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Research Article

Effects of Heating Therapy on Pain, Anxiety, Physiologic Measures, and Satisfaction in Patients Undergoing Cystoscopy

Oh Suk Kwon,[1] Bokyeong Kwon,[1] Jihye Kim,[1] Bo-Hwan Kim[2,*]

[1] Department of Urology, Gachon University Gil Medical Center, Incheon, Republic of Korea
[2] Department of Nursing, College of Nursing, Gachon University, Incheon, Republic of Korea

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SUMMARY

Purpose: Cystoscopy is the most common procedure used to diagnose urological diseases; however, it is invasive and can be associated with pain and anxiety. Although pain relieving medications, such as lidocaine lubricants, are used during cystoscopy, the procedure still causes discomfort. Therefore, non-medical intervention is needed to reduce pain and anxiety during the procedure and increase patient satisfaction. The aim of this study was to evaluate the effect of heating therapy on pain, anxiety, physiologic measures, and satisfaction during cystoscopy.

Methods: This was a single-blinded, single-center, randomized controlled trial. A total of 145 participants who underwent cystoscopy between August 2017 and October 2017 were recruited and randomly assigned to an experimental or control group. Before and after cystoscopy, all the participants self-reported the degree of pain they felt, while pain was objectively assessed by trained nurses. Anxiety was evaluated using the validated Korean version of the State-Trait Anxiety Inventory. Blood pressure and pulse rate were also recorded as physiologic measures. After cystoscopy, satisfaction was measured in the experimental group only using the Korean version of the Client Satisfaction Questionnaire.

Results: Heating therapy reduced both subjective and objective pain and anxiety in the experimental group compared to the control group. Heating therapy also decreased the systolic and diastolic blood pressure and pulse rate in the experimental group compared to the control group. Women reported significantly greater satisfaction than men.

Conclusion: Heating therapy during cystoscopy is a convenient and effective nursing intervention that decreases pain and anxiety and enhances patient satisfaction.

The study has been registered with the Clinical Research Information Service Registry, and the trial registration number is [12616000803493].

Introduction

Cystoscopy is now preferentially recommended over invasive testing for the evaluation of asymptomatic microscopic hematuria and thus the identification of bladder cancer or other urological diseases [1–3]. However, even though cystoscopy is the most common procedure in daily urology practice, it is invasive and can be associated with pain and discomfort [4]. In particular, conscious patients are directly exposed to various stimuli during cystoscopy, which increases anxiety [5]. The pain and anxiety associated with cystoscopy can activate the sympathetic nervous system [6], resulting in various physiological responses, such as increased cardiac output, elevated blood sugar level, peripheral vascular contraction, and elevated blood pressure (BP) [7].

A variety of medical interventions, such as intra-urethral injection of lidocaine lubricant [8] or flexible cystoscopy [9], have been used to alleviate pain and anxiety during cystoscopy. Flexible cystoscopy is generally less painful than rigid cystoscopy; however, it is expensive, visualizes a smaller area, and requires more skill from urologists, and is therefore not favored [10,11]. In addition, some studies have reported that lidocaine lubricants can relieve pain and discomfort during cystoscopy [12]. However, some other authors have described self-reports of discomfort from patients who were administered lidocaine lubricants during cystoscopy

Oh Suk Kwon: https://orcid.org/0000-0001-8511-2770; Bokyeong Kwon: https://orcid.org/0000-0003-4996-3257; Jihye Kim: https://orcid.org/0000-0001-9411-8023; Bo-Hwan Kim: https://orcid.org/0000-0001-6932-9718

* Correspondence to: Bo-Hwan Kim, PhD, Department of Nursing, College of Nursing, Gachon University, 191, Hambakmoero, Yeonsu-gu, Incheon, Republic of Korea.

E-mail addresses: kosnurse@gilhospital.com, bokmany@gilhospital.com, jmp0530@gilhospital.com, bhkim@gachon.ac.kr

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[13]. Thus, despite the use of these medical interventions, patients undergoing cystoscopy still complain of post-procedural pain and anxiety [2].

Heating therapy involves the use of heat to relax the muscles [14], facilitate blood circulation [15,16], and promote metabolism [17], thus relieving pain [18–20]. It is inexpensive, saves time, and requires no special training or skill [16,20]. Furthermore, heating therapy elicits a sympathetic reaction that increases blood circulation in areas other than those directly in contact with heat [21,22]. Heating therapy can also relieve pain by temporarily increasing the threshold of pain delivery fibers [18].

Generally, acute pain causes anxiety, which increases the fear of pain, depression [23], sleep disturbances [24], and interferes with concentration and cognition [25]. Anxiety is triggered by a threat stimulus or an anticipated threat. As such, it increases attention to the trigger stimulus, leading to physiological arousal and avoidance actions [26]. Anxiety around pain causes individuals to avoid the stimulus and over-react to the body sensations that accompany it.

According to previous studies on the use of non-pharmacological interventions during cystoscopy, music therapy is an effective intervention that lowers pain and anxiety in patients during cystoscopy [27–29]. In another study, playing a video appeared to be the best distraction method during cystoscopy [30]. Hand-holding during cystoscopy has also been shown to reduce patients' anxiety, pain, and dissatisfaction [31]. Recently, two studies demonstrated that heating therapy is an effective intervention; however, only females were evaluated in those studies [32,33].

Therefore, the aim of the present study was to measure the effects of heating therapy on pain, anxiety, physiological measures that are affected by pain and anxiety, and satisfaction in patients undergoing cystoscopy in South Korea. The objectives were to determine: (1) whether the experimental group experienced more pain relief than the control group; (2) whether the experimental group experienced lower anxiety than the control group; and (3) whether the satisfaction differed between men and women in the experimental group.

Methods

Study design

This was a single-blinded, single-center, randomized controlled trial (RCT). It was conducted for 3 months, from August 2017 to October 2017.

Setting and sample

We included patients who were to undergo cystoscopy for the diagnosis and treatment. The inclusion criteria were as follows: (1) patients older than 18 years; (2) had sufficient intellectual capacity to communicate and comprehend the details of the study; (3) understood the purpose of the study; (4) provided informed consent; and (5) had urinary problems such as blood in the urine, urinary tract infections, overactive bladder, pelvic pain, etc. We excluded patients diagnosed with bladder cancer as their diagnoses may induce anxiety. Patients who were already in pain were excluded because their pain could not be differentiated from pain due to cystoscopy.

Initially, 166 eligible patients were assessed for possible inclusion in the trial during their scheduled visit for cystoscopy at the urology outpatient clinic of [masked for blinded review]. Of these, seven patients did not meet the inclusion criteria, five patients declined to participate, and eight patients had other reasons for not participating in the study. A total of 146 patients were randomized at a 1:1 ratio into two groups using computer-generated random numbers. Seventy-three patients each were allocated to the control and experimental groups. However, only 72 patients were enrolled in the control group because one patient refused to complete the post-intervention survey and dropped out. Figure 1 shows the Consolidated Standards of Reporting Trial diagram of the procedure of patient enrollment, randomization, and analyses in this study.

The sample size for the RCT was calculated using G*power 3.1.5 freeware [34], based on an effect size of 0.7 for pain intensity according to the methods used in a previous study on the effect of music therapy during cystoscopy [35] since there was no study on heating therapy for cystoscopy in urology when we planned our study. With a statistical power of 0.95, a two-tailed significance level of 0.05, and an allocation ratio of 1 (control vs. experiment), we estimated a sample size of 110 patients in total. We set the attrition rate at 33.0% considering high dropout rates in human health RCT [36]. Thus, the recruitment target was 146 patients.

Ethical considerations

Ethical approval for this study was provided by the Gil Hospital Institutional Review Board [No, (GCIRB2017-242)]. The study has been registered with the Clinical Research Information Service Registry, and the trial registration number is [12616000803493]. Patients were informed that their participation was voluntary and that they could withdraw from the study at any time. They were reassured that their withdrawal would not prevent them from receiving the care that they would normally receive. The participants were identified using research codes, and the research information remained confidential.

Measurements

Pain

The patients' subjective pain was assessed immediately after the procedure using a combined numeric rating scale and face rating scale to maximize our understanding of the self-reported pain associated with cystoscopy. Patients were asked to indicate how much pain they felt from 0 (no pain) to 10 (the worst pain).

Before beginning the study, one male and one female nurse were trained to assess pain and check pain monitoring. After training, they consistently measured pain values to assess the patients undergoing cystoscopy. Using the same methods described by Suh in 1990, they observed the patients' pain objectively during the cystoscopy procedure, monitoring four areas: (1) sweating; (2) changes in facial expressions; (3) changes in posture; and (4) changes in the voice [37]. A five-point Likert scale (1–5) was used to score each area, with the total score ranging from 4 (least pain) to 20 (most pain). In the present study, Cronbach's alpha for pain was 0.82.

Anxiety

We measured the anxiety level using the validated Korean version of the State-Trait Anxiety Inventory (STAI), which comprises two subscales of 20 multiple-choice questions each. The STAI was developed by Spielberger, Gorsuch and Lushene in 1970 [38] and was translated into Korean by Kim and Shin in 1978 [39]. Each subscale of the STAI, a 5-point scale (1–5), is summed up to obtain a total score between 20 and 80 points, with larger scores indicating greater anxiety levels [38,39]. In the present study, we measured STAI trait anxiety, which can affect state anxiety. Cronbach's alpha for STAI trait anxiety was 0.82, whereas that for STAI state anxiety was 0.88.

Physiological measures

The physiological measures we recorded included BP and pulse rate (PR), both of which could be affected by pain and anxiety [6].

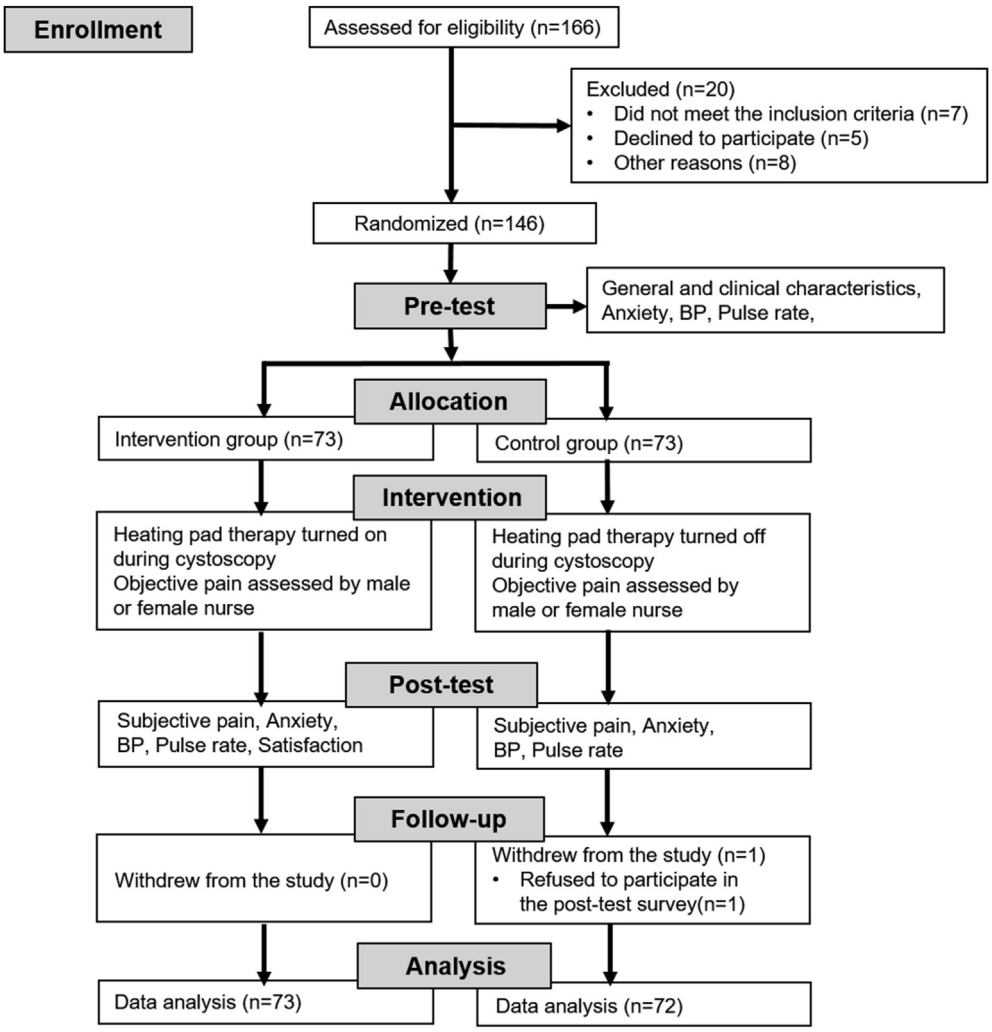

Figure 1. CONSORT Flow Diagram. CONSORT = Consolidated Standards of Reporting Trial.

BP and PR were measured thrice on each patient's left brachial artery using an electronic OMRON M3 Comfort® HEM −7134-E BP monitor (Omron Healthcare Co., Ltd. Kyoto, Japan), with 30 seconds between each measurement. An interval of no less than 1 minute was allowed between measurements, and the total measuring time was within 5 minutes. The measurements were taken within 10 min before and after the cystoscopy procedure. We used the average BP and PR values for analysis.

Satisfaction

Patient satisfaction was assessed using the Korean version of the Client Satisfaction Questionnaire (CSQ-8 Korean). The CSQ-8 was developed by Attkisson and Greenfield in 1994, and they permitted the use of the CSQ-8 Korean through a confirmation e-mail [40]. The questionnaire consisted of eight questions, each answered on a four-point scale (score range of 1–4) with the total score ranging from 8–32; higher values indicate higher satisfaction. In the present study, Cronbach's alpha for satisfaction was 0.90.

Procedure

Cystoscopy was performed in a 1-day outpatient clinic by eight qualified urologists following a standard protocol. All cystoscopies were performed with the patients placed in the dorsal lithotomy position; no additional manipulations, such as stent removal or bladder biopsy, were performed. Before each cystoscopy procedure, the external genital area was disinfected using povidone-iodine, and 10 mL of 2.0% lidocaine jelly was instilled in the intra-urethral area. Cystoscopy was performed using s rigid cystoscope (Karl Stortz, Tuttlingen, Germany) connected to a digital video monitor, which was used for all procedures.

In the experimental group, the electric heating pad therapy was initiated before disinfection and lidocaine gel injection and continued throughout the rigid cystoscopy procedure. The pad was warmed to a temperature between 40°C and 45°C and applied to the lower abdomen or sacrum area of the patient. The control group underwent cystoscopy with the electric heating pad therapy turned off. All patients viewed their procedures on a video monitor while they were being performed, and the urologist briefly mentioned each step of the procedure (i.e., instillation of analgesic, insertion of the scope, and intravesical scoping). The duration of the entire procedure was 20 minutes per patient. The urologist performing the treatment and the two nurses assessing objective pain, BP, and PR were blinded to the allocation; therefore, variables other than the experimental treatment were not affected.

Data collection

Data were collected after all participants provided informed consent. Most patients provided self-reported consent; however,

we helped some elderly patients who had difficulty in reading the small letters on the survey. Before cystoscopy, a pre-test was carried out. Sociodemographic and clinical characteristics were recorded, and the state and trait anxiety levels were measured within 10–15 min. BP and PR were measured 10 min before cystoscopy. During the procedure, one male and one female nurse who assisted with the cystoscopy observed the patients' pain objectively. The post-test assessment, which included the evaluation of subjective pain, state anxiety, and BP and PR measurements 10 min after cystoscopy, was then carried out. Satisfaction was measured only in the experimental group.

Data analysis

We used IBM SPSS 25.0 for data analysis (IBM Corp, Armonk, NY, USA). Nominal variables were expressed as numbers and percentages (%) and compared using the Chi-squared test, whereas continuous variables were presented as means with standard deviations. First, the Kolmogorov–Smirnov test was conducted to assess the normal distribution of all continuous variables. Since STAI-S anxiety, subjective and objective pain, and satisfaction scores were not normally distributed, they were compared between groups using the Mann–Whitney U test. STAI-S anxiety, subjective and objective pain scores, and satisfaction were compared between the two groups using the Student's t-test for normally distributed data. Additionally, systolic and diastolic BP and PR were analyzed using an analysis of covariance (ANCOVA) model to control the covariates (history of cystoscopy and the basic values of dependent variables) and identify the effects of heating therapy on the experimental group. Anxiety (STAI-S) and subjective and objective pain were analyzed using ranked ANCOVA after rank transformation to correct the covariates. All p <.05 were considered statistically significant.

