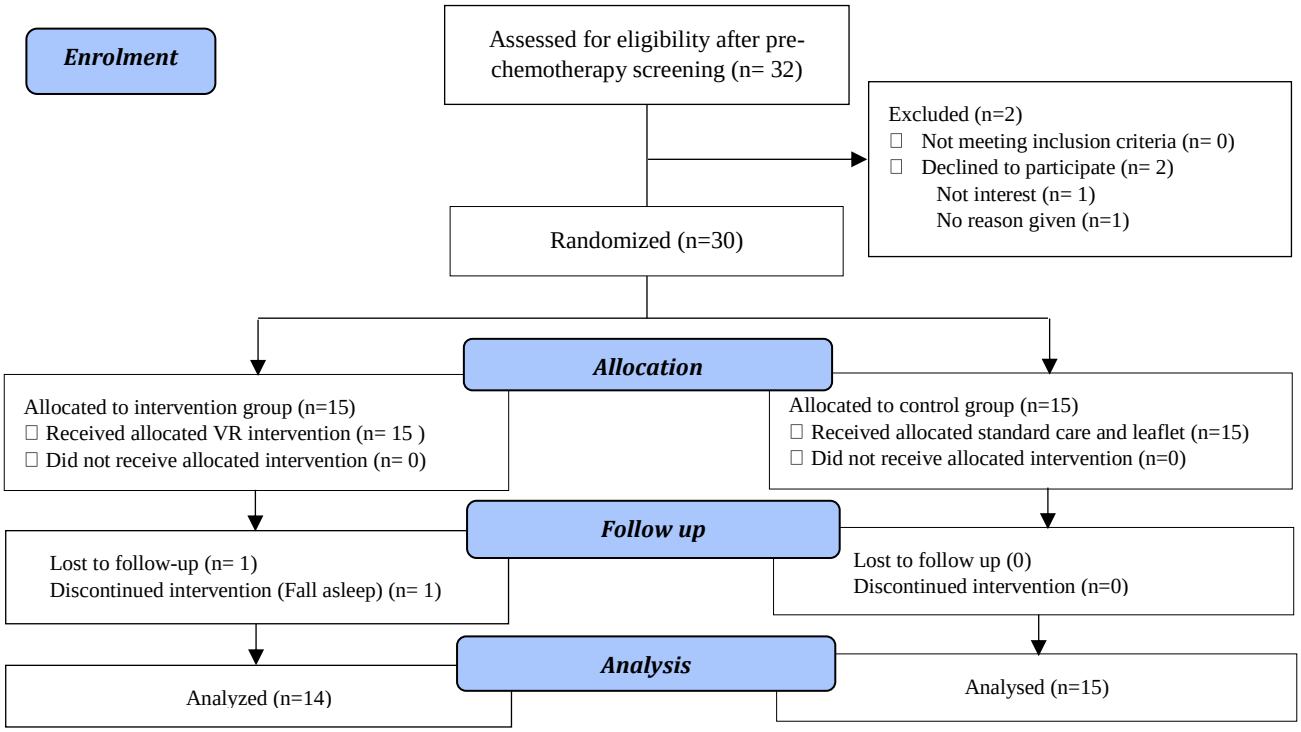


Diagram 1. CONSORT flow diagram

Preliminary effect of intervention

Table 2 presents the comparison of within groups and between groups following intervention. The comparison of within groups using Wilcoxon test showed that the SVR group had a significant increase in comfort (P=0.001), a significant change in pulse rate (P=0.005), and a significant decrease in SBP (P=0.048) following the SVR intervention. However, no significant differences were observed in other outcomes (P>0.05). In the control group, there was a significant increase in comfort (P=0.025) and a significant reduction in anxiety (P=0.006), while no significant differences were observed in other preliminary outcomes.

