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## Research Article

# The Effects of Aroma Essential Oil Inhalation on Stress, Pain, and Sleep Quality in Laparoscopic Cholecystectomy Patients: A Randomized Controlled Trial

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## SUMMARY

**Purpose:** Patients undergoing cholecystectomy report experiencing stress related to the surgery, complaining of pain and poor sleep quality. Aromatherapy is known to have positive effects on these complaints. However, the effect of aromatherapy on cholecystectomy patients has yet to be determined. The aim of this study, therefore, was to investigate the effects of aromatherapy on laparoscopic cholecystectomy patients' stress, pain, and sleep quality.

**Methods:** This study was a randomized controlled trial involving 69 adults who underwent laparoscopic cholecystectomy. Essential oil therapy was given to an intervention group, and almond oil was given to a placebo group. The outcome variables were stress, pain, and sleep quality.

**Results:** There were no differences between the groups in terms of demographic and clinical characteristics and pretreatment dependent variables. After the intervention, subjective stress ( $F = 7.43$ ,  $p < .001$ ), objective stress ( $F = 2.70$ ,  $p = .034$ ), parasympathetic nerve activity ( $F = 2.65$ ,  $p = .036$ ), pain ( $F = 8.74$ ,  $p < .001$ ), analgesics administration ( $F = 22.43$ ,  $p < .001$ ), and sleep quality ( $F = 5.23$ ,  $p < .001$ ) were significantly different between the intervention, placebo, and control groups. Sympathetic nerve activity was not significantly different. The effect sizes regarding the sleep quality of the intervention versus control group and the intervention versus placebo group were 1.92 and 1.52, respectively.

**Conclusion:** Postoperative aromatherapy received by cholecystectomy patients was effective in reducing stress and pain and improving sleep quality. No side effects of aromatherapy were reported during the experimental treatment.

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## Introduction

The incidence of gallbladder disease is gradually increasing in Korea due to the influence of Westernized lifestyles, high-protein and high-fat diets, and the rising prevalence of obesity [1–3]. Cholecystectomy and antibiotic therapy are common treatments for inflammation caused by gallbladder disease. Open cholecystectomy has the disadvantages of involving large surgical incisions, severe pain, and long hospital stays; therefore, laparoscopic cholecystectomy may be performed to minimize surgical incisions and shorten hospital stays [3–5].

Laparoscopic cholecystectomy requires three incisions, and patients undergoing such surgery under general anesthesia still experience stress, complaining of severe postoperative pain [4,6] and discomfort during hospitalization. Accordingly, relieving stress, assuaging anxiety, and lessening pain, i.e., ensuring patient comfort, are paramount during postoperative care [6,7]. To realize this, patient-controlled analgesia (PCA) and intermittent analgesics are regulated by the administration [8–10], and nursing provides relaxation therapy and breathing methods [11]. For short hospitalizations following laparoscopic cholecystectomy, however, nonsteroidal and narcotic analgesics are used instead of PCA to control pain.

Laparoscopic cholecystectomy patients may also suffer from psychological helplessness and sleep disorders [12,13], which can be triggered by environmental changes that occur during hospitalization and surgery [14]. Sleep is a basic human need, and sound sleep provides stability and relaxation, which is essential for maintaining mental homeostasis and physiological health [15]. Stress and sleep disorders affect the autonomic nervous system,

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with various physiological changes occurring in the body activating the sympathetic nervous system and inhibiting the stimulation of the parasympathetic nervous system [12]. As sleep deficiency is a form of stress and postoperative pain interferes with sleep, a patients recovery is negatively affected; therefore, active efforts to overcome sleep deprivation are necessary [12,15].

Aromatherapy using ingredients extracted from plants is a complementary therapy that is known to help relieve stress [16], reduce pain [17], and improve sleep [18]. Aromatherapy involves various applications of essential oils. The oils can be inhaled [19], applied to the skin [20], applied through massaging [21], or used during foot bathing [16]. The aromatherapy essential oils used in this study were intended to balance the autonomic nervous system by activating the parasympathetic nerve. Since lavender oil, ylang-ylang oil, and marjoram oil are effective for insomnia treatment and gentle sedation, these oils were blended and applied [11,13,16–18,22]. Among the various aromatherapy methods, the method that is frequently used safely is the inhalation method. In this study, the inhalation method using an aroma stone was employed, having the advantages of being portable and easy to use [18,23,24].

Stress-related aromatherapy has been actively studied in the field of nursing and medicine [23,25] with a focus on elderly patients [14] and patients undergoing coronary artery bypass surgery [26]. Aromatherapy research on relieving pain in patients after surgery, including tonsillectomy [27] and gynecological surgery, has also been carried out [28,29]. However, there have been no aromatherapy studies on patients undergoing laparoscopic cholecystectomy. Moreover, studies on aromatherapy for improving sleep have focused on elderly inpatients [14], hemiplegic patients [18], and inpatient cancer patients [15], with few studies examining the effects of aromatherapy on surgical patients.

This study was conducted to identify the postoperative comfort and symptom improvement effect of applying a proven, safe aroma inhalation therapy. A blended essential oil containing lavender, ylang-ylang, marjoram, and neroli was inhaled by patients who underwent laparoscopic cholecystectomy to treat gallbladder

disease, and attempts were made to determine the oil's effects on stress, pain, and sleep quality on the first and second days after surgery.

**Methods**

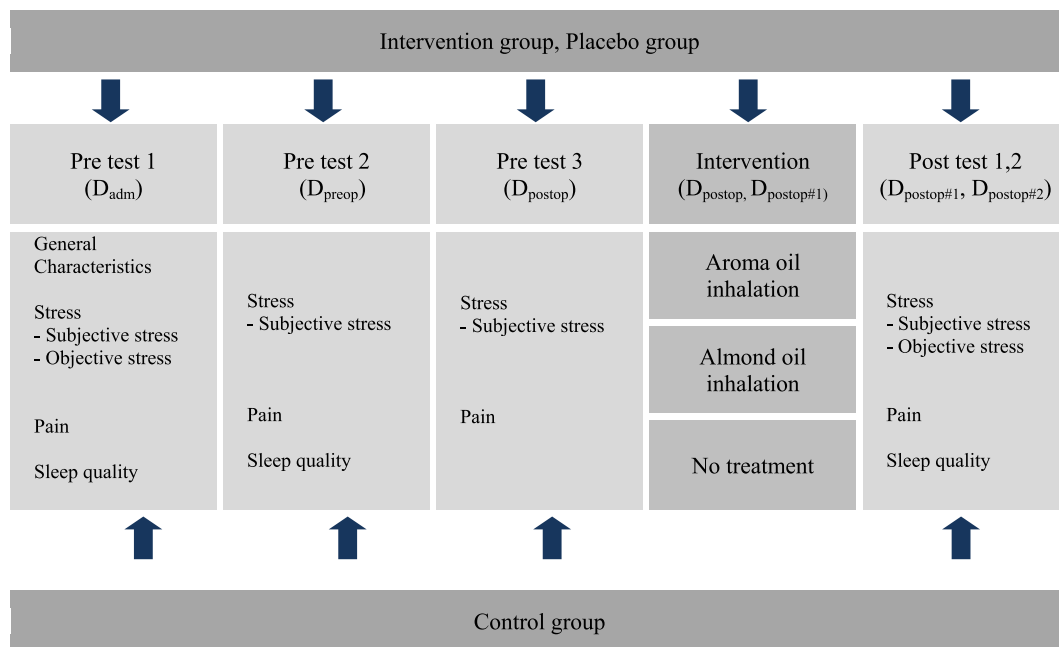
*Study design*

This study used a randomized, single-blind, parallel-group controlled trial to investigate the effects of aroma essential oil inhalation on stress, pain, and sleep quality in patients undergoing laparoscopic cholecystectomy. The study design is shown in Figure 1.

*Study participants*

The participants were patients diagnosed with gallbladder disease at Eulji Medical Center in Daejeon City, South Korea, who were recommended for laparoscopic cholecystectomy. The sample size was calculated using G-power 3.1.9.2., considering alpha, power, the number of groups, the number of measurements, the correlation coefficient of repeated measures, and the effect size obtained from previous studies using the statistical method of repeated measures ANOVA. The values used were alpha .05, power .95, number of groups 3, number of measurements 3, a correlation coefficient of .20, and the effect size .27 was obtained by substituting .07 partial eta squared in a previous study [18]. The required number of patients was 69, which was then set at 75, considering a dropout rate of 10%.

The researcher explained the study in accordance with research ethics regulations to patients admitted for laparoscopic cholecystectomy, checked the inclusion criteria and exclusion criteria, and selected 85 patients. To be included, patients had to be scheduled to undergo laparoscopic cholecystectomy under general anesthesia, able to communicate, fully understand the purpose and procedure of the study, and agree to participate sincerely. Patients taking



Note. D<sub>adm</sub>= admission date;D<sub>postop</sub>= after surgery on the day of operation;D<sub>postop#1</sub>= 1<sup>st</sup> day after surgery;D<sub>postop#2</sub>= 2<sup>nd</sup> day after surgery;D<sub>preop</sub>= before surgery on the day of operation

Figure 1. Study Design.

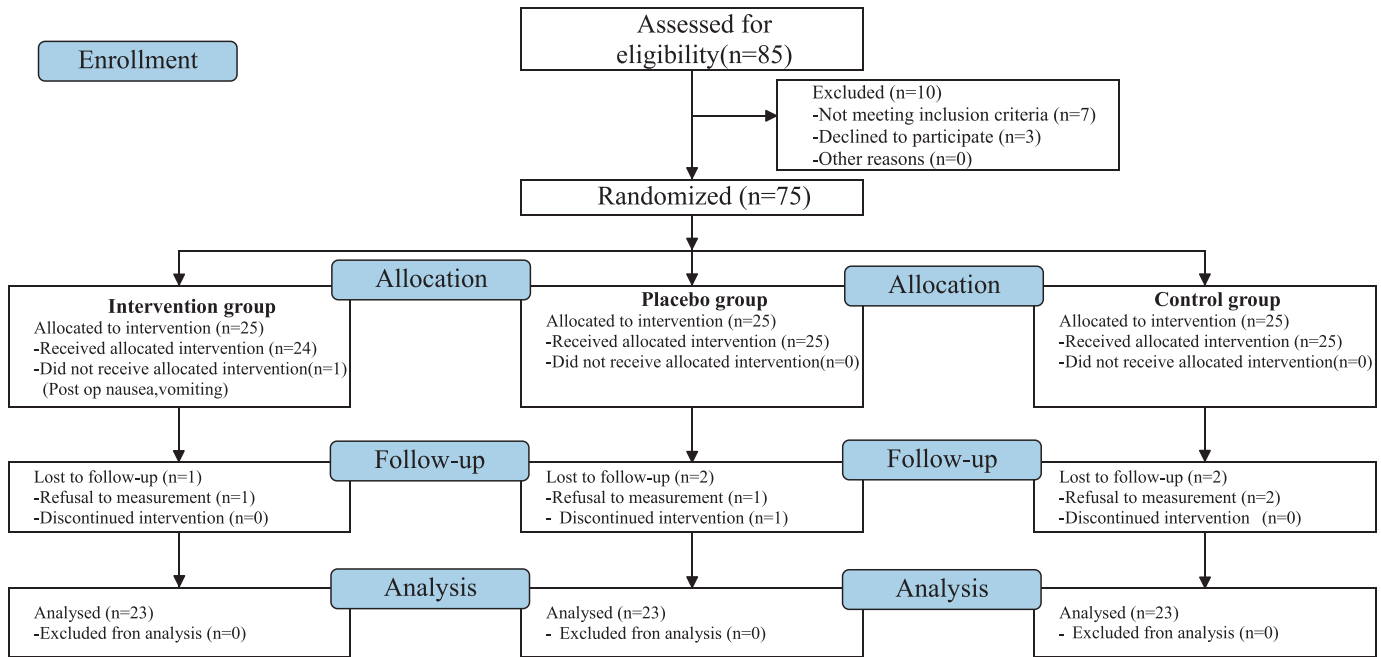


Figure 2. Flow Diagram.

antidepressants or sleeping pills, those with allergies that could affect inhalation of aroma essential oils, and those with low blood pressure were excluded. The 75 patients were chosen after the exclusion of seven patients taking antidepressants and sleeping pills and three who did not consent to participation in the study.

The study was conducted after randomly assigning 25 patients to each group—the intervention group, the placebo group, and the control group—using Excel’s random number method. No information was provided to the patients about their assigned group; however, for the researchers, blindness could not be maintained due to the nature of the aromatherapy intervention. During the study, one of the intervention group patients was unable to continue due to vomiting immediately after surgery, and another participant inhaled the aroma essential oil but then refused post-measurements to be obtained. One of the placebo group patients withdrew from the study after being unable to identify a smell, and another participant also withdrew because of the discomfort felt during postmeasurement. Two of the control group patients were excluded because they refused postmeasurement; therefore, the total study patients numbered 23 in each group (Figure 2).

**Outcomes**

*Baseline characteristics*

To confirm the homogeneity between the three groups, the patients completed a questionnaire on demographic characteristics.

*Primary outcomes*

**Stress.** For measuring the degree of stress perceived by the patients, subjective stress was measured using an 11-point numeric rating scale (NRS), from no stress (0 points) to extreme stress (10 points). The patients’ subjective stress was measured on the day of admission, the morning of surgery, immediately after surgery, and the first and second days following surgery (Figure 1). Objective stress was evaluated based on a stress index, sympathetic nerve activity, and parasympathetic nerve activity. The autonomic

nervous system was continuously measured for 2 minutes 30 seconds using Canopy9 professional 4.0 (IEMBIO, Chuncheon, Korea). This is a device that measures the degree of autonomic nervous system abnormality and stress using an accelerated pulse wave graph (APG) and heart rate variability (HRV). It is a method of measuring sympathetic and parasympathetic activity by quantifying a current stress state using a standard induction method. The machine is noninvasive and produces fast results. The stress index was based on HRV. The index ranged from 1 to 10—the higher the number, the more an individual was experiencing stress. As the measured sympathetic nerve activity increased and the measured parasympathetic nerve activity decreased, the more an individual was experiencing stress. Objective stress was measured on the day of hospitalization and the first and second days after surgery.

**Pain.** The pain experienced by the patients was measured using an 11-point numeric rating scale (NRS), from no pain (0 points) to severe pain (10 points). This was measured on the day of hospitalization, the morning of surgery, immediately after surgery, and the first and second days after surgery. Another method was to check the number of pain control injections. Since pain is a subjective concept, to objectively evaluate pain levels, administration records were checked to establish the number of times analgesics of the same component were administered.

*Secondary outcomes*

**Sleep quality.** For measuring sleep quality, the VSH sleep scale [30], translated by Kim et al. [31], was used after obtaining approval from the original author and the author of the translation. Eight of nine items were measured using a 10-point scale, resulting in a score ranging from 0 to 80 points: the higher the total score, the higher the quality of sleep. This was measured on the day of hospitalization, the morning of surgery, and the first and second days after surgery.

The reliability at the time of tool development was Cronbach’s  $\alpha = .82$ . The reliability of this study using Cronbach’s  $\alpha$  was  $\alpha = .83$ ,  $\alpha = .90$ ,  $\alpha = .70$ , and  $\alpha = .79$ , on the day of admission, the day of

surgery, the first day after surgery, and the second day after surgery, respectively.

### Intervention

In this study, routine postoperative care was provided to all patients according to the code of ethics. Essential oil therapy was given to the intervention group, almond oil therapy, chosen because the oil's color was similar to the essential oil used for the intervention group, was given to the placebo group, and routine care was received by the control group. The essential oils used in this study were produced by Neumond (website: <http://www.neumond.de>) and purchased from Bestbeing, Korea (website: <http://www.bestbeing.co.kr>). The oils used were selected and blended by MH, an international aromatherapist, and applied by inhalation following the instructions.

Essential oils can be classified into top notes, middle notes, and base notes [32]. The duration of fragrances varies depending on the oil, with top notes usually evaporating within 3 hours. The scent retention time of middle notes can be as short as 5 hours or as long as 3 days. As time passes, the reverberation becomes extremely light. The oils used in this study were ylang-ylang (middle note), lavender (middle note), marjoram (middle note), and neroli (middle or top note) [32]. Based on the characteristics of each oil, blending was conducted under the guidance of aroma experts. The lavender, ylang-ylang, marjoram, and neroli oils were mixed in a ratio of 5:2:1:0.5 and stored in a refrigerator.

The oils were inhaled immediately after surgery and again over the next two days. For the aroma intervention and placebo groups, three drops of oil were placed on an aroma stone located 30 cm from the patients' beds upon returning to their wards after surgery and at 9 pm. At 8:00 am and 9:00 pm on the first and second days following surgery, the aroma and almond oils were reapplied. All interventions and measurements were performed by the same researcher. For controlling confounding variables, different group patients were not placed in the same room, and intervention was performed outside of mealtimes to prevent contamination of the aroma fragrances with the smell of food. At the time of the intervention, no adverse reactions related to the aromas were experienced; however, one participant refused to continue, suffering from severe nausea following surgical anesthesia.

### Ethics approval and consent

The research proposal was submitted to the institutional review board of the Eulji Medical Center as per the regulations on research ethics and collected data after obtaining approval (Approval no. 2019-04-018). The patients were recruited through public announcements, and the purpose and procedure of the study, the inclusion/exclusion criteria, and the possibility of withdrawing freely at any time was explained. Upon agreeing to participate in the study, the patients were asked to provide written consent.

### Data collection

The data were collected at Eulji Medical Center in Daejeon City, South Korea, from June 1 to August 15, 2019. The researcher measured subjective stress, objective stress, pain, and sleep quality three to five times in total on the day of admission, the morning of surgery, immediately after surgery, and on days 1 and 2 after surgery. For protecting personal information, a unique ID was assigned to each patient. After the experiment, \$10 gift certificates were offered to the patients in each group.

### Data analyses

The collected data were analyzed using SPSS for Windows version 25.0 (IBM Corp., Armonk, NY, USA). The general characteristics of the patients were analyzed by frequency, percentage, and average. Verification of the homogeneity of the patients' general characteristics was confirmed by ANOVA,  $\chi^2$ -test, and Fisher's exact test. Verification of the homogeneity of the dependent variables of the three groups was analyzed using one-way ANOVA. The groups were also analyzed using ANOVA and repeated measures ANOVA to verify the effects of stress, pain, and quality of sleep before and after the intervention, and a posthoc test was performed using Scheffe's procedure. Additionally, the effect size was calculated by Cohen's *d* formula, and the significance was evaluated with a 95% confidence interval and a significance level less than 5.0%. In this study, per-protocol analysis was performed, and only patients who completed the performance in their assigned groups were analyzed. Missing data were processed and analyzed using listwise deletion; however, no cases were excluded due to missing values.

### Results

#### *The general characteristics of the patients and homogeneity verification*

There were 69 patients in this study, 23 in each group, and the mean ages were 47.78, 54.57, and 57.96 years in the intervention, placebo, and control groups, respectively. The patients' subjective stress, objective stress, parasympathetic activity, sympathetic activity, pain, and sleep quality were not significantly different among the three groups; therefore, the three groups were considered to be homogeneous (Table 1).

#### *Verification of the effects of aroma essential oil inhalation*

##### *Stress*

There was no significant difference in the stress scores between the groups on the day of admission, before surgery, and immediately after surgery. Immediately after the surgery and before the intervention, the subjective stress scores in the intervention, placebo, and control groups were 7.78, 7.30, and 6.96, respectively. After the intervention, the subjective stress scores on the first day after surgery were 1.22, 4.09, and 5.30 in the intervention, placebo, and control groups, respectively, and 0.65, 2.78, and 3.87 on the second day after surgery. Subjective stress was significantly different between the groups on the first ( $F = 29.24, p < .001$ ) and second day ( $F = 17.40, p < .001$ ) after surgery, and the effect sizes, 95% confidence interval of the intervention group versus the control group and the intervention group versus the placebo group were  $-2.40 (-3.16/-1.64)$  and  $-1.49 (-2.14/-0.83)$  on the first day after surgery, and  $1.86 (-2.56/-1.17)$  and  $-1.17 (-1.79/-0.54)$  on the second day after surgery, respectively (Table 2). There was a significant group-by-time interaction effect ( $F = 7.43, p < .001$ ).

There was no significant difference in objective stress on the day of admission, but there were significant differences between the groups on the first day ( $F = 7.14, p = .002$ ) and second day ( $F = 9.09, p < .001$ ) after surgery. The effect sizes, 95% confidence interval of the intervention versus the control group and the intervention versus placebo group were  $-1.03 (-1.65/-0.42)$  and  $-0.93 (-1.53/-0.32)$  on the first day after surgery, and  $-1.25 (-1.89/-0.62)$  and  $-1.14 (-1.76/-0.52)$  on the second day after surgery, respectively. There was a significant group-by-time interaction effect ( $F = 2.70, p < .034$ ).

There was no significant group-by-time interaction effect regarding sympathetic activity ( $F = 0.74, p = .566$ ); however, there

**Table 1** Homogeneity test of General Characteristics, Dependent Variables between the Three Groups (N = 69).

Characteristics	Category	Inter. (n = 23)	Plac. (n = 23)	Cont. (n = 23)	X <sup>2</sup> or F	p
		M(SD)or n (%)	M(SD)or n (%)	M(SD)or n (%)		
Age (yr)	Range	47.78 (11.72)	54.57 (16.49)	57.96 (12.91)	68.20	.668
Gender	Women	10 (43.5%)	11 (47.8%)	9 (39.1%)	0.35	.838
	Men	13 (56.5%)	12 (52.2%)	14 (60.9%)		
Job	No	4 (17.4%)	11 (47.8%)	10 (43.5%)	5.40	.067
	Yes	19 (82.6%)	12 (52.2%)	13 (56.5%)		
Subjective stress		4.04 (1.97)	3.35 (1.92)	3.96 (2.65)	0.68	.511
Objective stress		4.70 (2.12)	4.57 (2.04)	5.09 (2.23)	0.37	.690
Sympathetic nerve activity		4.88 (1.07)	4.46 (1.38)	4.46 (1.13)	0.95	.394
Parasympathetic nerve activity		4.40 (1.09)	4.27 (1.32)	4.23 (1.09)	0.14	.874
Pain		0.91 (1.65)	1.22 (2.06)	1.13 (2.12)	0.15	.863
Sleep quality		49.78 (15.58)	52.09 (13.31)	52.39 (12.79)	0.27	.765

Note. Cont. = Control group; Inter. = Intervention group; Plac. = Placebo group; SD = Standard deviation; Yr = Year.

was a significant group-by-time interaction effect concerning parasympathetic nerve activity ( $F = 2.65$ ,  $p = .036$ ) (Table 2).

### Pain

The patients' immediate pain after surgery was 9.70, 9.91, and 9.39 in the intervention, placebo, and control groups, respectively; there was no significant difference. Pain on the first day after surgery was 2.35, 5.04, and 5.52 in the intervention, placebo, and control groups, respectively; there were significant differences between the groups ( $F = 26.79$ ,  $p < .001$ ). Pain on the second day after surgery was 0.57, 3.74, and 3.43 in the intervention, placebo, and control groups, respectively; there were significant differences between the groups ( $F = 29.14$ ,  $p < .001$ ). There was also a significant group-by-time interaction effect ( $F = 8.74$ ,  $p < .001$ ). Furthermore, there was a significant difference between the groups regarding the frequency of analgesics administered ( $F = 22.43$ ,  $p < .001$ ). The effect sizes, 95% confidence interval of the intervention versus the control group and the intervention versus placebo group were  $-2.21$  ( $-2.94/-1.47$ ) and  $-1.68$  ( $-2.36/-1.01$ ) on the first day after surgery, and  $-2.13$  ( $-2.86/-1.41$ ) and  $-2.12$  ( $-2.85/-1.40$ ) on the second day after surgery, respectively (Table 2).

### Sleep quality

There were no significant differences in sleep quality among the groups before and on the first day after surgery. The quality of sleep improved in all three groups on the day after surgery and two days after surgery; however, the levels of improvement exhibited by the placebo and control groups were lower than the intervention group, with there being a significant difference in sleep quality on the second day after surgery ( $F = 26.36$ ,  $p < .001$ ). There was also a significant group-by-time interaction effect ( $F = 5.23$ ,  $p < .001$ ) (Table 2). The effect sizes, 95% confidence interval of the intervention versus the control group and the intervention versus placebo group were  $1.92$  ( $1.22/2.62$ ) and  $1.52$  ( $0.86/2.17$ ), respectively.

## Discussion

As the incidence of gallbladder disease increases, the number of laparoscopic cholecystectomies increases. Despite the stress, pain, and poor sleep quality that occur after such procedures, prior to this study, there had been no intervention research on laparoscopic cholecystectomy postoperative discomforts, hence the necessity for this study. This study involved men and women participants of various ages. The aim was to reduce the stress, pain, and deterioration of sleep quality experienced by patients following

laparoscopic cholecystectomy by applying an aroma essential oil inhalation method that was nonrepulsive, safe, and effective.

Regarding stress, the autonomic nervous system is distributed in internal organs and blood vessels, regulates vital functions, and is composed of sympathetic and parasympathetic nerves [12]. When the sympathetic nerve is excited in response to a sudden environmental change, phenomena such as an increase in blood pressure and an increase in heart rate occur, and the parasympathetic nerve plays a role in stabilizing the body [12]. Aroma essential oils can be classified into oils with calming parasympathetic properties and oils with stimulating sympathetic properties [22]. The aromatherapy essential oil used in this study comprised marjoram, neroli, and ylang-ylang, which affect the parasympathetic nervous system, and lavender, which maintains the balance of the autonomic nervous system [33]. This blended oil is understood to have helped relieve stress and increase the activity of parasympathetic nerves in the patients undergoing cholecystectomy.

The results in this study agree with the results of prior studies on aromatherapy examining the stress relief of coronary angiography patients [34] and the stress relief of nurses in specialized departments [16]. Furthermore, in studies on the general population, lavender has been found to enhance parasympathetic activity and have significant effects on stress relief and sleep [35]. Thus, based on the results of this study, the inhalation of essential oils blended with lavender, ylang-ylang, marjoram, and neroli is considered to be effective in relieving stress, enhancing parasympathetic nerve activity, and helping to calm people.

In this study, the analysis of the effect of aromatherapy on the pain experienced by patients following laparoscopic cholecystectomy identified significant differences between the intervention, placebo, and control groups. The patients in the intervention group experienced significantly lower pain than the patients in the other groups. In the 48 hours after surgery, the number of additional pain control measures employed besides regular analgesics was significantly lower in the intervention group than in the other groups. These results are consistent with the results of studies examining lavender, geranium, and peppermint oil hand massages given to vascular dialysis patients receiving arteriovenous fistula puncture treatment [36]; the inhalation of lavender oil [37]; the application of lavender oil to puncture sites [20]; lavender and roman chamomile oil used to treat tonsillectomy patients [27]; and a study finding that the inhalation of lavender oil reduced the number of painkillers administered to pediatric tonsillectomy patients [38]. Aromatherapy was found to alleviate pain in all of the studies. The findings in this study are considered to be the result of applying essential oils to calm patients. Thus, it appears clear that

**Table 2** Comparison of Stress, Pain, Sleep Quality between the Three Groups (N = 69).

Variables	Inter. G (n = 23)	Plac.G (n = 23)	Cont.G (n = 23)	Inter vs.Plac	Inter vs.Cont	F*	p	F(p)**
	Mean ± SD (CI 95%)	Mean ± SD (CI 95%)	Mean ± SD (CI 95%)	Effect Size	Effect Size			
<b>Subjective stress</b>								
D <sub>adm</sub>	4.04 ± 1.97 4.04 (3.19–4.89)	3.35 ± 1.92 3.35 (2.52–4.18)	3.96 ± 2.65 3.96 (2.81–5.10)			0.68	.511	Time 64.34 (<.001) G*T 7.43 (<.001) Group 6.83 (.002)
D <sub>preop</sub>	4.96 ± 2.402 4.96 (3.92–6.00)	4.96 ± 2.55 4.96 (3.85–6.06)	4.83 ± 2.04 4.83 (3.95–5.71)			0.46	.460	
D <sub>postop</sub>	7.78 ± 1.59 7.78 (7.09–8.47)	7.30 ± 2.03 7.30 (6.43–8.18)	6.96 ± 1.94 6.96 (6.12–7.80)			1.14	.327	
D <sub>postop#1</sub> (post test)	1.22 ± 1.68 <sup>a</sup> 1.22 (0.49–1.94)	4.09 ± 2.15 <sup>b</sup> 4.09 (3.16–5.02)	5.30 ± 1.72 <sup>b</sup> 5.30 (4.56–6.05)	1.49	2.40	29.24	<.001	
D <sub>postop#2</sub> (post test)	0.65 ± 1.43 <sup>a</sup> 0.65 (0.03–1.27)	2.78 ± 2.15 <sup>b</sup> 2.78 (1.85–3.71)	3.87 ± 1.98 <sup>b</sup> 3.87 (3.01–4.73)	1.17	1.86	17.40	<.001	
<b>Objective stress</b>								
D <sub>adm</sub>	4.70 ± 2.12 4.70 (3.78–5.61)	4.57 ± 2.04 4.57 (3.68–5.45)	5.09 ± 2.23 5.09 (4.12–6.05)			0.37	.690	Time 0.06 (.938) G*T 2.70 (.034) Group 6.47 (.003)
D <sub>postop#1</sub> (post test)	3.61 ± 1.41 <sup>a</sup> 3.61 (3.00–4.22)	5.04 ± 1.67 <sup>b</sup> 5.04 (4.32–5.76)	5.61 ± 2.35 <sup>b</sup> 5.61 (4.59–6.62)	0.93	1.03	7.14	.002	
D <sub>postop#2</sub> (post test)	3.13 ± 1.10 <sup>a</sup> 3.13 (2.65–3.61)	5.30 ± 2.46 <sup>b</sup> 5.30 (4.24–6.37)	5.61 ± 2.57 <sup>b</sup> 5.61 (4.50–6.72)	1.14	1.25	9.09	<.001	
<b>Sympathetic nerve activity</b>								
D <sub>adm</sub>	4.88 ± 1.07 4.88 (4.42–5.35)	4.46 ± 1.38 4.46 (3.87–5.06)	4.46 ± 1.13 4.46 (3.97–4.95)			0.95	.394	Time 0.50 (.607) G*T 0.74 (.566) Group 4.16 (.020)
D <sub>postop#1</sub> (post test)	5.17 ± 0.99 <sup>a</sup> 5.17 (4.74–5.60)	4.52 ± 0.92 <sup>b</sup> 4.52 (4.12–4.92)	4.13 ± 1.07 <sup>ab</sup> 4.13 (3.68–4.59)			6.41	.003	
D <sub>postop#2</sub> (post test)	4.85 ± 0.63 4.85 (4.57–5.12)	4.40 ± 1.37 4.40 (3.81–4.99)	4.22 ± 1.29 4.22 (3.66–4.77)			1.85	.165	
<b>Parasympathetic nerve activity</b>								
D <sub>adm</sub>	4.40 ± 1.09 4.40 (3.93–4.88)	4.27 ± 1.32 4.27 (3.70–4.84)	4.24 ± 1.09 4.24 (3.77–4.70)			0.14	.874	Time 0.18 (.840) G*T 2.65 (.036) Group 4.66 (.013)
D <sub>postop#1</sub> (post test)	4.98 ± 1.03 <sup>a</sup> 4.98 (4.54–5.43)	4.22 ± 1.04 <sup>b</sup> 4.22 (3.77–4.67)	3.96 ± 1.44 <sup>b</sup> 3.96 (3.34–4.58)			4.63	.013	
D <sub>postop#2</sub> (post test)	5.07 ± 0.71 <sup>a</sup> 5.07 (4.77–5.39)	4.00 ± 1.35 <sup>b</sup> 4.00 (3.42–4.59)	3.88 ± 1.47 <sup>b</sup> 3.88 (3.24–4.51)			6.70	.002	
<b>Pain</b>								
D <sub>adm</sub>	0.91 ± 1.65 0.91 (0.2–1.63)	1.22 ± 2.07 1.22 (0.32–2.11)	1.13 ± 2.12 1.13 (0.21–2.05)			0.15	.863	Time 405.46 (<.001) G*T 8.74 (<.001) Group 16.35 (<.001)
D <sub>preop</sub>	0.48 ± 1.12 0.48 (–0.01–0.96)	0.65 ± 1.97 0.65 (–0.20–1.50)	0.39 ± 0.94 0.39 (–0.02–0.80)			0.20	.817	
D <sub>postop</sub>	9.70 ± 1.02 9.70 (9.25–10.14)	9.91 ± 0.42 9.91 (9.73–10.09)	9.39 ± 1.25 9.39 (8.48–10.30)			0.84	.436	
D <sub>postop#1</sub> (post test)	2.35 ± 1.30 <sup>a</sup> 2.35 (1.79–2.91)	5.04 ± 1.85 <sup>b</sup> 5.04 (4.25–5.84)	5.52 ± 1.56 <sup>b</sup> 5.52 (4.85–6.20)	1.68	2.21	26.79	<.001	
D <sub>postop#2</sub> (post test)	0.57 ± 0.90 <sup>a</sup> 0.57 (0.18–0.95)	3.74 ± 1.91 <sup>b</sup> 3.74 (2.91–4.57)	3.43 ± 1.67 <sup>b</sup> 3.43 (2.71–4.16)	2.12	2.13	29.14	<.001	
<b>Frequency of analgesics administration</b>								
	1.83 ± 0.94 1.83 (1.42–2.23)	3.39 ± 0.78 3.39 (3.05–3.72)	3.48 ± 1.08 3.48 (3.01–3.95)			22.43	<.001	
<b>Sleep quality</b>								
D <sub>adm</sub>	49.78 ± 13.58 49.78 (43.91–55.65)	52.09 ± 11.31 52.09 (46.33–57.84)	52.30 ± 11.85 52.30 (47.18–57.43)			0.27	.765	Time 57.60 (<.001) G*T 5.23 (<.001) Group 0.65 (.528)
D <sub>preop</sub>	42.35 ± 13.25 42.35 (36.62–48.08)	50.17 ± 15.47 50.17 (43.48–56.87)	51.26 ± 15.66 51.26 (44.49–58.03)			2.47	.092	
D <sub>postop#1</sub> (post test)	57.00 ± 7.37 57.00 (53.81–60.19)	56.43 ± 5.77 56.43 (53.94–58.93)	53.52 ± 4.24 53.52 (51.69–55.36)	0.08	0.58	2.28	.111	
D <sub>postop#2</sub> (post test)	71.35 ± 4.10 <sup>a</sup> 71.35 (69.58–73.12)	65.09 ± 4.16 <sup>b</sup> 65.09 (63.29–66.88)	59.00 ± 8.11 <sup>c</sup> 59.00 (55.49–62.51)	1.52	1.92	26.36	<.001	

Note. CI= Confidence Interval; Cont. = Control group; D<sub>adm</sub> = admission date; D<sub>postop</sub> = after surgery on the day of operation; D<sub>postop#1</sub> = 1<sup>st</sup> day after surgery; D<sub>postop#2</sub> = 2<sup>nd</sup> day after surgery; D<sub>preop</sub> = before surgery on the day of operation; F\* = ANOVA; F\*\* = Repeated measurement ANOVA; Inter. = Intervention group; Mean ±SD = Mean ± Standard Deviation; Plac. = Placebo group. Means for each group with different superscript(a,b) indicate a significant difference (Scheffe' test; p<.05).

aromatherapy involving the inhalation of essential oils is effective in reducing pain.