Results

Baseline characteristics and homogeneity test

The demographic data and clinical variables are presented in Table 1. The average ages of the experimental and control groups were 63.05 and 65.50 years, respectively, and most of the participants in both groups were men. There were no statistically significant differences between the two groups in terms of age, sex, education level, reason for cystoscopy, history of bladder surgery, and STAI-T. However, the control group showed a significantly higher frequency of history of cystoscopy than the experimental group ($\chi^2 = 10.15$, $p = .001$).

Table 1 *Homogeneity Test for the General and Clinical Characteristics of the Two Groups (N = 145).*

		Exp. (n = 73)	Con. (n = 72)	χ^2/t	p
		Mean (SD)/N (%)			
Age, years		63.05 (11.04)	65.50 (11.34)	−1.32	.190
Gender	Men	39 (53.4)	48 (66.7)	2.64	.104
	Women	34 (46.6)	24 (33.3)		
Education level	Below middle school	33 (45.2)	42 (58.3)	2.50	.114
	Above high school	40 (54.8)	30 (41.7)		
Reason for cystoscopy	Diagnosis	57 (78.1)	48 (66.7)	2.36	.124
	Treatment	16 (21.9)	24 (33.3)		
History of cystoscopy	Yes	36 (49.3)	54 (75.0)	10.15	.001
	No	37 (50.7)	18 (25.0)		
History of bladder surgery	Yes	33 (45.2)	39 (54.2)	1.16	.281
	No	40 (54.8)	33 (45.8)		
STAI-T		47.19 (7.23)	48.48 (5.11)	−1.25	.215

Exp. = experimental group; Con. = control group; SD = standard deviation; STAI-T = state-trait anxiety inventory-trait anxiety.

Homogeneity test for the outcome variables of the two groups pre-intervention

We assessed STAI-S anxiety and physiological measures such as BP and PR pre-intervention (Table 2). Pain was not measured pre-intervention because none of the participants had pain before cystoscopy. Systolic (t = 2.30, p = .023) and diastolic (t = 2.73, p = .007) BP were significantly higher in the experimental group than in the control group. However, PR and STAI-S anxiety were not significantly different between the two groups.

Effect of heating therapy on the outcome variables of the two groups

The effects of heating therapy on pain, STAI-S anxiety, systolic and diastolic BP, and PR in the two groups are presented in Table 3. In this study, ANCOVA or ranked ANCOVA was used to control the covariates (history of cystoscopy and the basic values of dependent variables). Post-intervention, subjective (F = 25.25, p < .001) and objective pain (F = 35.55, p < .001) were significantly lower in the experimental group than in the control group. In addition, STAI-S anxiety (F = 55.74, p < .001), systolic (F = 6.91, p = .010) and diastolic (F = 10.57, p = .001) BP, and PR (F = 33.97, p < .001) were significantly decreased in the experimental group compared to the control group.

Satisfaction

Satisfaction of the participants in the experimental group was measured after cystoscopy (Table 4). The mean total satisfaction score was 27.86. Total satisfaction reported by women after heating therapy was significantly greater than that reported by men (Z = −2.25, p = .024). In particular, women felt more satisfied than men in terms of the following: (1) "anxiety reduction" (Z = −1.99, p = .046); (2) "deal more effectively with problems through heating therapy" (Z = −2.08, p = .037); and (3) "intention of coming back to heating therapy" (Z = −2.07, p = .038).

Discussion

Heating therapy has been used for decades to relieve muscle pain, such as back pain and dysmenorrhea [41,42]. Nevertheless, in the nursing clinical area, the scientific evidence for the analgesic effectiveness of heating therapy is limited because well-designed research studies are lacking [18]. The results of this RCT provide important nursing evidence on pain and anxiety in patients undergoing cystoscopy. In the present study, we evaluated the use of heating therapy as a non-medical nursing intervention for the

Table 2 *Homogeneity Test for the Anxiety and Physiological Measures of the Two Groups (N = 145).*

		Exp. (n = 73)	Con. (n = 72)	t/Z	p
		Mean (SD)			
Anxiety (STAI-S)[a]		56.26 (6.74)	57.27 (5.52)	−0.76	.450
BP, mmHg	Systolic	137.55 (19.41)	130.79 (15.78)	2.30	.023
	Diastolic	81.49 (10.28)	76.89 (9.99)	2.73	.007
PR, beats/min		77.64 (12.54)	75.65 (10.83)	1.02	.308

Exp. = experimental group; Con. = control group; BP = blood pressure; PR = pulse rate; SD = standard deviation; STAIS = state-trait anxiety inventory-state anxiety.
[a] Mann–Whitney U-test.

Table 3 *Comparison of the Pain, Anxiety, and Physiological Measures of the Two Groups (N = 145).*

Variables		Group	Pre-intervention	Post-intervention	F	p
			Mean (SD)	Mean (SD)		
Pain*	Subjective	Exp.(n = 73)	-	4.10 (1.30)	25.25	<.001
		Con.(n = 72)	-	5.15 (1.17)		
	Objective	Exp.(n = 73)	-	6.96 (2.30)	35.55	<.001
		Con.(n = 72)	-	9.18 (2.42)		
Anxiety (STAI-S)*		Exp.(n = 73)	56.26 (6.74)	43.78 (5.48)	55.74	<.001
		Con.(n = 72)	57.27 (5.52)	50.87 (5.70)		
BP, mmHg	Systolic	Exp.(n = 73)	137.55 (19.41)	132.30 (20.32)	6.91	.010
		Con.(n = 72)	130.79 (15.78)	133.61 (17.77)		
	Diastolic	Exp.(n = 73)	81.49 (10.28)	77.32 (8.88)	10.57	.001
		Con.(n = 72)	76.89 (9.99)	78.93 (11.82)		
PR, beats/min		Exp.(n = 73)	77.64 (12.54)	74.07 (11.77)	33.97	<.001
		Con.(n = 72)	75.65 (10.83)	78.04 (11.61)		

*ANCOVA or ranked ANCOVA after rank transformation were applied to adjust for history of cystoscopy and the baseline values of dependent variables.
Exp. = experimental group; Con. = control group; BP = blood pressure; PR = pulse rate; SD = standard deviation; STAI-S = state-trait anxiety inventory-state anxiety.

management and relief of pain, reduction of anxiety, and increase of satisfaction in patients undergoing cystoscopy. Although many medical intervention studies have been conducted to evaluate the ideal therapy for the reduction of pain and discomfort during cystoscopy, only a few nursing intervention studies are available.

Heating therapy showed an effective reduction in the score for subjective and objective pain. The results demonstrating relieved pain in the present study are consistent with those of the other two studies on women who underwent cystoscopy in which the experimental group experienced less pain when compared with the control group [32,33]. This pain reduction may have occurred because heating therapy increases blood flow [14,19] and temporarily increases the threshold of pain delivery fibers [43]. According to review articles, heating therapy, by increasing the temperature of the skin and muscle has the following physiological effects: (1) pain relief, (2) increased blood flow and metabolism, and (3) increased elasticity of the connective tissue [44]. An increase in tissue temperature stimulates vasodilation and increases tissue blood flow, which promotes healing by increasing the supply of nutrients and oxygen to the site of injury [18]. As a result, the rate of local tissue metabolism is also increased by warming, which may further promotes healing and relieve pain [44].

Heating therapy also resulted in significantly lower anxiety in patients undergoing cystoscopy. These results were consistent with those reported by the cystoscopy [32] and urodynamic studies [33] conducted on women. They reported that heating therapy significantly lowered the state anxiety scores of the study subjects compared to those of the control subjects. Heating therapy relieves tension and stress and helps relieve feeling [45]. Heating treatments such as spa or balneotherapy also have anxiolytic effects and have previously been applied to ameliorate stressful interventions [46,47].

Previous non-pharmacological intervention studies on patients who were undergoing urological procedures involved music therapy [29,35,48], hand-holding or use of a stress ball [30,31], viewing of the cystoscopy video with explanation [49], virtual reality distraction [50], and heating therapy [32,33]. The authors of one study that involved music therapy suggested that music therapy was the most effective intervention for the reduction of pain and anxiety [51]. Although very few studies have investigated heating therapy compared to music therapy, previous studies on heating therapy demonstrated excellent effects in terms of reduction of pain and anxiety [32,33]. To identify the effects of heating therapy in patients undergoing cystoscopy in the future, more studies of heating therapy as a non-pharmacological nursing intervention are needed.

We tried to identify the effects of heating therapy on the regulation of BP and PR. Before the initiation of treatment in the present study, the systolic and diastolic BPs of the participants in the experimental group were higher than those of the participants in the control group; thus, there was no homogeneity between the two groups. To solve this problem, we used ANCOVA to compare the effect of heating therapy. As the results show, the decrease in systolic BP, diastolic BP, and PR after the procedure were significantly higher in the experimental group than in the control group. According to previous studies, heating therapy could reduce the resting heart rate and noradrenaline release [52] and also decrease the BP by improving the endothelium-dependent dilatation [37], arterial stiffness, and intima media thickness [53]. In addition, heating therapy showed positive effects on the cardiovascular system according to a review article that consisted of articles published over a period of 25 years [45]. Therefore, heating therapy is a useful nursing intervention for patients undergoing cystoscopy.

Unlike our results, a previous study indicated that although heating therapy decreased the anxiety, pain, and distress of women undergoing cystoscopy, their systolic BP, diastolic BP, and PR were increased [32]. In another urodynamic study, heating therapy was used by Kim et al in 2018 to treat women with stress urinary incontinence, and their results showed no significant difference in

Table 4 *Comparison of Satisfaction According to Sex in the Experimental Group that Received Heating Therapy.*

	Total (n = 73)	Male (n = 39)	Female (n = 34)	Z	p
		Mean (SD)			
Total score of satisfaction with heating therapy (range: 8–32 score)	27.86 (3.60)	26.95 (3.80)	28.91 (3.08)	−2.25	.024
1. Quality of heating therapy	3.55 (0.50)	3.49 (0.51)	3.62 (0.49)	−1.11	.267
2. Pain relief conferred by heating therapy	3.27 (0.71)	3.13 (0.73)	3.44 (0.66)	−1.87	.062
3. Anxiety reduction by heating therapy	3.41 (0.74)	3.23 (0.84)	3.62 (0.55)	−1.99	.046
4. Recommend heating therapy to a friend	3.47 (0.50)	3.36 (0.49)	3.59 (0.50)	−1.95	.052
5. Satisfaction with application time of heating therapy	3.38 (0.57)	3.33 (0.48)	3.44 (0.66)	−1.25	.210
6. Deal more effectively with problems through heating therapy	3.52 (0.65)	3.36 (0.63)	3.71 (0.63)	−2.08	.037
7. Overall satisfaction with heating therapy	3.59 (0.49)	3.49 (0.51)	3.71 (0.46)	−1.88	.060
8. Intention of coming back to heating therapy	3.67 (0.47)	3.56 (0.50)	3.79 (0.41)	−2.07	.038

the BP and PR measurements between the experimental and control groups [33]. In both of these studies, a small sample of 37 individuals each was assigned to the experimental and control groups; therefore, objective physiological BP and PR may not have had a significant effect. In the future, various strict randomized studies might be needed to investigate whether heating therapy mitigates the changes in physiologic measures induced by cystoscopy.

Finally, patient satisfaction is a commonly used indicator of the quality of medical services and the effectiveness of nursing interventions [54]. In the present study, the satisfaction survey regarding heating therapy was only administered to the experimental group because it addressed satisfaction with heating therapy during cystoscopy and thus could not be administered to the control group. To identify patient satisfaction with the nursing intervention, we compared the responses of the participants who received heating therapy. When the score of total satisfaction was converted into 100%, women reported 90% satisfaction and men reported 84% satisfaction. Specifically, women were more satisfied in terms of the following survey items: “anxiety reduction by heating therapy,” “deal more effectively with problems through heating therapy,” and “intention of coming back to heating therapy.” Therefore, heating therapy can be considered an effective nursing intervention for women undergoing cystoscopy as it may provide psychological stability and physical relaxation, thus reducing anxiety and discomfort. A plausible reason for these results may be that women tend to favor heating therapy more than men in Korean culture [55].

There were some limitations to the present study. First, measurement of patients' subjective pain and anxiety during the cystoscopy examination was done by memory immediately after the examination because it is difficult to measure pain and anxiety levels during cystoscopy. This should be considered when interpreting the relationship between BP/PR and pain/anxiety during the test. Second, despite using a single-blinded, RCT, participants might have known those who were in the control or experimental group depending on whether the warm heating pad was applied after cystoscopy. Therefore, we suggest the use of three test groups, including a control group with the application of a heating pad which is turned off, the experimental group with the application of a heating pad which is set to a low level of heating, and other experimental group with the application of a warm heating pad. Third, although the same cystoscopy protocol was used for each patient, the procedure was not conducted by the same urologist. In future studies, it is necessary to have the same urologist perform the cystoscopy procedure to reduce confounding factors. Moreover, the outcomes should be interpreted with caution because we included men with benign prostatic hypertrophy, which can cause pain during cystoscopy. Lastly, post-cystoscopy pain tends to persist in some patients and may occasionally last up to 2–3 days after the procedure; therefore, we suggest that in future studies, [4].

Conclusion

Heating therapy reduces the pain and anxiety in patients undergoing cystoscopy and decreases their BP and PR, which are physiological indicators of pain and anxiety. Considering the high satisfaction score recorded in the present study, we believe that heating therapy is a useful independent nursing intervention. Moreover, as heating therapy using an electric heating pad is simple, convenient, and cost-effective, it may be considered an effective non-pharmacological nursing intervention.

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Conflict of interest

The authors declare no conflicts of interest.

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Research Article

Working Conditions and Fatigue in Japanese Shift Work Nurses: A Cross-sectional Survey

Ryohei Kida,* Yukie Takemura

Department of Nursing Administration, Division of Health Sciences and Nursing, Graduate School of Medicine, The University of Tokyo, Japan

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SUMMARY

Purpose: This study aimed to identify the working conditions (working hours, overtime work, number of night shifts, number of holidays, and work intervals) associated with fatigue, based on the shift patterns, and determine their thresholds.
Methods: From January to February 2020, a web-based questionnaire was sent to 4601 shift work nurses at 47 hospitals in Japan. The multivariate logistic analysis was conducted to predict high- and low-fatigue groups by working conditions, and receiver operating characteristic analysis was performed to clarify the high-fatigue thresholds by shift pattern.
Results: A total of 386 shift work nurses participated in this study. The threshold (fatigue was 3.0 or higher) of the two-shift rotation was 9 hours 50 minutes for daily working hours during day shifts (Odds ratio [OR] = 1.57, $p < .01$), 17 hours 15 minutes for daily working hours during night shifts (OR = 1.20, $p < .01$), and 8.0 days for the number of night shifts (OR = 1.09, $p = .02$). The threshold of the three-shift rotation was 9 hours 45 minutes (OR = 1.59, $p < .01$), 2.9 days for the number of midnight shifts (OR = 1.53, $p < .01$), and 2.0 times for the interval between day-shift and night-shifts within 12 hours (OR = 1.39, $p < .01$).
Conclusion: Working hours and the number of night shifts are important for two-shift rotation, and working hours for the assignment of midnight shift are important for three-shift rotations. Nurse managers should manage shifts according to nurses' shift patterns.

Introduction

Fatigue is defined as a condition in which individuals experience a decreased ability to perform activities at the desired level due to mental and/or physical lassitude or exhaustion [1,2]. Fatigue in nurses has a negative impact on them and patient care. According to prior research, fatigue in nurses is related to their performance [3,4], wellness [5], care outcomes related to nurses' satisfaction [6,7], health [8,9], quality of care [10], and patient safety [11,12]. Moreover, long-term fatigue leads to severe physical and mental health problems [2]. Shift work disrupts circadian rhythms and leads to fatigue [13]. Therefore, the prevention of fatigue is important for both health care of the nurses and sustaining high-quality care.