Furthermore, the comparison of the mean differences between groups evaluating the impact of the intervention showed that compared to the control group, there was a significant improvement in comfort in the SVR group (Z=-3.108; P=0.002; Cohen's d=0.78), with a medium effect size. Between-group comparisons revealed non-significant differences in anxiety (P=0.844; Cohen's d=0.74, medium effect), pain (P=0.178; Cohen's d=0.35, small effect), pulse rate (P=0.12; Cohen's d=0.12, small effect), and DBP (P=0.13; Cohen's d=0.57, medium effect). However, there were significant differences between the two groups in pulse rate (Z=-1.988; P=0.047; Cohen's d=0.12, small effect) and SBP (Z=-2.273; P=0.023; Cohen's d=0.6, medium effect). The post-hoc analysis, which was based on the mean differences between groups, revealed that the observed power for non-significant outcomes ranged from 2.8% to 19.8%. In contrast, comfort demonstrated a significantly higher observed power value of 96%.

Table 1. The baseline characteristic of patients

Characteristics	**n (%)/mean (SD)**		***P***
	SVR group (n= 14)	**Control group (n= 15)**	
Age (years)	53.2 (12.7)	52.5 (11.6)	*0.96*
Gender			
Male	3 (21.4)	2 (13.3)	*0.65*
Female	11 (78.6)	13 (86.7)	
Education			
Low education	2 (33.3)	4 (66.7)	*0.79*
Medium education	7 (50.0)	7 (50.0)	
High education	5 (55.6)	4 (44.4)	
Occupation status			
Work	3 (21.4)	5 (33.3)	*0.68*
No work	11 (78.6)	10 (66.7)	
Marital status			
Single	0	1 (6.7)	*1.00*
Married	12 (85.7)	12 (80.0)	
Widow/widower	2 (14.3)	2 (13.3)	
Income/month			
Greater (>) Monthly minimum wage	3 (21.4)	5 (33.3)	*0.68*
Less or equal (≤) Monthly minimum wage	11 (78.6)	10 (66.7)	
Accompanied during chemotherapy			
Yes	13 (92.9)	12 (80.0)	*0.6*
No	1 (7.1)	3 (20.0)	
Cancer stages			
Stage I	1 (7.1)	1 (6.7)	*0.91*
Stage II	2 (14.3)	2 (13.3)	
Stage III	5 (35.7)	3 (20.0)	
Stage IV	1 (7.1)	1 (6.7)	
Unidentified	5 (35.7)	8 (53.3)	
Length of time since diagnosis			
< 6 months	5 (35.7)	7 (46.7)	*0.71*
≥ 6 months	9 (64.3)	8 (53.3)	
No of chemotherapy cycles			
1st	3 (21.4)	2 (13.3)	*0.82*
2nd	1 (7.1)	2 (13.3)	
3rd	2 (14.3)	2 (13.3)	
4th	1 (7.1)	3 (20.0)	
5th	2 (14.3)	3 (20.0)	
> 5th	5 (35.7)	3 (20.0)	

Characteristics	n (%)/mean (SD) SVR group (n= 14)	Control group (n= 15)	*P*
ECOG score performance			
0	10 (71.4)	15 (100)	*0.04*
1	3 (21.4)	0	
2	1 (7.1)	0	
Having comorbidities			
Yes	4 (28.6)	4 (26.7)	*1.00*
No	10 (71.4)	11 (73.3)	
Pre – comfort score	118.3 (10.9)	120.9 (4.8)	0.37
Pre – anxiety score	2.2 (2.0)	1.8 (2.2)	0.69
Pre – pain score	2.7 (2.5)	2.5 (2.3)	0.78
Pre – pulse rate (beat/minutes)	100.3 (17.2)	90.2 (14.0)	0.14
Pre – SBP (mmHg)	137.6 (20.1)	114.3 (20.0)	<0.001**
Pre – DBP (mmHg)	78.7 (12.0)	65.9 (10.9)	0.01*