Previous studies have shown the positive effects of aromatherapy on sleep quality. These studies have examined elderly patients [14], hospitalized cancer patients receiving hand massages using lavender oil [15], hemiplegic patients receiving hand, arm, and décollete massages using lavender, bergamot, and clary sage oils [21], and hypertension patients undergoing inhalation therapy using lavender, ylang-ylang, and marjoram oils [39]. However, in studies examining the application of lavender oil used in hand massages given to nursing students [40], there was no significant improvement in the quality of sleep. In sum, although aromatherapy has not been found effective in every study, several studies have identified a positive effect on sleep. In this study, the patients' subjective sleep quality increased after surgery, with the intervention group demonstrating a significantly higher quality of sleep. Thus, this study adds to the research demonstrating the positive effect of aromatherapy on sleep.

There are some limitations of this research. Despite the patients and the outcome measurer not being informed of the groups to which they were assigned, the essential oil used for the aromatherapy released a scent; therefore, the experiment could not be completely blind. This may have led to performance bias. Additionally, since there were few research participants, there is a limit to the external validity of generalizing the research results. Thus, to verify the effectiveness of aroma essential oil inhalation in alleviating stress, reducing pain, and improving sleep, further studies examining various aroma essential oils and various blending ratios to dependent variables, as well as analyses using a variety of indicators, are recommended.

## Conclusion

The results of this study showed that inhalation of a blended oil comprising lavender, ylang-ylang, marjoram, and neroli for two days following surgery relieves stress, alleviates pain, and is helpful for sleep. Thus, nursing intervention using a blended aromatherapy oil inhalation method will benefit postoperative patients by improving recovery times, thereby expediting their return to daily life.

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## Data availability

The data for this study are available from the corresponding author on reasonable request.

## Conflict of interest

The authors declare there is no conflict of interest.

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## Research Article

# Psychological Processes of Postpartum Mothers with Newborns Admitted to the Intensive Care Unit

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## SUMMARY

**Purpose:** This research aims to explore the psychological processes of postpartum mothers during the admission of their newborns to the intensive care unit. It is hoped that the findings from this study will serve as a reference for clinical medical staff in providing individual and holistic patient care.

**Methods:** Using grounded theory methodology, we collected data through semistructured, one-to-one in-depth interviews. When data saturation occurred, 12 participants were involved through the constant comparative analysis process.

**Results:** The psychological processes consisted of a core category and three main categories. The core category was “worrying about the baby and striving to fulfill maternal responsibilities.” The three main categories were as follows: “impact on the maternal role,” “recognition of the maternal identity,” and “exhibition of maternal role.” The entire process may be affected by intrinsic and extrinsic factors, such as breast milk supply, timing of skin-to-skin contact, seriousness of the newborn’s health conditions, the support system, and the style of postpartum confinement care.

**Conclusion:** It is recommended that the neonatal intensive care unit should adopt family-centered care, taking an initiative to empathize and care for the mother, assisting skin-to-skin contact for the mother and baby as soon as possible, maintaining established breastfeeding, providing the correct concept of postpartum care, and encouraging participation in support groups. These activities can reduce the impact of the situation on the maternal role and improve maternal identity recognition.

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## Introduction

Globally, there are at least 15 million preterm births every year, and the number of premature babies and preterm babies with very low birth weight is increasing year by year [1]. In 2018, the number of neonates born in Taiwan was 181,601 [2], among which premature babies accounted for approximately 8–10% and preterm babies with very low birth weight accounted for about 0.9%. The vital signs of babies born preterm and newborns with congenital abnormalities or diseases need to be monitored at all times in case of an emergency where they may need immediate attention to maintain physiological stability. They are often admitted to the intensive care

unit at birth. Approximately 80–90% of babies born prematurely are directly admitted to the neonatal intensive care unit after birth [3]. It is a joy for parents to give birth to a healthy newborn, but if the newborn needs to be treated in the intensive care unit due to premature delivery or disease, parents may experience tremendous psychological and societal stress, thus affecting their adaptation to the parent role [4]. In addition to worrying about the health conditions, sequelae, and future developmental issues of preterm infants, these parents face constant pain from the threat of potentially losing their babies. Such stresses often cause emotional shocks, lead to changes in the family system, and affect the quality of life. Moreover, parents’ mental health may be affected because they are often stuck in self-blame because of their inability to fulfill their responsibilities as a result of separation from their babies [5–7].

The results of previous studies in Taiwan related to experience of mothers with newborns admitted to the intensive care unit include grief reactions due to a newborn baby that were different from what they expected, including shock, fear, self-blame, crying, sleep disturbance, betraying the expectations of her in-laws, and

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worrying about the newborn's illness and prognostic, uncertainty, and striving to become a true mother [8]. Based on the principal investigator's 20-year clinical experience, the principal investigator has observed that medical staff and family members often focus on the newborns and overlook the mothers' emotional response and needs, inadvertently leaving the mothers in danger of experiencing emotional distress. Some medical staff may not even know how to respond to a mother's emotional breakdown. Past research has indicated that mothers with newborns in the intensive care unit often do not receive adequate mental and spiritual support, especially for their inner needs [4]. For example, there may be a lack of empathetic communication from medical staff, limited parent–child contact due to the separation from the infants, fear of getting close to the babies when visiting, self-blaming, and emotional crying. These mothers rarely receive proper assistance and timely support from the medical team [7].

The establishment of an early parent–child relationship is crucial for mothers and newborns and helps nurture the physical, psychological, and emotional development of newborns. Mother–child separation has a long-term impact on the parent–child relationship, which may continue into the child's school age [6]. Therefore, how to address the early separation between mothers and preterm babies in intensive care units effectively in a timely manner is an important topic that cannot be overlooked.

Other studies have pointed out that medical personnel is not only the primary caregivers of newborns but also the supporters of family adaptations [4]. If the medical team can actively support and assist mothers during their hospitalization, try to understand postpartum mothers' psychological processes, and put themselves in the shoes of these mothers, also help through the stressful [4]. Psychological processes are the mother's subjective description of the inner psychological process through memory, review, and experience [9]. Other helpful measures include keeping mothers apprised of newborns' conditions and treatment procedures, establishing a good doctor–patient relationship, actively listening to patients, assisting patients in coping with difficult situations and crises, helping patients avoid fear and insecurity, adopting a family-centered holistic care plan, elevating the mothers' and families' learning ability, strengthening the skills of mothers and families in baby care, providing useful channels of information, and caring for the mothers' life and emotional needs. These win–win measures can reduce mothers' depression, help mothers practice maternal roles, establish parent–child relationships, reduce patients' sense of loss from their separation from newborns, improve family functions, and reduce the negative impact on the family and infants [7,10,11].

In Taiwan, most studies on mothers' experience and adjustment process for experiencing premature birth did not really focus on the mother to systematically understand the psychological processes of postpartum mothers with newborns admitted to the intensive care unit. Furthermore, as research in Taiwan and abroad has rarely adopted qualitative grounded theory research methods to explore the psychological processes of postpartum mothers during their newborns' admission to the intensive care unit, the current research sought to address this gap. This article focuses on psychological processes of postpartum mothers with newborns admitted to the intensive care unit. The reason for choosing the grounded theory methodology for my study is that the psychological processes are a characteristic of time history, and it is suitable to use grounded theory to conduct research [12]. The aim is to explore psychological processes of postpartum mothers with newborns admitted to the intensive care unit. It is hoped that the findings from this study will serve as a reference for clinical medical staff in providing individual and holistic patient care.

## Methods

### Study design

This study used grounded theory methodology to explore Taiwanese postpartum mothers' psychological processes during their newborns' admission to the intensive care unit. Grounded theory emphasizes the importance of field data collection and analysis, mainly focusing on understanding human interactions and social processes [12].

### Settings and participants

In this study, data from 12 mothers were collected in the neonatal intensive care unit or pediatric outpatient clinic through purposive sampling at a medical center in northern Taiwan. Inclusion criteria included mothers who had newborn infants admitted to the intensive care unit within 6 months, a willingness to participate, provided informed consent, and the ability to communicate in Mandarin or the Taiwanese dialect. Mothers whose newborns passed away after being treated in the neonatal intensive care unit were excluded from this study. Table 1 presents the demographics of the study participants.

### Data collection

Data were collected from 2018 to 2019. After obtaining consent from the participants, interviews of all 12 subjects were conducted by the first author (C-K Lee) in the hospital's neonatal intensive care unit or pediatric outpatient consultation room. Following the semistructured interview guidelines, the researcher guided the participants in talking about key issues, including the following questions: "What did you experience during your baby's stay in the intensive care unit?", "How did you face or deal with what you experienced?", "What psychological shocks did you experience?", "How did you deal with them?", and "What else do you want to say?"

Each interview lasted about 50 to 60 minutes. To ensure that the participants could share their thoughts freely, they were assured that the contents would be deemed valuable and kept confidential. Each interview was recorded with the participant's prior approval.

**Table 1** Participant Characteristics (N = 12).

Characteristics	n	(%)
Age (years)		
25–30	6	50
31–35	6	50
Levels of education		
College	12	100
Marital status		
Married	12	100
Birth parity		
First born	10	83.3
Second child	2	16.7
Delivery mode		
Normal spontaneous delivery	7	58.3
Caesarean Section	5	41.7
Occupation		
Business	6	50
Medical industry	3	25
Housewife	3	25
Postpartum confinement customs		
Confinement by oneself	4	33.3
Confinement by husband's family	8	66.7
Reasons for admission to intensive care unit		
Preterm newborns	8	66.7
Rapid breathing caused by neonatal meconium aspiration	4	33.3

The recording was later transcribed into verbatim manuscripts by research staff and verified by the interviewees. To increase the richness and depth of the data being collected, the principal interviewer received qualitative research interview training and completed graduate-level courses to improve interviewing skills. The interview contents, wording, and questioning techniques were adjusted accordingly in consultation with qualitative research experts. Data collection continued until data saturation was reached in all categories, that is, until no new categories of information appeared.

### Data analysis

Data analysis consisted of three stages: open, axial, and selective coding. The first stage involved open coding and the development of substantive codes from a line-by-line examination of the data. Words, groups of words, or phrases were then categorized under a conceptual label. Subsequently, the categories and subcategories were connected according to their properties and dimensions in the axial coding process. Finally, the categories and subcategories were integrated and refined through a process of selective coding (Table 2). Example of the audit trials used for one category and subcategories in the study.

During the data analysis process, the data collection, sampling, and analysis of data involved constant comparative analysis. For example, inductive data helped to identify the category of events and feelings experienced by postpartum mothers during their newborn's admission to the intensive care unit. Researchers then applied deductive reasoning during the data analysis process to identify the factors affecting the degree of data saturation relating to postpartum mothers' psychological processes during the newborn's admission to the intensive care unit. Thus, findings were obtained inductively from the data collected and were confirmed deductively by a further theoretical sampling of the data.

### Research trustworthiness

The rigor was determined using four criteria: credibility, transferability, dependability, and confirmability [13]. In this study, credibility was ensured by a series of methods, including audit trial and member check. The researcher was flexible and open minded in the process of obtaining information from the participants. During the process of data collection, the researcher tried to avoid becoming deeply involved with the participants and tried to avoid being subjective in accepting or rejecting data. The researcher also

selected a natural and comfortable setting for the interviews. For example, the interviews were conducted in a private conference room to allow the participants to behave naturally. Objectively analyze the interview data, coupled with the researcher's own reflection, and constantly discuss with the instructor whether the text analysis is correct, to reduce the impact of research bias. In addition, to enhance the generalizability of the data, the participants' age, level of education, and occupation were not a part of the exclusion criteria. Therefore, the content described by the interviewees was rich, and the results of the study can be applied to cases with similar postpartum experiences.

### Ethical considerations

The research proposal was approved by the ethics committee of the Institutional Review Board (Approval no. FEMH-2018-C-071) of the northern medical center. The researcher ensured that the participants completely understood the informed consent form and that confidentiality was guaranteed. Personal details were changed to protect the mothers' anonymity. When the participants experienced psychological issues and were in need of support, the research team would refer them to social workers or psychologists.

## Results

### Participant characteristics

When data saturation was reached, a total of 12 mothers, aged 25 to 35 years, were interviewed. All of them were college graduates and married. Among them, eight mothers had their preterm newborns admitted to the intensive care unit (two were twins), and four mothers had their newborns admitted because of rapid breathing caused by neonatal meconium aspiration. In the following narratives, the participant of mother is abbreviated as P.

The result gave a core category and three main categories. The core category was "worrying about the baby and striving to fulfill maternal responsibilities." The three main categories were as follows: "impact on the maternal role," "recognition of the maternal identity," and "exhibition of maternal role." The entire process may have been affected by intrinsic and extrinsic factors, such as breast milk supply, skin-to-skin contact opportunities for mother and baby, seriousness of the newborn's health conditions, the support system, and the style of the traditional postpartum confinement care. The results are shown in Figure 1.

**Table 2** Example of the Audit Trials Used for One Category and Subcategories in the Study.

Significant statements	Concept	Subcategory	Category
"... I felt completely different from what I anticipated...I really cannot accept that." [P3]	Consisted of disbelief	The negative feelings	Impact on the maternal role
"...Why has this happened to me only..." [P5]	Self-blame		
"I was sorry because of my stupidity ... I blamed myself." [P5]	Melancholy		
"When I saw them, I feel guilty." [P6]	Melancholy	Inability to perform a mother's responsibilities	
"I felt a little depressed, and I cried inexplicably. I struggled with anxiety... I could not sleep." [P6]			
"I felt that life was hopeless, and I lacked confidence about the future... I was having a low mood..." [P7]	Could not hold newborns	Inability to perform a mother's responsibilities	
"I dared not hold my baby... I did not want to touch him because I feared he would have some kind of infection." [P6]	Could not care for newborns		
"... I could not even hold my baby... I felt incompetent and ill-suited to be a mother." [P11]	Could not feed newborns		

**Core category: worrying about the baby and striving to fulfill maternal responsibilities**

According to the findings of this study, the psychological process of postpartum mothers during their newborn's admission to the intensive care unit revolved around worrying about the baby and striving to fulfill maternal duties. The participants reported that during the newborn's stay in the intensive care unit, they were constantly worried about the changes in the baby's condition, fearing that they might lose the babies at any time, worrying about baby care issues after returning home, and feeling uncertain about the future.

*...I am afraid of losing him... [P2]*

*...Whenever I received a call from the hospital...I was afraid of receiving bad news. I felt a great deal of ambivalence. [P3]*

*I worry about how to take care of my baby when discharged from the hospital. [P5]*

In addition, in terms of striving to fulfill maternal responsibilities, this study found that although it was impossible for them to care for and feed their newborns, such as other mothers whose newborns were not in intensive care, the interviewees generally expressed that when they realized that they were mothers, and they felt that they would do their best to overcome all challenges. They would adjust to place their focus on the newborns,

give the babies the best treatments possible, and hope that they would get better and better.

*Pumping breast milk is something I can do for my baby; I would do my best to provide him the best nutrition possible. [P3]*

*Nothing else is more important than my baby; I don't care about anything else. [P12]*

**First categories: impact on the maternal role**

The impact on the maternal role included two subcategories: The negative feelings and the inability to perform a mother's responsibilities.

**The negative feelings**

The negative feelings consisted of disbelief, self-blame, and melancholy.

Most mothers were shocked and were unable to accept the facts when faced with a newborn baby that was different from what they expected. They felt disbelief.

*I imagined that he would be a baby with bright and lucent skin color...How could he be so tiny, and his skin color was dull, with tubes all over him...I felt completely different from what I anticipated...I really cannot accept that. [P3]*

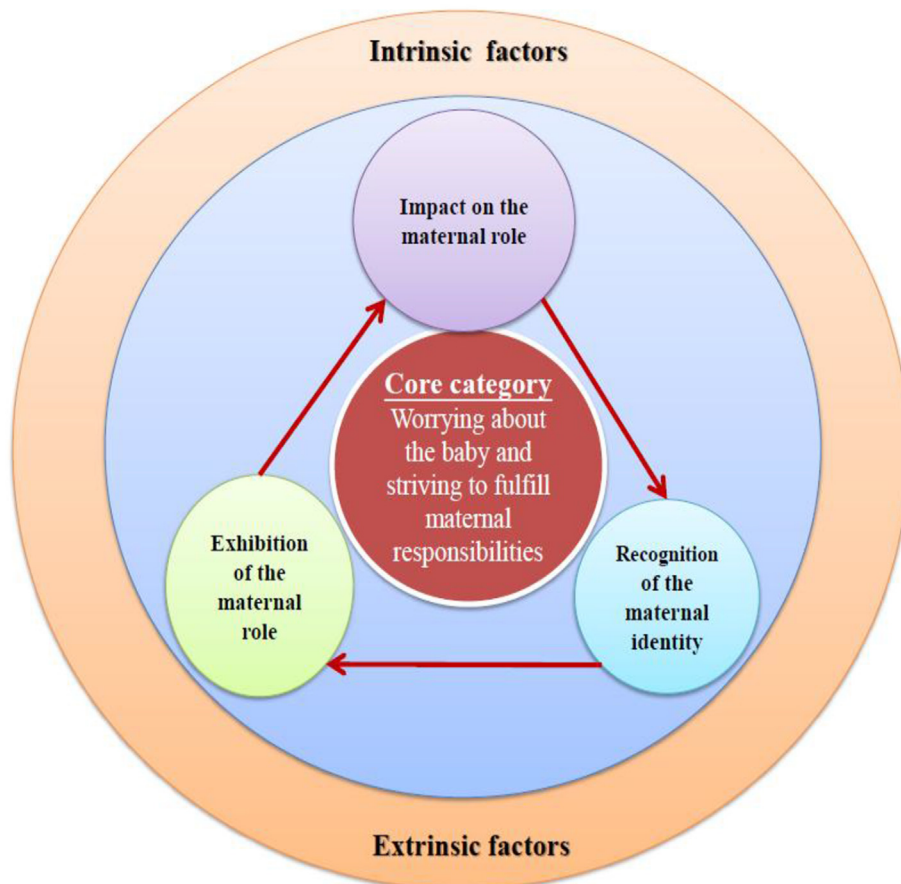


Figure 1. Psychological Processes of Postpartum Mothers with Newborns admitted to the Intensive Care Unit.

This study found that the participants believed that the newborns' conditions might have resulted from their negligence during pregnancy. They self-blamed and felt that they let their family members down.

*I kept telling her that I was sorry because of my stupidity. I let her suffer from premature birth. I blamed myself. [P5]*

*I disappointed my husband and parents-in-law. When I saw them, I apologized, and I cried. [P6]*

The mothers experienced deep feelings of sadness and frequent and inexplicable daily crying, which resulted from worries about their newborns, uncertainty about the newborns' status, and inability to care for and feed the babies. They felt melancholy.

*I felt a little depressed, and I cried inexplicably. I struggled with anxiety...I could not sleep. [P6]*

*I felt that life was hopeless...I was struggling with having a low mood...[P7]*

#### *Inability to perform a mother's responsibilities*

Most participants expressed that they could not hold, care for, and feed their newborns as other mothers could.

*I dared not hold my baby...I did not want to touch him because I feared he would have some kind of infection. I dared not touch premature babies in the past, not to mention how tiny he was, that made it harder for me to touch him. (P6).*

#### *Second categories: recognition of the maternal identity*

Recognition of the maternal identity involved three sub-categories: Truly feeling like a mother, mothers are strong, and undertaking the maternal responsibilities. The mothers in this study said that they felt distant when they first saw their newborns, but they experienced subtle feelings after their first skin-to-skin contact with the newborns. They recognized their maternal identity and wanted to be strong for the babies. They wanted to fulfill their responsibilities as a mother and were willing to adjust their expectations and accept reality.

#### *Truly feeling like a mother*

The participants said felt distant when they first saw their newborns. They feared to touch the newborns at first because they were afraid of the tubes and equipment connected to the newborns; after their first skin-to-skin contact with the baby, they recognized that the precious newborns were outcomes of their efforts during their pregnancies.

*After more than a month, I finally had my first contact with my baby. It was a wonderful feeling. I finally felt that she was really my baby, and I was a real mother. [P4]*

*When I first saw him, I doubted if he really was my child...I felt a little strange and unfamiliar...but after I touched him for the first time...I was deeply moved...He was born after the efforts of my eight months of pregnancy!... He is my heart..." [P12]*

#### *Mothers are strong*

In this study, the mothers expressed that having a newborn naturally stimulated their motherly love. To protect the babies and ensure that they grew up safely, mothers must become stronger to be able to face everything in life.

*I'm already a mother...If I feel sad, who is going to take care of my baby?... If I don't toughen up, who will take care of the kid for me. [P1]*

*The moment I touched him for the first time, I suddenly thought of the words 'All mothers are strong.' No matter what lies ahead, he is my child...I will take care of him for the rest of my life. [P9]*

#### *Undertaking the maternal responsibilities*

In this study, the participants indicated that despite the gap between expectations and reality in terms of their baby, no matter what the future held, they would accept reality by adjusting to the situation and undertaking the parenting responsibilities of raising the baby.

*If the baby cannot fully develop, or if the baby has a mental deficiency, I will accommodate and accompany him...I would discuss with my husband, adjust my work and family situation, and deal with whatever happens. [P3]*

*I would go with the flow; no matter what the future is for the child, I must take care of him. [P10]*

#### *Third categories: exhibition of maternal role*

Maternal role attainment consisted of two subcategories: Doing their best to fulfill their maternal responsibilities and self-adjustment in facing the future. Most mothers in this study said that their focus was on the newborns and that they did not care much about everything else. They would do everything in their power to fulfill their duties. In terms of the future, they would adjust themselves to face the challenge of uncertainties.

#### *Doing their best to fulfill their maternal responsibilities*

In this study, all mothers expressed that their lives were centered around their babies. They pumped milk for the newborns, learned new skills in caring for the newborns, gave the babies the utmost love, and hoped that the babies would grow up safely.

*I eat any food that helps to produce more milk...I dared not eat pig's feet in the past...but now I swallow them...I want to give my baby the best food... [P3]*

*I can also take the opportunity to learn how to take care of the baby once the baby can go home...When I have questions, I ask the nursing staff or search the internet. [P6]*

#### *Self-adjustment in facing the future*

Most mothers expressed that they experienced a sense of uncertainty about their newborns' health conditions and the future. They took various initiatives, such as keeping in shape, having a positive attitude, managing their emotions, balancing family and work, and actively seeking assistance, to prepare themselves and the newborns for future challenges.

*I went to see a Chinese medicine practitioner...because I needed to take good care of my body to face future challenges... [P1]*

*After praying, I feel a lot better... Prayers give me the strength to keep going... [P5]*

*I gave up my job...so I could take care of the baby... [P7]*

*There is a social media group for mothers with premature babies...I received a lot of relevant information and support that helped me... [P11]*

### *The entire process has been affected by intrinsic and extrinsic factors*

This study found that the main intrinsic factors that affected the mothers' psychological processes included breast milk supply and the timing of skin-to-skin contact with the babies. The extrinsic factors included the newborns' conditions, support systems, and the traditional postpartum confinement customs.

#### *Breast milk supply*

A small number of mothers in this study could not provide breast milk to their newborns because they were not able to pump enough breast milk. Their depression worsened because they could not perform their duties as a mother, which significantly impacted their maternal identity and maternal role attainment. However, when there was sufficient breast milk, the mothers could pump and feed the newborns. They felt that they were mothers, fulfilling their basic responsibilities for their babies. Thus, the impact of breast milk supply on their maternal identity was small.

*I really didn't have breast milk. I started crying. I was really depressed at the time and couldn't do anything for the baby... [P3]*

*I pumped quite a lot, and the amount is sufficient... I just want to stock as much as I can to help my baby...this is the least I can do for her. [P7]*

#### *Timing of skin-to-skin contact*

This study found that the timing of skin-to-skin contact between the mother and the newborn was an important factor affecting the mothers' psychological processes. It also affected the timing of the mothers' recognition of their maternal identity.

*It was more than a month before I felt the first contact...I finally felt that I was really a mother...very subtle feeling...[P2]*

*The first time I touched my baby was about one week after he was born...I felt his vitality when I touched him. [P7]*

#### *Seriousness of the newborns' health conditions*

In this study, most mothers self-blamed or had negative feelings about their newborns' unstable conditions. Many of the babies had numerous tubes and equipment attached to their bodies. The negativity, self-blame, and increased depression impacted the mothers' maternal role. A small number of babies deteriorated suddenly after their conditions stabilized. The mothers could not adjust their emotions to accept the change and continued to blame themselves for not taking good care of their newborns. This sudden change of the babies' status impacted the mothers' psychological processes, moving them away from fulfilling their maternal role. However, when the newborns were stable, the mothers' psychological processes and maternal identity were less affected.

*It caught my heart...seeing so many needles inserted into her body...so many machines were connected to her body. I blamed myself... [P7]*

*I may lose my baby at any time...I couldn't stop my negative thoughts, and I was really depressed... [P3]*

#### *Support system*

In this study, the support and encouragement from some participants' spouses and family members helped reduce the mothers' self-blame and depression. The situation thus had a smaller impact

on the maternal role. However, when there was a lack of spousal and family support, the impact was much greater. This study also found that empathy from the medical staff and their assistance with skin-to-skin contact between the mother and the baby reduced the mothers' self-blame and melancholy, lessened the negative impact on the maternal role, and enhanced the recognition of their maternal identity.

*My husband encouraged me constantly...My biggest supporter was my husband. [P3]*

*The doctor...told me not to blame myself because he knew that I blamed myself very much. Hearing what the doctor said...I felt at ease, a bit relaxed. [P12]*

*The nurse in the room...opened the incubator and taught me how to touch my baby appropriately, so I finally dared to touch her... [P8]*

#### *Traditional postpartum confinement customs*

In this study, mothers were restricted by traditional postpartum confinement customs and were not allowed to go outside of the house to visit their newborns or come into contact with their newborns. This caused the mothers to become more depressed, as they were unable to perform and fulfill any maternal responsibilities. The confinement had a great and profound effect on the maternal role. On the other hand, in this study, the participants had their own ideas about confinement and were not subject to all confinement rules. They visited the newborns daily, had a better understanding of the status of the newborn, and even had opportunities to feed the newborn and fulfill maternal duties. This revised postpartum confinement had less of an impact on maternal role attainment.

*My parents-in-law would not let me go out of the house because they were afraid that I would be affected by the wind...I was home waiting for them to tell me about the baby's condition...I felt that I had depression. [P4]*

*During the confinement period...I didn't have any breast milk. I couldn't feed my baby with breast milk...I couldn't fulfill my responsibility. I was so sad. [P11]*

*I put a lot of effort into pumping...I personally delivered it to the hospital every day for my baby...I had no time to be depressed. [P2]*

## **Discussion**

This study described the psychological processes and factors influencing postpartum mothers whose newborns were admitted to the intensive care unit. The results showed that the core category of "worrying about the baby and striving to fulfill maternal responsibilities" throughout the entire psychological process was similar to what was documented in past literature. Mothers often worry about their newborns' health conditions, fear the loss of their babies, and do not have the help of the medical team after discharge, among other things. When a mother recognizes her maternal identity, she will begin to rebalance her life, attempt to overcome all challenges, and seek assistance from external resources. In addition, mothers will familiarize themselves with the needs of the newborns, strive to carry out their maternal duties, and develop a positive perspective toward their experiences [4,14,15]. If the medical staff supports the mothers empathetically and actively provides information related to newborns and baby care skills, the mothers would be satisfied with their medical



experiences. Even if their needs and expectations associated with the newborns cannot be met, their stresses could be reduced, and their ability to cope with stress positively could be improved [4].

This study reported that postpartum mothers whose preterm or sick newborns needed treatments in the intensive care unit after birth often experienced many negative feelings, mismatched expectations, self-blaming, and depression. These findings are consistent with what has been reported in the literature. To date, many Taiwanese women still cannot escape from the stereotypical gender roles created in traditional Chinese society. They still strive to meet the spouse's and senior family members' expectations to have a son carry on the family name. If the family line cannot continue, these women bear considerable pressure, thereby resulting in negative feelings [14]. In addition, in both domestic and foreign societies, mothers are the main caregiver of newborns. Taiwan's current health insurance adopts the Diagnosis-Related Group system for hospitalizations related to childbirth. If a newborn continues to be hospitalized due to illness, the mother must be discharged first. Traditional postpartum confinement customs strongly discourage mothers from leaving the house, which prevents them from visiting their newborns at the hospital. The mother–child separation has a great impact on the fulfillment of maternal duties. In addition, family dysfunction, lack of support, or individual depressive tendencies may lead to postpartum depression, which may in turn affect parent–child interactions and create similar impacts on the maternal role [14,15]. During the study period, it was found that the support and encouragement from spouses were extremely important for the mothers. It is recommended that healthcare professionals take the initiative to encourage the patients' spouses, as part of the patient care instructions for families, to be caring and empathetic towards the mothers' emotional responses. This action can reduce the negative impact of the situation on the maternal role, which has also been suggested by previous literature [15]. Most mothers mentioned that empathy and assistance from the medical staff helped reduce their self-blame and depression. The opportunities offered by the medical staff for the mothers to carry out their maternal duties and establish parent–child relationships helped the mothers to reduce the sense of loss in their maternal identity. This finding is also consistent with the results of past literature [4].