There have been many reports on working conditions that induce fatigue in shift-work nurses. Recent reviews by Gifkins et al. [14] and Min et al. [15] identified shift work arrangement (consecutive and night shifts), length of shifts, overtime, rotating shifts, quick returns, high work demands, and the number of night or evening shifts as work conditions that cause fatigue. It has also been reported that night shifts are associated with sleepiness and that counterclockwise shift rotation lowers sleep quality [16,17]. In other words, working hours per shift, overtime, the number of night shifts, inadequate recovery period, and counterclockwise shift rotation are important factors of fatigue among shift nurses.

Meanwhile, the results of previous studies on the length of shifts are not consistent. Generally, longer working hours are associated with higher fatigue levels [14,15], but there have also been reports of lower fatigue in 12-hour shifts than in 8-hour shifts [17]. A review of studies of Japanese nurses found that the length of working hours was associated with fatigue, but that two-shift workers who

Ryohei Kida: https://orcid.org/0000-0003-0138-9946; Yukie Takemura: https://orcid.org/0000-0003-2861-8673
* Correspondence to: Ryohei Kida, Department of Nursing Administration, Division of Health Sciences and Nursing, Graduate School of Medicine, the University of Tokyo, 7-3-1, Hongou, Bunkyou, Tokyo 113-0033, Japan.
E-mail addresses: rkida-tky@ns-adm.com, yukitake-tky@umin.ac.jp

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worked 16-hour night shifts reported less fatigue than three-shift workers [18]. Thus, the findings on the length of working hours are not consistent. This is because the number of hours worked in each shift varies across countries (e.g. 12 hours in European countries, 8 and 16 hours in Japan) [19–21]. Furthermore, if the number of hours worked per month is held constant, the length of each shift is a trade-off between the number of hours worked and the number of days off or intervals between work [20]. That is, each element of work conditions depends on the rotation type and is interrelated. In addition, factors such as quick return and counterclockwise shift rotation are more characteristic of three-shift rotation than of two-shift rotation [22–24]. Recovery from fatigue requires sufficient holidays, but the factors causing fatigue and their corresponding effects may differ between nurses who work without sufficient holidays and those who are given sufficient holidays. Therefore, the work conditions that lead to fatigue may differ depending on the rotation pattern and the number of holidays. In addition, the threshold values of these factors are unknown.

The Japan Nursing Association has published guidelines for shift work nurses in Japan [25]. The guidelines provide recommendations on appropriate working hours, the number of night shifts per month, and enough holidays, but due to insufficient nurse staffing, it is difficult to implement all of these recommendations. Nonetheless, nurse managers must assign adequate shift work to nurses to protect their health and ensure stable and high-quality care. For more specific and efficient work environment management, evidence for accurate reference points (thresholds) that link shift work to fatigue, which in turn affects nurses' physical and mental health, is needed. Therefore, the purpose of this study was to identify the working conditions (i.e., working hours, overtime work, number of night shifts, and number of holidays) associated with fatigue, based on the shift patterns (two or three rotations) and the number of holidays (more or less groups), and determine the threshold of the associated working conditions.

Methods

Study design

This study is a cross-sectional study.

Survey setting and period

To conduct the logistic analysis accurately, the sample size needs to be ten times more than the events [26]. Since we presumed that five independent variables were to be entered this time, at least 50 samples were required. However, to reflect nationwide work conditions and fatigue and minimize sampling bias (e.g., location, bed size, and hospital function), we requested more target hospitals to participate in this study.

Through convenience sampling, 11 hospitals consented to participate; however, due to the bias related to bed size and region, additional hospitals were randomly selected from the list of hospitals nationwide. Using random sampling to include staff nurses working in hospitals of various bed sizes, we categorized the target hospitals as follows: under 99 beds, 100–199 beds, 200–299 beds, 300–399 beds, and over 400 beds. To avoid bias related to the number of nurses included in each bed size category, extractions and requests were repeated until the number of documents distributed in each bed size category reached 1000 shift work nurses. We sent the informed consent documents to the nurse administrators at the selected 338 hospitals, of which, 47 hospitals were ultimately included in this study, as they provided consent. The login information (explanation documents, URL, and QR code for login) for the online survey was distributed to participants via the nurse administrators of these hospitals, and the participants logged in at their discretion and answered the web-based anonymous self-report questionnaire. The survey was conducted from January to February 2020.

Participants

The participants to whom the questionnaires were distributed were 4601 nurses working in the target hospital. The inclusion criteria were full-time or part-time nurses who worked in shifts. The exclusion criteria were nursing managers, schedulers, and newcomers within 6 months.

Measurements

Fatigue

Fatigue was assessed by the Brief Job Stress Questionnaire developed by Shimomitsu et al. [27]. It comprehensively measures workplace stressors and stress reactions, and is widely used to conveniently measure job stress among Japanese workers including nurses, because of its use being recommended by the Ministry of Health, Labor and Welfare [28]. In this study, we used the "fatigue" subscale. It comprises three items, assessed on a 4-point Likert scale ranging from 1 = '*almost never*' to 4 = '*almost always*' Item examples include 'I am very tired,' 'I feel exhausted,' and 'I feel languid.' The reliability and validity of the overall scale and its subscales were previously verified by Shimomitsu et al. [27]. The average score of this scale is expressed as a value between 1.0 and 4.0. Those with an average score of 3 or more always perceive at least two items as high fatigue, which suggests that they are in a state of fatigue on a daily basis. The manual for this scale recommends that 3.0 or 4.0 be judged as having a stress reaction as a simple measure of stress response [27]. Therefore, in this study, 3.0 was set as a cutoff and used to divide participants with either high or low fatigue categories. The Cronbach's α of this subscale was 0.912 in this study.

Work conditions

To measure daily working hours, participants were asked their daily start and end time for each shift pattern (day, night, evening, and midnight shifts)—an example of the item regarding this is '*At what time did you start/end [day shift] in the past month?*' In addition to measuring daily overtime working hours, we asked for the start and end times set by their facilities for each shift pattern—an example of an item regarding this is '*According to the rules of your hospital, what time does the shift [day shift] have to start/end?*'. In this study, the difference between daily working hours and working hours set by their facilities was considered daily overtime work.

To confirm the number of days of night shifts (including evening and midnight shifts) and holidays (including a day off and requested rest days) per month, participants were asked the number of days of night shifts and holidays in their latest schedule—an example of the item regarding this is '*How many days have you been assigned [day shift] in the past month?*'. In Japan, in the two-shift rotation, the night shift is generally from approximately 17:00 to 9:00 the following morning. However, in the three-shift rotation, the evening shift is from 16:00 to 0:00, and the night shift is from 0:00 to 8:00. In other words, the night shift of the two-shift rotation is equivalent to two days when converted to the three-shift rotation. Therefore, for the two-shift rotation, one night shift was counted as two days. We converted them into days per 30 days

since the schedule span was different for each participant. A short interval between work hours hinders recovery from fatigue and leads to a stress response. According to the Japan nursing association's guidelines [25], for two-shift rotations, it is recommended to have an interval of 24 hours or more after the night shift, and for three-shift rotations, it is recommended to have an interval of 12 hours or more for inter-working intervals. Therefore, we asked the number of times of inter-working intervals in the latest schedule that were less than 24 hours for the two-shift rotation or 12 hours for the three-shift rotation—an example of an item regarding this is '*How many quick returns have you experienced within 24/12 hours in the past month?*'

Additionally, we asked participants to provide their age, sex, nursing experience (years), and marital status as demographic characteristics.

Statistical analysis

We calculated descriptive statistics to verify the relationship between work conditions and fatigue. The bivariate logistic analysis was conducted with each work condition variable as the independent variable and the fatigue group (high or low) as the dependent variable. The multivariate logistic regression analysis (stepwise method) was performed to identify the work conditions associated with high-level fatigue in each rotation type (two- or three-shift rotation) and the number of holidays (fewer than 10 holidays per month and 10 or more holidays per month; this is because Japanese nurses are assigned approximately 10 holidays per month [21]). At each step of the analysis, socio-demographic variables (age, sex, and marital status) and work conditions were entered. Variables entered in the two-shift rotation model included daily working hours per day shift, daily working hours per night shift, daily overtime work per day and night shift, number of night shifts and holidays per month, and interval between workdays within 24 hours. Variables entered in the three-shift rotation model included daily working hours during the day, evening, and midnight shifts, daily overtime work during day, evening, and midnight shifts, number of evening and midnight shifts holidays per month, and interval between workdays within 12 hours (evening shift to day shift, and day shift to midnight shift). The variables entered in less than 10 holidays model and 10 or more holidays model included daily working hours during day and night shifts, daily overtime work per day and night shift, and number of night shifts and holidays per month. In the stepwise method, the inclusion criteria were $p < 0.05$, and the exclusion criteria were $p > 0.1$. After that, to determine the threshold of the working conditions associated with high fatigue, predictive probabilities were calculated for each variable. The points with maximum sensitivity and specificity were searched by a receiver operating characteristics (ROC) analysis for each rotation type or the number of holidays. Missing data were excluded from all analyses.

Ethical considerations

The questionnaire was completed anonymously. Participants were provided with documents that explained the ethical considerations of this survey, and they were informed that participation was voluntary, and nonparticipation would not cause them any disadvantages. After reading the documents, if participants agreed to complete the survey, they logged in to the survey screen on the web and checked a box at the top of the questionnaire to confirm their consent. Those who did not agree were not shown the survey screen and were not asked to respond. This study was approved by the Research Ethics Committee of the Graduate School of Medicine, the University of Tokyo (No. 2019142NI).

Results

Participants' characteristics

Table 1 shows participant characteristics. Of the 4601 shift work nurses, 640 logged onto the website for the survey. After excluding those who declined to participate or were managers or schedulers (74 people), 566 nurses were included. Finally, after excluding newcomers (e.g., recently arrived nurses or nurses transferred within six months) and surveys with missing data (180 surveys), the data of 386 nurses were analyzed (Figure 1).

The average age of participants was 36.5 years and approximately 90% were female. The average number of years of nursing experience was 13.1. There were 58, 66, 89, 86, and 87 nurses for under 99 (15.1%), 100–199 (17.1%), 200–299 (23.1%), 300–399 (22.3%), and 400 beds (22.5%), respectively. Approximately half of all the participants were in the high-fatigue group, and the proportion was high in the three-shift rotation group. The start and end times of each shift varied according to the rules of their hospital, but the mode of two-shift rotation was 8:30 (63.2%) for the start time and 17:00 (30.5%) for the end time of the day shift. The mode of the night shift was 16:30 (39.9%) at the start time and 9:00 (29.8%) at the end time. The mode of the three-shift rotation is 8:30 (98.5%) for the start time of the day shift, 17:15 (64.6%) for the end time, and 16:30 (80.0%) for the start time of the evening shift. The end time was 1:00 (55.4%), the start time of the midnight shift was 0:30 (75.4%), and the end time was 9:15 (43.1%). Daily working hours during day shifts were 9 hours 53 minutes for the two-shift rotation and 9 hours 40 minutes for the three-shift rotation. Daily working hours during the night shifts of the two-shift rotation were 17 hours 08 minutes, and that of the evening and midnight shifts for the three-shift rotation were approximately 9 hours 30 minutes. Overtime hours were approximately one hour for each working shift for both shift rotations. The average number of days of night shifts per 30-day period was 8.5, with two-shift rotations slightly higher. The average number of days of holidays per month was 10.3.

Multivariate logistic analysis

The results of the multivariate logistic analysis have been presented in Table 2. In all models, the variance inflation factor for all variables was less than 2.0; thus, there was no problem of multicollinearity. Variables associated with high fatigue were selected via the inclusion and exclusion criteria for a stepwise method. The controls and socio-demographic variables were excluded from all models.

For the two-shift rotation, daily working hours during day shifts, daily working hours during night shifts, and the number of days of night shifts were significantly associated with high fatigue (OR = 1.57, $p < .01$; OR = 1.20, $p < .01$; OR = 1.09, $p = .02$, respectively). For the three-shift rotation, daily working hours during midnight shifts, number of days of midnight shifts, and the interval between workdays within 12 hours (day shift to midnight shift) were significantly associated with high fatigue (OR = 1.59, $p < .01$; OR = 1.53, $p < .01$; OR = 1.39, $p < .01$, respectively).

For the group with fewer than 10 days of holidays per month, daily working hours during day shifts, daily working hours during night shifts, and the number of days of night shifts were significantly associated with high fatigue (OR = 1.41, $p < .01$; OR = 1.21, $p < .01$; OR = 1.11, $p < .01$, respectively). For the group with 10 or

Table 1 *Participant Characteristics and Descriptive Statistics.*

	Two-shift rotation (n = 321)			Three-shift rotation (n = 65)		
	Mean or n	*SD* or %		Mean or n	*SD* or %	
Age	35.67	10.07		40.35	9.41	
Gender						
Women	285	88.8		56	86.2	
Men	36	11.2		9	13.8	
Nursing experience (years)	12.35	9.45		16.60	9.04	
Marital status						
Unmarried	168	52.3		23	35.4	
Married	134	41.7		35	53.8	
Other	19	5.9		7	10.8	
Number of beds at unit	40.99	12.20		40.60	11.70	
Fatigue						
Low	178	55.5		26	40	
High	143	44.5		39	60	
	Mean	(Min–Max)	*SD* or %	Mean	(Min–Max)	*SD* or %
Work conditions						
Working hours (per shift)						
Day shift	9:53	(8:15–13:20)	0:56	9:40	(8:30–12:00)	0:41
Night shift[a]	17:08	(10:30–19:45)	1:28	–	–	–
Evening shift[b]	–	–	–	9:25	(7:00–11:30)	0:44
Midnight shift[b]	–	–	–	9:46	(8:30–14:45)	0:57
Overtime work (per shift)						
Day shift	1:13	(0:00–4:34)	0:53	1:00	(0:00–3:15)	0:42
Night shift[a]	0:57	(0:00–3:15)	0:38	–	–	–
Evening shift[b]	–	–	–	0:52	(0:00–3:00)	0:38
Midnight shift[b]	–	–	–	0:51	(0:00–2:39)	0:37
Number of night shifts (days per month)						
Night shift[a]	8.69	(0.94–18.95)	3.09	–	–	–
Evening shift[b]	–	–	–	4.19	(0.00–10.65)	2.11
Midnight shift[b]	–	–	–	3.49	(0.00–7.74)	1.78
Number of holidays (days per month)	10.30	(1.50–17.14)	2.26	10.09	(1.50–14.52)	2.55
Interval between workdays (times per month)						
Within 24 hours[a]	0.38	(0.00–4.74)	0.80	–	–	–
Evening shift to day shift within 12 hours[b]	–	–	–	0.34	(0.00–5.00)	0.83
Day shift to midnight shift within 12 hours[b]	–	–	–	2.00	(0.00–6.00)	1.88

Note: SD: standard deviation, Min: minimum.
[a] Only two-shift rotation. For "Number of night shifts (days per month)," one night shift was counted as two days because the shift is spread across two days, from evening to the following morning.
[b] Only three-shift rotation.

more days of holidays per month, daily working hours during day shifts and daily working hours during night shifts were significantly associated with high fatigue (OR = 1.49, $p < .01$; OR = 1.25, $p < .01$, respectively).

ROC analysis

The ROC analysis was performed for variables that were significant in the logistic regression analysis; the results have been presented in Table 3.

The thresholds of daily working hours for day shifts, daily working hours for night shifts, and the number of night shifts for two-shift rotations were 9 hours 50 minutes, 17 hours 15 minutes, and 8.0 days, respectively. The thresholds of daily working hours for midnight shifts, number of midnight shifts, and the interval between workdays within 12 hours (day shift to midnight shift) for three-shift rotations were 9 hours 45 minutes, 2.9 days, and 2.0 days, respectively.

For the group with less than 10 holidays per month, the daily working hours for day shifts, daily working hours for night shifts, and the number of night shifts were 9 hours 20 minutes, 17 hours, and 8.0 days, respectively. For the group with 10 or more days of holidays per month, the daily working hours during day shifts and daily working hours during night shifts were 9 hours 10 minutes and 17 hours 50 minutes, respectively.

Discussion

Approximately 83.0% of the participants in this study had a two-shift rotation, and their daily working hours were 9 hours 52 minutes during day shifts and 17 hours 08 minutes during night shifts. In a European survey, 12-hour rotations were common [19]; however, in a two-shift rotation, which is mainly used in Japan, day shifts are shorter and night shifts are longer than European countries. Moreover, half of the study samples experienced high fatigue, and the ratio was high in the three-shift rotation group. In three-shift rotations, circadian rhythms are easily disturbed by evening shifts and midnight shifts, and recovery time is often required [13]; thus, this may be a type of shift work in which fatigue tends to accumulate despite the short working hours of the night shift.