SD, standard deviation; ***P<0.001; *P<0.05*

Table 2. Comparison of within groups and between groups following intervention

Variable	SVR group (n=14)		*P* [a]	Control group (n=15)		*P* [a]	Mean difference (SD)		*Z*	*P* [b]	*Cohen's d effect sizes*	*Observed power*
	Baseline	After		Baseline	After		SVR group (n= 14)	Control group (n= 15)				
Comfort	118.3 (10.9)	131.9 (10.7)	0.001*	120.9 (4.8)	124.8 (7.2)	0.025*	13.6 (7.4)	3.9 (6.6)	-3.108	0.002*	0.78	96%
Anxiety	2.2 (2.0)	1.4 (1.5)	0.084	1.8 (2.2)	0.6 (0.4)	0.006*	0.8 (1.7)	1.3 (2.1)	-.197	0.844	0.74	10.5%
Pain	2.7 (2.5)	2.0 (1.7)	0.071	2.7 (2.2)	2.8 (2.7)	0.596	0.7 (1.5)	0.3 (1.7)	-1.346	0.178	0.35	9.9%
Pulse rate (beats/minute)	100.3 (17.2)	87.0 (10.5)	0.005*	90.2 (14.0)	88.6 (14.7)	0.410	13.3 (14.7)	1.6 (14.2)	-1.988	0.047*	0.12	58.6%
SBP (mmHg)	137.6 (20.1)	128.9 (20.4)	0.048	114.3 (20.0)	117.3 (18.1)	0.210	9.0 (16.7)	3.1 (11.1)	-2.273	0.023*	0.60	19.8%
DBP (mmHg)	78.7 (12.0)	75.6 (12.3)	0.413	65.9 (10.9)	68.9 (11.1)	0.378	3.1 (9.7)	2.9 (10.8)	-1.158	0.247	0.57	2.8%

SD, standard deviation; [a] *Wilcoxon t test*; [b] *Mann - Whitney U test*; [*] *P <0.05*

Evaluation of acceptability and interview responses from SVR group

A quantitative evaluation was conducted using the TAM approach. The results revealed that the Perceived Usefulness (POU) variable had a mean of 3.8 (SD=0.4; t=7.0; P<0.001), indicating a high level of perceived usefulness. The Perceived Ease of Use (PEOU) variable had a mean of 3.7 (SD=0.5; t=5.4; P<0.001), indicating that the SVR is considered easy to use. The Acceptance of Information Technology (AOT) variable had a mean of 3.6 (SD=0.4; t=6.1; P<0.001), indicating a high level of acceptance of the technology. These results suggest that the application of SVR is perceived as useful, easy to use, and acceptable (Table 3).

Table 3. Results for Technology Acceptance Model Evaluation and Acceptability of the SVR intervention survey (n=13)

TAM variables and items	Mean (SD)	*t*	*P*[a]
Perceived of Usefulness (POU)	3.8 (0.4)		
I am able to deal with the current situation better with the SVR device	3.7 (0.9)		
Using the SVR device makes it difficult for me during chemotherapy*	3.5 (1.2)		
SVR device decreases my productivity during chemotherapy*	4.1 (0.8)		
SVR device can improve my chemotherapy adherence	3.5 (0.8)	7.0	<0.001
The virtual relaxation content of the SVR device is useful during chemotherapy	4.1 (0.8)		
I feel calm after receiving virtual relaxation content from the SVR device during chemotherapy	3.8 (0.7)		
SVR helped me get comfortable during chemotherapy	3.9 (0.8)		
Perceived Ease of Use (PEOU)	3.7 (0.5)		
I learned easily how to use the SVR device	3.4 (1.1)		
I had difficulty using the SVR device*	3.8 (0.6)		
I can use this SVR device to deal with my current situation	3.9 (0.7)	5.4	<0.001
I can understand the virtual environment presented in SVR clearly	4.0 (0.7)		
I had difficulty in understanding how to interact with the SVR device*	3.7 (0.8)		
SVR can be used flexibly	3.8 (0.9)		
SVR can be easily accepted	3.6 (0.8)		