A new finding from this study was that the mothers felt distant when they first saw their newborns. The mothers feared to touch the newborns at first because they were afraid of the tubes and equipment connected to the newborns. They were hesitant and feared that they would interfere with any procedures or cause infections to the babies, so they refrained from any physical contact. Some mothers even said that when they saw the newborns, they questioned, "Is she my child?" They felt that everything was unrealistic. However, as soon as the medical staff arranged for them to have skin-to-skin contact with the newborns, the mothers immediately felt that "she is really my child" and that they were mothers. The mentality that "mothers are strong" emerged spontaneously. Regarding the gap between reality and expectations relating to the newborns, the mothers were able to adjust their mindset, accept the newborns' conditions, and move forward with assuming the maternal responsibilities. Previous studies have pointed out that parent–child skin contact could enhance parent–child connection. Mothers' participation in caring for newborns and breastfeeding can help mothers feel capable and confident about fulfilling maternal responsibilities [7]. In this study, new finding an in-depth investigation further showed that the timing of the skin-to-skin contact was the turning point in recognizing their maternal identity. It was also the critical moment when the mothers began taking an initiative to carry out their maternal responsibilities. Thus, early skin-to-skin contact can help mothers develop their maternal

identity and turn their negative feelings into positive thinking. Recognition of the maternal identity is crucial in that it reduces the duration and extent of the impact of the newborns' admission to the intensive care unit on the mothers' maternal role.

Mothers said that their baby was the center of their life and that they did not care much about anything else. They strove to fulfill their maternal responsibilities and adjusted themselves to face the challenges of the uncertain future. Some mothers also mentioned that they benefited greatly from the suggestions shared by mothers who had similar experiences. Therefore, it is recommended that medical staff proactively provide referral resources to help mothers improve their learning ability and strengthen their caregiving skills. Furthermore, if hospital staff members are empathetic towards mothers' emotions as well as the challenges that they face in their lives, the stresses that mothers experience would be reduced. Empathy would also help mothers greatly in their attainment of the maternal role [15,16].

Findings from this study showed that the psychological processes could be affected by intrinsic and extrinsic factors, including (1) breast milk supply, (2) timing of skin-to-skin contact, (3) seriousness of the newborn's health conditions, (4) support system, and (5) traditional postpartum confinement customs.

- (1) Breast milk supply affects the impact of newborns' admission to the intensive care unit on mothers' maternal role attainment. As documented in past literature, mothers' participation in feeding babies is considered the only thing that they can do for the baby. Breast milk is beneficial for newborns, and more importantly, this feeding method can only be provided by the mother. Therefore, mothers feel that they are capable of taking care of the baby, and the impact on the maternal role is reduced [17]. Therefore, it is crucial to teach mothers how to breastfeed babies and maintain breast milk production.
- (2) Timing of skin-to-skin contact can potentially reduce the impact of the newborn's conditions on the maternal role. It is the turning point of maternal role attainment. This is an important new finding of this study. Therefore, when the mother first visits the baby, medical staff should assist mothers in establishing skin-to-skin contact with the baby, thus shortening the impact of the situation on the maternal role.
- (3) The increase in the mother's negative feelings as a result of the seriousness of the newborn's health conditions can greatly impact the maternal role. This finding is consistent with what has been reported in past research: the uncertainties of the newborns' survival, coupled with mothers' insufficient caregiving knowledge and concerns about the child's subsequent disability, developmental delays, and baby care challenges, can increase the mothers' stress [14,15]. But participants in this study were classified only as preterm newborns and rapid breathing babies (in Table 1). This is the limitation of this study.
- (4) In this study, the mothers expressed that empathy and support from family members (spouses in particular) and healthcare professionals can help the mother overcome the depression period. Other research has also reported that healthcare professionals, the internet, support groups, and mutual support from mothers or friends with the same experience are of great help to the establishment of parental roles [17]. In domestic societies and abroad, mothers often play the role of the main caregiver; therefore, more attention should be paid to mothers' emotions compared with those of other family members. When mothers cannot receive adequate support and empathy from a dysfunctional family

or medical staff, they often experience postpartum depression, which, in turn, affects parent–child interactions, as mentioned in the literature [15]. Therefore, the healthcare professionals' empathy towards the mother's feelings, appropriate support, and encouragement of parent–child skin-to-skin contact are critical factors affecting the maternal role and identity attainment.

- (5) Traditional postpartum confinement customs have many rules and restrictions with the goal of restoring the mothers' health to the status before pregnancy. Previous literature has documented that Taiwanese women cannot go to the hospital to visit their babies because of the restrictions imposed by traditional postpartum confinement customs. Such customs affect the fulfillment of maternal responsibilities and impact maternal role development [14]. Different from the findings of previous research, this study found that modern women have independent ideas. The traditional norms of confinement are no longer suitable. Most mothers are concerned about confinement, but they have different ideas. They are not subject to a specific pattern, and they use their own method of confinement to restore health. For example, they stay indoors as much as they can. When they have to go out, they bundle up to avoid catching a cold. They may also use Chinese medicine to help restore their strength. They order special confinement meals so that they can have a balanced diet to restore their body to the condition before pregnancy without any help from their mother or mother-in-law. They visit the babies at the hospital every day without restrictions. They stay updated on the newborn's status and even have opportunities to feed the newborns to fulfill their maternity responsibilities. This showed that traditional confinement customs may have minimal impact on maternal role attainment. However, the study also found that a small number of mothers were still affected by the traditional confinement customs because they lived with their mother or mother-in-law. They were pressured by their mother-in-law or mother to follow the rules, which were not to leave the house or visit their newborn babies. This caused the mothers to become more depressed and to feel incapable of performing and fulfilling their maternal duties. This situation caused a negative impact on maternal role attainment and maternal identity recognition. Because mothers' different views and ways of confinement can affect their psychological processes, it is recommended that healthcare professionals give the mothers and family members the correct concept and suggest methods of confinement so that the mothers can choose the most suitable way of confinement, reduce the impact of newborns' admission to the intensive care unit on the maternal role, and improve the fulfillment of the maternal role.

## Conclusions

The strengths of the study different from the findings of previous research, first using grounded theory to analyze the mother's psychological processes in the neonatal intensive care unit. The results may also help to reduce the impact of newborns' admission to the intensive care unit on mothers' maternal role and enhance mothers' self-confidence towards carrying out their maternal duties. The limitations of the study adopted. Because the mothers interviewed in this study were all married, the results from this study are not generalizable to teenage or single mothers.

The recommendations of this research for healthcare professionals include adopting a “family-centered” neonatal intensive

care unit care model, being empathetic, and implementing active listening when helping patients deal with the life challenges and emotional difficulties faced by mothers and their families. Other recommendations include setting up support groups to encourage sharing experiences and arranging for the mother and the baby to have skin-to-skin contact as early as possible to allow mothers to recognize their maternal identity early and turn their negative feelings into positive thinking. In addition, immediately after childbirth, mothers should be taught how to pump breast milk and maintain lactation to enhance their self-confidence towards their maternity roles. Using video systems to allow mothers to see their babies virtually can enhance the parent–child connection. Actively providing the correct concept and methods of postpartum confinement and helping mothers choose a method best suited for them can reduce the impact of the newborn's conditions on the maternal role and enhance the fulfillment of maternal responsibilities. It is also suggested that future research can further explore and construct a practical care theory for mothers with newborns admitted to the intensive care unit and provide a reference to clinical staff aiming to offer individualized and unique patient care.

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## Institutional review board

The institutional review board of the medical center in North Taiwan (Research Ethics Review Committee Far Eastern Memorial Hospital) approved the study (IRB No.: FEMH-106128-E).

## Conflict of interest

All authors declare that there are no conflicts of interest.

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## Research Article

## Using an Early Warning Score for Nurse Shift Patient Handover: Before-and-after Study

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## ABSTRACT

**Purpose:** This study aimed to examine the impact of using an early warning score for shift patient handover on nurse and patient outcomes.

**Methods:** A before-and-after study was conducted with nurses and patients in three general wards in a tertiary teaching hospital. A short-time nurse education on the National Early Warning Score 2 and the use of a checklist for score calculation were performed from June 4, 2019 to June 30, 2019. Outcomes of nurse response (safety competency, handover quality, teamwork, safety climate, and documentation of vital signs and clinical concerns), patient response (deterioration occurrence postadmission, hospitalization length, and discharge status), and adverse events (mortality, cardiopulmonary arrest, and unplanned intensive care unit admission) were measured using questionnaires and medical record reviews. Data from 89 nurses and 388 patients were analyzed.

**Results:** Regarding nurse outcomes, handover quality ( $p < .001$ ), teamwork ( $p = .004$ ), safety climate ( $p = .018$ ), and recordings of vital signs ( $p = .047$ ) and clinical concerns ( $p = .008$ ) increased after early warning score use. However, no significant change in the safety competency scores was observed. Regarding patient outcomes, there were no significant changes in the occurrence of deterioration, hospitalization length, discharge status, and occurrence of adverse events between preintervention and postintervention.

**Conclusion:** Despite no significant changes in patient outcomes, using a simple, evidence-based early warning score for patient handover enhanced socio-cultural factors for patient safety, with improved patient monitoring. The findings provide evidence that supports the active implementation of an early warning score to improve patient safety.

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## Introduction

Unnecessary patient harm related to medical management is a leading cause of disease burden in many countries [1,2]. Therefore, patient safety has become a critical issue for global healthcare. In particular, unanticipated clinical deterioration in hospital wards with increased inpatient complexity has received considerable attention. Approximately 1 in 30 inpatients met the criteria for calling a rapid response team at a single set of vital signs [3]. Over 20.0% of ward inpatients with no or low risk of deterioration on

admission experienced deteriorating conditions needing escalated care at 24 hours postadmission [4]. Early warning scores (EWSs) to detect and respond to patients' deterioration risks have been introduced to hospitals as a safety system [5]. Among them, weighted and aggregated EWSs, such as the modified early warning score (MEWS) and the National Early Warning Score (NEWS), have shown good abilities to predict serious adverse events of in-hospital mortality, unplanned transfer to intensive care units (ICUs), and cardiac arrest [6–8]. Although EWSs are routinely used in several countries such as Australia, the Netherlands, the United Kingdom, and the United States [9], efforts to use an EWS in an effective and efficient way in other countries are needed. In this regard, it is important to explore the impact of using EWSs in various settings.

Prior research has shown that the introduction of EWSs affects nurses' work performance and patient outcomes. For instance,

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nurses' vital sign measurements and observation recordings have improved [10–15]. An hour-long EWS education led to an improvement in safety culture and teamwork in surgical wards [16]. In addition, studies have demonstrated that EWS implementation positively affects patient outcomes by reducing events, such as in-hospital mortality, cardiac arrest, and unplanned ICU admission [14,17]. However, there have been inconsistent findings regarding the effect of EWSs on patient outcomes, including length of hospital stay [17,18]. A systematic review found that using EWSs impacted nurses' competence in assessing, referring, and coping with patients at risk of deterioration in contradictory ways [19]. These findings may indicate the necessity for additional studies on the impact of using EWSs in real practice on nurse and patient outcomes.

Nurses play an important role in caring for patients on the frontline. Effective patient handover between nurses is essential for providing safe and reliable care. However, handover can be a risk to patient safety because of the possibility of loss of patient care information. A recommended practice regarding patient handover is prioritizing the handover of patients at the highest risk of deterioration and clearly communicating patient stability [20]. EWSs can be used to prioritize patients at risk of deterioration during nurse shift handovers in hospital wards. The use of EWSs will facilitate communication among nurses.

Therefore, the purpose of this study was to examine the impact of using an EWS for patient handover on nurse and patient outcomes. The intervention was based on major factors affecting nurses' effective use of EWSs [21]. In addition, in outcome assessment, we used a categorical framework of nurse response, patient response, and adverse event occurrence based on previous studies regarding the effects of handover tools on improving patient safety [22]. The specific hypotheses were as follows: After using an EWS, (1) nurses' patient safety competency, handover quality, teamwork, safety climate, and documentation of vital signs and clinical concerns will be improved; (2) patient outcomes of deterioration occurrence and length of stay will decrease, and patient status at discharge will be improved; and (3) the occurrence of adverse events of unexpected in-hospital mortality, cardiopulmonary arrest, and unplanned transfer to ICUs will decrease.

## Methods

### Study design

We employed a before-and-after study design using a questionnaire and medical record review. We chose this design because nurses often work in teams at wards located close to one another, which could be a contamination threat. This study was part of a three-year project regarding human factors and systems approach for patient safety. This study reports on the impact of EWS use for patient handover in general wards.

### Settings and participants

This study was conducted in three general wards in a tertiary teaching hospital in Seoul, South Korea. The hospital had 851 inpatient beds and nurse staffing level 1 (<2.0 patients per nurse). The three study wards had 140 beds (48, 49, and 43). Nurses worked in shifts—day (07:00–15:00), evening (14:30–22:30), and night (22:00–07:30) duty—with a 30-minute shift handover time. Assuming a medium effect size (Cohen's  $d = 0.5$ ), based on the effect sizes of previous studies evaluating the impact of EWS education on nurses' knowledge, confidence, and performance [13,23], at least 34 subjects were required to achieve 80.0% power at a 5.0% level of significance using a two-tailed paired  $t$ -test. However, there

were differences in interventions and measured outcomes among studies. Thus, considering our study purpose and the sample sizes in similar studies [12,13,23], we invited all nurses who worked in the three wards. Of 90 nurses, 89 participated in the study. One nurse could not participate for personal reasons.

Medical records ( $\geq 19$  years and hospitalization length of  $\geq 2$  days) of patients discharged from the wards during the three months before and after EWS use were retrospectively reviewed. Assuming a medium effect size ( $d = 0.5$ ), based on the effect sizes of previous studies investigating the impact of EWS use on the frequency of vital sign recordings [10,11], at least 128 subjects (64 in each group) were needed to attain 80.0% power at a 5.0% level of significance, using a two-tailed independent two-sample  $t$ -test. However, there were differences in the measured outcomes among studies, and the interventions, including study settings and targeted patients were different from ours. Thus, a pragmatic sample size of approximately 250 per time period was determined based on similar studies [12]. For avoiding selection bias, samples were randomly chosen using a research randomizer (<https://www.randomizer.org/>). Planned admissions to ICUs or high-dependency beds for routine postoperative care were excluded. After deleting cases with incomplete data, we included a random sample of 388 patients: 188 patients before EWS use and 200 patients after EWS use (Figure 1).

### Intervention

Major factors affecting nurses' effective use of EWSs included education, support from a rapid response team, workload, familiarity with and advocacy for the patient, and clinical expertise [21]. In the study wards, a rapid response team was not implemented. The nurse staffing level was not changed during the study period. As nurses continuously worked in teams in their wards, we assumed that nurses' familiarity with and advocacy for the patient were similar. Clinical expertise was included as a participant characteristic [21]. Thus, we provided education on EWS use in two steps to facilitate nurses' use of it. This was motivated by the practical issue of gathering nurses together because they were working in shifts. In addition, nurse managers' support was considered important in facilitating the use of EWSs in practice. First, the first author trained head nurses in the study wards during an hour-long session on the NEWS version 2 (NEWS2) system, including NEWS2 calculation, score-dependent responses, and a checklist to confirm clinical concerns and calculate NEWS2. NEWS2 scores were calculated based on a weighted and aggregated scoring system using the parameters of respiration rate, oxygen saturation, oxygen supply, systolic blood pressure, pulse rate, consciousness level, and temperature [8,24]. The scores were categorized into four groups: low, low-medium, medium, and high risk, with recommendations for appropriate clinical responses [8]. The educational session duration was designed based on a previous study, considering a busy clinical practice [12]. We selected the NEWS2 because it was validated in Korean hospitals and had the highest performance [24]. Next, the trained head nurses educated nurses in small groups in their wards, including the use of shift handover time. For consistent nurse education, we explained the study protocol to head nurses and provided standardized educational material to ensure accurate delivery of the content. The first author visited the wards frequently to check that the content was being consistently delivered according to the study protocol. If necessary, the first author supported staff education by asking nurses whether they had any questions about NEWS2 education during her visits to the wards. In addition, we posted the NEWS2 system in the wards to facilitate recognition of the system and clinical response. Nurses were asked to use a checklist to calculate the NEWS2 system, focusing on patients at high risk of

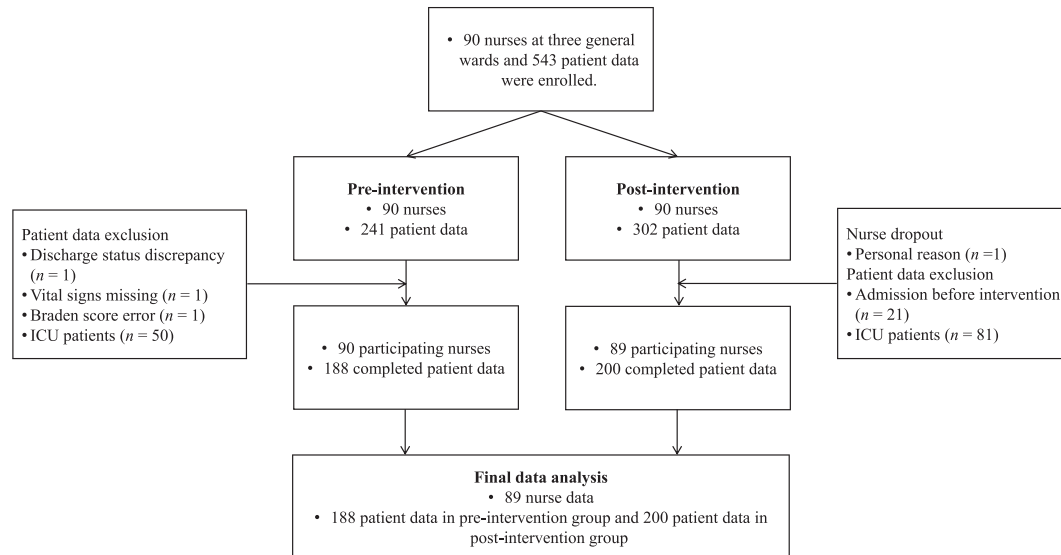


Figure 1. Flow diagram of the participants' selection process.

deterioration based on vital sign abnormalities [20]. The first author reviewed the completed checklists during her frequent visits to the wards. The checklist was used for two weeks. The checklists used from June 12, 2019 to June 30, 2019 were returned to the research team. After that, nurses were encouraged to use the NEWS2 to identify patients at high risk for deterioration without submission of completed checklists. Similar studies showed that knowledge and skills acquired from an hour-long EWS education were retained four months postintervention [12]. Thus, utilizing 30 minutes to one-hour-long education sessions on NEWS2 and checklist use for approximately two weeks was considered sufficient for learning the NEWS2 system.

### Outcomes

Nurse and patient outcomes were assessed using a framework of nurse response, patient response, and adverse event occurrence [22]. As a primary outcome, nurse response consisted of patient safety competency, handover quality, teamwork, safety climate, and recordings of vital signs and clinical concerns. Patient safety competency refers to the knowledge, skills, and attitudes concerning patient safety [25]. It was measured using 16 items rated on a 5-point Likert scale [25]. Handover quality refers to the degree of technical and nontechnical performance in patient handover and includes information transfer, shared understanding, and the working atmosphere [26]. It was measured using a 12-item modified patient handoff quality assessment tool rated on a 4-point scale [26,27]. Teamwork refers to perceptions of group-level team skills and behavior, and it comprises the components of team structure, leadership, communication, mutual support, and situation monitoring [28]. It was measured using the 35-item Teamwork Perceptions Questionnaire rated on a 5-point Likert scale [28]. Safety climate is defined as the perception of a strong and proactive organizational commitment to safety [29]. It was measured using the 7-item subscale of the Safety Attitudes Questionnaire rated on a 5-point Likert scale [29]. Higher scores indicated higher competency and more positive perceptions. These tools have been validated in Korean hospital settings [25,27,30]. In this study, the internal consistency reliability was .90, .83, .96, and .83, respectively.

The frequency of vital sign recordings was measured for the second hospitalization day based on the finding that deterioration

frequently occurred within two days after admission [6,24]. We included both the full and partial sets of vital sign measurements. Clinical concern refers to nurses' judgment or a feeling that something is wrong with a patient [31], and it is an indicator of clinical deterioration. It was measured using a modified clinical worry score [24,32] based on nursing records for 24 hours before the event for patients with adverse events and for 24 hours after admission for those without adverse events [24]. Clinical worry scores were calculated based on the existence of signs and symptoms that indicate deterioration, such as changes in breathing, changes in circulation, rigors, changes in mentation, agitation, pain, no progress, patients' comments, and subjective nurse observation [24,32]. Inter-rater reliability for the clinical worry score was calculated using nursing records from the total hospitalization days for two-week patient data before EWS use. Cohen's kappa value was 0.88, indicating excellent agreement. In addition, the first author re-reviewed a random sample of 30 patients to check the validity of the clinical worry scores. The agreement was 83.3%.

Patient responses included the occurrence of clinical deterioration, length of hospital stay, and discharge status. The occurrence of clinical deterioration was calculated in two ways: (1) the proportion of patients with a NEWS2 score  $\geq 2$  at approximately 24 hours after admission among those with a NEWS2 score of 0 or 1 at admission [4] and (2) the proportion of patients with an increase in NEWS2 risk category of  $\geq 1$  at 24 hours after admission. The length of stay and patient status at discharge (improved, maintained/diagnosis only, worsened, and death) were retrieved from the medical record system.

Adverse events included unexpected in-hospital mortality, unplanned admission to ICUs or higher-dependency treatment beds, and cardiopulmonary resuscitation (CPR). Unexpected mortality was defined as patient death without a do-not-resuscitate order [24].

### Data collection procedures

The preintervention survey was conducted using a self-report questionnaire from May 9, 2019 to May 22, 2019. The questionnaire included items on patient safety competency, handover quality, teamwork, and safety climate. We also collected data on nurses' age, sex, education, years of nursing, workplace, job position, and experiences of unexpected clinical deterioration in the

past six months on a 5-point scale from 1 (never) to 5 (very often). Questionnaires with return envelopes were distributed to nurses through the nursing department of the study hospital. The completed surveys were returned in the enclosed envelopes to a predetermined location in each ward for researcher collection. The intervention of nurse education and NEWS2 checklist use for intershift patient handover was implemented from June 4, 2019 to June 30, 2019. The postintervention survey was conducted using the same questionnaire between June 25, 2019 and July 5, 2019. Since the intervention completion time for nurse education and checklist use differed slightly due to the ward situation, the start date of the postintervention survey slightly differed between the wards. Random samples of medical records were retrospectively reviewed for vital sign measurements, recordings of clinical concerns, clinical deterioration, and occurrence of adverse events by the first author and a trained registered nurse. Data on patients' age, sex, education, marital status, height, weight, admission and discharge dates, discharge status, admission route and method, medical diagnoses, Morse Fall Scale score, Braden score, and acuity level were also collected. Patient acuity was classified into four levels, with a higher level indicating higher acuity [33].

### Ethical consideration

Ethical approval for the study protocol was received from the Institutional Review Board of the study hospital (Approval no. 2019-03-004). The participants were provided with explanations of the study's purpose and procedure, along with assurance of anonymity and data confidentiality. Written informed consent was obtained from all nurse participants. As an honorarium, each participant was given a gift card worth approximately 5 USD.

### Data analysis

Data were analyzed using SAS (version 9.4; SAS Institute Inc., Cary, NC, USA). The general characteristics of nurses and patients were summarized using descriptive statistics, such as frequency, percentage, mean, and standard deviation (SD). The responses regarding nurses' experiences of unexpected clinical deterioration were dichotomized into a "frequent" (4/5) or "infrequent" (1/2/3) experience. The discharge status was categorized into "improved" or "others." After Shapiro-Wilk tests for normality, we conducted paired *t*-tests or Wilcoxon signed-rank tests to determine differences in nurses' patient safety competency, handoff quality, teamwork, and safety climate before and after the intervention.

Independent *t*-tests and Chi-square tests were conducted to determine differences in general and disease-related patient characteristics between preintervention and postintervention. Independent *t*-tests were conducted to identify differences in the frequencies of vital sign recordings, clinical concerns, and length of stay between preintervention and postintervention. Chi-square tests or Fisher exact tests were performed to identify differences in clinical deterioration, discharge status, and adverse event occurrence between preintervention and postintervention. Statistical significance was set at a two-tailed  $p < .05$ .

## Results

### General characteristics and homogeneity of participating nurses and patients

The nurses' general characteristics are shown in Table 1. Their mean age was 31.48 years (SD 8.36; range = 23–56). The mean year of nursing ( $n = 69$ ) was 8.55 (SD 8.50; 95% confidence interval = 6.51–10.59). Of the nurses, 23.6% responded that they

frequently experienced unexpected clinical deterioration in the past six months, and 46.1% had the experience of CPR calls.

The patients' general and disease-related characteristics are shown in Table 2. The mean age was 65.22 years (SD 12.77) in the preintervention group and 62.80 years (SD 15.55) in the postintervention group. The two patient groups did not statistically differ with respect to general and disease-related characteristics (Table 2).

### Impact of using NEWS2 on nurse and patient outcomes

Scores for handover quality ( $t = 4.42, p < .001$ ), teamwork ( $z = 2.68, p = .004$ ), and safety climate ( $t = 2.42, p = .018$ ) significantly increased after NEWS2 use. The frequency of vital sign recordings ( $t = -1.99, p = .047$ ) and documentation of clinical concerns ( $t = -2.67, p = .008$ ) increased after NEWS2 use. However, there was no significant change in nurses' patient safety competency scores ( $t = 1.52, p = .133$ ) between pre- and post-NEWS2 use (Table 3).

The mean length of stay did not statistically differ between pre- and post-NEWS2 use ( $t = -0.08, p = .937$ ). The proportion of patients with NEWS2  $\geq 2$  at 24 hours postadmission among those with a NEWS2 score of 0 or 1 at admission was 18.6% and 23.5%, respectively. The proportion of patients with an increase in the NEWS2 risk category of  $\geq 1$  at 24 hours postadmission was 7.5% and 3.5%, respectively. These proportions did not statistically differ between pre- and post-NEWS2 use. In addition, the proportion of patients with improved health status at discharge was 97.3% and 94.0%, respectively. No significant difference in discharge status was found between pre- and post-NEWS2 use (Table 3).

Adverse events occurred in four of the preintervention patients and one of the postintervention patients: one died, two transferred to the ICU or treatment rooms, and one experienced cardiac arrest in the preintervention group; and there was one unplanned ICU admission in the postintervention group. The two patient groups did not statistically differ with respect to the occurrence of adverse events (Table 3).

## Discussion

This study demonstrated that using NEWS2 to prioritize patients at high risk for deterioration in nursing intershift communication improved the socio-cultural factors of handover quality, teamwork, and safety climate in the wards. In addition, it led to increased nursing documentation of patient conditions. Despite no significant changes in patient outcomes, these findings might

**Table 1** General Characteristics of Participating Nurses ( $N = 89$ ).

Variable	Category	<i>n</i>	%
Gender	Men	2	2.2
	Women	87	97.8
Age (years)	23–25	24	26.9
	26–30	27	30.3
	31–35	19	21.4
	36–56	19	21.4
Education	3-year college	4	4.5
	4-year university	68	76.4
	Graduate school	17	19.1
Ward type	A	35	39.3
	B	25	28.1
	C	29	32.6
Job position	Staff nurse	83	93.3
	Manager	6	6.7

Note. A, B, and C are the anonymous name of study wards.



**Table 2** General and Disease-related Characteristics of Patients.

Variable	Category	Preintervention (n = 188)		Postintervention (n = 200)		$\chi^2/t$	p
		n	%	n	%		
Gender	Men	110	58.5	110	55.0	0.49	.486
	Women	78	41.5	90	45.0		
Age (years)	<65	91	48.4	100	50.0	0.10	.753
	≥65	97	51.6	100	50.0		
	Mean (SD)	65.22	(12.77)	62.80	(15.55)		
Marital status	Married	163	86.7	166	83.0	3.03	.220
	Unmarried	10	5.3	20	10.0		
	Others <sup>a</sup>	15	8.0	14	7.0		
Education	Middle school or lower	27	14.4	26	13.0	4.13	.248
	High school	26	13.8	31	15.5		
	College or higher	15	8.0	28	14.0		
	Others <sup>a</sup>	120	63.8	115	57.5		
Body mass index <sup>b</sup>	Underweight	14	7.4	17	8.5	2.35	.503
	Normal	61	32.5	64	32.2		
	Overweight	46	24.5	37	18.6		
	Obese	67	35.6	81	40.7		
Admission route	Outpatient clinic	146	77.7	168	84.0	2.52	.112
	Emergency room/transferred	42	22.3	32	16.0		
Admission method	On foot	133	70.7	149	74.5	3.80	.150
	Using others' assistance/wheel chair	11	5.9	18	9.0		
	Using stretcher cart	44	23.4	33	16.5		
Primary medical diagnosis	Circulatory diseases	47	25.0	37	18.5	8.78	.118
	Neoplasm	46	24.5	43	21.5		
	Factors affecting health status	51	27.1	51	25.5		
	Digestive diseases	16	8.5	31	15.5		
	Respiratory disease	4	2.1	2	1.0		
	Others	24	12.8	36	18.0		
No. of additional medical diagnoses	0	16	8.5	19	9.5	2.10	.718
	1	21	11.2	30	15.0		
	2	28	14.9	27	13.5		
	3	33	17.5	28	14.0		
	4–14	90	47.9	96	48.0		
	Mean (SD)	3.86	(2.76)	3.73	(2.72)		
Morse fall score	Low risk	53	28.2	57	28.5	0.45	.650
	Moderate risk	95	50.5	98	49.0		
	High risk	40	21.3	45	22.5		
Braden score	No risk	178	94.7	180	90.0	4.69	.192 <sup>c</sup>
	Low risk	6	3.2	11	5.5		
	Moderate risk	3	1.6	3	1.5		
NEWS2 risk group on admission	High or very high risk	1	0.5	6	3.0	3.50	.358 <sup>c</sup>
	Low risk	178	94.7	185	92.5		
	Low-medium risk	8	4.3	7	3.5		
	Medium risk	1	0.5	5	2.5		
Patient acuity classification on admission	High risk	1	0.5	3	1.5	1.25	.777 <sup>c</sup>
	Level 1	2	1.0	5	2.5		
	Level 2	100	53.2	105	52.5		
	Level 3	77	41.0	82	41.0		
Ward type	Level 4	9	4.8	8	4.0	0.84	.656
	A	54	28.8	66	33.0		
	B	67	35.6	68	34.0		
	C	67	35.6	66	33.0		

Note. NEWS2 = National Early Warning Score version 2; SD = standard deviation.

A, B, and C are the anonymous name of study wards.

<sup>a</sup> This category included the “missing” response in medical records.

<sup>b</sup> n = 199 in the postintervention group.

<sup>c</sup> Fisher's exact test.

indicate that using evidence-based EWS for patient handover improved nurses' safety-related performance.

Interestingly, the use of NEWS2 enhanced handover quality, teamwork, and safety climate. This is similar to the finding of a previous study that reported improved teamwork after EWS education [16]. Using NEWS2 to assess patient condition may foster clear communication and understanding of the importance of patient information as a mutual agenda and provide an opportunity for cross-checking, thereby improving the quality of patient handover and teamwork. Most of all, the effect on handover quality was highest ( $d_2 = 0.49$ ). Furthermore, using NEWS2 to identify and

respond in a timely manner to deteriorating events strengthened nurses' value of prioritizing patient safety. However, there was no significant change in nurses' safety competency. This finding may indicate the need for multiple strategies to improve safety competency. Therefore, a structured approach for assessing the patient's condition and sharing information is recommended for shift patient handover in the wards. To do this, NEWS2 should be considered as a tool.