This study revealed that the work conditions that are associated with high fatigue differ depending on the rotation pattern. A review article [14,15] showed that overtime and night shifts lead to fatigue. However, our study provides further insight as it identified the different factors that differ based on the shift patterns and influence fatigue in shift work nurses. In addition, our findings provided the threshold for each important work condition.

In the two-shift rotation, the number of night shifts per month and total working hours in the day and night shifts were significantly associated with high fatigue. Although some reports

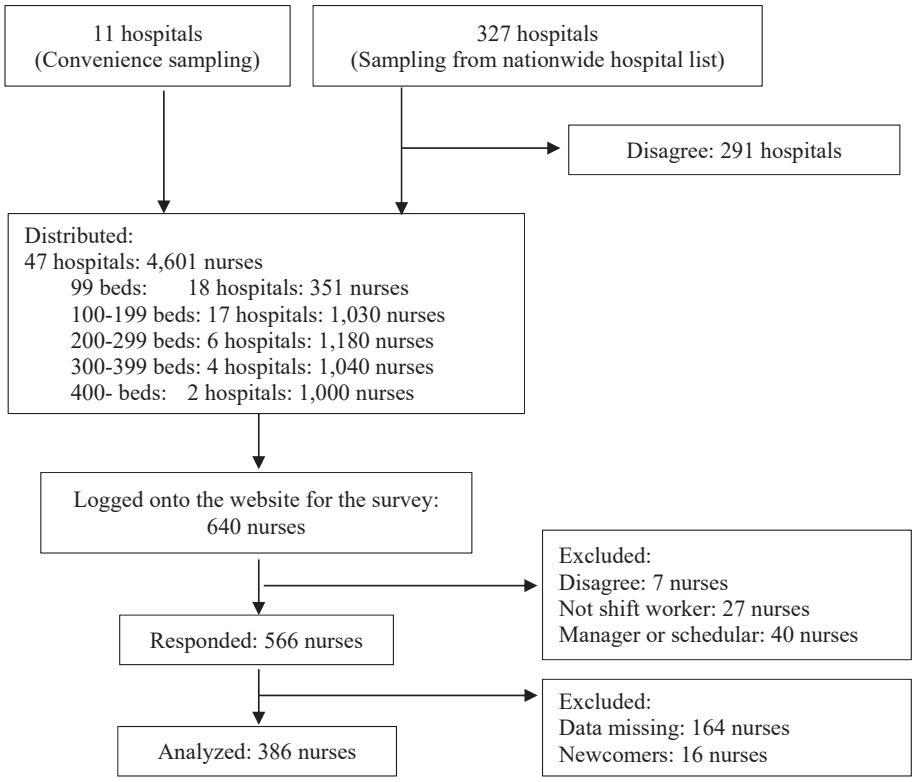

Figure 1. The process of participants selection.

indicate that nurses who work two-shift rotation shifts are more likely to recover from fatigue [29], the results of this study were consistent with the inferences of review articles [14,15], and indicated that long working hours could cause fatigue and health problems in nurses. In addition, the findings of this study imply that, in the two-shift rotation, day shifts should not exceed 9 hours and 50 minutes and night shifts should not exceed 17 hours and 15 minutes to prevent fatigue. Long day shifts to compensate for night shift hours—for example, 12-hour day shifts—might be inappropriate. Nursing organizations should adopt shift patterns other than the traditional day and night shifts to avoid long working hours. Additionally, nurse managers should monitor the total working hours rather than overtime hours and restrain nurses' night shift to no more than eight per month to prevent fatigue.

In three-shift rotation, the working hours and number of night shifts for midnight shifts were associated with high fatigue. This finding suggests that working hours and frequency of shifts—especially for midnight shifts—are important factors for consideration in three-shift rotations. A three-shift rotation consists of a diverse combination of three patterns: day, evening, and midnight, which is more likely to disrupt nurses' internal rhythm [13]. Working long hours at midnight, when they should be resting, and working frequent midnight shifts can easily cause fatigue, which in turn also affects their recovery. In addition, the number of short intervals from day shift to midnight shift being associated with high fatigue is the characteristic of three-shift rotations. Night shift and quick return negatively affect the circadian rhythm and subsequent recovery from fatigue [29–32], and day shift to midnight shift work involves a counterclockwise shift rotation, which does not follow circadian rhythms [33]. Quick returns from day shift to midnight should be more tightly restricted. Nurse managers in departments with three-shift rotations should pay particular attention to the working hours and frequency of midnight shifts and provide sufficient rest periods before and after midnight shifts to avoid fatigue among nurses.

For both groups with few and many holidays, daily working hours during day and night shifts were associated with fatigue. However, in the group with many holidays, there was no association between the number of days of night shifts and fatigue, but in the group with few holidays, this association was found. Furthermore, daily working hours during night shifts for the group with few holidays were shorter than those for the group with many holidays. It is important that nurses with fewer holidays manage their time by working shorter hours and fewer night shifts. Alternatively, it should be to secure enough personnel for everyone to take a holiday of 10 days or more a month.

Limitations

This study had some limitations. First, in the ROC analysis' results, both the area under the curve (AUC) and discrimination performance were low. The items related to work conditions are single items created for this study and were collected using a self-report questionnaire. Therefore, their reliability and validity are not verified. Real working hours data (e.g., time clock data) should be used to improve the results' accuracy. Second, a multivariate analysis for the other organizational factors was not conducted in this study. Therefore, the results did not consider the effects of other confounding factors associated with fatigue. Other organizational factors (e.g., quantitative/qualitative workload, job control, social support, and leadership) have been shown to influence stress responses, including fatigue. Future research may need to consider

Table 2 *Steps in the Multivariate Logistic Regression Analysis.*

	Odds ratio	95% CI	*P* value
Two-shift rotation			
Daily working hours (per shift)			
Day shift	1.57	1.21–2.04	<.01
Night shift	1.20	1.01–1.40	<.01
Number of night shifts (days per month)	1.09	1.00–1.18	.02
Three-shift rotation			
Daily working hours (per shift)			
Midnight shift	1.59	1.03–2.16	<.01
Number of night shifts (days per month)			
Midnight shift	1.53	1.28–1.78	<.01
Interval between workdays (per month)			
Day shift and midnight shift within 12 hours	1.39	1.05–1.72	<.01
Less than 10 holidays per month			
Daily working hours (per shift)			
Day shift	1.41	1.16–1.72	<.01
Night shift[a]	1.21	1.09–1.47	<.01
Number of day night shifts (per month)[b]	1.11	1.09–1.23	<.01
10 or more holidays per month			
Daily working hours (per shift)			
Day shift	1.49	1.05–2.10	<.01
Night shift[a]	1.25	1.03–1.51	<.01

Note: The dependent variable is fatigue (low fatigue = 0, high fatigue = 1). Independent variables were entered in the models using a stepwise method. The following variables were excluded by the stepwise method: Daily overtime work, number of holidays per month, and interval between workdays were excluded from the two-shift rotation model. Daily work hours per day and evening shift, daily overtime work, number of evening shifts and holidays per month, and interval between evening shift and day shift within 12 hours were excluded from three-shift rotation model. Daily overtime work and number of holidays were excluded from the group with fewer than 10 holidays model. Daily overtime work, and number of night shifts and holidays per month were excluded from the 10 or more holidays per month model. The control variables were excluded from all models. CI: confidence interval.

[a] For the three-shift rotation, the values used the sum of the evening and the midnight shift value.

[b] For "Number of days of night shifts (per month)" of two-shift rotation, one night shift was counted as two days because the shift is spread across two days, from evening to the next morning.

Table 3 *Receiver Operative Characteristics Analysis.*

	AUC	Threshold
Two-shift rotation		
Daily working hours (per shift)		
Day shift	0.63	09:50
Night shift	0.63	17:15
Number of night shifts (days per month)	0.65	8.00
Three-shift rotation		
Daily working hours (per shift)		
Midnight shift	0.60	9:45
Number of night shifts (days per month)		
Midnight shift	0.64	2.90
Interval between workdays (per month)		
Day shift and midnight shift within 12 hours	0.62	2.00
Less than 10 holidays per month		
Daily working hours (per shift)		
Day shift	0.62	09:20
Night shift[a]	0.59	17:00
Number of day night shifts (per month)[b]	0.64	8.00
10 or more holidays per month		
Daily working hours (per shift)		
Day shift	0.63	09:10
Night shift[a]	0.66	17:50

Note: The dependent variable is fatigue (low fatigue = 0, high fatigue = 1). In the notation "XX:YY," XX stands for hours and YY stands for minutes. Only those variables that were significant in the logistic regression analysis have been listed. AUC: area under the curve.

[a] The values for the three-shift rotation comprise the sum of the evening and the midnight shift values.

[b] With respect to the "number of days of night shifts (per month)" in the two-shift rotation, one night shift was counted as two days because the shift was spread across two days (from evening to the next morning).

these factors. Third, the response rate was low and there were a lot of missing data. This may be because there were many items, many nurses dropped out, and the survey was conducted during the year-end and New Year holidays, which are busy periods.

Conclusion

Our study clarified the relationship between work conditions and fatigue and presented the thresholds for each work condition related to fatigue in shift work nurses. For two-shift rotations, long working hours on both day and night shifts were associated with high fatigue. For three-shift rotations, daily working hours during midnight shifts, the number of days of midnight shifts, and quick returns from day shift to midnight were associated with high fatigue. Additionally, our study identified the difference in threshold between the group with few holidays and the group with many holidays. The results of our study provide specific reference points in labor management when assigning shifts on different wards and when adjusting nursing staff schedules.

Our study showed that each shift rotation pattern has different working conditions necessary to avoid fatigue. In addition, their thresholds were identified. Based on our findings, nurse managers should mainly pay attention to total working hours in two-shift rotations, protect the health of shift work nurses. In three-shift rotations, they should mainly consider the working hours, frequency, and assignment of midnight shifts. In addition, being aware of these factors and thresholds related to nurses' work life for each shift pattern can help them manage and avoid fatigue.

Author contributions

Study design: Ryohei Kida, Yukie Takemura, Data collection: Ryohei Kida, Yukie Takemura, Data analysis: Ryohei Kida, Manuscript writing: Ryohei Kida, Yukie Takemura.

Conflict of interest

There are no conflicts of interest to declare.

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Research Article

Effectiveness of Virtual Reality Interactive Play for Children During Intravenous Placement: A Randomized Controlled Trial

Mei-Feng Hsu,[1,*] Yew-Wha Whu,[2,*] I-Chen Lin,[3] Chieh-Yu Liu,[4] Fei-Chen Lai,[5] Pei-Ching Liu,[6] Chi-Wen Chen[6,*]

[1] Department of Nursing, Da-Yeh University, Taiwan
[2] Department of Nursing, Far Eastern Memorial Hospital, Taiwan
[3] College of Computer Science, National Yang Ming Chiao Tung University, Taiwan
[4] Department of Speech Language Pathology and Audiology, National Taipei University of Nursing and Health Sciences, Taiwan
[5] Department of Nursing, Changhua Christian Children's Hospital, Taiwan
[6] College of Nursing, National Yang Ming Chiao Tung University, Taiwan

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SUMMARY

Purpose: This study aimed to evaluate the effectiveness of an interactive virtual reality (VR) play intervention including instructional play and emotional catharsis play sessions in reducing children's pain and fear during intravenous placement.
Methods: A randomized controlled trial with parallel groups was conducted. The sample consisted of 134 hospitalized children aged 6–12 years (intervention group: $n = 69$; comparison group: $n = 65$). The intervention involved one immersive intravenous scene in VR before the actual intravenous placement and one emotional catharsis VR play after injection. The comparison group received an educational photo book about intravenous placement before receiving intravenous placement. The children and their caregivers rated their pain and fear by using the Wong–Baker FACES Pain Rating Scale and the Children's Fear Scale. The time required for successful intravenous insertion was also compared between the two groups.
Results: Children's pain ($p = .028$) and fear scores ($p = .004$) were significantly lower in the intervention group than in the comparison group. Their caregivers' pain and fear scores (both $p < .001$) were significantly lower in the intervention group. The time required for successful intravenous insertion did not differ significantly between the intervention and comparison groups.
Conclusions: The interactive play intervention with VR effectively reduced children's levels of pain and fear during the intravenous placement procedure. The results of this study can serve as a reference for the implementation of a feasible, child-friendly care practice for clinical intravenous placement in school-aged children.

Introduction

Invasive treatment is a stressful process for hospitalized children. An intravenous injection is a common invasive treatment [1]. Although school-aged children can communicate the location and intensity of pain verbally, they often exhibit muscle tightening, body stiffness, fist clenching, painful stimulus avoidance, and procrastination during injection processes. They worry about displaying uncontrolled behaviors and attempt to appear brave to maintain control. If the child is not provided with an initial explanation of procedures or is provided with deceptive information, they can fear and distrust their medical care and medical caregivers and may not cooperate [2,3]. If a child's behavioral reaction during the injection process is intense, achieving a successful injection becomes difficult. Negative experiences with this medical process or unfamiliarity with the environment increases pain caused by intravenous injections and affects children's attitude toward future medical care, physical discomfort, and mental trauma [3].

Therapeutic play is a treatment in which games are designed with plans, goals, and skills in mind to understand the development, threatening life events, and internal conflicts of children who

Mei-Feng Hsu: https://orcid.org/0000-0002-0330-8022; Yew-Wha Whu: https://orcid.org/0000-0003-2174-1185; I-Chen Lin: https://orcid.org/0000-0001-9924-4723; Chieh-Yu Liu: https://orcid.org/0000-0003-3283-028X; Fei-Chen Lai: https://orcid.org/0000-0002-1415-2107; Pei-Ching Liu: https://orcid.org/0000-0002-5068-1014; Chi-Wen Chen: https://orcid.org/0000-0003-0306-1207
* Correspondence to: Chi-Wen Chen, RN, PhD, College of Nursing, National Yang Ming Chiao Tung University, Taiwan.
E-mail address: chiwenchen@nycu.edu.tw
* Equal contributions.

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are ill, as an interventional care activity [4,5]. In therapeutic play, children inhabit the role of a third party to express their inner feelings; understand their inner worries, fears, and defense mechanisms; and deal with their concerns and anxieties. Medical staff members gain insight into children's needs and feelings in order to effectively implement health education about nursing interventions, medical treatment, and procedures [6]. Therapeutic play has three main forms, namely instructional, emotional outlet, and physiologically enhancing play [7].

Virtual reality (VR) is a computer-generated simulation that provides an immersive, multisensory, and three-dimensional environment in which a child can experience a changed sense of reality and concentrate on immersing themselves in it [8]. An immersive therapeutic play strategy that can be easily implemented can help alleviate the pain and fear of school-aged children receiving intravenous placement. Most studies on VR have applied the distraction principle to assist in reducing children's pain, fear, and anxiety by providing a comfortable environment for video watching [9–11] and interactive gaming [12,13]. Various VR programs have been extensively used for children and adolescents in intravenous placement or venipuncture [9–12,14,15]. In addition to distraction strategies, Wong et al. [15] used a hospital-based adventure story with cartoon characters for informative purposes. Eijlers et al. [16] asserted the need for further research on the effects of VR exposure as a preparation approach for medical procedures. This approach could be especially effective for children at a concrete operational stage who have the capacity for logical thinking [17]. In addition to providing instructional play before treatment, VR can minimize children's pain, fear, and anxiety during intravenous placement; improve their psychological construction, interpretation, and communication; and enhance their sense of control and participation in treatment. Following intravenous placement, immersive cathartic play can guide children in expressing their emotional feelings of the medical care process. Therefore, this study aimed to develop a VR play intervention, including instructional and emotional catharsis play sessions for hospitalized school-aged children undergoing intravenous placement, and examine the effectiveness of this strategy compared with an educational photo book about intravenous placement in reducing children's pain and fear during the procedure.

Specifically, we determined the effectiveness of the intervention on the basis of the following items:

Hypothesis 1. The intervention group with VR play intervention will have a lower pain score than the comparison group with educational book.

Hypothesis 2. The intervention group with VR play intervention will have a lower fear score than the comparison group with educational book.

Hypothesis 3. The intervention group with VR play intervention will take less time required than the comparison group with educational book.