TAM variables and items	Mean (SD)	*t*	*P*[a]
Acceptance of Information Technology (AOT)	3.6 (0.4)		
I am comfortable using the SVR device	3.8 (0.9)		
I enjoy the virtual environment presented on the SVR device	4.1 (0.3)		
SVR provides boring virtual relaxation*	3.3 (1.0)		
The SVR provided the virtual relaxation experience I needed	3.8 (0.9)	6.1	<0.001
I had chemotherapy easier through the use of SVR	3.8 (0.8)		
I feel that the virtual relaxation viewing from the SVR device is not suitable for my current situation*	3.4 (1.2)		
Virtual content duration in SVR is sufficient	3.0 (1.2)		
Overall - TAM evaluation	3.7 (0.3)	7.6	<0.001

Higher score indicates higher level of agreement with the statement; strongly agree=5, agree=4, neutral=3, disagree=2, strongly disagree=1. [a] *One sample t test with threshold value= 3. *Unfavorable item*

Table 4 presents a qualitative analysis of the participants' responses, which were mapped into five themes: comfort, relaxation, calmness, duration, and limitation. The comfort theme reflects the responses of patients who felt comfortable experiencing the virtual reality content (e.g., "Comfortable, relaxed", "It's just comfortable"). The relaxation theme captures the experiences of participants who felt as though they were in the virtual world (e.g., "Good, like I feel in the forest", "That's good, it's like in a forest, in a pine forest, right?"). The calmness theme represents the participants' feelings related to their preferred content (e.g., "I like the music; the atmosphere is also supportive", "Yes, it is calmer to see nature"). The duration theme shows the participants' responses regarding the appropriate duration of the intervention (e.g., "15 minutes maybe", "That's enough"). The limitation theme reflects participants' negative responses to the VR content (e.g., "Yes, sometimes it's blurry, sometimes it's clear"). No serious side effects were reported in the SVR group.

Table 4. Theme and comment for evaluation of SVR intervention

Theme	Participant illustrative quotes
Comfort	"It's just comfortable" "No, it's comfortable – make me relief" "It's more, it's more refreshing" "How do I say? more comfortable" "Comfortable, relaxed" "Fun, exciting, enjoyable" "It's fun if you want to relax"
Relaxing	"Wonderful, I am feeling like in the forest" "That's good, it's like in the forest, in a pine forest, right?" "Look at it, nature, and someone is walking"
Calming	I like the music; the atmosphere is also supportive" "I'll be honest, I like nature" "Yes, it is calmer to see nature" "Hmm… I like listen the song" "I like to see the forests. Also, but that is I have never been there"
Duration	"15 minutes maybe" "Yes, like the video now" "7 minutes maybe yeah" "I think too long" "Less time" "That's enough (10 minutes)" "10 minutes maybe" "Just enough, that's enough (10 minutes)"
Limitation	"Yes, sometimes it's blurry, sometimes it's clear" "The picture is too fast, so maybe that's what makes me dizzy?" "The pictures are still shadows, so sometimes it doesn't look real, it's real… but the shadows don't look real" "The only drawback is that it's stuck, limit to move"

Discussion

This pilot randomized controlled trial aimed to evaluate the feasibility, acceptability, and preliminary effects of an SVR intervention in cancer patients during a single chemotherapy session. Firstly, this study represents the first RCT pilot study conducted in a chemotherapy setting in Indonesia, with a high participation rate. Secondly, the preliminary findings indicated that the SVR intervention improved patient comfort as a primary outcome compared

to the control group, with a medium effect size as measured by Cohen's d. Additionally, significant changes were observed in pulse rate and systolic blood pressure. Thirdly, both quantitative and qualitative evaluations demonstrated that the SVR intervention is feasible and acceptable for cancer patients undergoing chemotherapy.