Nursing documentation of vital signs and clinical concerns increased after the use of NEWS2. This is consistent with the findings of previous studies [10,11,13,15]. In particular, the

**Table 3** Impacts of Using NEWS2 on Nurse and Patient Outcomes.

Variable	Preintervention		Postintervention		<i>t</i> <sup>a</sup> / <i>Z</i>	<i>p</i>
	Mean	SD	Mean	SD		
<i>Nurse response</i>						
Patient safety competency	3.37	0.39	3.43	0.45	1.52	.133
Handover quality	3.02	0.43	3.16	0.41	4.42	<.001
Teamwork	3.61	0.44	3.73	0.40	2.68 <sup>b</sup>	.004
Safety climate	3.29	0.57	3.41	0.58	2.42	.018
No. of vital signs recordings per day	5.18	3.95	6.11	5.15	-1.99	.047
Clinical concerns	0.58	0.85	0.82	0.89	-2.67	.008
<i>Patient response</i>						
Length of stay (days)	5.88	5.40	5.93	5.09	-0.08	.937
	<i>n</i>	%	<i>n</i>	%	$\chi^2$	<i>p</i>
Patients with clinical deterioration at 24 h after admission						
NEWS2 $\geq 2$ at 24 h postadmission from 0–1 on admission	35	18.6	47	23.5	1.39	.239
NEWS2 risk category increase $\geq 1$ at 24 h postadmission	14	7.5	7	3.5	2.95	.086
Patients with improved status at discharge	183	97.3	188	94.0	2.58	.108
<i>Occurrence of adverse event</i>						
Unanticipated mortality, unplanned admission to ICUs, or cardio-pulmonary resuscitation	4	2.1	1	0.5	2.02	.203 <sup>c</sup>

Note. NEWS2 = National Early Warning Score version 2; SD = standard deviation.

<sup>a</sup> Paired *t*-test or independent *t*-test.

<sup>b</sup> Wilcoxon signed-rank test.

<sup>c</sup> Fisher's exact test.

measurement of a partial set of vital signs, such as blood pressure and body temperature, increased. Generally, a full set of vital signs is routinely monitored every eight hours for all hospitalized patients in the wards. Although the frequency of vital sign measurements depends on the patient's condition, nurses' additional measurements of vital signs may reflect their clinical concerns about patients' deteriorating condition. In relation, the documentation of clinical concerns was enhanced. Considering that cases with critical deterioration during the study period were rare, this finding may indicate that education on the NEWS2 system raises nurses' awareness of the importance of vital sign measurements and promotes documentation of clinical concerns as a result of monitoring patient condition. Although there was not a large difference in the frequency of such documentation, it could increase nurses' workload in a busy clinical environment. Therefore, systems to support nurses' recordings of patient monitoring and observation data in electronic medical record systems should be designed to facilitate early detection and timely response to deterioration.

In the present study, approximately one in five patients with no or low deterioration risk at admission experienced deteriorating conditions requiring urgent ward-based responses at 24 hours postadmission. This is consistent with the findings of a previous study [4]. These findings may indicate the importance of patient monitoring during the early period of hospitalization to prevent further deterioration. However, despite a slightly decreasing trend in the occurrence of clinical deterioration after admission, no statistical significance was identified between pre- and post-NEWS2 use. This finding may be related to the fact that patient condition at 24 hours postadmission may be closely related to the patient's characteristics. The random samples did not differ for individual and disease-related characteristics. Although this study was conducted based on reports that deterioration frequently occurred within 48 hours after admission [6], additional studies with an expanded time frame for vital sign measurements are recommended.

The patients' length of stay and discharge status did not significantly differ between pre- and post-NEWS2 use. This was consistent with the findings of a previous study showing that there was no significant change after EWS use [17]. This finding may be due to an appropriate response to and management of deterioration. Additionally, it might be related to current practices of managing hospitalization length depending on patients' diseases.

As for adverse event occurrence, no significant changes were observed after NEWS2 use. This was consistent with the findings of a previous study [18] but differed from that of another study [14]. This finding may be attributable to the rarity of adverse events during the observation period of three months. Most patients were at no or low risk of deterioration. Another reason could be that 24/7 resident coverage was already in place in the wards [18].

To the best of our knowledge, this is the first study to apply NEWS2 to routine shift handover practice in general wards in Korean hospitals. Additionally, this study investigated the impact based on theoretical backgrounds [21,22] and had a high participation rate among nurses. For minimizing bias, random samples of patient data were analyzed. Our findings expand the body of knowledge on the effects of EWS use, especially on nurse response. The findings indicate that NEWS2 is easy to use and helps clarify communication about patient condition and prioritization of patients at risk for deterioration. Based on the current study findings, the use of evidence-based EWSs in daily practice should be encouraged. A checklist or poster for score calculation and appropriate responses will facilitate the use of EWSs. Further, efforts to support nurses' efficient use of EWSs should be made at the system level. Therefore, the introduction of an EWS in electronic medical record systems is recommended.

However, this study has several limitations. First, the generalizability of the findings is limited because this study was conducted with subjects in only three wards in a tertiary hospital. Second, although we analyzed randomly sampled patient data, the effects of the intervention were evaluated with a nonrandomized, before-and-after study design, which may affect the causal pathway. We could not exclude the impact of potential confounders, including secular trends and the Hawthorne effect, which could lead to an overestimation of the effectiveness. Thus, the findings must be interpreted cautiously. However, this study was conducted over a relatively short time period, and there were no significant changes that could have affected the participants during the study period. Meanwhile, the use of study designs, such as interrupted time series, could improve statistical analysis. Third, although studies have reported how the educational effects of EWSs were retained for up to six months [12], we did not address the long-term effects of the intervention. Fourth, the target subjects of the intervention were nurses. A multidisciplinary approach is recommended to fully

implement an EWS system. In addition, considering the rarity of adverse events, including mortality, we suggest that future studies should investigate the effects of EWS uses on patient outcomes with more patient data.

## Conclusion

While there was no impact on patient outcomes, the use of NEWS2 for patient handover positively influenced nursing practice. In particular, using NEWS2 led to better quality handoffs, enhanced teamwork, and improved safety culture. Furthermore, nurses' documentation of patients' condition improved. These findings have important implications for the adoption of evidence-based EWS. NEWS2 can be used as a common language to identify and better communicate with patients at high risk for deterioration. Further, we suggest that future studies focus on the effects of EWS use on patient experience and satisfaction as patient-centered outcomes, as well as healthcare utilization.

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## Conflict of interest

The authors declared no conflict of interest.

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## Research Article

# Effects of a Neonatal Supportive Positioning Training Video Program for Preterm Infants on the Knowledge and Performance of Nurses in Neonatal Intensive Care Units



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## SUMMARY

**Purpose:** The purpose of this study is to develop and apply a neonatal supportive positioning (NSP) training video program for premature infants, using a position support mat for nurses in neonatal intensive care units (NICUs), and to verify its effect on nurses' performance.

**Methods:** Thirty-five NICU nurses were included in the study. For the pre-test, preliminary check-ups were conducted, questionnaires about NSP knowledge on preterm infants were distributed, and NSP performance using neonatal dolls were video recorded for each participant. PowerPoint presentations and videos were used to educate participants on NSP. Furthermore, a 20-minute one-on-one training session was conducted using an NPS kit. Two weeks after the training, we repeated the process of distributing questionnaires about NSP knowledge and recording nurses' performance videos using neonatal dolls. Questionnaires and videos collected before and after the training were compared.

**Results:** After NSP training, the mean knowledge score of the participants improved significantly from  $23.71 \pm 3.62$  to  $29.51 \pm 2.29$  ( $Z = -5.09, p < .001$ ). The performance score for postural supportive positioning was  $38.03 \pm 7.46$  before training and  $80.06 \pm 9.85$  after receiving training, indicating a high-performance score after NSP training ( $Z = -5.16, p < .001$ ).

**Conclusion:** Our NSP training video program increased nurses' NSP knowledge and performance. Continuous training NICU nurses on NSP, using a standardized training video program, can help improve the care of premature infants.

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## Introduction

Globally, owing to the increase in maternal age and multiple pregnancies, 11.1% of childbirths occur prematurely, and this number continues to increase [1]. In Korea, the birth rate of premature infants under 37 weeks of age in 2019 was 8.1%, a 1.4-fold increase when compared to 2009 [2]. Although the advancement of medical technology has increased the survival rate of extremely low birth-weight infants, it has also increased the risk of long-term

problems, such as behavioral status, growth, and development, occurring along with short-term issues, such as medical and surgical problems related to short gestational periods and delays in behavioral status, growth, and development [3].

Generally, premature infants can survive after receiving essential medical treatment such as ventilator support and venous tube insertion in the neonatal intensive care unit (NICU) [4]. For premature infants, perinatal nerve damage and long-term prognosis are very important issues [5]. The risk of neurodevelopmental disorders in premature infants is higher than that in full-term infants [6]. The causes of neurodevelopmental disorders in premature infants include inadequate sensory stimulation exposure in NICUs, painful medical treatments [6], lack of routine care such as touching or handling babies, and bathing or weighing them [7,8]. Stress adversely affects the development of premature infants by affecting physiological processes and central nervous

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system organization [7,8]. Recognizing these factors led to the development of developmental supportive care (DSC) [9,10], which is a form of nursing that promotes neurosensory and emotional development, while reducing stress in premature infants during admission to the NICU [11]. It includes a space that provides clinical practices such as environmental management, sensory stimulation, interaction, and cooperation with family and medical staff related to the individual characteristics and needs of premature infants [9,10].

During developmental supportive care, the maintenance of an appropriate position for premature infants is an important factor [7]. Unlike full-term infants, premature infants develop from the tail to the head [7]. In addition, due to the limited experience of flexion in the uterus, the tension of the flexor muscles is not well developed, and thus there is no adequate strength and elasticity [7,11]. As a result, premature infants maintain their body in an outstretched position [12] and their developmental processes such as normal head control, hand and eye control, and normal standing are disturbed [7].

Furthermore, studies have also reported that the lack of appropriate neonatal supportive positioning (NSP) leads to deformation of the skeleton and muscles and affects brain development, leading to abnormal neurological signs [13]. In fact, motor development is delayed in premature infants compared to full-term infants [14], or self-regulation ability and oral feeding skills are poor [15]. For this reason, the neonatal intensive care unit recommends using various methods such as wrapping the premature infant in a blanket or making a border or nest to maintain the proper position of the premature infant [12]. Wrapping the baby in a swaddling bag is the easiest and safest way to support the position [16]. Posture support nursing, including wrapping with swaddling, is effective in maintaining the flexion of the extremities, not only in the development of muscles and nerve roots, but also in promoting self-regulation, improving motor skills, and reducing pain and hospitalization in premature infants [6,17,18].

NSP has a positive effect on the developmental process of premature infants; as such, position support care is very important for the optimal growth of premature infants [19]. One of the factors affecting the development of premature infants is their interaction with the environment and care providers [9]. Therefore, NSP is an essential practical skill for nurses in NICUs [9]. In order to provide effective NSP in nursing practice to premature infants, nurses must acquire knowledge and understanding of the necessity and precise methods involved [19]. However, it was found that nurses in NICUs lack knowledge about the purpose of NSP, the timing and principle of NSP provision, the development of muscle tone, and the ability to perform position support nursing [10,19]. Furthermore, nurses perceive the lack of nursing performance and lack of support for training as obstacles to developmental NSP [10,11]. Overseas, developmental assessment tools and NSP guidelines for premature infants are widely used in nursing practice [19,20]. However, in Korea, it is operated as a one-time educational program through job training at academic societies or hospitals [19]. In addition, standardized training programs are not yet utilized [19]. These circumstances may prevent nurses from applying NSPs to premature infants.

The purpose of this study was to develop and apply an NSP training video program for nurses in NICUs who care for premature infants, and to verify its effect on nurses' knowledge and performance. Our research hypotheses were 1) Nurses' NSP knowledge scores will be higher after receiving NSP training than before receiving training, 2) Nurses' NSP performance scores will be higher after receiving NSP training than before receiving training.

## Methods

### Design

This study employed a one group, pre- and post-test experimental design to evaluate the effectiveness of the NSP training video program for nurses in NICUs who care for premature infants.

### Participants

The participants were nurses who directly participate in nursing care for premature infants in the NICU of a tertiary hospital in Incheon, Korea. Nurses who received the NSP training for premature infants before, and who did not directly participate in nursing care for premature infants were excluded.

A commonly used indicator of effect size is Cohen's median effect size, which is suitable when the power is 0.8 or higher [21]. To identify the number of participants required for this study, G\*Power 3.1 program was used. For paired t-test analysis, when the median effect size was 0.5, significance level  $\alpha$  was 0.05, and power (1- $\beta$ ) was 0.80, 28 individuals was calculated as the minimum sample size. Based on this, and considering the dropout rate, 40 nurses were recruited. The final sample comprised 35 nurses, after excluding four nurses who transferred to another ward and one nurse who resigned.

### Research tools

#### Knowledge of NSP for premature infants

The NICU nurses' knowledge of NSP for premature infants was assessed using the knowledge of NSP assessment tool developed by Kim [22]. The tool consists of 33 items, with the five items pertaining to NSP methods and nine items pertaining to NSP theory. Regarding NSP method and its advantages and disadvantages for each position, there were nine items in the supine position, six items in the prone position, three items in the lateral position, and one item in the sitting position. For each question, correct answers were scored as 1 point, and incorrect answers and those marked "do not know" were scored 0. The total score ranged from 0 to 33, and the higher the score, the higher the knowledge about NSP. The Kuder–Richardson 20 (KR20) value was .75 at the time of scale development [22], and .59 in this study.

#### Performance of NSP for premature infants

To measure nurses' performance of NSP for premature infants, we used the assessment tool developed by Kim [22]. In order to increase the objectivity of the evaluation tool, Kim [22]'s scale was modified and supplemented as a checklist with reference to the guidelines for supporting the position of premature infants [23]. To verify the content validity and item reliability of the revised checklist, nine experts (five nurses with more than 10 years of clinical experience in the NICU, two neonatal physicians, and two nurses specializing in newborns) were consulted to verify whether the contents are appropriate, received, corrected, and supplemented. In accordance with the opinion of the experts, 17 items (1, 2, 4, 5, 6, 7, 8, 9, 10, 11, 12, 14, 15, 17, 19, 20) regarding the impact of not introducing the importance of holding and physical support were modified to the same extent as in the NSP Knowledge Educational materials. Item 3, 20, and 22 were kept the same as the contents of the position support education using the position support mat. Five items (16, 21, 23, 24, 25) that were different from the position support education developed in this study were deleted. The final tool consisted of 20 items, including items on

diaper change (1), holding (5), supine position (4), prone position (5), lateral position (4), and other (1). Each item was evaluated on a 5-point scale ranging from 5 (strongly agree) to 1 (strongly disagree), where a higher score indicated higher NSP performance. At the time of scale development, Cronbach's  $\alpha$  was .77 [22]; in this study, the pre-test Cronbach's  $\alpha$  was .83 and post-test Cronbach's  $\alpha$  was .85.

**Developmental support mat**

The NSP mat was (Positioning mat SSS/SS/S/M/L, AKACHANNO SHIRO CORP, Fukuoka, Japan) developed at Nagoya Metropolitan Children's Hospital in Japan to promote the development of premature infants through position support. In developmental nursing, nesting or swaddling babies to maintain a posture that resembles the fetal position is referred to as developmental support [24]. A developmental support mat can be used in both methods of nesting and swaddling, and it can be opened and closed in such a manner that it does not have to be removed during treatment or care. The mat helps in NSP performance, and the soft material helps to stabilize premature infants. Nakano et al. [25] observed that using the development support mat enabled proper posture in premature infants, which facilitates flexion posture and movement pattern toward the center of the body, similar to that of the fetus.

**Intervention: NSP training video program**

The NSP training video program for premature infants was developed based on the five steps of analysis, design, development, implementation, and evaluation of the ADDIE model [26], which is a teaching design model for systematically planning education (Figure 1).

**Analysis**

In order to confirm the details of the contents of the NSP training video program for premature infants, domestic and foreign literature [9,17,19,24,27] and postural support guidelines for premature infants [23] were reviewed. Through a literature review, the concept and components of nursing care for premature infants and developmental support were identified, and the contents, knowledge, and performance of positional support nursing for premature infants were derived. Through previous studies, it was found that nurses lacked accurate knowledge about supportive positioning, and that supportive positioning care was performed inappropriately [17,19].

**Design**

Based on the results derived from the analysis stage, the goal of the NSP training video program for premature infants was

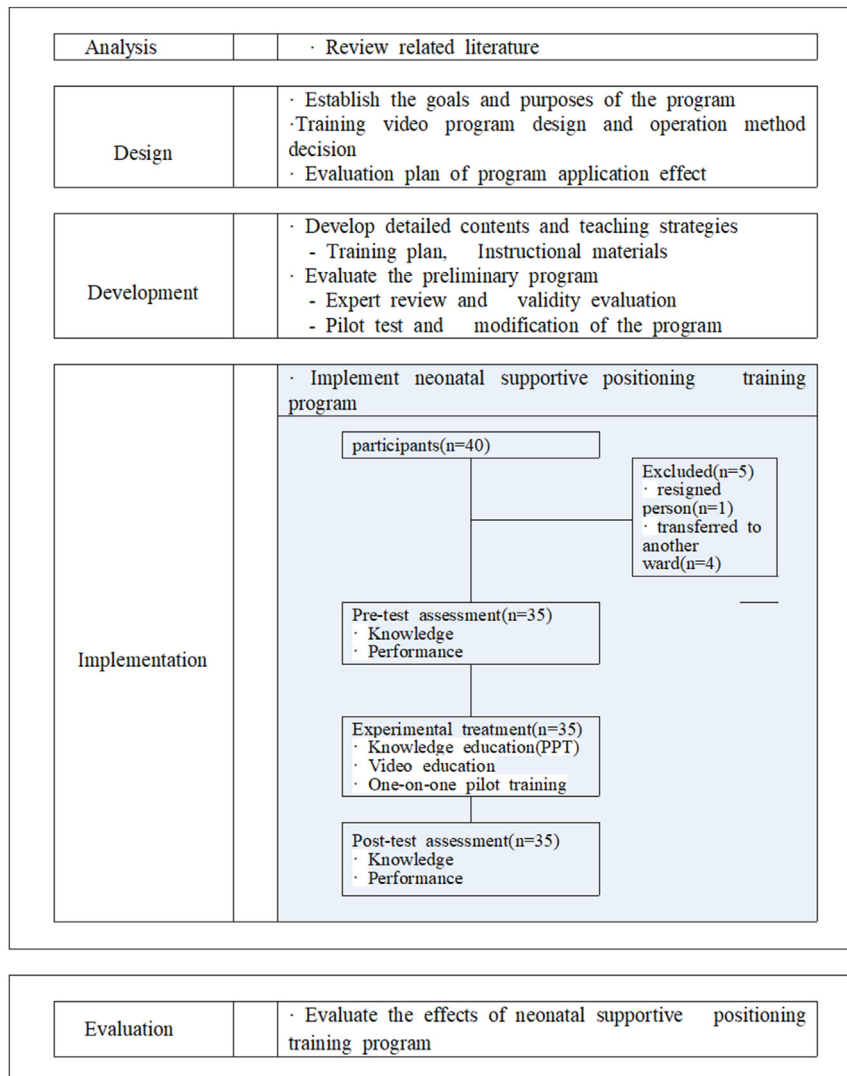


Figure 1. Process of Program Development (Gustafson & Branch, 2002).

established. Accordingly, a training program suitable for achieving that goal was designed, and an operation method was determined. The NSP training video program for premature infants was 62 minutes long and comprised three-stages (lecture, video education, and one-on-one pilot training).

#### Development

Lecture materials for NSP Knowledge Education were developed. To improve NSP performance ability, performance training materials using videos were developed.

##### (a) Lectures (NSP Knowledge Educational materials)

Knowledge-related information on positional support nursing for premature infants was developed based on a literature review. Educational materials were prepared in lecture format based on the definition of premature infants, the advantages of developmental nursing, positional support nursing, and positional supportive care. Information regarding symptoms that may appear when proper positional support is not provided and the ideal posture in supportive positioning care were also included. To verify and consequently improve the content validity of the training program, ten experts (five nurses with more than 10 years of clinical experience in the NICU, two nurses specializing in neonatal care, and three nurses specializing in newborns) were invited. In accordance with the opinions of the experts, all terms explained in the educational materials were corrected to textbook expressions. For instance, “low weight infants” was corrected to “low-birth-weight infants.” In the performance-related training materials, the importance of holding and the effect of not introducing positional support were corrected and supplemented. The content validity of the training program was .90.

##### (b) Video Education

Educational videos can help improve nurses' clinical skills and knowledge [28,29]. Therefore, video training materials were produced for performance-related educational content. The educational video used involved a diaper changing method that involved supine positioning using a position support nursing mat and a doll that was researched and developed at Nagoya Metropolitan Children's Hospital in Japan (Positioning mat SSS/SS/S/M/L, AKA-CHANNO SHIRO CORP, Fukuoka, Japan). To verify and consequently increase the content validity of the training program, ten experts (five nurses with more than 10 years of clinical experience in the NICU, two nurses specializing in neonatal care, and three nurses specializing in newborns) were consulted. In accordance with the opinions of experts, the content relating to the diaper change in the training video was revised and the video was re-filmed. The content validity of the training program was .78.

##### (c) One-on-one demonstration and performance training

A 20-minute-long one-on-one pilot training was conducted with participants who had completed the knowledge education involving a lecture and video. As premature infants are a vulnerable group and involving them in the study can cause ethical concerns, we conducted one-on-one pilot training and performance evaluation using a premature infant doll. The researcher performed one-on-one training demonstrations using a developmental support mat and a doll of a similar proportion to that of a premature infant. After the demonstration, the participants were asked to perform what they had learned on the preterm infant doll using a developmental support mat. The researcher corrected the participants' mistakes, if any.

#### Implementation

In the implementation stage, the NSP training video program for premature infants, completed through the stages of analysis, design, and development, was applied in the following phases: lecture, video, and one-on-one pilot training program.

To increase the evaluation credibility of the reviewers of the NSP performance checklist, the researcher (a nurse) and one neonatal medical doctor in the NICU compared the video training data with the NSP performance checklist. At this time, the evaluations for the item 1 and item 11 were different, so after sharing opinions, the standards were revised in the same as the contents of the position support education.

The video was evaluated by a researcher (nurse) and a neonatal medical doctor at a NICU. Before evaluating the video, the researcher (nurse) and the doctor checked the video in light of the training data and the postural support nursing performance checklist to define criteria for the evaluation system.

To confirm the reliability of the researcher's performance observation, one neonatal medical doctor at the NICU and the researcher observed five cases of the same performance video and evaluated it using the NSP performance checklist to determine the intra-class correlation coefficient. The agreement between the two was .91.

#### Procedure

This study was conducted from June 1 to August 28, 2019.

*Pre assessment.* NSP knowledge was assessed using self-report questionnaires. An incubator equipped with a camcorder (HDR-AS50, SONY, 2018) was set up in an independent room without patients. A doll of a similar size to that of premature infants and the NSP tools were prepared. The participants were asked to enter the room alone and to perform the NSP using the doll and relevant tools, which was recorded. The process of NSP was carried out by reviewing the video recorded using a camcorder installed in the incubator. The performance video was evaluated using the checklist by one researcher (nurse) and a neonatal medical doctor in the NICU.

#### Intervention

##### (a) Lecture (NSP knowledge educational materials)

Using the developed NSP training video program, this study utilized a researcher-conducted knowledge training via a lecture for 30 minutes at a time.

##### (b) Video Education

To increase the continuity of the educational effect, five days after the lecture, video training using educational videos was conducted for 12 minutes at a time.

##### (c) One-on-one demonstration and performance training

After video training, one-on-one training was provided. This training was conducted for 20 minutes at a time using the premature infant model and the NSP training video program (Table 1).

*Post assessment.* NSP knowledge was assessed using self-report questionnaires. In order to prevent the learning effect, two weeks after the experimental intervention [30], the participants were surveyed with a questionnaire about their knowledge of NSP. A video was recorded to investigate NSP performance. An incubator equipped with a camcorder (HDR-AS50, SONY, 2018) was set up in



**Table 1** Neonatal Supportive Positioning Training Video Program.

	Neonatal supportive positioning training video program contents	Methods	Time
Knowledge	<b>Developmental support nursing</b> · Causes of premature birth · Increased premature birth rate · Definition of premature infants · Characteristics of neonatal posture · Neuromuscular maturity assessment · Need for neonatal supportive positioning care · Possible effects of premature infants without proper position support · Efficacy of postural support nursing in the posture and motor development of premature infants	Lecture	15 min
	<b>Neonatal supportive positioning care of premature infants</b> · Purpose, principles, and methods of neonatal supportive positioning care · Neonatal supportive positioning care in the acute phase · Neonatal supportive positioning care in the stable phase · Standards of good posture · Preparation of posture · Order of use of the neonatal supportive positioning training video tool · Examples of using the neonatal supportive positioning care tool · How to take care of the neonatal supportive positioning care · Effects and cautions of using the neonatal supportive positioning care tool · Symptoms of incorrect positioning support care · Cautions of handling the care tool	Lecture	15 min
Performance	<b>Neonatal supportive positioning care video</b> · Supportive positioning care using cotton flannel · Changing diapers · Neonatal supportive positioning care using the tool and holding (supine->lateral->prone position)	Video	3 min 3 min 6 min
	<b>Neonatal supportive positioning care practice</b> · Diaper changing practice · Training and modification of diaper replacement practice and performance	One-on-one practice included using a doll	10 min
	· Supportive positioning care · one-on-one demonstration and performance training (supine->lateral->prone position)		10 min

an independent room without patients. A doll of a similar size to that of premature infants and the NSP tools were prepared. The participants were asked to enter the room alone and to perform NSP using the doll and relevant tools. The recorded video of the NSP process was reviewed.

The performance videos of the participants were evaluated using the performance of NSP for premature infant checklist. In order to minimize the halo effect, the video was evaluated by two people: one researcher (nurse) and one doctor. The findings of the medical doctor and researcher (nurse) were compared. Further, information on pre- and post-videos was not provided during performance evaluation.

#### Statistical analysis

The collected data were analyzed using the SPSS 25.0 (IBM Corp., Armonk, NY, USA), statistics program as follows.

- 1) To present the general characteristics of the participants, frequency, percentage, mean, and standard deviation (SD) were calculated.
- 2) To evaluate knowledge and performance of NSP, frequency, percentage, mean, and SD were calculated.
- 3) Wilcoxon signed-rank test was performed to analyze the differences between pre-and post-test knowledge and performance of NSP.

#### Ethical Considerations

To ensure the safety of the participants, this study was approved by the Institutional Review Board of G University (IRB NO: 1044396-201805-HR-122-01). Before collecting data, a consent

form for participation in the study was obtained from the nurses who voluntarily agreed to participate.

## Results

### General characteristics of the participants

A total of 35 nurses participated. Among them, 30 (85.7%) graduated with a four-year degree in nursing. Their mean age was  $24.89 \pm 2.56$  years. The mean clinical and NICU experience was  $2.10 \pm 2.23$  and  $1.70 \pm 1.77$  years, respectively, and all participants were general nurses. Thirty-four (97.1%) participants responded that NSP education was necessary and 21 (60.0%) reported excessive workload as the most common cause of its dearth (Table 2).

### Knowledge of NSP

To verify the effectiveness of the NSP training video program, the difference in knowledge before and after the intervention was assessed (Table 3). The knowledge score was  $23.71 \pm 3.62$  before NSP education and  $29.51 \pm 2.29$  after NSP education ( $Z = -5.09$ ,  $p < .001$ ). The research hypothesis 1 was supported.

Among the subcategories, the item "Extremely low birth weight infants are encouraged to take supine position during the first few days of life to prevent elevated cerebral blood flow" had the highest correct response rate with an increase of 54.3% after the program. The item with an increased incorrect answer rate was "Maintaining physiological flexion from around 36 weeks of gestation," with -5.7%.

### Performance of NSP

To verify the effectiveness of the NSP training video program, the difference in performance before and after the intervention was

**Table 2** General Characteristics of the Participants (N = 35).

Characteristics	Category	n (%)	M ± SD
Age (years)	23 ~ < 26	22 (62.9)	24.89 ± 2.56
	≥ 26	13 (37.1)	
Education	College	5 (14.3)	2.1 ± 2.23
	University	30 (85.7)	
Total clinical experience (years)	1 ~ < 3	25 (71.4)	2.1 ± 2.23
	≥ 3	10 (28.6)	
NICU experience (years)	1 ~ < 3	29 (82.9)	1.71 ± 1.77
	≥ 3	6 (17.1)	
Position	General nurse	35 (100)	
The need for neonatal supportive positioning care education	No	1 (2.9)	
	Yes	34 (97.1)	
Causes of lack of performance in neonatal supportive positioning care	Excessive workload	21 (60)	
	Lack of education and knowledge	9 (25.8)	
	Lack of resources to supportive positioning	3 (8.6)	
	Lack of awareness of supportive positioning	1 (2.8)	
	Risk of extubation and line deviation	1 (2.8)	

assessed (Table 4). The performance score for NSP was  $38.03 \pm 7.46$  before the training and  $80.06 \pm 9.85$  after training ( $Z = -5.16$ ,  $p < .001$ ). The research hypothesis 2 was supported.

Among the sub-items, the item with the highest percentage of correct answers after the implementation of the NSP training video program was “Always keep holding at least one hand even when changing posture,” showing a difference of 3.55 points out of 5.

The item with the lowest score after training was  $1.00 \pm 0.00$  for “Place a roll under the front ankle as your baby is in the prone position to keep the feet in a straight line,” which remained the same even after training.

## Discussion

We developed an NSP training video program and evaluated its effectiveness in improving NSP knowledge and performance of nurses in NICUs and the results of this study support positive developmental effects in premature infants. In particular, NSP education using lectures was included in the program so that NSP, which could increase the positive effect on the development of premature infants, could be performed. The participants also watched educational videos that were created to supplement and maximize the educational effect. Finally, by conducting a one-on-one demonstration and performance training, the participants' mistakes were corrected. This training program was designed to improve nurses' knowledge and performance by conducting a three-step program consisting of a lecture, video training, and a one-on-one demonstration and performance training.

The nurses who participated in this training program displayed a significant increase in their knowledge of NSP care for premature infants after training. This finding is similar to that of the study by Mohammed et al. [31], which verified the effects of NSP training in NICU nurses in Egypt and observed a significant increase in the knowledge score from  $12.3 \pm 4.4$  to  $18.0 \pm 2.4$  after NSP training. In addition, the same results as [11,32] showed a significant effect of providing developmental support nursing care on nurses' knowledge and performance before and after training regarding premature infants' sleep. The results of this study suggest that knowledge education improves the knowledge of the participants. Knowledge is acquired through training, and correct nursing is performed based on that knowledge [33]. In this study, the participants' knowledge improving as a consequence of education shows that

accurate knowledge was acquired through the NSP training video program, and that correct NSP can be practiced with premature infants based on this knowledge.

In this study, the score for performance of the NSP significantly increased by 42.03 points after receiving training. Through this, it can be seen that the NSP training video program for premature infants is effective in improving the nurse's NSP performance. This finding was consistent with the results of a study by Liaw et al. [34], in which 13 nurses in the NICU had a significantly increased performance score after the NSP training video program, along with positive changes in their nursing behavior. Furthermore, Jeanson [35] conducted a one-on-one on-site program for nurses in a NICU using a standardized infant position assessment tool and observed that the performance score increased from 8.3 before education to 8.7 and 9.2 during and after receiving the training, respectively. This indicates that nurses' performance level of NSP could be increased. Our results are consistent with those of this study.

Additionally, we observed that knowledge and performance scores in terms of NSP increased by the scores increased, respectively, after receiving training. This suggests that our training program had positive effects on both NSP knowledge and performance. In particular, since there were greater differences in the performance scores of NSP, the NSP training video program was considered to be effective. More effecting in improving performance ability than increasing knowledge. Education using videos, improves the clinical skills and knowledge of nurses [28,29]. It is thought that the video and one-on-one pilot training of the NSP training video program for premature infants developed in this study were the factors that maximized the educational effect. In addition, to further increase the effect on knowledge, it is necessary to provide and use continuous and standardized NSP training video programs, and not a one-time training program.

NSP in the early stages of life is fundamental in preventing developmental differences between premature and full-term infants, and for the optimal growth and development of premature infants [9]. In addition, it can be seen that systematic education on NSP is necessary for nurses in NICUs to provide appropriate NSP to premature infants. The NSP training video program developed in this study produced positive results on the knowledge and performance of NSP. This implies that the application of this training program can narrow the developmental gap between premature infants and full-term infants in the long-term. In addition, it can help in the proper motor development and growth of premature infants. Hence, it can be said that the NSP training video program for premature infants is a useful program that can improve nurses' NSP knowledge and performance, and support the growth and development of premature infants. Later the development of a systematic NSP training video program based on the theoretical basis and future studies applying NSP training are necessary. In addition, to further increase the effect on knowledge, it is considered that continuous and standardized NSP training, not one-time training, is necessary.