Methods

Design and setting

A parallel, two-arm, multicenter, randomized controlled trial was conducted at the pediatric wards of two medical centers in northern and central Taiwan between June and September 2020. The study was registered with the ClinicalTrials.gov (NCT04558086).

Participants

We included children aged 6–12 years who were recommended to receive intravenous placement by a physician. We excluded children who had developmental delay, epilepsy, visual or hearing impairment, nearsightedness with more than 8.0 diopters or farsightedness with more than 5.0 diopters, or head trauma sustained in the past month; required blood transfusion and blood preparation; received two or more intravenous injections; were undergoing chemotherapy; had experienced VR-induced dizziness; or had a history of vertigo.

The G*Power 3.1.2 program was used to calculate the required sample size; the calculation revealed that for analysis of covariance (ANCOVA) with two groups, a minimum sample size of 128 was required to achieve a power level of 80.0%, an alpha level of 0.05, a medium Cohen's f effect size of 0.25, and a total of 8 covariates, including the children's age, gender, frequency of past intravenous injections, prior use or nonuse of VR, fear scores in pretest, caregiver's age and gender, and registered nurses' years of work experience. Assuming a 5.0% dropout rate, we recruited a total of 134 participants in this study.

Randomization

Allocation concealment was used to randomly assign the enrolled participants into two groups. A staff member not involved in the study used Random Allocation Software 2.0 for the block randomization of the two medical centers; the allocation results were placed in opaque, sealed envelopes, which the participants opened after they and their primary caregivers signed the consent forms.

Interventional instrument

The VR headset HTC Vive was used in this study. The head-mounted display device of the VR Cosmos helmet presented a multiangle view of the virtual world, allowing for a fully immersive experience for the participants. A detector captured the movement of the participants and interacted with the virtual environment. In addition, the wireless hand controller mirrored the participants' hand actions (e.g., grasp or aim) in the virtual world. A light sensor was affixed to the helmet and front end of the controller to locate the position of the controller in the three-dimensional space. The scenes and scripts of the interactive VR play were designed on the basis of clinical implementations of intravenous placement and a literature review (Table 1). We cooperated with the research team of the third author to develop the VR play entities.

Participants allocated to the intervention group underwent instructional and emotional catharsis play sessions executed in the VR environment. The instructional play consisted of one immersive intravenous scene in VR to inform the participants about the purpose and process of injection and what must be done prior to receiving actual intravenous placement. The interactive scene lasted approximately 5 min. The scene started from opening the treatment room, where the child could look around the setting with the handheld controller while listening to the purpose and explanation of intravenous placement procedures along with soft background music. Each participant was asked to stretch out their arm on a red pillow. They then watched the sequence of procedures that followed, namely the trying of a blue rubber band around their arm, disinfection and injection of the intravenous area, deposition of blood in a test tube, placement of a sticker on the needle, and connection of the needle with the long fluid tube. Finally, a rabbit

Table 1 *Design for Virtual Reality Interactive Play.*

Virtual reality interactive play	Instructional play	Emotional catharsis play
Purpose	To inform the participants about the purpose and process of injection and what must be done prior to receiving actual intravenous placement	To forger the feeling of pain and fear of intravenous placement, and relaxation
Content	Immersive intravenous scene	Interactive play
Intervention timing	Before injection	Post injection
Time taken	5 min	5 min
Background music	Soft music	Brisk and relaxing rhythmical music

and two figures representing bacteria entered into the room and announced that a game in which participants must eradicate the bacteria after completing the intravenous placement. The instructional play scene is illustrated in Figure 1.

The postinjection emotional catharsis play session began with an interactive VR scene in which figures representing bacteria were running and jumping in the treatment room, with brisk but relaxing rhythmical music. The rabbit said the following: "Welcome back, little warrior! You were really brave just now. There are a lot of bad bacteria here making our body sick; let's destroy them!" Each participant held a hand controller with the non-injected hand to play for 5 min. Finally, the rabbit clapped its hands and said the following: "You are really amazing. You can make us healthy by stopping the bacteria!" The scene of the emotional catharsis play is also illustrated in Figure 1.

Participants allocated to the comparison group were provided with an educational photo book on intravenous placement entitled *Detective Conan: The Truth about Needles* developed by Hsieh et al. [18] before receiving intravenous placement. The main content of the book outlines the aim of intravenous placement, sensory and procedural information, and care considerations for hospitalized school-aged children.

Tools

Wong–Baker FACES pain rating scale

One of the primary tools in this study was pain. The degrees of pain experienced by the children and reported by their primary caregivers were measured using the Wong–Baker FACES pain rating scale (WBFPS) [1]. The scale contains six cartoon faces with pain ratings of 0–10, with 0 representing 'no pain' and 10 representing 'excruciating pain'. The internal reliability coefficients for the WBFPS were determined to be 0.82–0.92, and the test–retest reliability was 0.90 [19]. The children and primary caregivers were asked to select the faces that best described the pain levels experienced by the children who received intravenous injections; the pain levels were subsequently converted into numerical values [1,19,20].

Children's fear scale

Similarly, the degrees of fear experienced by the children and their primary caregivers were measured using the Children's Fear Scale (CFS) [21]. The scale consists of five cartoon faces with fear ratings of 0–4, with 0 representing 'no fear' and 4 representing 'extreme fear'. The CFS was also determined to have satisfactory reliability and validity. The children and their primary caregivers were asked to select the faces that best described the fear levels of the children who received intravenous injection; the fear levels were subsequently converted into numerical values [21–23].

The time required for successful intravenous insertion

The time required for successful intravenous insertion in this study was defined that began the moment the participants were fitted with the tourniquets and the injection sites determined and ended when the venous catheters (No. 24) were inserted and blood returned to the return blood cavities.

Data collection

All participants and their primary caregivers were provided with an explanation of the study's objectives and their questions

Figure 1. The scenes of instructional play (left) and emotional catharsis play (right) sessions.

were answered by the first author. After signing a consent form, they completed demographic information form. The participants completed the CFS, and a NT$ 200 voucher was gifted to their primary caregiver. After opening the sealed envelopes, the participants were assigned to either the intervention group or the comparison group. The intervention group received VR interactive play, and the comparison group received the educational photo book about intravenous placement. During intravenous injections by the primary care nurses, the time required for successful intravenous insertion was calculated by the first author. After the completion of intravenous placement in the comparison group or after the emotional catharsis play in the intervention group, the participants and their primary caregivers were requested to complete the WBFPS and CFS. The participants in the comparison group were then invited to play the emotional catharsis game.

The study design, procedure, and reporting followed the CONSORT recommendations on randomized controlled trials [24]. All instruments used for data collection were demonstrated to have psychometric adequacy. We further examined the content validity to verify the relevance, accuracy, and suitability of the VR play scenes and scripts. As part of the two-round content verification, five experts were invited to rate the play content from 1 ('the content is very inappropriate and must be deleted') to 5 ('the content is very appropriate and must be retained'). Next, we invited two students from each of the following grades to experience the use and operation of the VR play: 1–2, 3–4, and 5–6. Based on the purpose and process of the intravenous placement in the VR play, the students were requested to rate the content from 1 ('do not understand at all') to 4 ('fully understand'). The content validity index in the second round was 0.90 for the experts and 0.96 for the students.

Ethical considerations

Ethical approval for this trial was obtained from the institutional review boards of two participating medical centers in Taiwan (108163-F & 200129). All included patients and their caregivers provided signed informed consent. The participants were permitted to withdraw from the study at any time without prejudice.

Data analysis

Descriptive statistics are presented as mean and standard deviation or as number and percentage for categorical variables. The significance of differences between the intervention and comparison groups at baseline and the time required for successful intravenous insertion were analyzed using the Student's *t* test for continuous variables or Fisher's exact test for categorical variables. ANCOVA was used to compare the levels of pain and fear between the two groups, after adjustment for the covariates. All analyses were performed using the Statistical Package for Social Science (version 22.0; IBM, Armonk, NY, USA). For all participants, a *p* value of <.05 was considered statistically significant.

Results

The flowchart of participant recruitment is illustrated in Figure 2. We initially assessed 179 participants for eligibility and randomized 134 (74.9%) of them. Of the randomized participants, 69 participants were allocated to the intervention group and 65 participants were allocated to the comparison group, and all of them completed the clinical trial. As presented in Table 2, before the interventions, the two groups were comparable in terms of baseline characteristics. The average age of the participants was 10.01 years (±1.71), and over half of the participants were girls (80; 59.7%). The majority were hospitalized for endocrine examination (116; 86.6%). Moreover, a quarter of the participants (34; 25.4%) had never received intravenous injection before. Over half of the participants (73; 54.5%) had no previous VR experience. The average age of the primary caregivers was 43.57 years (±5.72), and most of these caregivers were mothers (104; 77.6%). The average age of the nurses who executed the intravenous injections was 28.62 years (±5.61), and their average work experience was 6.58 (±5.41) years. The two groups did not differ significantly in demographic or clinical characteristics, except for prior use or nonuse of VR and caregivers' age. The intervention group had significantly fewer participants who had used VR than did the comparison group (34.8% vs. 56.9%, $p = .015$). The average age of the caregivers in the intervention group was significantly younger than that of those in the comparison group (42.28 ± 4.61 vs. 44.94 ± 6.45 years, $p = .007$). No adverse events occurred during the trial. Moreover, no patient experienced VR sickness, seizures, discomfort, or infection-related events related to the VR experience.

Analysis of pain intensity

As presented in Table 3, the degrees of pain (1.33 ± 1.60 vs. 2.06 ± 2.00, $p = .028$) experienced by the children who received

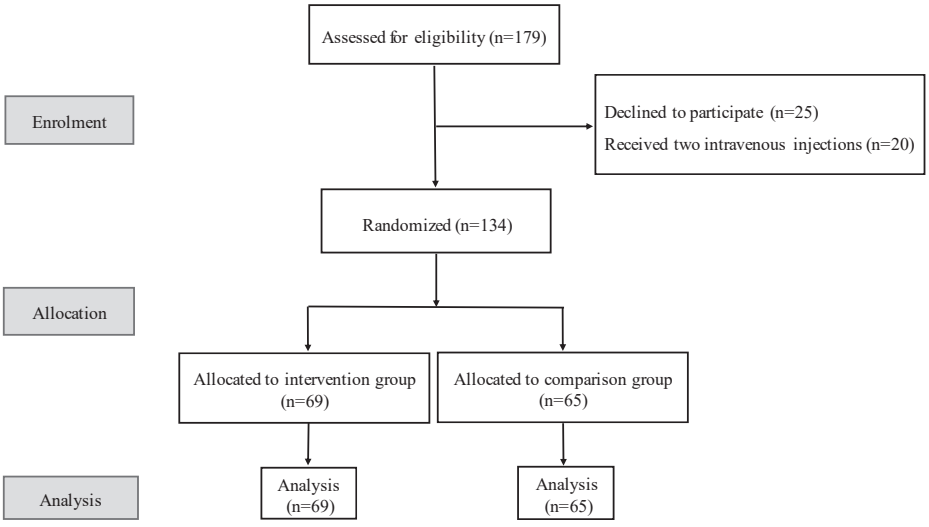

Figure 2. Participant Flowchart.

Table 2 *Baseline Demographic and Clinical Characteristics of Participants (N = 134).*

Variable	Intervention group ($n = 69$) Mean ± *SD*/*n* (%)	Comparison group ($n = 65$) Mean ± *SD*/*n* (%)	*p*
Child			
Age	9.81 ± 1.70	10.22 ± 1.70	.172
Male	32 (46.4)	22 (33.8)	.139
Reason for admission, endocrine examination	56 (81.2)	60 (92.3)	.077
Times of past intravenous injection received	1.55 ± 1.33	1.71 ± 1.65	.544
Have used virtual reality	24 (34.8)	37 (56.9)	.015
Caregiver			
Age	42.28 ± 4.61	44.94 ± 6.45	.007
Relationship, mother	55 (79.7)	49 (75.4)	.679
Nurse			
Age	29.04 ± 6.28	28.17 ± 4.79	.365
Registered nurse working years	6.79 ± 5.83	6.37 ± 4.95	.657

Note: Student's *t*-test or Fisher's exact test; *SD*, standard deviation.

intravenous injections were significantly lower in the intervention group than the comparison group, after adjustment for the children's age, gender, frequency of past intravenous injections, prior use or nonuse of VR, fear scores in pretest, caregiver's age and gender, and registered nurses' years of work experience. Additionally, the degrees of pain (1.13 ± 1.51 vs. 2.68 ± 1.74, $p < .001$) assessed by the primary caregivers were also significantly lower in the intervention group, after adjustment for the aforementioned covariates.

Analysis of fear intensity

As to the prior needle-related fear intensity in the pretest, the mean score of fear intensity in the intervention group (1.58 ± 1.27) was higher than that in the comparison group (1.38 ± 1.33). However, the fear perceived in the pretest by the two groups children differed non-significantly ($t = 0.870$) (Table 3). Similarly, the degrees of fear (0.36 ± 0.64 vs. 0.95 ± 0.96, $p < .001$) assessed by the primary caregivers were also significantly lower in the intervention group, after adjustment for the aforementioned covariates (Table 3). The degrees of fear experienced by the children who received intravenous injections were significantly lower in the intervention group compared with the comparison group, after adjustment for the children's age, sex, frequency of past intravenous injections, prior use or nonuse of VR, fear scores in pretest, caregiver's age and sex, and registered nurses' years of work experience (0.28 ± 0.54 vs 0.65 ± 0.94, $p = .004$).

Analysis of time required for successful intravenous insertion

The average seconds required for successful intravenous insertions were taken in the intervention group (51.89 ± 21.51) and in the comparison group (50.91 ± 16.29). Of all participants, five were excluded due to the external factors, including disinfecting for multiple times or finding blood vessels for a long time due to dirty or cold hands. The time required for successful intravenous insertion did not differ significantly between the two groups (Table 3).

Discussion

The main findings of the present study are that interactive play with VR intervention was effective and reduced children's pain and fear during intravenous placement. According to our review of the literature, this is the first randomized controlled trial to investigate the effects of both VR exposure and distraction in children during intravenous placement. The lack of other similar protocol studies means that comparing our results with those of other studies would be difficult. However, these results are consistent with those of studies that have examined the effects of similar concepts of therapeutic play, such as dramatic, instructional, or role-play sessions, on the pain, anxiety, and fear of school-aged children during needle-related procedures [25–29]. Silva et al. [3] employed the dramatic therapeutic play technique and evaluated the corresponding outcomes by using the Child Drawing: Hospital instrument; they did not observe a significant difference in the degree of anxiety between the intervention and control groups. Hsieh et al. [18] provided children with an educational photo book (the book used in our comparison group) about intravenous placement before the procedure, and patients watched their favorite music video during the procedure; they observed that fear intensity was

Table 3 *Main Study Outcomes (N = 134).*

Variable	Before IV placement Mean ± *SD*	After IV placement Mean ± *SD*	F	*p*
Pain score by child			5.00	.028
Intervention group ($n = 69$)		1.33 ± 1.60		
Comparison group ($n = 65$)		2.06 ± 2.00		
Pain score by caregiver			28.51	<.001
Intervention group ($n = 69$)		1.13 ± 1.51		
Comparison group ($n = 65$)		2.68 ± 1.74		
Fear score by child			8.53	.004
Intervention group ($n = 69$)	1.58 ± 1.27	0.28 ± 0.54		
Comparison group ($n = 65$)	1.38 ± 1.33	0.65 ± 0.94		
Fear score by caregiver			20.30	<.001
Intervention group ($n = 69$)		0.36 ± 0.64		
Comparison group ($n = 65$)		0.95 ± 0.96		
	Intervention group ($n = 66$) Mean ± *SD*	Comparison group ($n = 63$) Mean ± *SD*	*t*	
Time required for successful intravenous insertion, seconds ($n = 129$)[a]	51.89 ± 21.51	50.91 ± 16.29	0.29	.772

Note: Analysis of covariance or Student's *t*-test; *SD*, standard deviation; Adjusted for children's age, sex, frequency of past intravenous injections, prior use or nonuse of VR, fear scores in pretest, caregiver's age and sex, and registered nurses' years of work experience.
IV: intravenous
[a] Five participants were excluded due to the external factors.

significantly and effectively reduced but pain was not. This may reflect that a variety of VR devices have been developed rapidly in these years. The intervention process in this present study was highly accepted by the participants. The findings still revealed significant effects on children's pain and fear that we controlled for the prior use or nonuse of VR as one of covariates.