This pilot trial in chemotherapy patients achieved high recruitment and retention rates, demonstrating the appeal of VR-based interventions in chemotherapy settings. Only a few patients declined to participate, with one citing disinterest in the intervention and the other providing no clear explanation. One participant was dropped from the study, not due to the intervention itself, but because they felt drowsy prior to starting the intervention as a result of a long journey to the hospital and activities at home. Compared to previous pilot studies, Tsuda and colleagues in 2016 (23) reported an adherence rate of 66.5% with a VR activity duration of 20 minutes, while Verzwyvelt and colleagues in 2021 (24) reported an adherence rate of 78.6% with virtual natural environment content lasting up to 15 minutes. The difference in adherence rates may be attributed to the short duration of our VR intervention, which consisted of approximately 10 minutes of 360-degree virtual video relaxation during a single chemotherapy session. The high participation and retention rates observed in our study are important for understanding participants' adherence to the study protocol and the successful completion of the study. These results provide a strong foundation for conducting a larger RCT study in the future.

Currently, there are few studies related to the application of VR to cancer patients undergoing chemotherapy (13,25). Our pilot study demonstrated preliminary effects that resulted in significant changes in comfort outcomes. These results suggest that VR interventions during chemotherapy can improve comfort levels in cancer patients, which is consistent with the findings of previous studies (26). In fact, comfort is one of the most successful indicators that patients are tolerant to chemotherapy procedures, and this improved outcome is likely to increase patients' hope, confidence, treatment adherence, and quality of life (27). Comfort is also a multidimensional outcome in nursing (physical, psychospiritual, environmental, and sociocultural), so nurses need to ensure and fulfil the needs of each aspect (10). In addition, this comfort fulfilment mechanism is obtained from a guided imagery relaxation approach packaged through virtual reality, which is very suitable for cancer patients undergoing chemotherapy (28). This method distracts patients from stressful situations during chemotherapy, relieves muscle tension, and guides the mind to be relaxed (25). Although comfort variable is statistically significant with a high power of observation, the effect size appears overestimated due to the small sample size. It is important to interpret this result with caution.

The analysis of secondary outcomes, such as anxiety and pain, revealed no significant differences. Statistical data indicated that the mean scores for pain and anxiety were low, suggesting that the participants in this study did not exhibit significant responses to these outcomes. As a result, no significant changes were observed following the intervention. Despite the lack of significance, further investigation of these outcomes, particularly pain and anxiety, is warranted due to their frequent co-occurrence and the potential for one symptom to exacerbate the subjective experience of the other (16). Cancer patients' pain and anxiety may recur due to exposure to medical procedures (e.g., intravenous access) and the short-term effects of chemotherapy (15). VR therapeutic intervention has been shown to be effective in overcoming these symptoms (11,18,25). In addition, when evaluated using Cohen's d, the effect sizes fall within the small to medium range, with the majority being of medium magnitude. This suggests that there may be significant differences between groups. However, to confirm the statistical power or obtain more precise effect estimates, it is necessary to increase the sample size, including the primary outcome in future RCT studies.

Our study findings indicate that the SVR intervention is acceptable, tolerable, and feasible to implement in a chemotherapy setting, as evidenced by the quantitative evaluation using the

TAM approach and positive feedback obtained through qualitative evaluation. However, based on participant responses and feedback, further improvements to the SVR intervention are necessary. Specifically, participants suggested adjusting the duration of the video according to patient preferences and, if possible, maintaining the quality of the video, as it sometimes appears blurry and unclear. These challenges arose during fieldwork due to difficulties in maintaining a stable internet connection, as the SVR video content needed to be accessed via a YouTube channel that supports 360-degree videos. On a positive note, most participants responded favorably to the nature panorama integrated with relaxation music, which made them feel comfortable and calm as if they were actually present in the virtual environment.