In this study, we observed that the NSP training video program positively affected the knowledge and performance of nurses especially those in the NICU. However, this study has several limitations. First, this study is limited, as the objective results on stress reduction in, and stability of, premature infants could not be assessed. Follow-up studies assessing whether nurses can provide psychological stability and comfort to premature infants by performing appropriate NSP using an objective indicator will be necessary. Second, in order to prevent the halo effect when evaluating performance, two researchers of this study conducted the evaluation comparing results, and did not provide information on the pre- and post-performance videos, but there is a limitation that suggests that the halo effect could not be completely excluded. In

**Table 3** Knowledge Scores for Neonatal Supportive Positioning Care (N = 35).

Items	Pre-Test n (%)	Post-Test n (%)	Differences in correct answer (%)	Pre	Post	Z	p	Differences M ± SD
				M ± SD	M ± SD			
Total Knowledge Scores				23.71 ± 3.62	29.51 ± 2.29	-5.09	< .001	5.8 ± 3.27
1. The uterine walls form a natural boundary for the developing fetus that acts to strengthen the muscle tone and provide resistance to fetal movement	33 (94.3)	34 (97.1)	2.8					
2. Maintaining physiological flexion from around 36 weeks of gestation	30 (85.7)	28 (80)	-5.7					
3. Premature infants are stable when maintaining physiological flexion	25 (71.4)	31 (88.6)	17.2					
4. Normal term infants without medical complications should be provided DP	3 (8.6)	13 (37.1)	28.5					
5. Before 38 weeks of gestation, the extensor muscle is more dominant than the flexor muscle	15 (42.9)	23 (65.7)	22.8					
6. Position change should be performed periodically to maintain the skin integrity of premature infants	31 (88.6)	33 (94.3)	5.7					
7. The skull of preterm infants and can be deformed if left in one position for a long time	34 (97.1)	35 (100)	2.9					
8. Keeping the baby's head in the midline of the body can reduce the risk of elevated intracranial pressure and intraventricular hemorrhage	20 (57.1)	33 (94.3)	37.2					
9. The higher the nesting, the more stable it	25 (71.4)	29 (82.9)	11.5					
10. When applying the nest, all sides of the body should touch the boundary of the nesting	28 (80)	34 (97.1)	17.1					
11. Nesting is not provided for babies undergoing phototherapy	28 (80)	33 (94.3)	14.3					
12. When swaddling a baby, wrap it tightly enough to inhibit spontaneous movement of the baby's torso and limbs	28 (80)	33 (94.3)	14.3					
13. Supine position has lower energy consumption than the prone position	20 (57.1)	24 (68.6)	11.5					
14. Supine position puts the infant at higher risk of aspiration than prone and lateral positions	31 (88.6)	30 (85.7)	-2.9					
15. Premature infants show more startle reflexes or disruptive movements in supine position than other positions	31 (88.6)	35 (100)	11.4					
16. In the supine position, it is difficult to maintain the flexion position because it is influenced by gravity	24 (68.6)	31 (88.6)	20					
17. If you do not provide supportive positioning in the supine position, premature baby's arms and legs may be externally rotated	27 (77.1)	33 (94.3)	17.2					
18. For the prevention of sudden infant death syndrome (SIDS), we recommend that you make the baby sleep in supine position	19 (54.3)	26 (74.3)	20					
19. Extremely low birth weight infants should be in supine position during the first few days of life to prevent elevated cerebral blood flow	13 (37.1)	32 (91.4)	54.3					
20. Attaching shoulder rolls in the supine position helps prevent excessive flexion of the neck and keep airway open	35 (100)	35 (100)	0					
21. The supine position increases the hyperextension and muscle tone of the head, neck, and shoulder compared to other positions	18 (51.4)	31 (88.6)	37.2					
22. When taking a prone position, the height of the pillow or roll under the head and chest should be 1 : 2	22 (62.9)	34 (97.1)	34.2					

(continued on next page)

**Table 3** (continued)

Items	Pre-Test n (%)	Post-Test n (%)	Differences in correct answer (%)	Pre	Post	Z	p	Differences M ± SD
				M ± SD	M ± SD			
23. The baby cries less and sleeps better in the supine position than prone position	30 (85.7)	34 (97.1)	11.4					
24. It is not easy for the baby to visually explore in the prone position	21 (60)	34 (97.1)	37.1					
25. Prone position is effective in improving the respiratory function of the baby, increasing the symmetry of the chest wall, and improving the gas exchange	22 (62.9)	32 (91.4)	28.5					
26. If the baby is placed in the prone position on a flat surface, it can be transformed into a frog-shaped leg by abduction or rotation	25 (71.4)	32 (91.4)	20					
27. When placing rolls or pillows under the baby's chest in prone position, the shoulders may become excessively extended if the width is wider than the gap between the shoulders	26 (74.3)	35 (100)	25.7					
28. Babies with inadequate physical activity are advised to take a lateral position to reduce the risk of aspiration	30 (85.7)	35 (100)	14.3					
29. Lateral position is a position that can minimize abduction and rotation of the hips	22 (62.9)	30 (85.7)	22.8					
30. When babies take a lateral position, their arms and legs are pulled toward the midline of body by gravity	23 (65.7)	28 (80)	14.3					
31. The sitting position is the recommended position for babies with severe gastric reflux	26 (74.3)	33 (34.3)	20					
32. If the width of the diaper placed between the baby's legs is too wide, the baby's hips and legs can be externally rotated	30 (85.7)	35 (100)	14.3					
33. The supportive positioning provided in the NICU affects the baby's neuro and motor development in the future	35 (100)	35 (100)	0					

Note. M = Mean; SD = Standard deviation.

**Table 4** Performance Scores for Neonatal Supportive Positioning Care (N = 35).

Items	Pre-Test M ± SD	Post-Test M ± SD	Difference	Z	p	Differences M ± SD
Total performance scores	38.03 ± 7.46	80.06 ± 9.85		-5.16	< .001	42.03 ± 10.17
1. When changing diapers, hold the baby's thighs and support the abdomen and hips	1.54 ± 0.92	3.89 ± 1.15	2.35			
2. Place the pillow under the shoulders, not head	3.06 ± 0.84	3.97 ± 1.12	0.97			
3. Hold the baby before doing anything that causes stress or pain to provide a sense of security	1.00 ± 0.00	3.54 ± 1.04	2.54			
4. When holding the baby, use the palm of your hand to provide direct touch	1.06 ± 0.24	4.29 ± 1.10	3.23			
5. When holding the baby, do enough over 30 seconds until the baby is stable	1.03 ± 0.17	3.66 ± 0.87	2.63			
6. Always keep holding at least one hand in the process of changing posture	1.11 ± 0.47	4.66 ± 0.94	3.55			
7. When in supine position, keep the baby's head on the center line of the body	2.43 ± 0.74	3.97 ± 0.51	1.54			
8. Put a pillow or roll under your shoulders when in supine position	3.14 ± 0.81	4.40 ± 1.22	1.26			
9. During supine position, bend legs so that the feet and hips are in a straight line and touch the lower wing	1.60 ± 1.06	3.46 ± 1.44	1.86			

**Table 4** (continued)

Items	Pre-Test M ± SD	Post-Test M ± SD	Difference	Z	p	Differences M ± SD
10. Before lying in the lateral position, hold the pillow between both arms and legs and hold it sufficiently	1.14 ± 0.49	3.34 ± 1.28	2.2			
11. When turning to the lateral position, roll and pull the baby like a log to avoid excessive stimulation	2.31 ± 0.96	4.37 ± 0.69	2.06			
12. When in lateral position, bend your legs so that your feet and hips are in a straight line and touch the lower wing	2.34 ± 0.87	4.23 ± 0.84	1.89			
13. When taking the lateral position, the baby's nose-neck-sternum-coccyx is maintained in a straight line	2.40 ± 0.88	4.40 ± 0.60	2			
14. When taking the prone position, put a pillow and a prostrate cushion on the baby's head and under the chest	2.77 ± 0.97	4.69 ± 0.83	1.92			
15. The pillow should have a ratio of 1:2 to the prone cushion	1.89 ± 0.83	4.43 ± 1.15	2.54			
16. Keep the prone cushion under the chest equal to the width of the baby's torso when in the prone position	1.86 ± 0.77	4.71 ± 0.79	2.85			
17. When tacking the prone position, roll the baby like a log without lifting the baby	1.91 ± 0.95	4.00 ± 0.87	2.09			
18. Place a roll under the front ankle if your baby is in the prone position, to keep the feet in a straight line	1.00 ± 0.00	1.00 ± 0.00	0			
19. Keep your hands close to your baby's face and around mouth	3.31 ± 1.23	4.66 ± 0.84	1.35			
20. After the posture change is completed, holding the baby for sufficient time and then release the hand.	1.11 ± 0.47	4.40 ± 0.91	3.29			

Note. M = Mean; SD = Standard deviation.

future studies, a follow-up study to prevent the halo effect using a complete double blocking device is needed. Third, the internal consistency of the knowledge measurement tool for NSP was low. Therefore, the score of knowledge may not have been perfectly measured in our sample. Lastly, this study was conducted on participants from a single institution. The researcher did not receive approval from the bioethics committee of other institutions owing to concerns about privacy and confidentiality because of the use of video recording. In order to prevent the testing effect that may occur during the experiment, a pre-test-post-test design was adopted. The post-inspection was conducted after a minimum duration of two weeks had passed since the pre-examination. However, it is possible that the potential exogenous variables were not fully controlled. In the future, follow-up studies are needed to prevent bias by using a control group at various institutions or to observe the actual performance of nurses. In spite of these limitations, this study tried to objectively confirm the change in the performance level by evaluating the performance level after NSP training through video recordings. In addition, it is meaningful that it provides the basis for standardized training materials that can be used in nursing practice using the position support mat created for the development of premature infants.

Based on the results of the study, we propose the following suggestions. First, in order to further solidify the validity of the training program, multidisciplinary experts involved in the nursing of premature infants need to confirm the content validity and carry out follow-up studies. Second, this study was conducted on nurses and, thus, cannot objectively assess stress reduction and stability in premature infants who are directly cared for by the nurses. Therefore, a follow-up study is needed on whether the provision of NSP provides stress reduction and stability for premature infants and can have positive results for development. Third, the target

population of this study is nurses in a NICU of a general hospital, therefore, the findings cannot be generalized and must be interpreted with caution owing to the limitations of experience and region. In future, a follow-up study must be conducted to verify the effectiveness of the knowledge and performance of NSP for nurses in NICUs considering various regions and clinical career.

## Conclusion

Despite the dearth of prior research on the development of NSP programs in Korea, this study developed a systematic NSP training video program and assessed its effects on nurses' education and performance regarding NSP. The NSP training video program for nurses in the NICU significantly improved the scores for knowledge and performance of NSP. In view of these results, the NSP training video program for premature infants can be said to be an effective nursing education program to improve the NSP knowledge and performance ability of nurses in NICUs. Our findings can help systematize NSP training and improve the knowledge and performance of nurses who provide direct nursing for premature infants.

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## Ethics approval and consent to participate

Informed written consent was obtained from all participants in accordance with the Declaration of Helsinki guidelines. The Institutional Review Board of Gachon University approved the study protocol (Approval no.: 1044396-201805-HR-122-01).

## Conflict of interest

The author declares no conflicts of interest.

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## Research Article

## Influencing Factors on Nursing Students' Learning Flow during the COVID-19 Pandemic: A Mixed Method Research

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## SUMMARY

**Purpose:** This study aimed to investigate the factors affecting nursing students' learning flow in COVID-19 pandemic situations through mixed-method research.**Method:** Of the 245 nursing students participating in the survey, 20 participated in a focus group interview. Quantitative data were analyzed using stepwise multiple regression analysis. Qualitative data were analyzed using content analysis.**Results:** The factors affecting the learning flow of nursing students during the COVID-19 pandemic were their self-regulated learning ability ( $\beta = .24, p = .001$ ); learning motivation ( $\beta = .23, p = .001$ ); self-efficacy in clinical practice ( $\beta = .14, p = .014$ ); and lecture type, or a mixture of recorded and real-time video lectures ( $\beta = .13, p = .022$ ). As a result of the qualitative study, eight categories and 22 subcategories were derived. The eight categories are: a lack of preparation in the starting of virtual classes, adapting and growing in a new learning environment, enhancing nursing knowledge and skills through virtual clinical training, self-regulation difficulties when studying alone due to social distancing, difficulty concentrating when learning online, disadvantages of virtual learning, concerns about academic performance, and missing opportunities to enjoy college life.**Conclusion:** Students attempted to discover their own learning expertise through virtual learning while concerned that they would be unable to fully establish their competence to work as actual hospital nurses due to a lack of clinical practice. In such a learning environment, systematic support and strategies are needed to increase the learning flow of nursing students.© 2022 Korean Society of Nursing Science. Published by Elsevier BV. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

## Introduction

The world was significantly impacted by the coronavirus (COVID-19) pandemic in 2020. As each country was quarantined to prevent virus transmission, people experienced significant changes in their daily lives. Although students and instructors were not fully prepared, virtual lectures began online during the national disaster situation [1].

When the COVID-19 pandemic struck in 2020, Korea converted most university classes to virtual instruction as a part of social distancing and in accordance with the Ministry of Education guidelines. Clinical practice has also been restricted in healthcare

centers for the safety of patients and students [2]. Nursing students were also required to take online classes to prepare for clinical practicums, which required nursing competency in the healthcare field [3], as well as national certification exams. Nursing students in the COVID-19 situation have experienced significant changes in their learning, such as a decrease in clinical practice due to virtual classes, difficulty concentrating on continuous learning [4], and difficulty interacting due to a decrease in direct contact with instructors [5]. Nursing students needed to maximize their potential and maintain high concentration in the process of acquiring theoretical and practical skills to grow as healthcare workers in this changing learning environment.

The learning flow piques the learner's interest in learning and encourages students to participate in active learning activities [6]. Virtual classes reduce the interaction between instructors and students, and a lack of study-related equipment reduces learning flow [1,5]. Clinical practice is also limited in terms of acquiring various nursing roles because it is based solely on indirect

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experiences within a limited virtual scenario [7]. Consequently, a strategy is required to enable nursing students to immerse themselves in learning and facilitate high academic achievement, even in virtual learning environments.

Self-regulated learning is one strategic effort to achieve a high learning flow [8]. Learners with self-regulated learning abilities engage in goal-oriented behaviors during the learning process and can demonstrate high concentration by practicing academic self-regulation, or specifically, by developing and implementing learning strategies [8]. During the COVID-19 pandemic, in which sudden changes have resulted in virtual classes, the learner's ability to self-regulate their learning is especially important because each learner must learn at their own pace without the assistance of peers or instructors [9].

Students with high self-efficacy also have confidence in their ability to complete tasks and have a strong sense of emotional control, which leads to a high learning flow experience and successful academic achievement [10]. Nursing students with a high sense of self-efficacy can positively control and cope with their emotions, allowing them to actively participate in clinical practice [11]. To respond effectively and creatively to the rapidly changing clinical practice educational environment caused by the COVID-19 pandemic, nursing students must believe that they can complete tasks without abandoning them, even in challenging situations.

Instructors can induce learners' active participation and cognition through various interactions, such as feedback and advice on learning activities and expressing interest and encouragement [12]. Fostering this instructor-student interaction is critical for inducing a successful learning flow [13].

The interaction between learners is defined as a self-directed, two-way communication activity in which learners create meaning through exchanging messages and sharing information with other students [14]. While interpersonal relationships have become difficult due to the COVID-19 pandemic, the need still exists for a plan to increase learners' interactions to ensure more effective academic achievements.

Learning motivation is a force that arouses a learner's interest or their strong tendency or will to learn, and it is one of the most important factors for students to engage in active learning [15]. Learning motivation encourages learners' activities and directs and maintains their progress, allowing students to immerse themselves in learning [16]. However, virtual learning decreases students' attention and interest in classes, which then decreases their motivation to learn [17]. For improving academic achievement during COVID-19, it is necessary to consider the types of motivation that can increase students' interest.

Self-leadership, academic self-efficacy [18], and positive psychological capital [19] were factors that influenced nursing students' learning flow prior to the COVID-19 pandemic. Factors related to the learning flow of nursing students in virtual education after the COVID-19 pandemic include learning motivation [20], quality of teaching and professional support [21], and online practice experience of nursing students [2]. However, research on the learning flow of nursing college students in a changing learning environment following the COVID-19 pandemic is still in its early stages.

To accurately reflect the learning situations altered by the COVID-19 pandemic, it is necessary to conduct a practical, diverse investigation of students' experiences in the current situation using a mixed-method research approach that combines quantitative and qualitative methods. Hence, this study aims to use the mixed-method approach to better understand the factors influencing the learning flow of nursing students, who must combine theoretical and practical education during the COVID-19 situation. We will prepare basic data for plans and intervention measures that will

assist nursing students in increasing their learning flow in a learning situation caused by COVID-19.

## Methods

### Study design

This study uses an explanatory, sequential mixed method that interprets the overall result by converging and merging qualitative data into quantitative data to understand the impact on the learning flow of nursing students during the COVID-19 pandemic. We identified the factors affecting students' learning flow by first conducting descriptive research as a quantitative research method. As a subsequent qualitative research method, we investigated the content of their experiences related to their learning flow through a focus group interview. The explanatory, sequential mixed method as a combined research design aids general logic and understanding through quantitative research and allows for the analysis and correction of statistical results from quantitative research by combining qualitative research methods. This is advantageous, as it highlights phenomena that would not have been discovered through solely quantitative research [22].

### Setting and samples

The targets of quantitative data collection were third- and fourth-year undergraduate nursing students (as of 2020) in three colleges located in the Republic of Korea. The subjects were students who had participated in virtual lectures, as well as actual clinical practice. The students understood the study's purpose and willingly agreed to participate in the research.

The study's sample size was calculated using a two-sided test for a regression analysis using G\*power software, version 3.1.9.7. As a result of calculations based on the significance level or specifically,  $\alpha = .05$ , the effect size = .15, and the ability to test  $(1 - \beta) = .95$  and 23 predictors, the minimum sample size was 234 people. By considering a dropout rate of 10.0%, the questionnaire was distributed online to 260 students. The final analysis used data from 245 people, excluding 15 questionnaires with insincere or incomplete responses.

Regarding the qualitative data-collection target, convenience sampling was performed on participants who were willing to take part in the research and who would provide a detailed description of their experiences. The sample size of a small group required for Krueger's suggested focus group interview is four to six people [23]. Thus, five focus group interviews were conducted, with a total of 20 people and 3 to 5 people in each group.

### Ethical consideration

This study was approved by the institutional review board of the Gyeongsang National University (Approval no. GIRB-A21-Y-0008).

### Measurements

#### General and learning-related characteristics

The general characteristics (gender, age, and grade as of 2020) and virtual learning-related characteristics (lecture locations, lecture learning tools, technical difficulties in such lectures, attendance patterns, the number of assignments, the number of the lectures, sleep patterns, disadvantages, and advantages) were structured.

It was necessary to clarify students' learning experiences following the COVID-19 pandemic when they responded to the

survey. Thus, the phrase “after the COVID-19 pandemic” was added to the beginning of each survey question.

#### *Learning flow*

This survey used the learning flow scale for adult learners as developed by Kim et al. [24]. This scale has nine subareas and 29 items and is composed of a five-point Likert scale, with a higher score indicating a higher degree of immersion. In the study by Kim et al. [24], Cronbach's  $\alpha$  was .94; in this study, Cronbach's  $\alpha$  was .92.

#### *Self-regulated learning ability*

For measuring the respondents' self-regulated learning ability, the self-regulated learning ability test tool developed by Gu [25] was used to measure the learning effect of adult learners in distance education, as modified and supplemented for adult learners by Choi [26]. This consists of seven items on a five-point Likert scale, with higher scores indicating a better ability to self-regulate learning. The reliability coefficient Cronbach's  $\alpha$  as calculated by Gu [25] was .83, Choi's [26] Cronbach's  $\alpha$  was .88, and that in the current study was .81.

#### *Self-efficacy in clinical practice*

As a self-efficacy tool for clinical practice, this study incorporated the self-efficacy measurement tool developed by Ahn [27], which is a combination of the Nursing Clinical Self-Efficacy Scale developed by Harvey and McMurray [28] and Parker's [29] self-efficacy tool for nurses. The phrasing was modified to fit the COVID-19 pandemic situation for nursing students. It consists of 25 questions and a 10-point Likert scale, with higher scores indicating higher self-efficacy in clinical practice. In Ahn's [27] study, the Cronbach's  $\alpha$  was .94, and in this study, the Cronbach's  $\alpha$  was .96.

#### *Instructor-student interactions*

The e-learning interaction evaluation tool developed by Ahn [30] for elementary and middle school students was modified and supplemented by Park [31] for cyber university learners in the first part of each question. The questionnaire consisted of seven questions asking how the instructor encourages interactions, with a five-point Likert scale for responses. A higher score indicates higher interaction. In An's [30] study, the Cronbach's  $\alpha$  was .87; in Park's [31] study, the Cronbach's  $\alpha$  was .93; and this study's Cronbach's  $\alpha$  was .91.

#### *Student-student interactions*

In order to examine the student-student interaction, the questions of the “Survey on the interaction of learners using social media” were developed by Choi [32]. This portion of the questionnaire consisted of two subdomains with 12 items on a five-point Likert scale, with a higher score indicating higher interaction. In Choi's [32] study, the Cronbach's  $\alpha$  was .91, and in this study, the Cronbach's  $\alpha$  was .91.

#### *Learning motivation*

The learning motivation test tool developed by Keller and Song [33] for learners was modified and supplemented by Choi [26] for adult learners, and the related phrasing was used to measure learning motivation in the current survey. It comprised four subdomains and 23 items on a five-point Likert scale; the higher the score, the stronger the motivation to learn. The reliability coefficient Cronbach's  $\alpha$ , as calculated by Keller and Song [33], was .88, the Cronbach's  $\alpha$  was .89 in Choi's [26] study, and the Cronbach's  $\alpha$  was .86 in this study.

#### *Semi-structured questionnaire used in qualitative research*

An open-ended interview was conducted regarding learning experiences in the context of the COVID-19 pandemic using a semi-structured interview questionnaire, as suggested by Krueger [23]. The specific interview questions were as follows:

- ◆ Introduction: Please tell us about the COVID-19 pandemic's impact on you.
- ◆ Transition: Please tell us how the COVID-19 pandemic has affected your learning.
- ◆ Key question: Please tell us about an experience in which you were well-immersed in learning or faced a difficult experience.
- ◆ Closing: What are the difficulties you have experienced other than in class and practice?

#### *Data collection*

Data for this study were collected from March 8 to April 17, 2021, at three nursing colleges located in the Republic of Korea. With permission from each university, enrollment notices were posted on department bulletin boards and group social networks, and subjects who voluntarily consented were recruited. For recruiting participants for the qualitative research, the purpose and method of the interview were explained to students who had previously completed the questionnaire, and students who wished to participate voluntarily were selected.

The students in this study had all previously completed virtual lectures, virtual practicums, and real-world healthcare system practicums. Some differences were observed in the operation of face-to-face and virtual classes among the three universities.

#### *Data analysis*

##### *Quantitative data analysis*

The collected data were analyzed using SPSS software, version 25.0 (IBM Corp., Armonk, NY, USA), with the analysis method as follows.

Descriptive statistics were used to calculate the characteristics of the study subjects and the degree of self-regulated learning availability, self-efficiency in clinical practice, instructor-student interactions, student-student interactions, and learning motivation. The Cronbach's alpha coefficient was used to confirm the research tool's reliability. The independent *t*-test or one-way ANOVA was used to compare major variables based on the study subjects' characteristics; Scheffe's test was used as a post-test. The Pearson's correlation coefficient confirmed the correlation between the main variables, and a stepwise multiple regression analysis was used to identify the factors affecting learning flow.

##### *Qualitative data analysis*

After the focus group interview was transcribed, Elo and Kyngäs' [34] content analysis method was used. The data obtained through the interviews were repeatedly reviewed, and related words or phrases were underlined and annotated in the margins. Main statements, including key content, were extracted; and open coding was performed to create categories and an abstraction. The analyzed data were then peer-reviewed by a nursing professor specializing in qualitative research, two professors with extensive educational experience, and one researcher with experience in qualitative research and attendance at various qualitative research seminars.

#### *Rigor*

For ensuring rigor in the qualitative research, the data were evaluated based on the criteria suggested by Guba and Lincoln [35].

The researchers confirmed its credibility by selecting participants with sufficient learning experience after the COVID-19 pandemic; they repeated the same questions during the interview and tried to describe the statements of the participants as they were. To prevent any omission or distortion of the interview content, the author reconfirmed the interview content with the participants after the interview was completed and randomly matched the transcript with the audio file to determine whether the transcript was accurately transcribed. To increase applicability, the researchers continued to collect and analyze data cyclically until the participants' statements reached a theoretical saturation point, at which new content was no longer produced. Additionally, after analyzing the interview data, two participants were asked if the content was clearly analyzed. To increase consistency, two researchers with comprehensive qualitative research experience repeatedly discussed the data analysis and interpretation of the results. Finally, neutrality was increased by separating the author's words through bracketing in the data collection and analysis processes; neutrality was subsequently maintained by eliminating the author's subjectivity and prejudice.

## Results

### Quantitative research results

#### Subjects' general and learning-related characteristics (Table 1)

The average age of the subjects was  $22.91 \pm 2.50$  years; regarding gender, 196 were women (80.0%), and 49 were men (20.0%). Most of the virtual learners observed lectures from home (93.5%). The most common technical difficulties in virtual lectures were the "connection failure as a result of too many users" (47.3%) and "building a high-quality internet communication network (such as Wi-Fi)" (39.2%). Regarding the number of assignments in virtual settings, 62.4% answered "too much," and 36.3% said they were "appropriate." The virtual lecture types included "combining recorded lectures and real-time video lectures" (53.9%), "real-time video lectures" (29.8%), and "recorded lectures" (15.5%). Of the disadvantages of virtual lectures, the most common were the "difficulty in maintaining concentration while in class" (66.1%) and "difficulty in self-learning" (38.4%). Regarding the degree of change in sleep patterns during virtual lectures, 40.4% answered "no change," while 59.6% replied, "a small change" or greater. As for the effects and advantages of virtual lectures, the most common responses were "no restriction on class time and place" (81.2%) and "repeated learning with video playback" (64.5%).

#### Subjects' self-regulated learning ability, self-efficacy in clinical practice, instructor-student interactions, student-student interactions, learning motivation, and degree of learning flow (Table 2)

The learning flow was rated as  $3.09 \pm 0.51$  of 5 points; self-regulated learning ability was  $3.06 \pm 0.65$  of 5; self-efficacy in clinical practice was  $7.78 \pm 1.28$  of 10, and instructor-student interaction was  $3.35 \pm 0.73$  of 5. Student-student interactions scored  $3.11 \pm 0.69$  of 5, and learning motivation was  $3.20 \pm 0.44$  of 5.

#### Differences in main variables depending on subjects' general and learning-related characteristics (Table 2)

No general characteristics exhibited differences in the subjects' learning flow, although, among the learning-related characteristics, the lecture type ( $F = 5.84, p = .003$ ) exhibited a difference. The learning flow was higher in lectures presented as a combination of recorded and real-time video lectures than solely real-time video lectures.

#### Relationship between the variables related to subjects' learning flow (Table 3)

Learning flow was found to positively correlate with self-regulated learning ability ( $r = .43, p < .001$ ), self-efficacy in clinical practice ( $r = .28, p < .001$ ), instructor-student interactions ( $r = .25, p < .001$ ), student-student interactions ( $r = .18, p = .006$ ), and learning motivation ( $r = .43, p < .001$ ).

#### Factors affecting the subjects' learning flow (Table 4)

The possible presence of auto-correlation and multicollinearity in the regression model were assessed through Durbin-Watson's statistic (1.97), the tolerance (0.60 to 0.97), and the variance inflation factor (1.03 to 1.66), confirming that the basic requirements for the regression analysis were satisfied. The analysis revealed that the variable with the greatest influence on learning flow was the self-regulated learning ability ( $\beta = .24, p = .001$ ), followed by learning motivation ( $\beta = .23, p = .001$ ), and clinical practice. Self-efficacy ( $\beta = .14, p = .014$ ) and the type of lecture combining recorded and real-time video lectures ( $\beta = .13, p = .022$ ) were found to have a major effect. In other words, the higher the self-regulated learning ability, learning motivation, and self-efficacy in clinical practice, the higher the learning flow in mixed lectures (combining recorded lectures and video lectures) rather than real-time video lectures, with an explanatory power of 27.1% ( $F = 22.30, p < .001, R^2 = .271$ ).

### Qualitative research results

Focus group interviews were conducted to determine the impact of virtual lectures and nursing students' clinical practice experiences on learning flow during the COVID-19 pandemic. The general characteristics of this study's focus group participants were as follows: Of the 20 people in five groups, 15 participants (71.0%) were female, and 5 participants (29.0%) were male, with an average age of 24 years. Regarding the grade, 13 students (65.0%) were juniors, and 7 (35.0%) were seniors.

The virtual clinical practice learning programs used in the three schools included Nursing Skills (produced by Elsevier), High-Fidelity Simulator, vSim® for Nursing (produced by Laerdal Medical), nursing case scenarios as developed by instructors, and videos related to nursing practice (YouTube).

#### Learning flow experience related to the COVID-19 pandemic

As a result of analyzing the interview data from the 20 participants in the focus group interview, eight categories and 22 sub-categories were derived; Table 5 displays their content.

**A lack of preparation in the starting of virtual classes.** Nursing students struggled in their studies because there were "inadequate communication networks, equipment, and facilities for virtual learning," such as computers with audio and video and free Wi-Fi. Participants claimed that "the number of assignments has increased" due to lecturers' concerns that students would not study in virtual classes. Further, respondents noted that it was difficult to concentrate in class when the "instructors just read off the slide word for word without further explanation or elaboration" in their video lecture recordings.

**Adapting and growing in a new learning environment.** Nursing students stated that the advantage of virtual classes is that they "can be listened to repeatedly at any time and from any location." Students felt that they had more time to focus on their studies because they saved time commuting. To adjust to virtual learning, participants "tried not to postpone learning and tried to find a learning method" to manage themselves by developing their "own

**Table 1** Subjects' General and Learning-related Characteristics (N = 245).

Characteristics	Categories	n (%)	M±SD
Age (year)	21–41	245 (100)	22.91 ± 2.50
Gender	Women	196 (80.0)	
	Men	49 (20.0)	
Grade	Junior	113 (46.1)	
	Senior	132 (53.9)	
Virtual lecture learning place <sup>a</sup>	Home	229 (93.5)	
	Dormitory	48 (19.6)	
	Café	41 (16.7)	
	Library	19 (7.8)	
	Reading Room	16 (6.5)	
	Others	2 (0.8)	
Virtual lecture learning tool <sup>a</sup>	Laptop	211 (86.1)	
	Tablet PC	81 (33.1)	
	Smartphone	71 (29.0)	
	Desktop PC	33 (13.5)	
	TV	1 (0.4)	
Technical difficulties in virtual lectures <sup>a</sup>	Connection failure as a result of too many users	116 (47.3)	
	Building a high-quality internet communication network (e.g. WIFI)	96 (39.2)	
	Preparation of auxiliary equipment such as webcams and speakers	67 (27.3)	
	Equipment preparation for lecture access (e.g. computer, tablet PC)	32 (13.1)	
	Others	20 (8.2)	
Attendance patterns during virtual lectures	Take classes according to timetable	149 (60.8)	
	Take all classes at once	60 (24.5)	
	Split a lecture several times	26 (10.6)	
	Take lectures over and over again	7 (2.9)	
	Others	3 (1.2)	
Amount of assignments in virtual lectures	Too much	153 (62.5)	
	Appropriate	89 (36.3)	
	A little	3 (1.2)	
Virtual lecture type	Combining recorded lectures and real-time video lectures	134 (53.9)	
	Real-time video lectures	73 (29.8)	
	Recorded lectures	38 (15.5)	
	Others	2 (0.8)	
Disadvantages of virtual lectures <sup>a</sup>	Difficulty in maintaining concentration while in class	162 (66.1)	
	Difficulty in self-learning	94 (38.4)	
	Connection failure or slow transmission speed	81 (33.1)	
	Hesitating to ask questions to the professor	60 (24.5)	
	No answer after asking the professor	20 (8.2)	
	Difficulty preparing learning tools for taking classes	16 (6.5)	
	Others	11 (4.5)	
Degree of change in sleep patterns during virtual lectures	None	99 (40.4)	
	A little	92 (37.5)	
	Much	33 (13.5)	
	Too much	21 (8.6)	
Advantages of virtual lectures <sup>a</sup>	No restriction on class time and place	199 (81.2)	
	Repeated learning with video playback	158 (64.5)	
	Classes without risk of infection with COVID-19	148 (60.4)	
	Reduction of commuting time	72 (29.4)	
	Improving concentration	25 (10.2)	
	Others	3 (1.2)	

Note. M±SD = mean ± standard deviation.