Previous interventional studies using VR for health education have mostly been executed in the context of children's surgical [30–35] and radiological exam preparations [36,37]. Koo et al. [38] conducted a meta-analysis of five studies and demonstrated the significant benefit of VR in reducing preoperative anxiety in children. Similar findings were reported for the preparation of school-aged children before chest X-ray and magnetic resonance imaging examinations: their anxiety was alleviated, and the use of general anesthetics was reduced [36,37]. Eijlers et al. [16] concluded that further research must be conducted on additional VR exposure strategies, apart from VR distraction strategies. Notably, in previous VR exposure designs, in addition to the first-person role designed by Ryu [34], third-person roles or cartoon characters as instructors were favored [30,31,35]. In the present study, we employed an interactive strategy for children to be completely immersed, from experiencing the treatment room settings to the process of intravenous placement. In addition, the immersive game of eradicating bacteria effectively reduced the degrees of pain and fear.

The time required for successful intravenous insertion did not differ significantly between the intervention and comparison groups. This finding is consistent with those of other studies on VR distraction strategies during intravenous placement, such as the use of a snow world [39], optional games [40], a rollercoaster application [41], and an under-the-ocean game [42]. However, Chen et al. [11] used four virtual environments (i.e., rollercoasters, space exploration, a wildlife park, and travel destinations) selected by school-aged children in an emergency department and revealed that the time required for successful intravenous insertion was significantly shorter in the VR group (53.50 ± 19.01 vs. 61.32 ± 25.78, $p = .046$). Many factors affect the time required for nurses to successfully achieve an intravenous injection, such as the preparation standards, the time it takes to search for a vein, and the cooperative state of the child. Because of the diversity of standard care groups, the preparation standards vary across hospitals and may include the participation of a child life specialist and the use of analgesics or local anesthesia. The VR intervention did not reduce or extend the time required for successful intravenous insertion and can still be used as a reference for clinical practice.

However, this study has some limitations. First, only 134 participants were recruited from two medical centers in northern and central Taiwan. Because of the Covid-19 pandemic, the rate of inpatient hospitalization for children has decreased. Most participants diagnosed in this study were hospitalized for endocrine examinations. Therefore, the results obtained from this small sample may not be generalizable to all hospitalized children or children with chronic illness. Second, this study used HTC Vive VR equipment with a high-end laptop, which provided an excellent immersive effect but must be set up in a fixed place. Wireless VR headsets may be more convenient to operate in future studies. Third, the interactive VR play intervention in our study included instructional and emotional catharsis play sessions; therefore, a comparison of the effects of these two play sessions on the pain and fear of school-aged children could not be performed. Future studies could compare the effects of a VR play intervention implemented at different time points, such as before, during, and after intravenous placement. Finally, we used only the WBFPS and CFS as subjective assessment tools; we did not perform an objective monitoring process to examine participants' pain and fear responses. Thus, future studies could include heart rate, respiratory rate, blood pressure, salivary cortisol, and other monitoring instruments to assess children's pain and fear during intravenous placement.

Conclusion

The VR interactive play intervention including instructional play and emotional catharsis play sessions is an effective method to decrease school-aged children's levels of pain and fear during intravenous placement procedure. In addition, the VR intervention does not extend the time required for successful intravenous insertion and could be used as a reference for clinical practice. This study validates VR interactive play as an age-appropriate, safe, and feasible intervention strategy that allows children to quickly immerse into a virtual environment from experiencing the treatment room settings to the process of intravenous placement. The results of this study can serve as a clinical reference for the implementation of a child-friendly care practice for intravenous placement in school-aged children.

Author contributions

All authors made substantial contributions. MFH, ICL, CYL, and CWC were responsible for the study conception and design. All authors participated in the data collection and analysis. MFH, YWW and CWC wrote the article with the input from all authors. YWW, ICL, CYL, FCL, PCL, and CWC supervised the study. All authors approved the final version for submission.

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Conflict of interest

The authors declare no potential conflicts of interest, real or perceived.

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Research Article

Cross-cultural adaptation and validation of a Chinese Preventive Health Model instrument for measuring the psychosocial factors in hepatocellular carcinoma screening among patients with hepatitis B

Caixia Li,[1] Xiling Lu,[2] Cho Lee Wong,[1] Fei Gao,[2] Carmen W.H. Chan[1,*]

[1] The Nethersole School of Nursing, The Chinese University of Hong Kong, China
[2] The Public Health Center, Henan Provincial People's Hospital, China

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SUMMARY

Purpose: Screening for hepatocellular carcinoma (HCC) as an effective instrument to reduce the burden of late diagnoses remains underutilized in China, much of the Asian countries, and in a sense all over the world. Modifiable psychosocial factors should be identified to improve screening utilization and reduce the burden of late diagnoses. However, valid psychosocial measures are unavailable. This study aimed to translate, culturally adapt, and validate the preventive health model (PHM) instrument for measuring psychosocial factors of HCC screening among patients with hepatitis B.

Methods: This study was conducted from June 2020 to April 2021 in three rigorous phases: (1) committee-based translation from English to Chinese; (2) cognitive interviews (n = 33) and Delphi expert consultations (n = 7) for cultural adaptation; and (3) a cross-sectional study (n = 305) for validation.

Results: In phase I, two items were reworded, and two retranslated for semantic equivalence. In phase II, issues related to comprehension, sensitive wording, wording clarity, question relevance, and cultural sensitivity were addressed by including pictures, rewording five items, and developing seven items. In phase III, exploratory and confirmatory factor analyses suggested a five-factor 20-item solution: it explained 76.9% of the variance; had adequate factor loading (.60–.91), convergent and discriminant validity; satisfactory model fit indices; and reliability (Cronbach's α, .86–.91). Known-group analysis showed that patients with optimal HCC screening behavior had significantly higher scores on each subscale than those not having such.

Conclusion: The Chinese PHM instrument is culturally sensitive, reliable, and valid to measure the psychosocial factors of HCC screening. It can help nurses and researchers to tailor strategies to improve clinical HCC screening practices in high-risk HCC regions.

Introduction

Hepatocellular carcinoma (HCC) is the third leading cause of cancer mortality worldwide [1]. The predominant cause of HCC is hepatitis B virus infection in most high-risk HCC areas, including China, with 55.1% HCC cases and 54.1% deaths attributable to hepatitis B [2]. Owing to the asymptomatic onset of HCC, more than 60.0% of patients are diagnosed at intermediate or advanced stages and have a median survival of less than one year [3]. Thus, international guidelines have highlighted the significance of screening patients with hepatitis B, using liver ultrasound with or without serum alpha-fetoprotein biannually, to detect HCC at an early stage and achieve better survival [4,5]. However, given the biannual repetitive nature of HCC screening, maintaining consistent patient utilization is a major challenge [6]. Unlike Japan and Korea, China does not have a national government-funded HCC screening program; participation in HCC screening mainly depends on personal compliance, ranging from 9.4% to 26.0% [7,8]. And, less than 50.0% of patients undergo subsequent screening rounds [9]. Worldwide, the pooled adherence rate to liver imaging

Caixia Li: https://orcid.org/0000-0002-8170-432X; Xiling Lu: https://orcid.org/0000-0002-4707-3296; Cho Lee Wong: https://orcid.org/0000-0001-6640-1323; Fei Gao: https://orcid.org/0000-0001-9936-7360; Carmen W.H. Chan: https://orcid.org/0000-0003-0696-2369

* Correspondence to: Carmen W.H. Chan, The Nethersole School of Nursing, The Chinese University of Hong Kong, 7/F Esther Lee Bldg, Shatin, N.T., Hong Kong, China.

E-mail address: whchan@cuhk.edu.hk

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every 6–12 months is only 32.0% among patients with hepatitis B [10].

To date, factors that influence HCC screening are understudied, and studies have largely relied on clinical data [11]. Old age, number of clinic visits, and cirrhosis are positively correlated with HCC screening utilization, whereas rural residence, low income, and educational level are negatively correlated [6,11]. The lack of further understanding of factors related to HCC screening has limited the intervention strategies to traditional outreach, patient reminders, and quality improvement programs, that have achieved less than 30.0% semi-annual HCC screening rates [6,12]. Thus, it is imperative to elucidate other modifiable psychosocial factors, which may be the main drivers of HCC screening utilization and targeted interventions [13,14].

Psychosocial factors are multidimensional, encompassing cognitive behavior responses, affective and social aspects; these can influence health outcomes by modifying behaviors [15]. The cognitive (cancer awareness), affective (cancer worry, shame, and stigma regarding cancer screening), and social aspects (social norms) of psychosocial factors have significantly influenced screening modality use in breast, cervical, colorectal, and lung cancer [16]. However, only a few studies have explored the psychosocial predictive roles of fear of HCC detection and perceived HCC screening efficacy with respect to HCC screening utilization [17–19]. The measures used also lack support from behavioral theories and applying a single question (e.g. 'I do not believe that HCC screening is an effective prevention') [18], which might not be able to capture the multidimensional psychosocial aspects of screening utilization. The dichotomous yes–no responses in most of these measures may not allow for sensitivity [18,20]. Moreover, none of these measures provide psychometric validation, thereby limiting the generalization and comparison of results across studies [17–19]. Thus, a multidimensional and reliable psychosocial measure based on health behavior theory is needed to understand patient compliance with HCC screening.

Drawing on the major constructs from the health belief model, self-regulation, and social cognitive theory, the preventive health model (PHM) has been advanced and extensively verified to identify major psychosocial constructs in cancer screening utilization [21,22]. These include salience and coherence (consistency between perceptions of undertaking cancer screening and beliefs for maintaining health); perceived susceptibility to cancer; response efficacy (perceived cancer screening efficacy); cancer worries (concerns over negative consequences of cancer screening); and social influence [21]. Based on these constructs, a five-factor, 16-item PHM instrument was initially developed for measuring colorectal cancer screening factors, which posits that screening is linked to higher salience and coherence, perceived susceptibility, response efficacy, and social influence, but lower cancer worries [21,23]. The correlations between these PHM psychosocial factors and colorectal cancer screening utilization have also been verified in empirical cross-sectional and longitudinal studies [24,25]. Strategies tailored to the psychosocial factors of the PHM instrument, including web-based screening messages [26], education [27], and decision support [24], have demonstrated positive predictive effects on intention and utilization of colorectal cancer screening. Owing to its extensive utilization and predictive effects, the PHM instrument has also been modified and reported to have established reliability and validity, and demonstrated consistent predictive effects on using screening modalities for breast [22], cervical [28], and prostate cancer [29] in two languages (English and Spanish) and among different populations (African-American, Australian, Caucasians, and Hispanic). Despite item deletion or addition has been made to the original PHM instrument, the five-factor structure is identical across studies [22,25]. Given its wide application and reliability, the PHM instrument has the potential to measure the psychosocial factors for HCC screening.

However, items in the original PHM instrument, such as 'colorectal cancer screening makes sense to me,' applied specifically to colorectal cancer and required modifications before being applied to HCC [21]. HCC screening also has some particularities with respect to colorectal cancer. It targets people with chronic diseases such as hepatitis B and aims to detect early-stage HCC to achieve curative treatment and prolong survival [5], whereas colorectal cancer screening targets average-risk adults and helps to detect and remove precursor polyps to prevent colorectal cancer development [30]. Therefore, the contents of the PHM instrument, including the perceived cancer susceptibility and response efficacy need to be adapted to consider the risk group and effectiveness of HCC screening. In addition, considering language and cultural differences, it is unknown whether the PHM constructs would be perceived in similar ways in current population. To maintain equivalence and accurately measure the psychosocial factors affecting HCC screening, this study aimed to: (1) translate the PHM instrument from English to Chinese by applying a committee-based approach; (2) adapt the instrument to achieve culture sensitivity and content validity through cognitive interviews and expert consultation; and (3) conduct psychometric validation via a cross-sectional study. The adaptation and validation of the PHM instrument form the basis for identifying the modifiable psychosocial factors for HCC screening and developing culturally sensitive interventions to improve real-world HCC screening practice and reduce HCC mortality globally.

Methods

Study design

This study adopted a methodological study design and were conducted in three phases to validate the Chinese version of the PHM instrument, including (1) translation of the PHM instrument from English into Chinese; (2) cultural adaptation and content validation of the PHM instrument through three-round cognitive interviews and two-round expert consultations; (3) validation of the Chinese version of the PHM instrument through a cross-sectional study among patients with hepatitis B.

Ethics

This study was approved by the Institutional Review Board of the XGZW university (Approval no. SBRE-20-072) and the HNPP hospital (Approval no. 2020169). All participants were informed about voluntary participation, data confidentiality, and signed a written informed consent form before participation. Each participant received a gift worth 10 Renminbi as appreciation for their cooperation.

Phase I: Instrument translation

The original preventive health model instrument

The PHM instrument was developed by professionals in cancer prevention, control, and behavioral epidemiology in the 1970s [21,23]. It has five subscales and 16 items measuring psychosocial factors to colorectal cancer screening, including salience and coherence (four items), cancer worries (two items), perceived susceptibility (four items), response efficacy (two items), and social influence (four items). The instrument was rated on a five-point Likert scale (1 = strongly disagree, 5 = strongly agree), and the original item 6 and item 12 were reversely scored. The subscale scores were standardized by averaging the corresponding items

and thus ranged from 1 to 5 [21]. The PHM instrument has been widely applied to evaluate psychosocial correlates of colorectal cancer screening [24,25] and demonstrated good construct, convergent, and discriminant validity, with Cronbach's α ranging from 0.61 for social influence to 0.91 for salience and coherence [21,23].

Translation process

After receiving permission from the developer via email, a committee-based translation approach according to the guidelines for cross-cultural adaptation of study instruments was applied from June 2020 to September 2020 [31]. The forward translation from English to Chinese was conducted by two independent and native Mandarin-speaking bilingual translators, including the researcher and a qualified linguistic specialist. A third bilingual independent translator, a Ph.D. candidate, compared the two forward-translated versions with the original instrument regarding discrepancies in words, sentences, and meanings. Identified issues were subsequently discussed and resolved by a committee (composed of one hepatologist, one nursing professor, two nursing specialists in hepatitis care, and all involved translators) to settle on an initial translated version. The blind back-translation was conducted by two other independent and native English-speaking translation experts, with one of them having a medical background. The two back-translated versions were compared with the original instrument by the committee to resolve any discrepancies.

Phase II: Cultural adaptation and content validation

The cognitive interviewing techniques and expert consultations were applied to: (1) examine differences in the perception of PHM constructs among the current population; (2) identify instrument issues for cultural adaptation; and (3) reach content validity.

Three-round cognitive interview for concept discussion and pilot testing

Setting and sample. Following the cognitive interview guideline [32], three rounds of interviews were conducted from October 2020 to January 2021 with 33 purposively selected patients with hepatitis B in a university-affiliated hospital in China to ensure adequate samples and variations in educational level and past HCC screening behavior. Eligible patients included those with hepatitis B and aged 18 to 65 years who were recommended to undergo HCC screening [4,5] in relation to factors of liver cirrhosis, family HCC history, or old age (men, >40 years old and women, >50 years old). Patients with hepatitis C, autoimmune hepatitis, alcoholic liver disease, HCC diagnosis, hepatic encephalopathy, or liver transplantation were excluded.

Data collection. Given the limited knowledge concerning the psychosocial factors for HCC screening [6], concept discussions were conducted through semi-structured interviews in the first round of cognitive interviews to explore patient perceptions HCC screening and its alignment with the PHM constructs. The constructs include salience and coherence (e.g. How do you perceive HCC screening for maintaining health?), susceptibility (e.g., How do you see disease progression from hepatitis B to HCC?), cancer worries, response efficacy (e.g. How do you see the pros/cons of HCC screening?), and social influence (e.g., What helped you undertake HCC screening?).

The adapted version from the first-round cognitive interview was pilot tested in the second round. Patients (n = 5) were asked to read each item, select a response, and express thoughts following the think-aloud approach [32]. Probing questions were also used to clarify their comprehension of the instructions and items (e.g., What do you think this question is asking?), and their memory retrieval, decision, and response processes. General questions were asked regarding uncomfortable items related to HCC, appropriateness of instrument length, and suggestions for improvement. Identified issues were revised and reassessed in the third round among different participants (n = 5). Each interview was conducted by the researcher with knowledge and field experience in qualitative studies, was audio-recorded, and lasted about 20 to 75 minutes.