While the statistical significance of our findings is important, it is equally crucial to delve deeper into the clinical significance of these results. The observed medium effect size in comfort, for instance, translates into tangible improvements in the well-being of cancer patients during chemotherapy. This improvement in comfort can potentially enhance the patient's overall experience, making the often-strenuous chemotherapy sessions more bearable. Furthermore, an increase in comfort could potentially lead to better treatment adherence (29). Patients who are more comfortable during their treatment sessions may be less likely to miss appointments, leading to more consistent treatment schedules and potentially better health outcomes. Lastly, the enhanced comfort provided by S-VR program could contribute to an overall improvement in the quality of life of cancer patients undergoing chemotherapy. By making the treatment experience more comfortable, patients may experience less distress and a better overall mood, which are key components of quality of life (27).

Our pilot study has several strengths. We used a novel approach to non-pharmacological therapeutic interventions in a population with cancer receiving chemotherapy, which is still rare in cancer care settings, especially in Indonesia. Although VR research in cancer populations is growing rapidly, this is a start to kick-start innovation and improve quality of care. Our study design evaluated this intervention comprehensively through quantitative and qualitative approaches, which resulted in important findings for future intervention improvements. We also produced a 360-degree video by ourselves as a form of originality for the intervention by utilizing VR goggles that are affordable in the marketplace. Our protocol fidelity was also strict to ensure the feasibility and accuracy of the intervention delivery (28).

Several limitations of this study must be acknowledged. Firstly, the pilot nature of our study resulted in a small sample size, which may have caused both a lack of statistical power and an overestimation of the actual effect size. Consequently, the reliability of the intervention results should be interpreted with caution, as it affects the generalizability of the trial results. A larger sample size in future studies would provide adequate power to test for significant differences. Secondly, this study did not conduct a follow-up, which would have provided important and useful results regarding the long-term efficacy of the intervention. Thirdly, while randomization and blinding have minimized the potential for bias, it is still necessary to control for potential covariates to obtain accurate effect estimates. This could be achieved through a post-intervention multivariable regression analysis. Furthermore, the specific characteristics of our study population, namely patients from a particular hospital in Indonesia, limit the generalizability of our findings. Variations in patient demographics, cultural factors, and healthcare settings might influence the feasibility and acceptability of the SVR intervention in different contexts. Therefore, caution should be exercised when interpreting the study's outcomes and applying them to a broader population. Future trials with larger sample sizes, comprehensive objectives, clearly defined time points, and relevant outcomes are needed to conclusively determine the usefulness and efficacy of the SVR intervention. In addition, we acknowledge the value of mixed methods as a comprehensive approach to investigate the feasibility and acceptability of the SVR intervention. This approach could provide a more comprehensive understanding of the

intervention's impact. However, our study did not fully utilize this approach, which we recognize as a limitation. We look forward to addressing these limitations in future research.

Despite the limitations we found, the promising results of this pilot study suggest several potential implications for practice. This study provided a new experience for cancer patients undergoing chemotherapy by using virtual reality technology in a safe, brief, and acceptable way to increase their comfort during treatment. Nurses are one of the drivers of this kind of innovation and its implementation in nursing care (30). We look forward to the widespread adoption of this protocol in clinical practice.

Conclusion

This study focused on testing the preliminary efficacy, acceptability, and feasibility of the SVR intervention for patients with cancer undergoing chemotherapy. Findings from this study suggest that the SVR intervention is potentially effective in facilitating comfort needs, easing anxiety, and distracting pain that may occur during chemotherapy for patients with cancer through our 360-relaxation content. The SVR intervention also appears to be easily acceptable and feasible in this setting. However, despite this potential, several limitations, either methodological (e.g., sample size, design, or measurement) or technical (e.g., device sophistication, network stability, and content preference), need to be further considered. Therefore, RCT trials with a larger sample size, more rigid design, and more consideration of the sophistication of VR relaxation tools and content preferences are needed to further identify the potential effectiveness of SVR interventions.

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Conflict of Interest

The authors declare no conflict of interest.

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