<sup>a</sup> Multiple responses.

schedule management method.” They proceeded “according to the timetable and tried to study by setting up a study plan.” Students were able to participate more actively in class when the “instructor encouraged interaction with the students” through chats or quizzes during their virtual classes, and they could be more immersed in the class when the “instructor prepared and applied various teaching methods in the virtual class.” Additionally, the participants stated that “interactions between students were facilitated due to the convenience of various video conferencing platforms (e.g., Zoom).”

*Enhancing nursing knowledge and skills through virtual clinical training.* Participants have been “able to gain a deeper understanding of specific medical conditions” after experiencing virtual clinical training (vSim® for Nursing). Additionally, the virtual simulation, included in the virtual clinical training, provided them “the overall procedures of nursing performance evaluations and

their significance in building confidence in the entire nursing process.” Nursing students felt that the virtual clinical training allowed them “to proactively try outperforming various medical treatments, improving their problem-solving skills using imaginary scenarios through case studies.” The respondents also believed that “if contactless clinical training preceded hospital in-person clinical training, the learning effect would be enhanced to improve their clinical performance ability.”

*Self-regulation difficulties when studying alone due to social distancing.* Participants noted that although they enjoyed the freedom to listen to lectures at their convenience through remote classes, they “put off watching the class video at the scheduled time.” These students were also anxious about the “pressure of having to carefully study results in repeatedly listening to the recorded lectures, thus increasing the time spent in lectures” and not missing any information. As the participants were concerned

**Table 2** Degree and Differences in Main Variables depending on Subjects' General Characteristics and Learning-related Characteristics (N = 245).

Characteristics	Learning Flow (1-5)		Self-regulated learning ability (1-5)		Self-efficacy in clinical practice (1-10)		Instructor-student interaction (1-5)		Student-student interaction (1-5)		Learning motivation (1-5)	
	M±SD	t/F(p)	M±SD	t/F(p)	M±SD	t/F(p)	M±SD	t/F(p)	M±SD	t/F(p)	M±SD	t/F(p)
Gender	3.09 ± 0.50	-70 (.483)	3.64 ± 0.66	-2.22 (.027)	7.70 ± 1.28	1.81 (.072)	3.32 ± 0.74	.90 (.368)	3.10 ± 0.67	-.02 (.985)	3.20 ± 0.45	-.57 (.570)
Man	3.04 ± 0.51		3.41 ± 0.52		8.07 ± 1.22		3.43 ± 0.67		3.10 ± 0.77		3.16 ± 0.37	
Grade	3.03 ± 0.52	-1.52 (.129)	3.57 ± 0.64	-72 (.474)	7.63 ± 1.38	-1.69 (.093)	3.34 ± 0.74	-.08 (.936)	3.08 ± 0.67	-.50 (.619)	3.19 ± 0.41	-.09 (.926)
Junior	3.13 ± 0.49		3.62 ± 0.64		7.90 ± 1.17		3.35 ± 0.71		3.12 ± 0.70		3.19 ± 0.46	
Senior	3.10 ± 0.44	.71 (.542)	3.37 ± 0.67	3.50 (.016)	7.98 ± 1.13	1.21 (.306)	3.29 ± 0.66	1.25 (.293)	3.04 ± 0.74	1.04 (.377)	3.18 ± 0.43	.15 (.928)
Attendance patterns during virtual lectures	3.06 ± 0.52		3.66 ± 0.64		7.65 ± 1.36		3.41 ± 0.72		3.15 ± 0.63		3.20 ± 0.41	
Take classes according to timetable <sup>b</sup>												
Split a lecture several times <sup>c</sup>	3.09 ± 0.54		3.70 ± 0.54	a < b <sup>f</sup>	7.97 ± 1.06		3.15 ± 0.89		2.93 ± 0.86		3.25 ± 0.47	
Take lectures over and over again <sup>d</sup>	3.30 ± 0.51		3.71 ± 0.59		7.87 ± 1.20		3.24 ± 0.56		3.17 ± 0.55		3.19 ± 0.44	
Amount of assignments	3.06 ± 0.51	.51 (.599)	3.58 ± 0.67	.23 (.797)	7.74 ± 1.35	1.16 (.316)	3.31 ± 0.75	.65 (.524)	3.06 ± 0.65	.94 (.394)	3.15 ± 0.43	1.45 (.237)
Appropriate	3.11 ± 0.49		3.63 ± 0.60		7.87 ± 1.14		3.42 ± 0.69		3.17 ± 0.75		3.24 ± 0.46	
A little	3.29 ± 0.51		3.71 ± 0.37		6.81 ± .50		3.33 ± 0.21		3.30 ± 0.45		3.39 ± 0.19	
During virtual lectures	3.04 ± .048	5.84 (.003)	3.55 ± 0.65	1.32 (.269)	7.83 ± 1.14	4.42 (.013)	3.18 ± 0.70	2.28 (.104)	3.24 ± 0.74	.85 (.430)	3.11 ± 0.50	2.02 (.135)
Recorded lectures <sup>e</sup>												
Real-time video lectures <sup>f</sup>	2.94 ± 0.51		3.52 ± 0.59		7.42 ± 1.48		3.28 ± 0.79		3.07 ± 0.73		3.15 ± 0.39	
Real-time video lectures <sup>f</sup> and real-time video lectures <sup>g</sup>	3.18 ± 0.50	F<g <sup>†</sup>	3.66 ± 0.68		7.96 ± 1.16	F<g <sup>†</sup>	3.44 ± 0.69		3.11 ± 0.69		3.24 ± 0.45	
Total	3.09 ± 0.51		3.60 ± 0.65		7.78 ± 1.28		3.35 ± 0.73		3.11 ± 0.69		3.20 ± 0.44	

Note. M±SD = mean ± standard deviation.  
<sup>†</sup> Scheffe test.

about “missing something important while studying alone,” they watched videos “over and over again with anxiety,” which took much longer than a face-to-face class.

*Difficulty concentrating when learning online.* Participants said that “due to the free nature of such lectures, the reversal of daytime and nighttime occurs, leading to irregular lifestyles,” and such learning patterns result in decreased concentration. As virtual classes allow for repeated viewing, even if one missed a point, there was always an opportunity to watch again; thus, the importance of the class is diminished, with people “lacking concentration and possibly even doing something else in class.” Further, participants said that they would “lose concentration in virtual classes if it was boring or of relatively low importance.”

The participants studied late at night when they could focus well. Their lives “became erratic” as a result of excess morning sleep. When a real-time Zoom class occurred in the morning, they reported difficulty focusing.

*Disadvantage of virtual learning.* Participants also complained of “physical fatigue, such as eye and waist pain, or a worsening of eyesight due to long periods of staring at the screen.” Students were also often “unable to ask questions,” as they were afraid of either disrupting the flow of the class, if they were to ask a question in the middle of the video lecture, or they found the attention burdensome. Some participants felt that it was “more difficult to match schedules in order to set a meeting time and to reach an agreement in opinions” during online cooperative learning. They perceived “communication barriers between students via the video conferencing platform.” Students thought that they were “unable to effectively communicate since it was difficult to detect fellow students’ comments on the online platform and to motivate active engagement in the meeting.”

*Concerns about academic performance.* Nursing students expressed anxiety that their “academic performance would be degraded due to the transition to virtual classes.” Participants questioned “the effectiveness of the communication skills learned in virtual clinical training when applied in practice” and were worried that they would not be able to work well as new nurses or that it might affect their future employment.

*Missing opportunities to enjoy college life.* Students expressed that the “closure of school facilities, such as the school library or study rooms, due to COVID-19” had impacted their studies. Participants also felt “it was disappointing that their chances of interacting with other fellow students” had been reduced as a result of the COVID-19 ban on school events and club activities.

**Discussion**

This study explored the COVID-19 pandemic’s effect on the learning flow of nursing students using a mixed-method approach. A majority of the participants attended virtual, remote classes at home using their laptops. The students in this study studied the virtual course according to the timetable offered by the college in order to maintain the same sensation as the school class. Virtual lectures were conducted in the form of recorded lectures, real-time video lectures, or a combination of real-time and recorded lectures, consistent with the results of a study by Kim et al. [1] on nursing college students.

The average score for the subjects’ learning flow was 3.09 ± 0.51 of 5, or a moderate level. A slight difference was observed between before and after the COVID-19 pandemic, given the study by Lee et al. [36] of nursing students, with 3.19 out of 5; and 2.86 in Kim’s

**Table 3** Relationship between Variables related to Subjects' Learning Flow (N = 245).

	Self-regulated learning ability r(p)	Self-efficacy in clinical practice r(p)	Instructor-student interaction r(p)	Student-student interaction r(p)	Learning motivation r(p)	Learning Flow r(p)
Self-regulated learning ability	1					
Self-efficacy in clinical practice	.26 (<.001)	1				
Instructor-student interaction	.37 (<.001)	.15 (<.001)	1			
Student-student interaction	.32 (<.001)	.085 (.183)	.50 (<.001)	1		
Learning motivation	.62 (<.001)	.25 (<.001)	.50 (<.001)	.39 (<.001)	1	
Learning Flow	.43 (<.001)	.28 (<.001)	.25 (<.001)	.18 (.006)	.43 (<.001)	1

**Table 4** Factors affecting the subject's learning flow (N = 245).

	B	SE	β	t	p	Cumulative Adj-R <sup>2</sup>	Change in Adj-R <sup>2</sup>
Constant	1.04	.24		4.32	<.001	-	
Self-regulated learning ability	.19	.06	.24	3.36	.001	.187	.187
Self-efficacy in clinical practice	.27	.08	.23	3.27	.001	.231	.043
Learning motivation	.06	.02	.14	2.49	.014	.255	.024
Combining recorded lectures and real-time video lectures	.13	.06	.13	2.31	.022	.271	.016

Note. Durbin-Watson = 1.969; F = 22.30; p < .001; R<sup>2</sup> = .271; Adj-R<sup>2</sup> = .259. Tolerance = .603-.967; VIF = 1.034-1.659. Reference group: Real-time video lectures.

[19] study. These findings suggest that nursing students, who were initially perplexed by the sudden onset of virtual classes as a result of COVID-19, subsequently adapted to use digital devices and adjusted to virtual learning.

Participants mentioned that the advantages of virtual lectures, which are beneficial to learning flow, are not only that students can choose the desired learning time and place but that this also provides the opportunity for repeated learning. The most significant advantage of this repeated learning from virtual courses is that they can be accessed at any time and from any location [37]. The flexible nature of such learning can benefit students' learning flow; even after the COVID-19 situation, the advantages of virtual classes can be further extended to and adopted into the curriculum.

Students in this study experienced a decrease in learning flow if the virtual learning environment was not smooth, for example, if disconnections occurred due to simultaneous connections. The technical problems arising during online programs are a key factor in the decrease in university students' concentration and learning motivation [38]. Further, participants believed that the number of assignments increased during virtual lectures and that using digital devices for an extended period of time increased fatigue and decreased learning flow. To enhance students' learning flow, instructors should select assignments of appropriate difficulty and quantity based on their students' learning levels so that learning does not become a burden.

Some students' sleep patterns were disrupted because of their irregular lifestyles. Due to the COVID-19 pandemic, 90.0% of medical students who continued to learn online in a constrained space experience changes in sleep habits and sleep distancing, leading to increased depression, anxiety, and fear of COVID-19 [39]. Various intervention programs, such as eye yoga exercises, can alleviate the physical exhaustion associated with virtual learning [40].

The most significant factor that influenced learning flow in this study was the respondent's self-regulated learning ability, with an average score of 3.60 ± 0.65 out of 5, or greater than the median level. This is slightly higher than the self-regulated learning ability

score of 3.49 measured in the study by Park et al. [41] on nursing college students before COVID-19.

Participants noted that poor self-regulated learning occurred because they delayed virtual learning time, or they did not concentrate in class because they thought they could listen to the lecture again later. For managing to learn effectively and efficiently, students who tend to postpone virtual lessons may benefit from using a schedule management app. Students feel as if they are attending a one-to-one class with the instructor when the professor's face is visible in the video [42]. Instructors should show their faces when video recording classes or using a cloud-based peer-to-peer software platform such as Zoom or Webex to increase students' concentration.

Learning motivation was the second most important factor affecting learning flow in this study. The student participants' average learning motivation score was 3.20 ± 0.44 out of 5. When compared with the score of 3.18 of 5 from Kim and Park's [43] study on college nursing students before COVID-19, the difference was not significant. When using various teaching methods, participants stated that they were completely immersed in their learning. On the other hand, these students also stated that if the class felt insincere or the video lecture was too long, their motivation to learn decreased, and they became bored. Passive learning situations, in which instructors talk without interacting with the students, make it difficult for the listener to maintain concentration for a long time [44]. Various strategies, such as having a quiz during class, are needed to increase students' motivation for learning in online settings. Previous research has found that students prefer video lengths of around 10 minutes for learning content [45]. It is necessary for instructors to organize the lectures into several short videos rather than combining them into one long video so as to reduce the burden on the learners and motivate learning.

Clinical self-efficacy in practice was the third factor affecting learning flow. The average clinical self-efficacy score of this study's student participants was 7.78 ± 1.28 out of 10. This score was comparable to Kim's [46] study of nursing college students prior to

**Table 5** Qualitative research results.

Categories	Subcategories	Meaningful statements
A lack of preparation in the start of virtual classes due to the COVID-19 pandemic	Inadequate communication network, equipment, and facilities for virtual classes	"Internet connection was suddenly lost during the lesson and I could only rejoice after a long time had passed. I was worried that I might have missed something important during the time I lost connection." (Participant 3 in Group 4)
	Limited learning skills for virtual classes	"Since it is virtual learning, it seems like more assignments are given out maybe out of fear that students might not study as hard. As assignments were of quantity rather than quality, the motivation to study dropped and not much time was left to study for the actual tests (because of the assignments)." (Participant 1 in Group 1)
Adapting and growing in a new learning environment	Capable of choosing the best time and place to study in enhancing concentration	"I liked the fact that as long as I had either a laptop or a tablet, or even just a smartphone, I could attend and listen to a lecture whenever and wherever I wanted without having to go to the lecture room." (Participant 3 in Group 2)
	Easy to repeat learning using recorded video	"In face-to-face, there was no way for me to catch up whenever I missed some part during the lecture. In contrast, even if I miss something during the lecture, I can now always pause, replay the missed part, and fully understand the part before moving on." (Participant 4 in Group 4)
	Striving to figure a good virtual learning method for oneself	"I tried to summarize and review everything thoroughly. I attempted to create my own schedule management method." (Participant 3 in Group 2)
	Capable of active participation in class through interactions with professors and students Boost student interaction utilizing video teleconferencing platforms (e.g. Zoom)	"I could concentrate better in a virtual lecture if the professors prepare quizzes or various videos related to the class." (Participant 4 in Group 4) "In virtual classes, it was convenient to gather in small-scale conference rooms where we could instantly find and share materials using our own computers." (Participant 2 in Group 3)
Enhancing nursing knowledge and skills through virtual clinical training	In-depth understanding of the case through online learning	"I was satisfied with being able to more to proactively try out performing various medical treatments, improving their problem-solving skills using imaginary scenarios through case studies." (Participant 4 in Group 3)
	Gaining confidence through repeated learning to solve nursing problems on one's own in a safe online environment	"I liked how I tried to solve the problem by myself from beginning to end using virtual practice. I was reminded of the overall procedures of nursing performance evaluations and their significance in building confidence in the entire nursing process." (Participant 3 in Group 3)
	Propose on virtual clinical training as a prerequisite for clinical practice	"Rather than directly going into clinical training at the hospital from the beginning, it was better to first experience the virtual clinical training which induced greater interests in learning." (Participant 1 in Group 3)
Self-regulation difficulties when studying alone due to social distancing	Putting off watching the class video at the scheduled time	"At first, I was following the timetable schedule faithfully but later found myself subsequently falling behind schedule." (Participant 4 in Group 1)
	Extending learning time because of the pressure to learn on one's own	"I listened to it over and over again in an anxious mind. I was concerned that I would miss something important while studying alone. I thought I should miss not even a single point and this pressure made me listen to a 2-hour lecture for more than 3 hours." (Participant 2 in Group 2)
Difficulty concentrating when learning online	Reduced concentration on learning as a result of an irregular lifestyle	"I studied late at night when I could concentrate well. As a result of my morning oversleep, my life became erratic. When there was a real-time Zoom class in the morning, it could be difficult to focus." (Participant 3 in Group 1)
	Loss of concentration in video classes as a result of thinking about listening again	"I often found it difficult to concentrate in class because I could listen to the recorded video later." (Participant 4 in Group 1)
	Variation in learning concentration depending on the professor's learning method and subject preference	"Even if the lecture was long, I would concentrate interesting subjects. But I lost concentration in virtual classes if it was boring or of relatively low importance" (Participant 2 in Group 2)
Disadvantage of virtual learning	Physical fatigue caused by excessive usage of digital devices	"Even in class, I had to look at my laptop, and even when I was doing my homework, I had to do it on my laptop, so it took a toll on my eyes. That, I believe, is why I felt more tired." (Participant 4 in Group 1)
	Burden in asking instructors questions in video lectures	"It was difficult to ask questions because I was afraid of disrupting the flow of the class if I ask a question during Zoom lectures." (Participant 1 in Group 2)
	Communication problems between learners during cooperative learning	"When having a group discussion with other students, it could be difficult to have an active discussion because the other person's microphone could not be heard well or the video function was not working properly." (Participant 2 in Group 5)
Concerns about academic performance	Doubts about academic accomplishments	"In hospital clinical training, we could observe and learn from how the nurses interact with patients when the patients make a request or ask questions. However, the interaction in the online practice platform was disappointing because we only had to ask pre-programmed questions and answers." (Participant 2 in Group 2)
	Concerns about having the ability to cope in a clinical situation	"Nursing students are suddenly unable to practice in the hospital due to the COVID-19. I'm concerned that getting a job will disrupt it. I'm also worried about my ability to function properly as a new nurse." (Participant 1 in Group 3)
Missing opportunities to enjoy college life	Inability to use the college's academic facilities properly due to social distance	"Due to COVID-19 social distancing measures, reading rooms were closed down, preventing their usage. Hence, by being cooped up studying only in my room all day, I felt my learning efficiency dropping." (Participant 4 in Group 2)
	Limiting the scope of human relationships due to a lack of access to classmates	"I am truly sorry that COVID-19 has resulted in the cancellation of school events and club activities, as well as fewer opportunities to interact with other students." (Participant 1 in Group 5)

COVID-19, or 7.77 out of 10 points. Eventually, researchers will need to determine how much practice at nursing colleges during COVID-19 has affected clinical self-efficacy in practice.

One of the most difficult issues involves finding a substitute for clinical practice at a time when face-to-face clinical practice is rendered infeasible due to COVID-19. This is because clinical

practice is important for students to gain their professional certifications in nursing college or medical school. In this study, nursing college students who experienced virtual clinical practice experienced a more in-depth understanding of specific diseases although they had not met patients face-to-face. They also experienced improved theoretical knowledge and gained an understanding of nursing procedures and core, basic nursing skills. Some participants wished to attend a virtual lecture that preceded clinical practice at the hospital. Despite the fact that it is a virtual practice, the students feel as if they have become nurses [2]. Students can strengthen their nursing competency, such as their critical thinking and problem-solving skills, after experiencing clinical practice through a virtual reality simulation (vSim® for Nursing) [47]. It is necessary to construct an environment most similar to the clinical practice settings, with a program that can provide a substitute for the students' clinical practice experience, as well as research on the effectiveness of using a variety of types of virtual content in education.

In the case of non-Korean-translated programs, such as vSim® for Nursing, students in this study encountered difficulties due to foreign languages, and some contents were difficult to understand because they differed from the Korean healthcare system. It may be difficult to focus in classes involving psychiatric scenarios, in which patient communication is crucial. Thus, it is necessary to develop a program that reflects the Korean healthcare context for safe and efficient virtual clinical practice.

The students in this study were also concerned that the sudden pauses in the hospital clinical practices from COVID-19 would prevent them from attaining sufficient clinical skills. Opportunities for clinical practice in the field had become increasingly scarce for nursing students even before COVID-19 due to the quantitative expansion of the nursing department's student intake and an increase in consumers' rights in the medical field in Korea [48]. Hence, highly effective and efficient virtual and specialized clinical training programs must be developed for instances in which it is difficult to conduct clinical practice virtually.

Even though the instructor-learner interaction exhibited a positive correlation with learning flow, this factor had no major impacts. Some participants felt burdened by asking questions of their instructors during video lectures, and it was difficult to communicate with instructors who were inexperienced in using digital devices. Instructors must communicate with students in various ways during virtual situations to increase the frequency of interactions and help to immerse them in learning. For example, instructors can use a chat window during the lecture or administer a quiz to review students' understanding of the class.

Student–student interaction positively correlated with learning flow, but this factor did not have a major impact. Students expressed that using various convenient features available on video conferencing platforms facilitated communication between students. Participants also reported communication issues between learners during cooperative learning and stated that it was difficult to study alone without the company of other students. Further, student interaction decreased as a result of the reduction in school events. In Ahn's [49] study, students feel “the burden of facial exposure” and “the long time it took to decide on something with team members” during virtual cooperative learning. To ensure smooth communication between learners during these virtual classes, instructors must provide clear guidelines for cooperative learning and offer appropriate feedback while monitoring the learning process.

Nursing students in this study struggled to “find suitable places and facilities to study” because the school facilities were closed due to COVID-19. Despite the tightening “social distancing” measures, students' need to study is also critical. Consequently, schools must continue to consider and apply the best ways to allow students to

use at least some of the campus learning spaces without violating the rules of social distancing.

This study also includes some limitations. First, only nursing college juniors and seniors from a variety of locations in the Republic of Korea were examined. Second, because the curricula and teaching methods applied at each of the three nursing institutions differed, it is difficult to generalize the research findings. Finally, due to the COVID-19 quarantine, focus group interviews with five groups were conducted face-to-face for one group, and video conferencing platforms were used for the remaining four groups. Thus, all the group interviews could not be conducted in the same setting, potentially leading to discrepancies in the research findings.

## Conclusion

This study's results reveal that for nursing college students to increase their learning flow in the learning situations caused by the COVID-19 pandemic, measures should be devised to improve their self-regulated learning ability, learning motivation, and clinical self-efficacy in practice. Further, this survey's student respondents favored the mixed-lecture format or a combination of recorded and real-time video lectures.

On the one hand, the nursing student respondents attempted to use online learning to develop their own learning expertise. These students were concerned that if the virtual clinical practice continued, they would be unable to fully establish their competence to work as real hospital nurses. Intervention studies to minimize student weariness are needed for more effective and efficient virtual learning.

For teachers to conduct efficient virtual lectures, it is also necessary to provide relevant education and assistance in teaching strategies at both the school and state levels. It is also critical to develop learning materials and tools for virtual clinical practice custom-tailored to the South Korean clinical setting for specialized areas in which clinical training is typically difficult, such as neonatal intensive care units and delivery departments.

## Conflict of interest

The author declared no conflict of interest.

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## Research Article

## Effect of Website-based Learning on Improved Monitoring of Adverse Drug Reactions by Clinical Nurses

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## SUMMARY

**Purpose:** The purpose of this study was to develop website-based learning contents to activate voluntary monitoring and reporting of adverse drug reactions (ADRs) for clinical nurses and to verify their effectiveness.

**Method:** Using a quasi-experimental control group pretest-posttest design with random allocation, a total of 60 nurses with more than 1 year of clinical experience were recruited from a university hospital in Seoul, Korea. A website was developed that provides learning contents including real cases and the latest drug-related knowledge, as well as video lectures. Knowledge on ADR monitoring, self-efficacy, ADR practice behavior, and medication performance ability were measured at 2 weeks after intervention. A small notebook for monitoring ADRs of nurses was given to the control group. Data were analyzed using descriptive statistics, the chi-squared test, and the independent *t* test using SPSS Statistics Software Version 21.0.

**Results:** The scores of ADR monitoring knowledge, self-efficacy, and ADR monitoring practice in the experimental group significantly increased after the intervention compared with the control group ( $p < .05$ ). However, there was no significant difference between the two groups in medication performance ability related to ADR monitoring.

**Conclusion:** To spread a safety culture in which voluntary ADR monitoring and reporting is activated, it is necessary for clinical nurses to share and communicate ADR-related information and real cases through an open website.

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## Introduction

Adverse drug reactions (ADRs) are unintended negative reactions that occur when drugs are used in appropriate doses and dosages for treatment, diagnosis, and prevention of diseases and refers to all cases in which a causal relationship with drugs cannot be excluded [1]. The expansion of the market due to the development of new drugs in polypharmacy in response to an aging population and complex chronic diseases increases the importance of preventing related side effects [2,3]. Pharmacovigilance activities related to the detection, evaluation, interpretation, and prevention of drug-related problems, including ADRs [1], are an important

factor in the safe administration of medication by healthcare providers [4].

Statistical data on ADRs by country revealed that, in Canada, side effects of outpatient medications resulted in more than two million emergency room visits and 700,000 hospital admissions, resulting in more than \$1 billion annually in healthcare costs [5]. The United States has reported the loss of \$30 billion in medical expenses each year [6]. In addition, preventive activities through monitoring of ADRs are essential for not only economic reasons but also patient safety and reduction of re-hospitalization rates [7]. Therefore, nurses must provide safe and effective medication, and continuous nursing education is required to prevent ADRs and encourage reports when they do occur [8,9].

Healthcare providers, such as doctors and nurses, recognize that drug administration is very important for patient safety in a hospital. In particular, nurses, who provide care closest to patients, are critical healthcare workers who can perform pharmacovigilance activities to monitor, recognize, and report ADRs [10,11]. However,

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in the clinical field, reports are often delayed due to busy work and are often ignored in the case of common side effects, sidelined in routing to others, or hidden in the case of serious side effects [12]. According to a study conducted with 300 nurses in Iran, after 4 months of training on ADR reporting, nurses' knowledge and attitudes were significantly improved, and the ADR reporting rate was increased [13]. In consideration of this reality, a randomized experimental study emphasized the need for continuous individual education to change nurses' behavior toward ADRs and mentioned web-based educational content as the most appropriate method [14]. To improve nurses' voluntary monitoring and reporting of ADRs, it is necessary to increase their sense of reality in the clinical field as to drug side effects, coping methods, and patient education contents. To establish a drug safety culture, it is essential to develop a program that allows educational institutions and nurses to share and communicate information, rather than a one-time education [15,16]. For the medium of education, nurses were found to prefer online e-learning due to conditions such as shift work [17,18]. In addition, to create a safe medication culture for patient safety, the education should be of a type that induces voluntary reporting and practice through web-based interactive communication such as a website, rather than a one-time presentation [19]. Development of website-based learning content can establish a system that plays an important role in the economic aspect by providing educational materials and information necessary to create a safe medication culture.

Therefore, the purpose of this study was to develop a communication-enabled website that includes error cases and learning content to enhance nurses' awareness of ADRs, to improve their voluntary reporting, and to verify the effect of website-based learning.

## Methods

### Study design

This study was a quasi-experimental control group pretest–posttest design with random allocation for developing website-based learning content and verifying its effectiveness on voluntary reporting of ADRs in nurses with more than 1 year of clinical experience.

### Development of website-based learning contents

The website, including the learning content, was developed according to the web-based learning design model with five steps: analysis, design, development, application, and evaluation. In the analysis stage, in July 2017, 210 clinical nurses were surveyed about their preferred educational form and content for ADR reporting. Among them, 10 individual interviews were conducted to explore the reasons for the difficulty of voluntary reporting. The survey revealed that they desired education mainly in four areas: side effects by organ system (20%), patient condition observation methods prior to and after administration (17.0%), ADRs (16.7%), and side effects reporting procedures (15.7%). In addition, the scope and contents of the learning contained in the website were checked through a literature review on ADRs and a search of the Korean Ministry of Food and Drug Safety website.

In the design stage, the information to be delivered was developed. On the main screen, the menu was divided into four headings: Online lectures, ADR evaluation cases, information on individual drugs provided, and frequently asked questions (FAQs) about ADRs; notice boards were composed of newsletters (Table 1). In addition, questions and answers, posters, slogan contest campaigns and information on prizes were made on the website to

facilitate mutual communication with learners and to strengthen motivation for learning. The “How in this case?” banner part is structured so that information necessary for patient safety can be shared by two-way communication through questions and prompt feedback from the manager and by sharing clinical cases. After a participant watched the video lecture, questions were answered when asked. By clicking on the banner of “Knowing it is medicine” on the website, learners can take five online lectures, totaling about 2 hours of learning (Table 2). To provide information, this researcher, a nurse at a local drug safety center, took an online lecture on procedures for reporting ADRs, drug side effects and allergic reactions, symptoms and their management, high-risk drugs that require monitoring, and patient cases with side reactions.

In the development stage, after selecting a developer, the purpose, target, and contents of the site were explained, and development was carried out through technical support for security policies, characteristics of each screen, and individual menu management. As an administrator, this researcher has the authority to organize and provide information on the website and allows learners to write questions and opinions on the notice board. Finally, in the application stage, the final website-based education program that was revised and completed after validation by the expert group was applied to the experimental group. A group of experts consisting of two pharmacists from local drug safety centers, one internal medicine professor, two nursing professors, and ten clinical nurses with more than 10 years of clinical experience, evaluated the website's properties and its learning content using a health information website evaluation criteria tool consisting of 13 questions [20]. The validity of the developed website after use by 10 nurses showed a content validity index (CVI) of 0.9 or higher in all questions. Some learning contents and parts that need to be supplemented in terms of continuity and ease of use were modified, and finally website-based learning contents were developed (Figure 1). A domain ([www.drugsafe.kr](http://www.drugsafe.kr)) was purchased, and the website was named “Drug Safety for Nurses.”

This research design was applied for the evaluation of the developed website-based education program. In the experimental group, consent was obtained for the use of personal information (e-mail, contact information, affiliation) for website membership registration and learning contents. Learning contents were developed to be linked to the Smart Teaching and Learning Center of the affiliated university and the experimental group was registered as students and connected with personal identifications (ID) and passwords through this link to take courses. Through the website manager page, we checked the number of accesses for learners to use the website.

### Setting and participants

The number of samples in this study was calculated based on the evidence of the educational effect with a large effect size in several previous studies on ADR reporting for clinical nurses [12]. Using G\*Power program 3.1.9.2, the number of samples that fit the *t* test with an effect size of .80, significance level of .05 for the two-tailed test, and power of 80% was at least 26 in each group.