Data analysis. Data were coded using an established approach for analyzing cognitive interviews [33], including transcription, patient interpretation summarization, problem identification following the Question Appraisal System [34], and revised decision making. All adjustments were performed following Delphi expert consultation.

Two-round Delphi expert consultation for content validity evaluation

Seven experts were purposively selected, as per previous literature [35]: a hepatologist; two hospital nurse directors with clinical and research experience in cancer prevention and four nursing faculty members from different institutions with expertize in instrument development, hepatitis B, or HCC-related research. All were professors with more than 20 years of work experience. Using email consultation, the experts were invited to rate the relevance (1 = *not relevant*, 2 = *a bit relevant*, 3 = *relevant but needs minor alteration*, 4 = *very relevant*) and clarity of items, comment on improvement or revisions during cognitive interviews, and suggest new items as needed. The item-level content validity index (I-CVI) and average scale-level CVI (S-CVI/Ave) were calculated, with values exceeding .78 and .90, respectively, considered as adequate content validity [36].

Phase III: Psychometric validation

Setting and sample

The study was conducted from January to April 2021 in three departments of a university-affiliated hospital in China. Patients were recruited by convenience sampling using the same selection criteria as those used in the cognitive interviews. Based on an appropriate sample size of 150 to 200 for exploratory factor analysis (EFA) and at least 150 for confirmatory factor analysis (CFA) [37], the minimum sample size was set to 300, following the principle that the minimum required ratio for a sample size is 5 to 10 participants per item to ensure factor stability [38].

Data collection

The demographic information and adapted PHM instrument was administered, which were self-completed by the patients with help from the researcher or two trained research assistants. Patient clinical data, including past HCC screening behavior, were collected from electronic medical records. Validation of the HCC screening behavior was done mutually by the researcher with one of the research assistants.

Data analysis. The SPSS 26.0 (IBM Corp., NY) and AMOS 23.0 (IBM Crop., Chicago) were used. Sample characteristics were summarized applying descriptive analysis. Differences between samples were compared using independent-samples *t*-test for continuous data with normal distributions, or the Mann–Whitney *U* test for non-normal distributions, and the chi-square test for categorical data. All analyses were two-sided, with $p < .05$ considered significant. Items were removed if the critical ratio (CR) or item–total scale correlation coefficient were not significant [38].

Since modifications were made, EFA and CFA were performed to test the underlying structure of the instrument and confirm its consistency with data from the current population. The total samples were randomly divided into two equal parts to perform EFA (n = 152) and CFA (n = 153). The EFA was conducted using principal component analysis (PCA) with varimax rotation [38]. The data were deemed suitable for EFA if the Kaiser–Meyer–Olkin (KMO) value > .60 and Bartlett's test of sphericity achieved a p value < .05 [39]. The number of potential factors was determined according to the formula of eigenvalue >1 and a scree plot representing all factors above the elbow [38]. Items were retained if the primary factor loadings and communities exceeded .40 [39]. CFA was conducted using the maximum likelihood [40]. Model fitness criteria were as follows: minimum discrepancy divided by its degree of freedom (CMIN/DF) < 2, comparative fit index (CFI) > .95, Tucker–Lewis Index (TLI) > .95, standard root mean squared residual (SRMR) < .08, and root mean square error of approximation (RMSEA) < .06 [40]. Convergent validity was considered sufficient if the average variance extracted (AVE) > .50, composite reliability (CR) > .70, and CR > AVE [41]. Discriminant validity was established when the AVE for each construct was higher than its shared variance and the square of the correlation coefficient, with other constructs [42].

To test against the external criteria of cancer screening behavior [38,43], known-group analysis was performed to test the PHM-based hypothesis that patients with optimal HCC screening behavior (undertaking liver ultrasound with serum alpha-fetoprotein at least semiannually in the past two years) [4] would have higher mean scores on each subscale, except cancer worriers, compared with those having suboptimal or poor HCC screening behavior (undertaking liver ultrasound with serum alpha-fetoprotein more than every six months or without undertaking HCC screening in the past 2 years).

For reliability, Cronbach's alpha coefficient, split-half (odd–-even) reliability coefficient, and test–retest reliability coefficient were used. The test–retest reliability was evaluated at a recommended two-week interval with 50 participants randomly selected from the total sample by calculating the intraclass correlation coefficient [38].

Results

Phase I: Instrument translation

In the forward translation, 'immediate family' was translated to 'family,' which also concerns close family in Chinese culture. 'Doctor or health professional' was translated to 'doctor or nurse,'" which is widely used to represent medical professionals in China. After back-translation, two items did not retain their original meaning. For the original item 2 ('*I want to do what members of my immediate family think I should do about colorectal cancer screening*'"), the multiple attributive adjuncts in literal translation challenged comprehension. Its back-translation, '*I want to take the colorectal cancer screening that my family members think I should take*,' emphasized the individual's motivation instead of the family's influence on screening utilization. After consolidation for semantic equivalence, the item was retranslated to '*Regarding colorectal cancer screening, I would like to listen to the views of my family*'. The original item 10 was retranslated for similar reasons ('*Regarding colorectal cancer screening, I would like to listen to the views of my doctor or nurse*'). 'Colorectal cancer'" was replaced with 'HCC' for this study.

Phase II: Cultural adaptation and content validation

For cultural adaptation, issues related to comprehension, sensitive wording, wording clarity, question relevance, and cultural sensitivity were identified and addressed during expert consultation and cognitive interviews with 33 patients (mean age: 45.70 [11.95] years) (Table 1). Table 2 illustrates the adaptation details, with expert comments and patient quotes.

Cultural adaptation

Regarding comprehension, 'HCC screening' was difficult for eight patients to understand owing to their lack of awareness or misperception that 'HCC screening' entailed an inspection of water, soil, or diet that may cause HCC. Thus, photographs demonstrating HCC progression and screening tests in the instruction to assist comprehension were included. As respondents indicated poor knowledge of 'curative treatment' and 'liver resection' as the primary treatment choice for early-stage HCC, 'better treatment' was finally adopted. Sensitive wording, such as 'very likely' and 'improve survival rates' for HCC risk and screening efficacy, made patients feel nervous and were, thus, revised to 'may' and 'prolong life' respectively. Two items had wording clarity issues: 'I will just be healthy' was reworded to 'it will not influence my health' and 'chance' to 'risk.' For question relevance, one item was reworded and another item, measuring colorectal polyp risk, was deleted because it did not apply to HCC. Two items in the response efficacy subscale were not aligned with HCC screening efficacy and were replaced by items 21, 22, and 23 (Table 2), which were developed based on HCC screening guidelines [4,5].

Cultural sensitivity was enhanced by seven new items added in the first round of concept discussion and expert consultation. For salience and coherence, most perceived a low need to undertake HCC screening or health checks if they had no discomfort or symptoms of abdominal distension or pain, black stool, or jaundice. For example, they mentioned that 'I would not go to the hospital unless I had symptoms (lower limb edema),' and 'Until I lost my appetite, I did not go to the hospital, where I was diagnosed with liver cirrhosis and ascites.' Item 7 was added to reflect the perceived salience of taking preventive actions in the absence of symptoms. For cancer worries, three experts believed that negative emotions and concerns about being a burden to their family if diagnosed with HCC were important to the perceived negative consequences of undertaking HCC screening in Chinese culture. Patients expressed similar feelings: 'If HCC was detected, my family would have to spend a large sum for the costs. Where would we get the money for treatment? I decided not to undertake HCC screening, regardless of the severity of my symptoms.' Thus, items 10 and 11 were added (Table 2). For perceived susceptibility, item 20 (Table 2) was added because of the common misconceptions among patients that HCC could be precluded by antiviral drugs and healthy lifestyles. For social influence, items 14, 15, and 16 were added, as suggested by all content experts and patients, to measure the influence of friends/colleagues and social media on the intention to undertake HCC screening.

Content validity

Consensus on cultural adaptations was reached in the second round of expert consultation. The Chinese PHM instrument comprised 5 subscales with 23 items (Table 3). The I-CVI was .86 for items 8, 9, and 12, and 1 for the remaining items; thus, the S-ICV/Ave reached .98, demonstrating excellent content validity [36].

Phase III: Psychometric validation

After excluding data from five patients with missing values due to survey incompletion (n = 3) or dropout (n = 2), the entire sample consisted of 305 individuals, with a mean age of 47.41 years. No statistical differences were found in the general data between the EFA and CFA samples (Table 1). The 23 items were all retained for

Table 1 *Demographic and Clinic Data of Participants (n = 338).*

Variables	Phase II: Total Sample (n = 33)	Phase III: Total Sample (n = 305)	EFA Sample (n = 152)	CFA Sample (n = 153)	$t/\chi^2/Z$ value	p
	N (%) or Median (IQR) or Mean (SD)				(EFA vs. CFA samples)	
Age	45.70 (11.95)	47.41 (8.87)	47.45 (8.99)	47.37 (8.77)	−.07	.941
Gender					.23	.633
Men	25 (75.8%)	221 (72.5%)	112 (73.7%)	109 (71.2%)		
Women	8 (24.2%)	84 (27.5%)	40 (26.3%)	44 (28.8%)		
Marital status					2.80	.094
With a partner	31 (93.9%)	286 (93.8%)	139 (91.5%)	147 (96.1%)		
Without a partner	2 (6.1%)	19 (6.2%)	13 (8.5%)	6 (3.9%)		
Residence					.23	.633
Urban	14 (42.4%)	84 (27.5%)	40 (26.3%)	44 (28.8%)		
Rural	19 (57.6%)	221 (72.5%)	112 (73.7%)	109 (71.2%)		
Education					1.50	.683
Elementary school	5 (15.2%)	107 (35.1%)	52 (34.2%)	55 (36.0%)		
Middle school	14 (42.4%)	118 (38.7%)	58 (38.2%)	60 (39.2%)		
High school	10 (30.3%)	37 (12.1%)	17 (11.2%)	20 (13.1%)		
College or postgraduate	4 (12.1%)	43 (14.1%)	25 (16.4%)	18 (11.7%)		
Monthly household income (RMB)					2.07	.558
< 2000	5 (15.2%)	83 (27.2%)	38 (25.0%)	45 (29.4%)		
2000-3999	18 (54.6%)	95 (31.2%)	53 (34.9%)	42 (27.5%)		
4000-5999	8 (24.2%)	86 (28.2%)	41 (27.0%)	45 (29.4%)		
≥ 6000	2 (6.0%)	41 (13.4%)	20 (13.1%)	21 (13.7%)		
Hepatitis B duration (months)	144 (288)	96 (207)	96 (192)	108 (213)	−1.16	.872
Liver cirrhosis					.43	.514
Yes	28 (84.8%)	236 (77.4%)	120 (79.0%)	116 (75.8%)		
No	5 (15.2%)	69 (22.6%)	32 (21.0%)	37 (24.2%)		
HCC screening interval (months)					3.47	.325
≤ 6	6 (18.2%)	77 (25.3%)	38 (25.0%)	39 (25.5%)		
7-12	9 (27.3%)	121 (39.7%)	62 (40.8%)	59 (38.6%)		
≥ 13	16 (48.4%)	59 (19.3%)	24 (15.8%)	35 (22.9%)		
None	2 (6.1%)	48 (15.7%)	28 (18.4%)	20 (13.0%)		

Abbreviations: CFA, confirmatory factor analysis; EFA, exploratory factor analysis; HCC, hepatocellular carcinoma; IQR, interquartile range; RMB, renminbi or Chinese yuan; SD, standard deviation.

significant CR between the first 27.0% high total score group and the last 27.0% low total score group (CR = 4.12–20.28, $p < .001$). The item–total scale correlation ranged from .30 to .80 ($p < .001$) [38].

Exploratory factor analysis

The KMO was .89, and Bartlett's test of sphericity reached statistical significance (chi-square = 2473.68, $p < .001$), demonstrating adequate sampling and variable relations [39]. The PCA and varimax rotation revealed five factors with eigenvalues above 1, consistent with the scree plot. Factor loadings and community values were above .40 for all items, except for item 20, which was thus eliminated. Item 3 was cross-loaded on factors 2 and 4 but was retained in factor 2 for its content coherence. Items 8 and 12 from factor 1 unexpectedly loaded on factors 2 and 4 and were deleted for not conceptually fitting the relocated factors. The five-factor solution for the adapted PHM instrument explained 76.9% of the total variance. Factor loadings and communalities of the 20 retained and 3 deleted items are presented in Table 3.

Factor 1, social influence, had five items, accounting for 41.4% of the variance. This factor reflected the desire to undergo HCC screening in compliance with key references' views and social media influence. Factor 2, salience and coherence, had five items, accounting for 13.9% of the variance. This factor measured the perception that undertaking preventive action is consistent with beliefs for maintaining good health. Such perception reflected the perceived sense to undertake HCC screening for health maintenance and whether the patient attended health checkups in the absence of symptoms. Factor 3, cancer worries, had four items, accounting for 9.3% of the variance. This factor reflected concerns on the negative consequences of undertaking HCC screening, including HCC diagnosis, negative emotions, and worries about burdens on the family. Factor 4, perceived susceptibility, had three items, accounting for 7.1% of the variance. This factor measured individuals' perceived risk of developing HCC. Factor 5, response efficacy, had three items, accounting for 5.2% of the variance. This factor reflected the belief that HCC screening effectively reduces disease threat, including early diagnosis of HCC with better treatments and survival.

Confirmatory factor analysis

CFA was performed based on the EFA results for the five-factor 20-item PHM instrument. The initial fit indices suggested a lack of fit with the data (CMIN/DF = 1.72, CFI = .95, TLI = .94, SRMR = .06, RMSEA = .07). Based on modification indices, a correlated error term between items 6 and 7—both related to a lower sense of undertaking preventive actions—was added. The final model provided a good fit to the data, with model fitness indices within suggested range (CMIN/DF = .47, CFI = .96, TLI = .96, SRMR = .06, RMSEA = .06) [40]. All items loaded strongly onto latent factors (.67–.94), with factor loading coefficients reaching significance ($p < .001$) (Figure 1).

Convergent and discriminant validity analyses

The AVE and CR values revealed that the five subscales had adequate convergent validity (Table 4). Discriminant validity was also acceptable, with AVE values generally higher than the square of the correlation between each pair of subscales [42] (Table 4).

Known-group analysis

Known-group analysis demonstrated that patients with optimal HCC screening behavior had higher subscale scores than those not (Table 4), including social influence ($z = -11.20$, $p < .001$), salience and coherence ($z = -12.51$, $p < .001$), cancer worries ($z = -2.56$, $p = .010$), perceived susceptibility ($z = -10.98$, $p < .001$), and response efficacy ($t = 18.95$, $p < .001$).