The criteria for selection of participants were nurses working at a university hospital in Seoul and general ward nurses with clinical experience of 1 to 25 years, excluding new nurses and chief nurses. New nurses were excluded from the participants because they had little experience with drug side effects and lacked drug-related clinical judgment skills that required critical thinking [21]. To secure the homogeneity of clinical experience among a total of 266 participants who met the criteria, 60 participants were selected through a randomization program (Microsoft Excel 2010), divided

**Table 1** Website-based Learning Content Composition for Adverse Drug Reactions.

Site map		Contents	Content classification
Online lecture	Knowing it is medicine!	Online lecture	<ul style="list-style-type: none"> <li>• Display format: Link to <a href="http://www.selc.or.kr">www.selc.or.kr</a> via banner</li> <li>- Under the management of the arbitration participant's list, email, and contact information</li> <li>Individual identification/password provided</li> <li>- E-learning progress management and encouragement, Q&amp;A, etc.</li> <li>- Communication possible</li> </ul>
Cases by drug system	What happened?	ADR evaluation case	<ul style="list-style-type: none"> <li>• Widely used in case data from the Korea Pharmaceutical Safety Administration is drug-oriented data and evaluation provided by the Ministry of Pharmacy Provide data on cases</li> </ul>
Drug information	Aha like that!	Drug information update	<ul style="list-style-type: none"> <li>• Provides a list of recently stocked drugs and precautions</li> <li>• Provides information on drugs that have been changed due to safety issues</li> <li>• Lists drugs that require caution when administering (high-risk drugs, etc.)</li> <li>• Suggestion of error points and solutions</li> <li>• FAQ provided</li> <li>• Comment function: general member</li> <li>- If you have any questions, you can communicate through comments</li> </ul>
FAQ	How in this case	FAQ information	<ul style="list-style-type: none"> <li>• Newsletter provided by local drug safety center</li> <li>• Trends and events on ADRs inside and outside the hospital</li> <li>• Excellent reporter and department selected by the regional drug safety committee</li> </ul>
Notice board uses	Newsletter	Provide information	Center motivation by uploading photos and lists
	Great reporter	Motivation	<ul style="list-style-type: none"> <li>• Information on events and usage through notices</li> <li>• Data can be downloaded and written by members in the data room</li> </ul>
	Notice board	Reference room, through notices, user guides, etc. Provide information	<ul style="list-style-type: none"> <li>• Promotion of events such as slogans, posters, and logos</li> </ul>
	Campaign	Motivation	

Note. ADRs = adverse drug reactions; FAQ = frequently asked questions.

into 5 years and less than 5 years, and assigned to an experimental group and a control group. All 60 participants agreed to participate in the study, and there were no dropouts; 30 in the experimental group and 30 in the control group were used for the final analysis.

#### Procedures and data collection

The experimental group and the control group were collected from the same hospital. To prevent the contamination of the experiment, after collecting control group data, we proceeded to the parallax design in which data for the experimental group were collected.

Control group data were collected from February to March 2018, and experimental group data were collected from March to April.

Considering the characteristics of nurses working in shifts, intervention activities of the experimental group asked participants to attend online lectures and upload new drug information and newsletters through the website for 14 days. The researcher monitored the learning history after registering as a course system administrator to check the learning history of the experimental group. To manage the learning history, it was registered as a course in the H university smart teaching and learning center system so that the researcher could check the learning history through the learning management system through the individual ID/PW of each experimental group. To protect the personal information of the test participants, when a member registered on the site, the administrator allowed access after approval, and security was maintained so that personal information and contents were not exposed.

**Table 2** The Contents of Online Lecture "Knowing it its Medicine."

List	Content	Running time
1. ADR terminology and how to report (basic)	<ul style="list-style-type: none"> <li>• What is an ADR?</li> <li>• The importance of ADRs in nurses</li> <li>• ADR reporting system</li> <li>• ADR evaluation method</li> </ul>	35 min
2. Clinical features of ADRs by system (basic)	<ul style="list-style-type: none"> <li>• Drug-induced skin/liver/renal/gastrointestinal/cardiovascular disease</li> </ul>	26 min
3. Prevention and management of ADRs (advanced)	<ul style="list-style-type: none"> <li>• Contrast adverse reaction management, computer program, symptoms, pretreatment, prevention</li> </ul>	17 min
4. Anaphylaxis symptoms and management (advanced)	<ul style="list-style-type: none"> <li>• Underlying diseases and causes</li> <li>• Symptoms</li> <li>• Examination and diagnosis</li> <li>• Treatment</li> </ul>	18 min
5. Drugs requiring monitoring (advanced)	<ul style="list-style-type: none"> <li>• High-risk and cause serious adverse reactions drugs</li> <li>• Management of side effects of anticancer drugs</li> <li>• Drugs need to be monitored by the Ministry of Food and Drug Safety in case of occurrence</li> </ul>	35 min

Note. ADRs = adverse drug reactions.

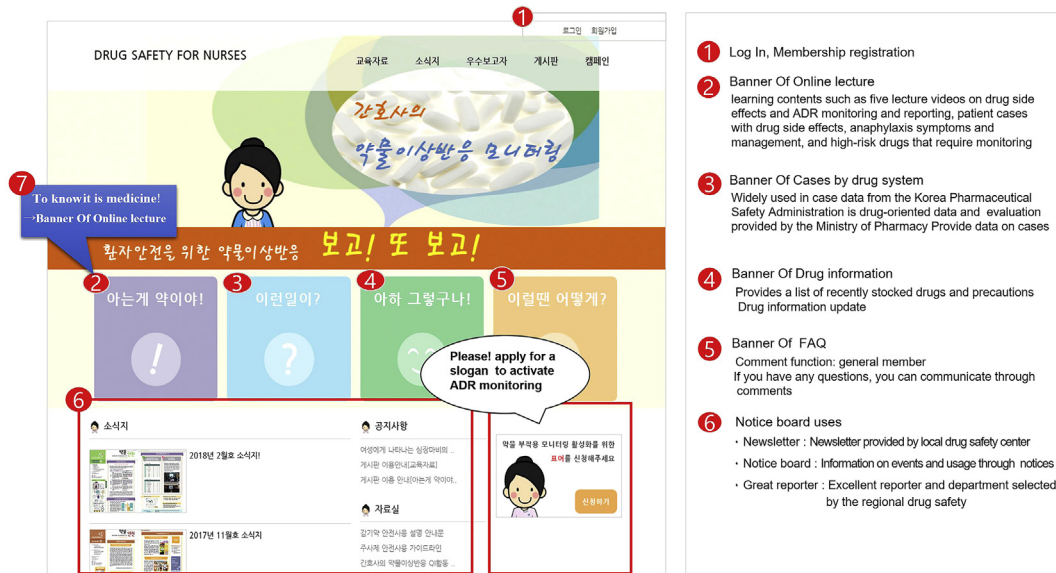


Figure 1. The first screen of website “Drug Safety for Nurses.”

The two groups’ pretest general characteristics, knowledge about ADR monitoring, self-efficacy, practice behavior, and medication performance ability were assessed prior to the intervention, using self-administered questionnaires. In the control group, a small notebook for nurse monitoring of ADRs was created and distributed, and a follow-up survey was conducted 2 weeks after the intervention. Based on previous literature showing that the period of transition to a behavioral change after individual learning was 2 weeks [22], the follow-up survey in this study was also conducted two weeks after completion of the 2 weeks learning access period. After that, learners were no longer allowed to access the website. The learners in the experimental group were able to access the website at any time, listen to lecture videos when needed, and browse materials at any time during a two-week period.

#### Data collection instrument

##### (1) Knowledge on ADRs

Questions related to the level of knowledge on ADRs were developed by a researcher with 6 years of experience in ADRs work at a local pharmacovigilance center and drug error management work in the Quality Improvement department. This tool consists of 20 questions with 1 point for a correct answer and 0 points for an incorrect answer, for a total of 20 points. This tool measured the CVI for each item from professional experts of 6 doctors and 4 nursing professors. Initially, there were 25 items, but 5 items with a S-CVI (scale-level content validity index) of .80 or less were removed through agreement with the experts. Item validity was in the range of .85–1.00, and the S-CVI was .94. The reliability of the KR-20 (Kuder-Richardson Formula 20) in this study was .60.

##### (2) Self-efficacy on ADR monitoring

The Korean version of the original tool developed by Sherer et al. [23] was used with the permission of the original author as an evaluation tool for the level of confidence in adapting to the ADR monitoring task. This tool consists of 10 questions on a 4-point

Likert scale (1–4 points), and each item has an S-CVI value ranging from .85 to .97. The higher the sum of each score, the higher the sense of self-efficacy. The validity was adequate, and the reliability of the tool was verified, with a Cronbach’s  $\alpha$  of .89.

##### (3) ADR monitoring practice

This tool developed by Kim and Lee [24] was used for the early detection of ADRs, establishment of rapid countermeasures and monitoring to prevent adverse reactions. It was developed based on the educational materials of the local pharmacovigilance center and consists of 10 questions such as checking and sharing patient information on ADRs, reporting adverse reactions, confirming drugs, and using the reporting system. This tool consists of a total 10 items on a 5-point Likert scale (1–5 points). A higher sum of each score indicates a higher sense of ADR monitoring practice. The reliability test in a Kim and Lee [24] study revealed a Cronbach’s  $\alpha$  of .86; that in the current study was .78.

##### (4) Medication performance ability related to ADR monitoring

The level of medication performance ability of the participants was examined using a tool modified by Kim and Lee [24] based on the perceived medication ability developed by Lee [25]. The tool consists of six questions related to understanding of the drug actions, necessary precautions, potential allergies, assessment of patient records, understanding the patient situation prior to and after administration, and drug education. On a 6-item, Likert-type 5-point scale (1–5 points), for each item, the higher was the score, the higher was the medication performance ability. Permission of the original author was obtained for use of this tool, which showed reliability through a Cronbach’s  $\alpha$  of .81.

#### Data analysis

The data were analyzed using IBM SPSS Statistics Software Version 21.0 (IBM, Armonk, NY, USA). General characteristics of the participants were analyzed as real numbers, percentages, and mean

**Table 3** General Characteristics of Participants and Homogeneity Test for Dependent Variables (N = 60).

Variables	Categories	Exp (n = 30)	Cont. (n = 30)	$\chi^2$ or t	p
		n (%) or M $\pm$ SD	n (%) or M $\pm$ SD		
Gender	Men	3(10.0)	0(0.0)	3.16	.237 <sup>b</sup>
	Women	27(90.0)	30(100.0)		
Age (years)		31.83 $\pm$ 6.68	30.87 $\pm$ 5.57	-0.59	.559
Education	College	6(20.0)	5(16.7)	0.51	.774 <sup>b</sup>
	Bachelor's	22(73.3)	24(80.0)		
	Master's	2(6.7)	1(3.3)		
Marital status	Married	10(33.0)	8(26.7)	0.32	.573
	Single	20(67.0)	22(73.3)		
Total clinical Experience (month)		99.10 $\pm$ 82.55	88.8 $\pm$ 71.81	0.54	.911
Working department	12~<36	7(23.3)	9(30.0)	0.33	.849
	36 $\leq$ ~<60	8(26.7)	6(20.0)		
	60 $\leq$ ~<120	7(23.3)	7(23.3)		
	$\geq$ 120	8(26.7)	8(26.7)		
Reporting experience	Medical ward	14(46.7)	15(50.0)	1.76	.184
	Surgical ward	12(40.0)	10(33.3)		
	Others <sup>a</sup>	4(13.3)	5(16.7)		
Education experience	Yes	16(53.3)	21(70.0)	-1.20	.273
No	14(46.7)	9(30.0)			
Knowledge	Yes	18(60.0)	22(73.3)	-0.94	.354
No	12(40.0)	8(26.7)			
Self-efficacy		14.57 $\pm$ 2.42	14.00 $\pm$ 2.27	1.06	.296
Monitoring practice		35.90 $\pm$ 4.31	37.27 $\pm$ 5.63	0.58	.561
Medication performance ability		32.83 $\pm$ 4.54	33.50 $\pm$ 4.29	0.91	.365
		21.27 $\pm$ 3.15	20.60 $\pm$ 2.46		

Note. Cont. = control group; Exp. = experimental group; M = mean; SD = standard deviation.

<sup>a</sup> Psychiatric ward, Emergency ward.

<sup>b</sup> Fisher's exact test.

and standard deviations. The prior homogeneity of the two groups was verified by the Chi-square test, Fisher's exact and *t* tests, and the Kolmogorov–Smirnov test for normality, and the Levene's test for equality of variance. To verify the effect of the intervention, the differences prior to and after the intervention were identified between the experimental group and the control group by independent *t* test.

### Ethical considerations

Ethics approval and consent to participate This study was Institutional Bioethics Committee (Approval no. HYUH 2017-06-014-002) of Hanyang University Hospital in Seoul, Korea. Prior to data collection, researchers explained to all respondents that all data acquired would not be used for other purposes than research, and respondents could refuse a survey at anytime. Participants in this survey provided their informed consent with written paper.

### Results

#### Verification of the effectiveness of the website-based learning interventions

#### 1) Homogeneity test of participant's general characteristics and variables

As a result of the analysis to verify the homogeneity of the general characteristics and dependent variables of the two groups, there was no statistically significant difference, and the two groups were homogeneous (Table 3). In this study, participants visited the website an average of 7.03 times, but mainly used learning content rather than commenting or posting, and mainly asked questions about how to use the program. This appears to be the result of the short mediation period and lack of publicity.

#### 2) Effects of website-based learning on research-dependent variables

The difference in ADR knowledge score of 2.93  $\pm$  2.80 in the experimental group was significantly higher than the 1.20  $\pm$  1.92 found in the control group ( $t = -2.80, p = .007$ ). The score difference of self-efficacy on ADR monitoring in the experimental group was 3.50  $\pm$  4.99 points, which was significantly higher than the -0.13  $\pm$  5.18 points of the control group ( $t = -2.77, p = .008$ ). The difference in scores of monitoring ADRs in the experimental group (5.07  $\pm$  6.28) was higher than the 1.27  $\pm$  6.19 found in the control group, and the difference was statistically significant ( $t = -2.36, p = .022$ ). The difference in post-pre scores of medication performance ability related to ADR monitoring in the experimental group was 1.93  $\pm$  3.29,

**Table 4** Comparison of Variables Between the Two Groups (N = 60).

Variables	Group	Pre	Post	Difference	t	p
		M $\pm$ SD	M $\pm$ SD	M $\pm$ SD		
Knowledge on ADR	Exp.(n = 30)	14.57 $\pm$ 2.42	17.50 $\pm$ 1.22	2.93 $\pm$ 2.80	-2.80	.007
	Cont.(n = 30)	14.00 $\pm$ 2.27	15.20 $\pm$ 1.85	1.20 $\pm$ 1.92		
Self-efficacy on ADR	Exp.(n = 30)	35.90 $\pm$ 4.30	39.40 $\pm$ 5.06	3.50 $\pm$ 4.99	-2.77	.008
	Cont.(n = 30)	37.27 $\pm$ 5.63	37.13 $\pm$ 6.70	-0.13 $\pm$ 5.18		
ADR monitoring practice	Exp.(n = 30)	32.83 $\pm$ 4.54	37.90 $\pm$ 5.36	5.07 $\pm$ 6.28	-2.36	.022
	Cont.(n = 30)	33.50 $\pm$ 4.30	34.77 $\pm$ 4.91	1.27 $\pm$ 6.19		
Medication performance ability	Exp.(n = 30)	21.27 $\pm$ 3.15	23.20 $\pm$ 3.33	1.93 $\pm$ 3.29	-1.67	.100
	Cont.(n = 30)	20.60 $\pm$ 2.46	21.13 $\pm$ 2.39	0.53 $\pm$ 3.19		

Note. ADR = adverse drug reaction; Cont. = control group; Exp. = experimental group; M = mean; SD = standard deviation.

which was higher than the  $0.53 \pm 3.19$  evident in the control group, but the difference was not statistically significant ( $t = -1.67, p = .100$ ) (Table 4).

## Discussion

The current study developed website-based learning content to establish a culture of information sharing and two-way communication by focusing on the behavior change of voluntary ADR monitoring by nurses in busy clinical settings [15,16]. For two-way communication with learners, the researcher gave responses to the learners' questions after listening to video lectures or through FAQs and notice board banners. In addition, efforts were made to strengthen learners' motivation to learn by posting a slogan contest campaign and prize information. However, considering that there were few inquiries related to nursing practice other than lecture-related inquiries, it is believed that this was because the focus was on learning due to the limited study period of two weeks. It is necessary to analyze the contents of the question through long-term application in the future.

Whereas information about drugs was previously shared through e-mail, oral, and written media, it was possible in this study to implement a positive environment in which open discussion about drug-related knowledge and opinions can be achieved by using a website. A similar system was shown to be an effective means of communication [26,27] that avoids time and space restrictions through the design and development of learning content using a website.

In this study, the knowledge on ADRs was significantly increased in the experimental group than in the control group, which supports the result that seven out of 13 studies in a systematic literature review on the effect of web-based education were more effective than traditional face-to-face education [28]. However, there was no significant difference between two methods in five studies [28]. Therefore, it is necessary to consider when designing an educational method that variables such as participant characteristics and educational topics can affect the effectiveness of the educational method.

Self-efficacy on ADR monitoring showed a statistically significant increase in the scores of the experimental group compared with the control group. This result supports the finding that web-based self-learning significantly increased self-efficacy in ventilator management education compared with face-to-face training [29]. However, it is contrary to the finding that there was no significant difference in self-efficacy in web-based anticancer chemotherapy nursing education compared with face-to-face education [30]. Repeated and continuous efforts are required to increase self-efficacy in complex clinical settings [27,30]. Since the developed website-based learning content can be continuously updated and allows repeated review and learning, it is expected to be used for nursing education management in the future.

In the monitoring practice of ADRs, the experimental group showed a significantly greater difference in scores prior to and after the intervention than did the control group. This result, although a single group study design, partially support the finding that after receiving in-hospital education on ADR monitoring for hospital nurses, their knowledge and attitudes were significantly improved compared with prior to education, and there were 26 voluntary reports after 4 months [13]. But, in this study, there seems to be some difference in that it was measured as a questionnaire asking the will to change behavior toward practice rather than as a measurement of the reporting rate. Since some nurses and other medical staff are not aware of their duty to report ADRs, it is necessary to produce a network that can provide feedback and promote the necessity, purpose, and method of reporting with a wide range of customized educational activities [18]. Since a

structured format for ADR monitoring is required for a safe medication culture for nurses [31], it is necessary to continuously apply the website-based learning developed in this study to nurses in practice as a practical method.

In terms of medication performance ability related to ADRs, there was no statistically significant difference in the increased scores between the experimental and control groups prior to and after the intervention. It is thought that the evaluation could not be done generously because only six items were extensively asked about their medication nursing capacity, and the difference in responses could not be confirmed with a short study period.

The strength of this study is that it was intended to contribute to the creation of a safety culture in hospitals by developing website-based learning contents that allow repeated learning and interaction of the latest information and case-oriented education to activate ADR reporting by clinical nurses. In particular, the study is significant in that it confirmed the importance of voluntary ADR monitoring and reporting by clinical nurses by verifying the effect through the experimental design of randomized subject assignment. In addition, it has established an educational platform for clinical nurses, and it is also suggested to verify the effectiveness of ADR after educational application for nursing students in the future [32].

However, it also had some limitations. First, the study sample was small and involved participants from one university hospital in Korea. In addition, as a self-report questionnaire, there is a limitation that posttest measurement was performed 2 weeks after the intervention. In the future, it is necessary to verify the effect of the intervention through more objective measurement and to confirm whether the effect of the experiment lasts for a longer period of time. The second limitation was that the study period was short, but as a result of the activation of ADR monitoring and reporting, the actual number of self-reports of the participants could not be confirmed. In this study, participants visited the website an average of 7.03 times, but mainly used learning content rather than commenting or posting, and mainly asked questions about how to use the program. This appears to be the result of the short mediation period and lack of publicity. Finally, there is a limitation in that the number of ADR-related nursing behaviors or reports of participants in the study could not be actually measured. Third, there is a limitation in that the number of ADR-related monitoring or reports of the study participants was not actually measured, so it is necessary to confirm this in future studies.

## Conclusion

The website content developed in this study included video lectures, case studies about ADRs, information on individual drugs, and FAQs about ADRs. In addition, various notice board functions were used to enable two-way communication such as sharing cases and providing feedback, providing drug safety information issued monthly by the local product safety center, and posting reports related to ADRs. Nurses who learned through the website significantly increased their knowledge of ADRs, self-efficacy, and monitoring practices compared with the control group. Sharing and communication through such an open website induces clinical nurses to practice monitoring for ADRs and activates voluntary reporting, leading to a safer medication culture in hospital settings.

## Availability of data and material

The data sets generated and analyzed during the current study are not publicly available due to participant's privacy and decision of IRB but are available from the corresponding author on reasonable request.



## Authors' contributions

HJK designed this study, performed data analysis, and drafted the manuscript. SYH designed this study, performed data collection, and drafted the manuscript. All the authors reviewed and approved the final version of the manuscript.

## Conflict of interest

The authors have no conflict of interest to disclose.

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## Research Article

## Development of a Health Promotion Application on Cancer Survivorship as an Educational Content for Nursing Students

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## SUMMARY

**Purpose:** This study aimed to develop a health promotion application for cancer survivorship (CS app) based on the adult learning and self-efficacy theories and evaluated its usability as an educational tool for nursing students.**Methods:** The CS app was developed according to ADDIE (analysis, design, development, implementation, and evaluation) model. It consisted of interventions involving medication, diet, exercise, stress management, symptom management, and regular medical checkup for cancer survivors on three different levels in terms of difficulty and complexity. It was designed to teach nursing students how to provide tailored care to cancer survivors as well as help survivors with their repetitive and regular health management. The Mobile App Rating Scale and the user version of the Mobile App Rating Scale were used for a heuristic evaluation of the CS app by the experts and student users.**Results:** The CS app was developed based on literature reviews and cancer survivorship guidelines. It was evaluated by 20 student users and five experts based on a 5-point scale and obtained a score of 3.97 and 3.66, respectively. Nursing students rated the CS app positively, mentioning that they were able to “learn about appropriate nursing interventions for patients in various cases” and that they became interested in caring cancer survivors’ health using the CS app.**Conclusions:** The CS app is an effective and user-friendly educational tool to increase the motivation of nursing students in learning cancer survivorship care. This highlights the potential of CS app as a useful learning tool for nursing students.© 2022 Korean Society of Nursing Science. Published by Elsevier BV. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

## Introduction

The World Health Organization has estimated the number of 5-year cancer survivors to be 43.80 million worldwide [1]. The US Centers for Disease Control and Prevention has forecast the number of cancer survivors to reach 22 million by 2030 [2]. An increased cancer survivor rate means that there are more cancer survivors in need of continuous lifetime management. Cancer survivors who complete their treatment regimen and begin the long-term management phase of their life face an array of potential physical,

mental, and practical problems [3]. To solve and prevent these problems, cancer survivors need lifelong management of chronic diseases, nutrition, lifestyle, and psychological well-being [4]. Failure to prevent and manage cancer survivors’ health problems can result in escalated medical costs for treating these problems, as well as diminished productivity [5].

Nurses play a key role in helping cancer survivors manage and improve their health. Therefore, educating nursing students on how to take care of cancer survivors is important for them to develop their nursing competencies. During nursing practicum, students generally learn about the care provided to patients hospitalized with an acute disease or for diagnostic testing. Teaching nursing students to care for cancer survivors in a hospital setting is difficult not only because of differences in health care services but also because of patient safety and risk of infection [6]. This suggests that during their clinical practicum, students face limitations in learning about nursing care for cancer survivors who require

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E-mail address: [esuh@snu.ac.kr](mailto:esuh@snu.ac.kr)<https://doi.org/10.1016/j.anr.2022.01.002>p1976-1317 e2093-7482/© 2022 Korean Society of Nursing Science. Published by Elsevier BV. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

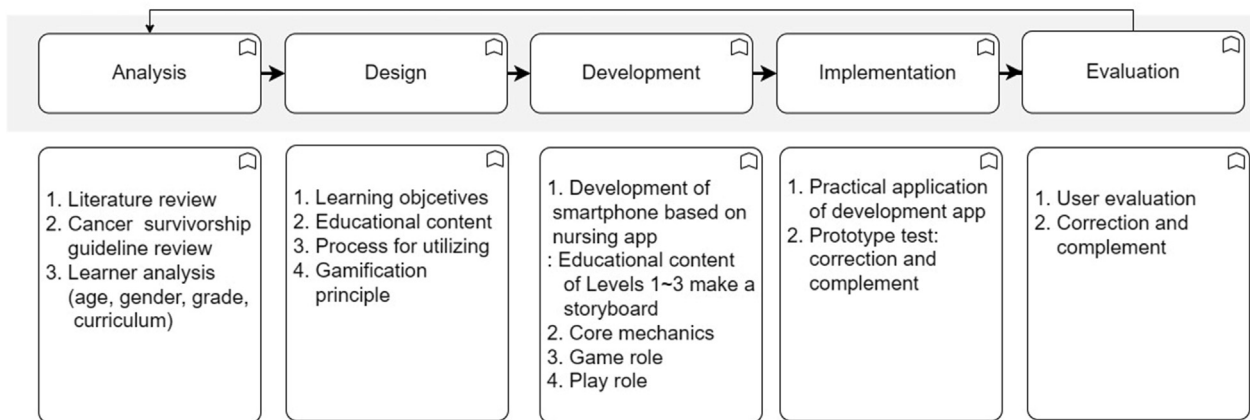


Figure 1. The Process of the Mobile App Development.

continuous management and care mostly within the context of living. To address such issues, various educational contents beyond clinical practicum courses need to be developed to boost nursing students' competency in caring for cancer survivors.

The accelerated digitalization of the world and consequent technological advances have led to the development of various teaching modalities that enhance learning outcomes among students. Thus, instructors now face demands to be creative and formulate various educational methods by incorporating information communication technology into learning. In particular, mobile applications have the benefit of engaging students and enhancing their clinical competence [7].

Computer-based learning, online learning, and educational apps are widely used in nursing education as well, and their effectiveness has been validated in many studies [8,9]. However, previous studies that developed nursing educational apps simply focused on a single skill, such as high-risk drug dosage calculation, basic nursing skills (vital signs, intravenous insertion, tube feeding, and tracheal suction), and tracheostomy care [10–12]. For example, Kang and Suh reported that using an app for hypertension and diabetes mellitus care increased the nursing students' knowledge and self-efficacy for chronic disease management [13]. However, the developed app was limited in that it only enabled unidirectional implementation of nursing intervention, as opposed to allowing interactions with patients.

Nurses evaluate, diagnose, intervene, and assess patients by communicating and interacting with them, which are active decision-making processes that change in accordance with patients' needs and values. To our knowledge, no study to date has attempted to develop an educational app for nursing students that boosts their nursing competencies while enabling appropriate patient interactions by specific cases involved.

This study was aimed to develop a cancer survival application (CS app) for nursing students and to evaluate its usability. Furthermore, it was to enable nursing students to acquire knowledge and nursing competency to improve the health of cancer survivors through the CS app.

## Methods

### *Theoretical framework for the development of the CS App*

The CS app for nursing students was developed based on Knowles' adult learning theory [14] and Bandura's self-efficacy theory [15] to increase students' knowledge and nursing self-efficacy. Cancer survivors were categorized based on the conceptual

framework for three-dimensional nursing simulation education (3D Simulation Framework) [16].

We applied the six principles of Knowles' adult learning theory to boost the effectiveness of education as follows: (1) Need to know: The participants of this study, nursing students, strive to enhance their competence as nursing professionals. (2) Experience: It is important to design a program tailored to nursing students' knowledge and competence. As such, in the analysis stage, we analyzed the nursing curriculum and developed a program with three levels based on basic knowledge about cancer survivorship to an advanced level. (3) Self-concept: The program was developed as a mobile application such that students could access the program without temporal and spatial limitations. They were allowed to choose from levels 1 to 3 at the program design stage. (4) Readiness: Nursing students have or are scheduled to undergo clinical practicum; they have high enthusiasm and are ready for clinical practice. (5) Problem oriented: In the symptom management tab, students can acquire problem-oriented thinking through conversations about health-related information for cancer survivors. (6) Intrinsic motivation: The program encompasses both extrinsic learning motivation, such as feedback, leaderboard, and heart rewards, and intrinsic learning motivation, such as quality of life score among cancer survivors. In the CS app, the patient's quality of life score must be 70 or higher to move to the next level, making nursing students more motivated to improve the patient's quality of life.

Bandura's self-efficacy theory was applied as follows: (1) As a strategy to help students obtain an enactive mastery experience, the program was divided into levels 1–3 such that students gain mastery experience as they advance to the next level. Furthermore, as patients' quality of life score increased or decreased based on the outcome of nursing interventions performed within the CS app, the CS app background also changed to provide visual stimulation. In addition, words of encouragement and challenge quizzes were given through pop-ups to help students accumulate mastery experiences. (2) To provide a vicarious experience, the latest knowledge and information were provided through videos and other educational materials prepared based on health guidelines for cancer survivors [17]. (3) For verbal persuasion, the patient icon in the CS app provided positive feedback, such as "I like it that I'm controlling my weight" and "I feel like I'm getting healthier with balanced meals" when the nursing student performed appropriate interventions. (4) Regarding physiological and affective status, nursing students' psychological anxiety was minimized, as they were able to access the CS app at a time and place of their convenience.

The CS app consisted of three levels. Each level was developed based on the 3D simulation framework [16]: the X-axis represented the scope

of practice, the Y-axis represented the complexity of simulation, and the Z-axis represented the student competency (determining which competency should be assessed based on which level).

The game elements of the program were the storyline (nursing storyboard), choice of level (three levels), feedback (visual and verbal feedback for care, including patient's comments and changes in quality of life score and app background), point system (heart reward), and leaderboard (scoreboard) [18].

#### CS app development

The CS app was developed based on the ADDIE (analysis, design, development, implementation, and evaluation) model [19] and the gamification principle [20]. In the analysis stage, we reviewed existing cancer survivorship care guidelines and studies, as well as the current nursing curriculum. In the design stage, we established learning objectives and incorporated learning content and game design elements. In the development stage, we collaborated with an IT company (TGRAM: AR/VR content studio) for CS app development. We also used an administrator server ([www.lvvyro.net](http://www.lvvyro.net)) for data management. Through the server, administrators can check users' app usage time and consultation answers. In the application and evaluation stage, expert and user evaluations were performed, and the CS app was modified and updated accordingly. A plot and algorithm were created, and the details of the digital algorithm to calculate the students' final scores were also written (Figure 1, Appendix 1).

#### CS app usability evaluation

##### Sample

Based on previous studies that evaluated usability after recent app development, the expert evaluation ranged from 2 to 69 people, and the user evaluation ranged from 5 to 35. In this study, five experts and 20 users were obtained in consideration of previous studies [13,21].

A panel of experts comprising two oncology nurse specialists, one nursing informatics expert, one professional app developer, and one nurse with more than 5 years of clinical experience evaluated the usability of the CS app. The CS app developer was different from the app developer in the panel of experts. We provided an explanation of the developed CS app and Mobile App Rating Scale (MARS) to the expert panel and asked them to use the CS app and evaluate it from March 15 to March 19, 2021. Five experts participated in the evaluation.

For user evaluation, 20 third-year and fourth-year nursing students who owned Android smartphones and had completed basic nursing and therapeutic communication were recruited. The recruitment announcement was posted on the school bulletin board and in an undergraduate group chat room from March 15 to March 19, 2021. After they were introduced to the CS app and user version of the MARS (uMARS), the nursing students were asked to use the CS app for 1 day (try out levels 1–3) and evaluate it.

After installing the CS app on their Android mobile phones, experts and nursing students directly ran the CS app to give patients in levels 1–3 appropriate nursing interventions according to the patient's condition; these interventions involved medication, diet, exercise, stress management, symptom management, and regular medical checkup.

##### Instruments

The expert usability evaluation was measured using the MARS tool after permission was obtained from the original developers and translator [21,22]. The MARS consists of 23 items for engagement (five items), functionality (four items), aesthetics (three items), information (seven items), and subjective quality of the app (four

items). It was evaluated on a 5-point Likert scale. A higher score indicated a higher perceived quality of the app. Cronbach  $\alpha$  was 0.90 at the time of development and 0.93 in this study.

The user usability evaluation was measured using the uMARS tool after permission was obtained from the original developers and translator [21,23]. The uMARS comprises 20 items for engagement (five items), functionality (four items), aesthetics (three items), information (four items), and app subjective quality (four items), and each item is rated on a 5-point Likert scale. A higher score indicated a higher perceived quality of the app. Cronbach  $\alpha$  was 0.90 at the time of development and 0.82 in this study.

In addition, the participants were asked the following open-ended questions about their experiences with the CS app.

- 1) Tell me about the problems you experienced while using the CS app (experts and users)
- 2) What do you think are the pros and cons of the CS app? (Experts and users)
- 3) Which aspect would the CS app be most helpful for among nursing students? (Experts)
- 4) Do you think the CS app is useful for learning? Why or why not? (Users)
- 5) What do you think needs to be corrected or supplemented in the CS app? (Experts and users)

#### Ethical considerations

Approval was first received from the institutional review board (Approval no.2007/001-013) at the university with which the authors were affiliated, and then the data collection for user evaluation began. The author who conducted the data collection is a doctoral student who does not have direct authority over the students who participated in the data collection. Students who voluntarily expressed willingness to participate in the study after reading the recruitment announcement were provided the consent form containing the study purpose, procedure, anticipated effects, potential risks, data management, and researchers' contact information. They also signed a written consent form. As a token of gratitude, the participants were given a coffee voucher worth 20,000 KRW. The participants were informed that they had the freedom to withdraw from the study at any time without being disadvantaged. Furthermore, they were informed that the collected data would only be used for research purposes, would be anonymously processed during analysis, and would be stored in a locked cabinet with restricted access until disposal after study completion.

## Results

The development and usability evaluation results of the CS app for nursing student education are discussed in this section.

#### Description and installation of developed items

##### Analysis

We reviewed cancer survival management guidelines using the keywords "cancer survival" and "guidelines" to check cancer survival management items. In addition to searching foreign literature such as PubMed, EMBASE, and CINAHL, Korean data were reviewed from DBpia, RISS, and the National Cancer Information Center (Appendix 2, 3).

Based on a manual for cancer survivorship, NCCN (National Comprehensive Cancer Network) clinical practice guidelines, the Cancer Experience Health Care Guide, and a literature review (activity, diet, health management), medication (anti-hormone therapy, drugs for chronic conditions), diet, exercise, stress management,

symptom management, and regular medical checkup were chosen as the items for the CS app. A counseling tab, where students provide counseling for cancer survivors, was added to level 3 (see Figure 2).

**Design**

Students could download the CS app using a file provided by researchers. Figure 2 shows screenshots of levels 1–3 in the CS app. The

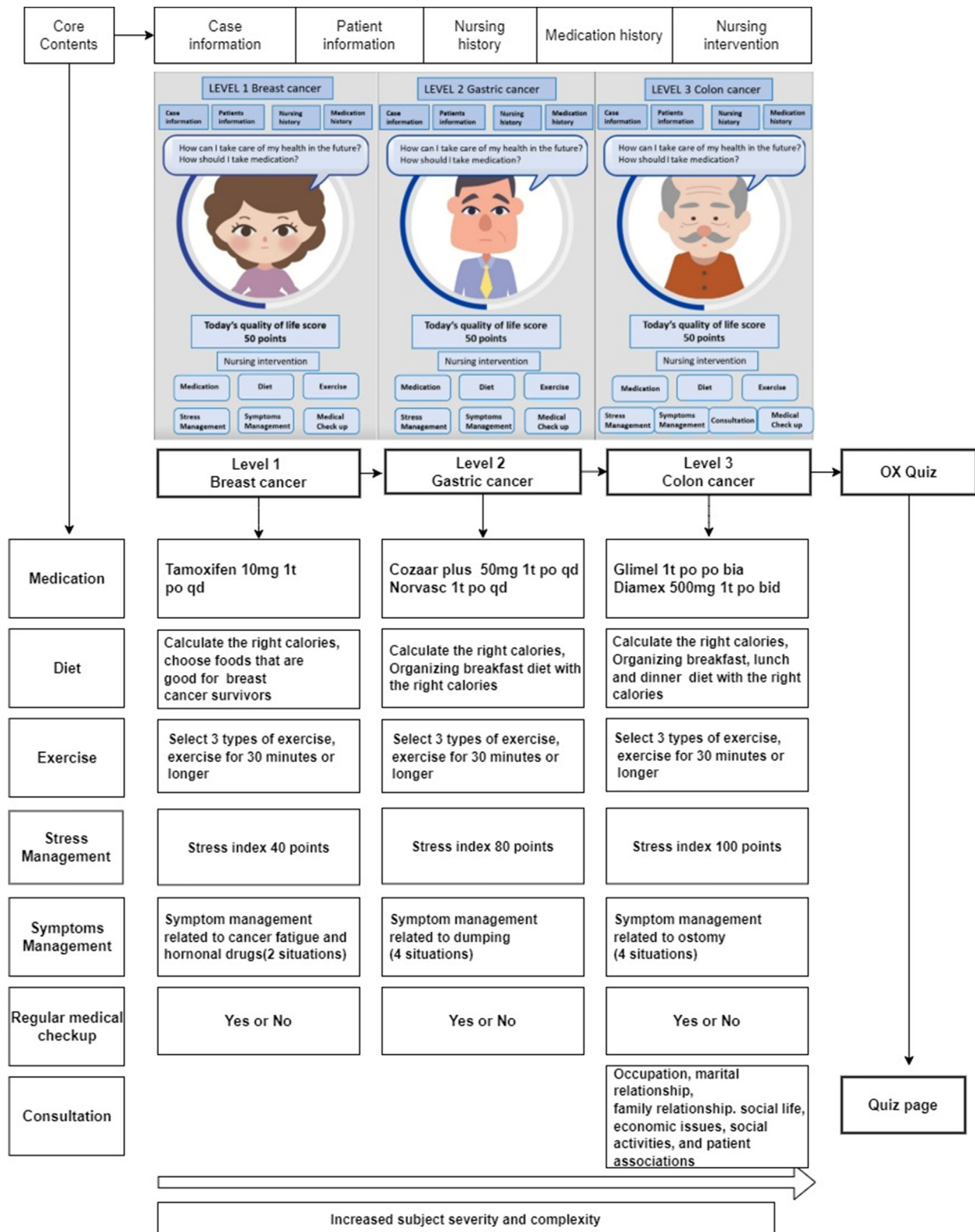


Figure 2. Main Contents and Levels of the Developed App.

patient's case, information, care history, and medication history can be accessed at the top of the screen. Nursing intervention, medication, diet, exercise, stress management, symptom management, and regular medical checkup tabs are shown at the bottom of the screen.

#### Development

The storyboard for developing the CS app included the login screen, initial screen (intro), main screen (main), and setting screen, and efficiency of presentation and the functionality for technical implementation were considered. To log in, users entered individual numbers in the login screen. The intro screen explained the learning goals of the CS app, whereas tabs for breast cancer, gastric cancer, colon cancer, and quizzes were shown on the main screen. The setting screen contained tabs for inquiry, educational materials, videos, FAQs (frequently asked questions), scoreboards, and sound effect settings for the CS app (Appendix 4).

The patient at level 1 is a breast cancer survivor. The objective of this level is to acquire knowledge about disease-specific medication, diet, exercise, symptom management, and health checkup. The patient at level 2 is a gastric cancer survivor. The tasks in this level include more complex, individual-specific medication administration, calculation of proper calorie intake, encouragement of the patient during exercise, a high-stress stage, and symptom management. The level 3 patient is a colorectal cancer survivor who requires more complex, situation-specific nursing interventions than level 2, such as counseling about marital relations, family, and social life.

Each level of the CS app was designed, so users could move from one level to the next after the first level is completed. The initial quality of life score of each patient is 50, and the score changes the next day based on the sum of the scores for medication, diet, exercise, stress management, symptom management, and regular medical checkup. If appropriate nursing intervention is implemented, the patient's quality of life score increases, and in the opposite case, the quality of life score decreases. Symptom management, one of the nursing interventions, was presented in a dialog format where the patient makes a complaint about his/her symptoms and the nursing student selects and provides an appropriate nursing intervention. The counseling tab in level 3 was designed in a way that the nursing student can directly write content that provides emotional support to the actual patient. As the background screen and narration of the patient change according to the patient's quality of life score, the nursing student strives to further improve the patient's situation. Appendix 4 explains how the quality of the score is calculated.

The CS app was developed for the Android operating system and will be registered on the Google Play Console. The system

requirements are Android 8.0 (Oreo) or higher, and the programming languages used were C# (Microsoft, Redmond, WA) and PHP (Zend Technologies, Cupertino, CA). Unity (Unity Technologies, San Francisco, CA) 2020.1.15 was used as a platform for development. MySQL (Oracle Corporation, Redwood City, CA) was used as the application database, and eight tables were created.

#### CS app implementation and usability evaluation

##### General characteristics of the participants to evaluate usability

Five experts participated in the evaluation of the CS app: one nursing informatics expert with PhDs, three oncology nurse specialists with master's degrees, and one app developer with more than 5 years of experience. Table 1 lists the general characteristics of the experts.

A total of 20 nursing students, 10 from the third year and 10 from the fourth year, participated in the user evaluation. Of these, 17 were female, and three were male. Four students had prior experience using an educational app (Table 1).

##### Survey analysis after CS app usability

The experts gave the highest rating (4.05) for functionality and the lowest (3.40) for engagement. The mean quality score given by experts was 3.66 out of 5. Nursing students gave the highest rating (4.35) for information and the lowest (3.45) for engagement. The mean quality score given by students was 3.97 out of 5 (Table 2).

Experts gave the question of whether the CS app has an achievable goal (part of the "information" subcategory) their highest rating (4.25 points). Conversely, nursing students gave the question of whether the CS app has visual information (part of the "information" subcategory) their highest rating (4.50 points). Both groups' lowest scores were given in the subjective quality subcategory: experts gave their lowest score (2.40) for how many times they thought they would use the CS app (none: two people; 3–10 times: two people; 10–50 times: one person), whereas nursing students gave their lowest score (2.65) for whether they were willing to pay to use the CS app (Table 2).

##### Comments from experts and nursing students

To the question, "Which aspect would the CS app be most helpful for nursing students," the expert panel answered that students could obtain information about each level and acquire an understanding of patients' situations and basic knowledge about health management of cancer survivors. Furthermore, the experts

**Table 1** General Characteristics of the Experts and User Groups (N = 25).

Variable	Category	Experts (n = 5)		Nursing students (n = 20)	
		n (%) or mean ± SD		n (%) or mean ± SD	
Gender	Women	4 (80.0)		17 (85.0)	
	Men	1 (20.0)		3 (15.0)	
Major	Nursing informatics	1 (20.0)			
	Nursing oncology	3 (60.0)			
	App developers	(20.0)			
Degree of education	PhD candidate	2 (40.0)			
	Master degree	2 (40.0)			
	Bachelor degree	1 (40.0)			
Duration of career		9.60 ± 4.72			
Grade	Junior			10 (50.0)	
	Senior			10 (50.0)	
Age				22.05 ± 1.97	
Experience of using of educational apps	Yes			4 (25.0)	
	No			16 (75.0)	

Note. SD = standard deviation.

**Table 2** Evaluation of the Experts and Nursing Students: Subcategory (N = 25).

Subcategory	Item	Expert (n = 5)		Nursing students (n = 20)	
		Mean ± SD		Mean ± SD	
Engagement	1. Entertainment	3.20 ± 0.84	3.40 ± 0.85	3.35 ± 0.88	3.45 ± 0.59
	2. Interest	3.40 ± 1.14		3.75 ± 0.91	
	3. Customization	3.40 ± 1.14		2.95 ± 0.60	
	4. Interactivity	3.00 ± 1.22		3.10 ± 1.22	
	5. Target group	4.00 ± 0.70		4.10 ± 0.79	
Functionality	6. Performance	4.20 ± 0.84	4.05 ± 1.16	4.10 ± 1.02	4.08 ± 0.63
	7. Ease of use	4.00 ± 1.73		3.90 ± 1.02	
	8. Navigation	3.80 ± 1.79		3.85 ± 0.88	
	9. Gestural design	4.20 ± 0.84		4.45 ± 0.69	
Aesthetics	10. Layout	3.60 ± 1.14	3.53 ± 1.17	3.85 ± 0.75	4.00 ± 0.51
	11. Graphics	3.40 ± 1.14		4.00 ± 0.79	
	12. Visual appeal	3.60 ± 1.34		4.15 ± 0.59	
Information	13. Accuracy of app description	4.00 ± 0.71	3.64 ± 1.02	-	4.35 ± 0.38
	14. Goals	4.25 ± 2.07		-	
	15. Quality of information	3.75 ± 1.87		4.45 ± 0.60	
	16. Quantity of information	3.25 ± 1.52		4.15 ± 0.88	
	17. Visual information	4.00 ± 0.71		4.50 ± 0.61	
	18. Credibility	3.80 ± 1.10		4.30 ± 0.47	
	19. Evidence base	2.50 ± 1.41		-	
	20. Would you recommend the app to people who might benefit from it?	3.66 ± 0.90		3.97 ± 0.41	
App subjective quality	21. How many times do you think you would use this app in the next 12 months if it was relevant to you? <sup>a</sup>	3.40 ± 1.14	3.10 ± 0.72	3.30 ± 0.80	3.13 ± 0.73
	22. Would you pay for this app? <sup>b</sup>	2.40 ± 1.34		2.85 ± 0.81	
	23. What is yours overall star rating of the app?	3.00 ± 0.00		2.65 ± 1.46	
		3.60 ± 0.89		3.70 ± 0.66	

Note. SD = standard deviation.

<sup>a</sup> Five-point Likert scale was used (1 = none, 2 = 1–2 times, 3 = 3–10 times, 4 = 10–50 times, 5 = >50 times).

<sup>b</sup> Item 22 were 5-point scale from 1 (definitely not) to 5 (definitely yes).

believed that the CS app would help students approach patients more easily.

To the question, “Do you think the CS app is useful for learning,” students affirmed that they were able to learn about cancer survivorship care. They also said that the symptom management tab was particularly easy to use and memorable because it allowed them to talk to the patient in the case. Moreover, the students mentioned that the CS app would be helpful for them to be prepared for clinical practicum courses and that it would help them develop an interest in nursing care and health management for cancer survivors. Regarding areas where the CS app needed revision, they said there was not enough space for students and instructors to interact and that it would be beneficial to have more timely feedback to allow them to check the intervention score and the patient's quality of life score immediately after the intervention (Table 3).

#### Total app usage time by expert and nursing students

After surveying the usage time to determine the utilization of and interest in the CS app, it was found that five experts spent an average of 8.92 minutes and nursing students 7.18 minutes on the CS app. The most recent nursing intervention of the day was reflected in the patient's quality of life score the next day. Only the latest quality of life score was reflected, and the number of daily logins was not checked (Appendix 5).

## Discussion

This study was aimed to develop a CS app for nursing students and evaluate it by experts and users (nursing students) for its usability. The CS app allowed the students to experience nursing interventions for cancer patients in mobile setting. In particular, the symptom management feature in the CS app was designed to enable a virtual conversation between the students and the

patients for them to learn how to interact with the patients. In addition, by differentiating patients' conditions in three levels, the CS app was designed to enable the students to learn the complexity of various patients cases step by step.

Through the CS app, students were given the opportunity to perform nursing interventions on patients in a virtual setting, which is often difficult in clinical training due to patient safety concerns. In contrast to other chronic illness care smartphone apps for nursing students, we developed a scoring system in which a patient's condition changed according to the user's performance in the CS app [13]. In this study, the change in the patient's quality of life intrinsically motivated the students to modify their inputs (nursing interventions). Furthermore, the results of nursing interventions conducted by the students were expressed as the quality of life in a comprehensive way.

Considering that MARS scores for an online educational app providing COVID-19 information ranged from 2.4–4.8 [24], the CS app developed in this study can be regarded as having a good quality rating overall, as its MARS scores surpassed 3.0 [25]. The expert ratings for each domain ranged from 3.40 to 4.05, with the highest rating for functionality and lowest rating for engagement. The user (nursing students) ratings for each domain ranged from 3.45 to 4.35, with the highest rating for information and lowest for engagement. The aforementioned COVID-19 educational app was also given a good rating for functionality and a low rating for engagement. It was speculated that the low rating for engagement could be due to the lack of eye-catching colors, graphics, and entertainment [24]. The low rating for engagement in the CS app may also be attributable to the absence of a channel for communication between the administrator and nursing student, apart from the researchers' contact information being missing. In a previous study, the expert usability evaluation for an emotional education mobile app for middle school students was 4.00 points, whereas the user evaluation was 3.96 points. The expert evaluation was higher than that in the present study, but the user evaluation was similar [26].



**Table 3** Comments From the Experts and Nursing Students (N = 25).

Category		CS app's Advantages
Expert	Information	1. Helpful for gaining knowledge about each disease 2. Enables students to engage in experiential thinking by determining the need for a specific intervention for a particular disease and performing the intervention 3. Provides information about each level 4. Provides an opportunity to gain an understanding of the patient's situation 5. Will make it easier for students to approach patients
	Correction	6. Priority intervention by disease is required 7. Add more game elements to arouse interest
Nursing student	Education	1. Can experience an educational method for health management of cancer survivors 2. The conversation-style design of the symptom management tab makes learning easy and memorable 3. Can comprehensively learn about the appropriate nursing interventions for patients in various cases 4. The quizzes were extremely helpful in retaining the learned contents, and taking the quizzes repeatedly allowed for repetitive learning 5. Was able to learn more clearly about the things that nurses should pay close attention to and provide care for, compared with other types of learning
	Information	6. Provides credible information and case-based scenarios that are effective for learning 7. Will be helpful in preparing for clinical procedures
	Engagement	8. Helped develop an interest about health management and health improvement for cancer survivors
	Correction	9. Lack of space for interaction between instructors and students 10. The app needs quick feedback to check the intervention score and the patient's quality of life score.

Note. CS app = cancer survivorship application.

This study has several theoretical implications. We applied Knowles' adult learning theory and the three aspects of Bandura's self-efficacy theory: enactive mastery experience (use of three levels), vicarious experience of success (educational materials), and verbal persuasion (feedback provided within the CS app). In addition, we implemented three levels of cancer survivor scenarios using the 3D simulation framework to provide an opportunity for students to experience different patient cases. Also, we incorporated the gamification theory to motivate students to participate [19]. Thus, the key significance of this study is that several theoretical principles were applied to develop the CS app for nursing student [7].

The analysis of the content evaluations in this study revealed that the participants used star ratings as a means of expressing their interest. However, a previous study that examined the usefulness of reviews and star ratings for online products found that star ratings had no relation to products or subjects; rather, text reviews were highly related to product selection [27]. In another study that evaluated an app developed for hyperlipidemia management, the lowest ratings in the subjective quality category were given to the item assessing whether experts and users were willing to pay to use the app (3.00 and 2.7, respectively) [21]. Furthermore, in a study evaluating an emotional education, mobile app developed to promote the mental health of middle school students, experts, and users both gave willingness to pay for the app 3.6 points [26]. In the present study, experts and student users gave 3.0 and 2.65 points for willingness to pay, respectively.

This is a notable result because it contradicts the high star rating of 3.70 given by students. Thus, it seems that students do not want to use the app if they need to pay for it because, despite gamification, these apps still differ from normal games developed purely for entertainment. In other words, even if educational apps feature high usability and practicability, student users may not actively purchase them. To address this issue, educational apps for professional study should be developed in collaboration with schools, industries, and developers, with funding from public institutions or industry–university foundations, so that the apps can be available for students at no cost to encourage active utilization.

In this study, nursing students positively rated the CS app, mentioning that they developed an interest in nursing care and management of cancer survivors, which highlights the potential of the CS app as a useful learning medium for nursing students. In the usability evaluation, patients' quality of life scores increased for all

nursing students with the exception of one, and all students strived to increase their patients' quality of life scores.

In the past, many attempts have been made to apply gamification to educational apps. After medical students used medical knowledge software based on gamification, they participated more actively when solving problems, and their correct answer rate significantly increased in the competitive team–based and individual quizzes and retests. Furthermore, the leaderboard was identified as the game-playing element that motivated users to participate [28]. In the present study, we intended to motivate participation by creating a “scoreboard” tab. However, in the CS app, the notification for competitions was not implemented. Subsequent studies should apply notifications for competitions or current performance to further motivate participation.

Finally, in the study of developing a virtual hypertension and diabetes management app for nursing student education [13], researchers could not reflect changes in the patient's blood sugar or sodium level in the app as precisely as the intervention of nursing students gave due to technical barriers. However, in this study, an algorithm to increase or decrease the quality of life score based on the nursing intervention performed by the student was developed. Thus, the changes in the patient's state stimulated the students' caregiving instinct. Using advances in information communication technology and establishing a technological foundation to develop an array of patient cases that are not commonly encountered during clinical training would be beneficial for nursing education.

This study contributes to the nursing academia at large in several ways. First, to our knowledge, this is the first study to develop an app for nursing students to learn about the promotion of cancer survivors' health. This is relevant in today's world where the number of cancer survivors is increasing; thus, nursing students must learn about the amount and quality of cancer survivorship care. Second, the students participated in this study became interested in and understood the importance of the care for cancer survivors. Third, through the CS app, knowledge of cancer symptom management and conversation skills with cancer patients was cultivated before clinical practice in advance what they should learn in clinical practice. Fourth, details of nursing care for cancer survivors in terms of their medication, diet, exercise, stress management, symptom management, and regular medical checkup to improve the quality of life were implemented through the CS app. Fifth, the intrinsic motivation of students was promoted by developing an algorithm in

which each patient's quality of life score increased and decreased according to the nursing care they provided.

However, this study also has a number of limitations. First, it did not implement a system of competition to increase participation in the app, nor did it implement a user interface that allowed interaction between the administrator and nursing students and among nursing students. Second, convenience samples were used for usability evaluation, and only the Android platform was used in consideration of the cost in the development process. Third, we attempted to create a question-and-answer tab to enable interactions between the administrator and the students and among the students after the usability evaluation but could not proceed with the update due to cost restrictions and lack of data storage. Thus, establishing a question-and-answer feature in the early design stage is important in future studies. Finally, the effect evaluation after CS app development has not yet been conducted; thus, further research is needed.

**Conclusion**

The CS app is expected to be an effective and user-friendly educational tool to increase the knowledge and self-efficacy of nursing students in learning cancer survivorship care. Nursing students stated that they were able to comprehensively learn about cancer survivor care and that the conversational feature in the symptom management tab allowed for easy and memorable learning. In particular, incorporating common patient symptoms through conversational interaction that enabled students to learn

about them consistently was a valuable element of learning for nursing students preparing for clinical practicum.

A key component of the CS app, developed based on gamification, was feedback, and it was the most mentioned feature among users. The CS app was modified by reflecting quick feedback, which appeared after the usability evaluation by the CS app users. We confirmed that proper feedback is an essential motivator and component of the instructor–user interaction. Developing additional apps containing more patient cases that enable interaction with nursing students and patients would contribute to the establishment of mobile apps as a complementary learning tool to clinical practicum. Subsequent studies should also implement and evaluate the CS app developed in this study.

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**Conflict of interest**

The authors declare no conflict of interest.

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**Appendix 1 Calculation Data Structure.**

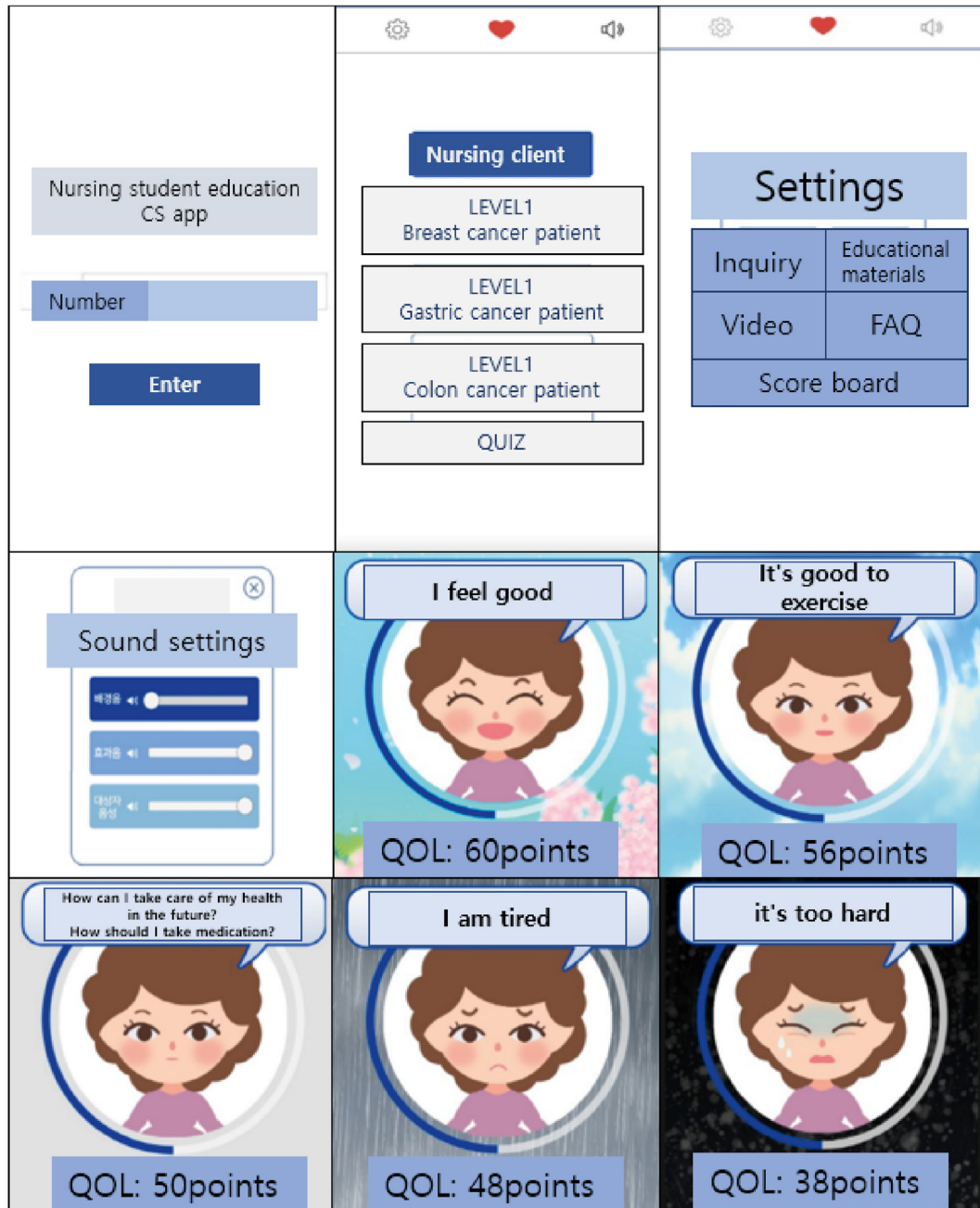
Quality of life score	Medication (20) + diet (20) + exercise (20) + stress management (20) symptom management (20) + regular medical checkup (20) = 120 points
0–120 points	<ol style="list-style-type: none"> <li>1. 110–120: Patient's quality of life score increased by 10 points</li> <li>2. 90–109: Patient's quality of life score increased by 8 points</li> <li>3. 70–79: Patient's quality of life score increased by 6 points</li> <li>4. 50–69: Patient's quality of life score decreased by 2 points.</li> <li>5. Fewer than 50: Patient's quality of life score decreased by 4 points</li> </ol>

**Appendix 2 Cancer Patient Guideline and Websites.**

No	Reference/website	Title	Journal
1	Arends J, Bachmann P, Baracos V, Barthelemy N, Bertz H, Bozzetti F, et al (2017)	ESPEN guidelines on nutrition in cancer patients	Clin Nutr, 36(1), 11–48.
2	Birken SA, Ellis SD, Walker JS, DiMartino LD, Check DK, Gerstel AA, & Mayer DK. (2015)	Guidelines for the use of survivorship care plans: a systematic quality appraisal using the AGREE II instrument	Implement Sci, 10, 63.
3	Coletta AM, Marquez G, Thomas P, Thoman W, Bevers T, Brewster AM, et al (2019)	Clinical factors associated with adherence to aerobic and resistance physical activity guidelines among cancer prevention patients and survivors	PLoS One, 14(8) e0220814.
4	Denlinger CS, Sanft T, Baker KS, Baxi S, Broderick G, Demark-Wahnefried W, et al (2017)	Survivorship, Version 2.2017, NCCN Clinical Practice Guidelines in Oncology	J Natl Compr Canc Netw, 15(9), 1140–1163.
5	Okubo R, Wada S, Shimizu Y, Tsuji K, Hanai A, Imai K, et al (2019)	Expectations of and recommendations for a cancer survivorship guideline in Japan: a literature review of guidelines for cancer survivorship	Jpn J Clin Oncol, 49(9), 812–822.
6	Yun YH, et al (2013)	Manual for cancer survivorship	Koonja.co.kr
7	<a href="http://www.cancer.go.kr">www.cancer.go.kr</a>	National Cancer Information Center Cancer Experience Health Care Guide Cancer Patient Life Guide (life management, diet, symptom management)	
8	<a href="https://www.macmillan.org.uk">https://www.macmillan.org.uk</a>	Macmillan Cancer Support	
9	<a href="https://www.nccn.org">https://www.nccn.org</a> (National Comprehensive Cancer Network)	NCCN Clinical practice guidelines in oncology (NCCN Guidelines) Survivorship Version 1. 2020-March 17.2020	
10	<a href="https://www.cancer.org">https://www.cancer.org</a>	Cancer care	
11	<a href="https://www.cancer.gov">https://www.cancer.gov</a>	National Cancer Institute (NCI)	
12	<a href="https://www.canceradvocacy.org">https://www.canceradvocacy.org</a>	National Coalition for Cancer Survivorship (NCCS)	
13	<a href="https://www.cancer.org">https://www.cancer.org</a>	American Cancer Society	
14	<a href="https://www.acsm.org">https://www.acsm.org</a>	American College of Sports Medicine	
15	<a href="https://www.cancernetwork.com">https://www.cancernetwork.com</a>	The Cancer Information Network	
16	<a href="https://preventcancer.aicr.org">https://preventcancer.aicr.org</a>	American Institute for Cancer Research	
17	<a href="https://www.asco.org">https://www.asco.org</a>	American Society of Clinical Oncology	

**Appendix 3** Literature Review of Cancer Patient Health Management.

No	Author	Title	Content	Journal
1	Park JH, Shin DW (2012)	Cancer Survivor 1 Million Era, Cancer Survivor Health Management	Prevention and screening for secondary cancer, chronic disease management and vaccinations, health habit management (smoking, obesity, nutrition, physical activity), psychosocial problem management	Research Institute for Healthcare Policy Korean Medical Association, 10(4), 66-72.
2	Lee JE, Shin DW, Cho BL (2014)	The current status of cancer survivorship care and a consideration of appropriate care model in Korea	Secondary cancer prevention and screening, management of accompanying diseases, lifestyle management, psychosocial problems	Korean Journal of Clinical Oncology, 10(2), 58-62.
3	Song CE (2018)	Integrative review of guidelines related symptom management and physical activity for developing of self-care management program for cancer survivors	Symptom management: fatigue, sleep disturbance, pain, depression, and anxiety Physical activity management: exercise (flexibility, strength, aerobic exercise recommended)	Journal of the Korean Contents Association, 18(4), 586-600.
4	Lee Y (2013)	Cancer Survivor's Health Management	Prevention and screening for secondary cancer, chronic disease management (hypertension, diabetes, hyperlipidemia, osteoporosis, anemia), diet, exercise, proper weight management	Korean Society for Health Promotion and Disease Prevention. Paper presented at 2013 spring conference. Seoul. Journal of Korean Academy of Nursing, 47(2), 143-163.
5	Park JH, Bae SH (2017)	Effects of psychoeducational intervention for cancer survivors: a systematic review and meta analysis	Among 41 papers, counseling and behavioral therapy were significant for psychological education intervention	Journal of Korean Academy of Nursing, 47(2), 143-163.
6	Viscuse PV, Price K, Millstine D, Bhagra A, Bauer B, Ruddy KJ (2017)	Integrative medicine in cancer	Role in the management of physical and emotional issues: physical activity, diet, dietary supplement, mind-body modalities, acupuncture, massage therapy	Curr Opin Oncol, 29(4), 235-242.
7	Sisler J, Chaput G, Sussman J, Ozokwelu E (2016)	Follow-up after treatment for breast cancer: practical guide to survivorship care for family physicians	Four main tasks: Survivorship care 1) surveillance (annual mammography) 2) management of long-term effects (pain, fatigue, lymphedema, distress, cardiac and bone health) 3) health promotion (physical activity) 4) care coordination	Can Fam Physician, 62 (10), 805-811.
8	De Lorenzo F, Apostolidis K, Florindi F, Makaroff LE (2018)	Improving European policy to support cancer survivors	Key priorities for action 1) timing and content of follow-up, rehabilitation 2) raising awareness of both short-term and long-term treatment-related effects 3) health maintenance 4) information regarding legal protections 5) psychological support.	Journal of Cancer Policy, 15, 72-75.



Appendix 4. Screen Capture in the CS App and Background Changes According to Quality of Life.

**Appendix 5** CS App Total Usage Time by Experts and Nursing Students (N = 25).

Category	Experts (n = 5)	Nursing students (n = 20)
	Mean ± SD	Mean ± SD
Usage time (minutes)	8.92 ± 3.11	7.18 ± 3.17

Note. SD = standard deviation.

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