Table 2 *Cultural Adaptation of the Chinese Preventive Health Model (PHM) Instrument Based on Expert Consultations and Cognitive Interviews.*

Identified Issues (Study Rounds)	Adaptation	Reasons for Adaptation
Comprehension Issue (Three rounds of cognitive interviews)		
HCC screening	Cartoon pictures of HCC progression and photographs of HCC screening tests (e.g. liver ultrasound) were used to explain HCC screening in the instrument's instruction.	During two rounds of cognitive interviews, most patients demonstrated unawareness of HCC screening. For example, P 10 said, 'I hadn't heard about HCC screening until you told me.' Some misperceived HCC screening as an epidemiological study on HCC risks. For example, 'I perceive that HCC screening relates to the study or screening of water, soil, or diet that may cause HCC, in a place where HCC incidence is high.' (P 24) Thus, we added pictures and photographs to the instrument to assist their understanding of HCC screening. These implements received high acceptability among patients with lower educational levels.
Curative treatment	Revised to 'liver resection' and finally to 'better treatment.'	In the second round of cognitive interviews, almost all patients reported not understanding 'curative treatment' and misperceived it as complete cure or whole liver resection after HCC diagnosis. 'Does it mean complete cure? I don't really think so. HCC cannot be cured.' (P 25) 'I believe that curative treatment is to resect the whole liver. Is it possible to live without a liver?' (P 24) The item was thus revised to 'liver resection' as it is the primary treatment of choice for early-stage HCCs. However, in the third round, we found that some may not know this detail. 'I don't think liver resection is the primary choice. I observed that they (patients with HCC) use transarterial chemoembolization.' Thus, the lack of knowledge may influence patients' comprehension of this item. It was finally revised to 'better treatment' to help those with lower educational level understand the item.
Sensitive wording (First-round expert consultation and second-round cognitive interview)		
It is very likely that I will develop HCC.	Revised to 'I may develop HCC in the future.'	As suggested by three experts in the first round consultation, 'in the future' was added to specify the period. Compared with 'may,' 'very likely' has a stronger meaning that HCC would happen. Experts suggested to use 'may' to replace 'very likely,' with the latter being potentially offensive in Chinese and could make patients feel nervous when answering the question.
Improve survival rates	Revised to 'prolong life.'	During the second round of cognitive interviews, two patients expressed that the use of 'improve survival rates' made them feel scared that they 'cannot survive' (P 26), and suggested to revise it to 'prolong life,' which is more psychological acceptable.
Wording clarity (First-round expert consultation)		
I will just be healthy.	Revised to 'it will not influence my health.'	As suggested by two experts in the first round of consultation, we revised 'I will just be healthy' to 'it will not influence my health.' The revision did not change the item's sense orientation but improved overall understanding of the item: 'it will not influence my health if I avoid having HCC screening.'
The chance that I might develop HCC is high.	Revised to 'the risk that I might develop HCC is high.'	The words 'chance' and 'risk' have a slight difference in Chinese. 'Chance' refers to the current probability of getting HCC, whereas 'risk' is the potential of getting HCC in the future. Given that patients typically undertake HCC examinations in hospital and are aware of their diagnoses, they may be inclined to rate 'no' if the item uses 'chance' without HCC diagnoses. Thus, as suggested by three experts in the first round of consultation, we used 'risk' to evaluate patients' perceived susceptibility of developing HCC.
Question relevance (First-round expert consultation)		
Compared with other persons my age, I am at lower risk for HCC.	Revised to 'compared with other persons without hepatitis B, I am at higher risk for HCC.'	Compared with age, hepatitis B infection is a major risk for developing HCC in China. As suggested by two experts in the first round of consultation, the revision is more relevant to the current population.
The chances that I will develop colorectal polyps are high.	Deleted.	The colorectal polyp relates to a different anatomical location of the gastrointestinal tract and is not relevant to HCC, which relates to the liver.
Items in original response efficacy subscale:	Deleted and replaced by three new items, including	The research team and content experts suggested the revision. First, the original items are not aligned with the current evidence on HCC surveillance efficacy regarding early diagnosis, more curative treatment, and better survival; these were deleted. After an integrative review of the current HCC surveillance guidelines, we developed three items to constitute this domain. The use of 'better treatment' and 'prolong life' were finally implemented. See revisions on wordings. The added items are also consistent with patients' perceived efficacy of undertaking HCC screening: 'HCC screening helps detect HCC early. The earlier you find HCC, the better the treatment would be. Now, I have liver cirrhosis and have the risk of developing HCC. I usually undergo CT scanning to check for HCC. If the results are negative, I will feel reassured.' (P 1)
When colorectal polyps are found and removed, colorectal cancer can be prevented.	Item 21: HCC screening is helpful for the timely detection of early-stage HCC.	
	Item 22: When HCC is detected in the early stages, curative treatment could be achieved.	
When colorectal cancer is found early, it can be cured.	Item 23: Early detection of HCC through screening can improve survival rates.	
Culture sensitivity (First-round expert consultation and cognitive interview)		
Salience and coherence	Added item 7: It doesn't make sense to me to go to hospital for health checkups if I didn't feel discomfort.	During the first round of cognitive interviews, most patients expressed that they undertook opportunistic HCC screening when they experienced symptoms. 'At that time, my face and eyes were yellow. I also felt bloated in my abdomen. There was irregular liver pain, but not too painful. It didn't hurt from time to time, but did for a while when it came up. So, I went [to the hospital] to have a liver ultrasound' (P 18). Thus, patients tended to perceive a lower need to undertake health checks or HCC screening if they do not feel uncomfortable or can stand the discomfort/pain. 'If my liver has problems, my ankle would be swollen; I could feel a pit after pressing. If there is no swelling and the examination results are normal, I will not go to the hospital […] unless I have the symptoms I just mentioned' (P 7). For patients from rural areas, they may believe that 'even if we feel uncomfortable, we don't even take medicine; just drink more water. If I can bear it, I won't have it checked' (P 22). 'For rural people, as long as you can move, you can do

(*continued on next page*)

Table 2 (*continued*)

Identified Issues (Study Rounds)	Adaptation	Reasons for Adaptation
		the labor. That's all. We never thought to have health examinations; we don't go to hospitals unless the disease is very serious' (P 2). Thus, to enhance the instrument's culture sensitivity, we added item 7 to assess for perceived salience, the felt need or importance, of undertaking preventive action in the absence of symptoms.
Cancer worries	Added item 10: I am worried that if HCC is detected, it will bring me fear and pressure. Added item 11: I am worried that if HCC is detected, it will bring an unbearable burden on my family.	Three experts believed that negative emotion and concern of being a burden to the family if diagnosed with HCC should also be assessed. Further interviews also revealed that patients had psychological distress toward HCC diagnoses, worried that they may bring a heavy burden to their family. This influenced patients' utilization of HCC screening. 'I don't want to think about it. The more I think about HCC, the more psychological pressure I feel' (P 8). 'When HCC is mentioned, my heart sinks' (P 5). 'If we don't know the diagnosis, we can still muddle along. If we know, what should my family and I do? Ordinary people don't have money' (P 17). Meanwhile, others expressed that undertaking HCC screening would help detect HCC at an early stage and reduce health costs and negative influences to them and their families (P 4). Thus, items 10 and 11 were added to help explore the predictive effects of these culture-bound perceptions.
Perceived susceptibility	Added item 20: I will not get HCC if I take anti-hepatitis B virus drugs and adopt a healthy lifestyle.	The cognitive interviews revealed the patients' misunderstanding of HCC risks. Most of them perceived that HCC could be precluded by antivirus drugs and healthy lifestyles; these patients had a lower perceived need for undertaking HCC screening. 'For me, I pay attention to my diet, have regular rest, and quit smoking and drinking last year. Further, I take antiviral drugs on time. I believe that the progression from hepatitis B to HCC is reversible. Anyway, I have a lower risk of HCC and don't consider HCC screening' (P 5). Thus, this item was added to further assess patients' perceived HCC susceptibility.
Social influence	Added item 14: My friends or colleagues think I should have HCC screening. Added item 15: I want to do what my friends or colleagues think I should do about HCC screening. Added item 16: Regarding HCC screening, I will refer to relevant information on the internet, TV, or in books.	All experts reported on the item inadequacy of this subscale and suggested to consider influences from social media and friends and colleagues who are also important members in one's social circle. During the cognitive interviews, the patients also expressed that information from social media helped them understand the importance of HCC screening. Reminders from friends/colleagues helped them undertake HCC screening. 'I also pay attention to HCC screening and search relevant information online. There is much information on HCC screening from Baidu' (P 5). 'In fact, when I came here [the hospital] this time, I didn't feel discomfort. There was a wedding ceremony, and I sat there drinking. Two friends said that my eyes were yellow and suggested that I go to hospital for examinations. So, I came here' (P 19).

Abbreviations: CT, computed tomography; HCC, hepatocellular carcinoma.

Reliability analyses

The Cronbach's α were 0.91 for the 20-item PHM instrument; and .91, .88, .87, .86, and .89 for the subscales of social influence, salience and coherence, cancer worries, perceived susceptibility, and response efficacy, respectively (Table 3). The split-half reliability coefficient was .79, and the intraclass correlation coefficient for test–retest reliability was .80 ($p < .001$), indicating established stability [38].

Discussion

HCC screening is underutilized globally and significantly precluded timely diagnosis of HCC [6]. Although exploration of its modifiable psychosocial factors has been highly emphasized [14], the lack of valid instruments has impeded progress. The three-phase study is the first that translated, culturally adapted, and validated a Chinese version of the PHM instrument for measuring psychosocial factors of HCC screening among patients with hepatitis B. The instrument provided new insights for future efforts to improve HCC screening practices across geographic regions.

In the first phase, cultural and linguistic issues were revealed in translating 'immediate family,' 'doctor or health professional,' and original items 2 and 10, consolidated through semantic translation. The translated version was easy to understand, except for the instruction, due to patients' miscomprehension of HCC screening. To avoid incorrect assumptions about HCC screening, the study added pictures demonstrating HCC screening, thereby also reducing response bias. Future studies should clarify patients' comprehension of HCC screening when administering the instrument.

In the second phase, the PHM instrument was adapted by considering the particularities of HCC screening, such as the risk group of hepatitis B and screening effectiveness; patients' cultural perceptions of undertaking HCC screening; and content experts' suggestions. The cognitive interviews revealed that patients' perceptions of HCC screening overlapped with the five PHM constructs but with slight differences. For salience and coherence, most patients perceived lower needs for health checkups and undertook HCC screening only when symptoms appeared. A total of 20.0–69.0% of high HCC risk patients believed that HCC screening was unnecessary in absence of abdominal pain [17,18,20]. Item 7 was thus added, consistent with previous cancer screening belief instruments that adopted items regarding attitudes toward preventive actions in absence of symptoms [43,44]. Measuring this perception is vital to HCC screening, given that early-stage HCC is typically asymptomatic and screening only after symptoms leads to late diagnoses [3].

The cancer worries factor measured the perceived negative consequences of cancer screening, including cancer detection [21]. Concern about HCC detection is common in patients with hepatitis B [19,20], which is why 13.8% of them do not undertake HCC screening [18]. However, the negative emotion and fear of being a burden to the family if diagnosed with cancer are also considered important aspects of cancer worries [45]. First, in Chinese culture, HCC has been perceived as incurable and implies death [46]. The negative emotions toward HCC are inevitable. Most patients in current study also expressed fear and anxiety when mention about HCC, such as 'my heart sinks.' This may influence their attitude toward early diagnosis of HCC and behavior in undertaking HCC screening. Item 10 was thus added to gather insights for future targeted psychological interventions to reduce the negative emotions relating to HCC and HCC screening. Second, familialism is highly valued in Chinese culture regarding responsibilities in supporting and self-sacrificing for family [47]. Some patients thus avoided HCC screening for possible HCC diagnoses that may bring

Table 3 *Items, Factor Loadings, Communalities, and Cronbach's Alpha Values of the Chinese Preventive Health Model (PHM) Instrument.*

Factors and Items	Factor Loadings					Communalities	Cronbach's α
	1	2	3	4	5		
Factor One: Social Influence							.91
[a]14. My friends or colleagues think I should have HCC screening	**.88**	.12	-.01	.16	.15	.85	
[a]15. I want to do what my friends or colleagues think I should do about HCC screening.	**.88**	.07	.08	.12	.18	.83	
13. I want to do what my doctor or nurse thinks I should do about HCC screening.	**.76**	.25	.15	.15	.36	.80	
[a]16. Regarding HCC screening, I will refer to relevant information on the internet, TV, or in books.	**.72**	.38	.06	.13	.16	.72	
2. I want to do what members of my family think I should do about HCC screening.	**.71**	.26	.09	.15	.14	.62	
Factor Two: Salience and Coherence							.88
[a]7. It doesn't make sense to me to go to hospital for health checkups if I didn't feel discomfort.	.20	**.87**	-.02	.05	.16	.82	
[c]6. It will not influence my health if I avoid having HCC screening.	.25	**.80**	.07	.04	.16	.74	
1. HCC screening makes sense to me.	.12	**.69**	.10	.37	.22	.69	
3. Having HCC screening is an important thing for me to do.	.20	**.61**	.13	**.48**	.32	.76	
4. Having HCC screening can help to protect my health.	.27	**.60**	-.01	.38	.17	.61	
Factor Three: Cancer Worries							.87
[a] 10. I am worried that if HCC is detected, it will bring me fear and pressure.	.02	.03	**.91**	.05	-.02	.84	
9. I am worried that HCC screening will show that I have HCC.	.07	-.01	**.90**	.11	.02	.83	
[a]11. I am worried that if HCC is detected, it will bring an unbearable burden on my family.	.01	-.05	**.83**	.17	.09	.73	
5. I am afraid of having an abnormal HCC screening test result.	.18	.21	**.73**	-.08	.06	.62	
Factor Four: Perceived Susceptibility							.86
[c]17. The risk that I might develop HCC is high.	.18	.18	.05	**.88**	.10	.84	
[c]19. I may develop HCC in the future.	.24	.12	.08	**.84**	.18	.82	
[c]18. Compared with other persons without hepatitis B, I am at higher risk for HCC.	.08	.22	.14	**.78**	.30	.77	
Factor Five: Response Efficacy							.89
[b]22. When HCC is detected in the early stages, better treatment could be achieved.	.29	.26	.07	.16	**.83**	.88	
[b]23. Early detection of HCC through screening can prolong life.	.25	.29	.06	.24	**.82**	.88	
[b]21. HCC screening is helpful for the timely detection of early-stage HCC.	.31	.20	.02	.30	**.72**	.75	
Total Scale							.91
Deleted Items							
8. Members of my family think I should have HCC screening.	.02	**.64**	.01	.09	.30	.51	
12. My doctor or nurse thinks I should have HCC screening.	.33	.40	.09	**.43**	.20	.50	
[a]20. I will not develop HCC if I take anti-hepatitis B virus drugs and adopt a healthy lifestyle.	.31	.29	-.06	.36	.28	.39	

Abbreviations: HCC, hepatocellular carcinoma.
Boldface indicates factor loadings that exceed the criterion .40.
[a] Newly added items for increasing cultural sensitivity.
[b] Newly added items for increasing question relevance.
[c] Corrected items.

their family economic and caring burdens. The added item 11 enhanced cultural sensitivity.

Regarding perceived susceptibility, most patients misbelieved that HCC could be precluded by antiviral drugs and healthy lifestyles. Indeed, 48.6% to 71.6% of patients with chronic liver diseases are unaware that a healthy diet does not sufficiently lower all HCC risks [17,20]. Item 20 was thus added but was finally deleted owing to poor factor loading. This may be because the item was reversely worded and could have confused patients after responding to previously positively worded items in this subscale. For social influence, influences from important social members (friends/colleagues) and social media in changing individual attitudes and behaviors toward cancer screening cannot be neglected [48], and were thus incorporated. These adaptations to the instrument have led to an excellent S-CVI/Ave (.98).

In the third phase, psychometric validation was conducted. Aligning with previous studies on Australians [25], African-Americans, and Caucasians [21], EFA and CFA also supported a five-factor structure. However, in contrast to the findings of Vernon et al. [23], social influence, instead of salience and coherence, accounted for the highest variance (41.4%) in the current study. This may be due to the increased number of items and may not sufficiently support that social influence has more predictive effects than salience and coherence on patient utilization of HCC screening. In addition, items 8 and 12 from social influence were relocated to different factors. Item 8 was loaded on salience and coherence. In Chinese culture, to avoid psychological harm to patients, medical professionals tend to avoid directly informing patients of cancer-related examinations and results; families are told first [49]. Patients would feel the need for HCC screening if their families believed so. Thus, responding to item 8 may lead to ambiguous meaning, being related to social influence from families and salience and coherence, the perceived need for HCC screening. Similarly, item 12 loaded on perceived susceptibility, which may be because patients would perceive HCC risks if their doctors suggested that they undergo HCC screening. Given the lack of conceptual consistency with relocated factors, both items were deleted.

The adapted PHM instrument also showed known-group validity, with significantly higher scores on each subscale among patients with optimal HCC screening behavior than those not. However, the PHM construct of cancer worries has been conceptualized as a barrier to cancer screening and negatively predicted cancer screening uptake in previous studies [23,24]. Based on concept discussions, this contradiction may be explained by patients' available resources and beliefs toward HCC screening efficacy. Patients with lower income may not be willing to undergo HCC screening to avoid being a burden to their families in case of positive diagnoses. Conversely, other participants, who believed that undertaking HCC screening helps to detect early-stage HCC with lower tumor burden, were more willing to undertake HCC screening to avoid negative influences on them and their families caused by late diagnosis of HCC. The predictive direction of cancer worries regarding HCC screening can be further explored. Regarding reliability, the Cronbach's α values of salience and coherence, cancer worries, and perceived susceptibility in the current study were similar to those in a previous report [23]. However, the coefficients were generally higher than other

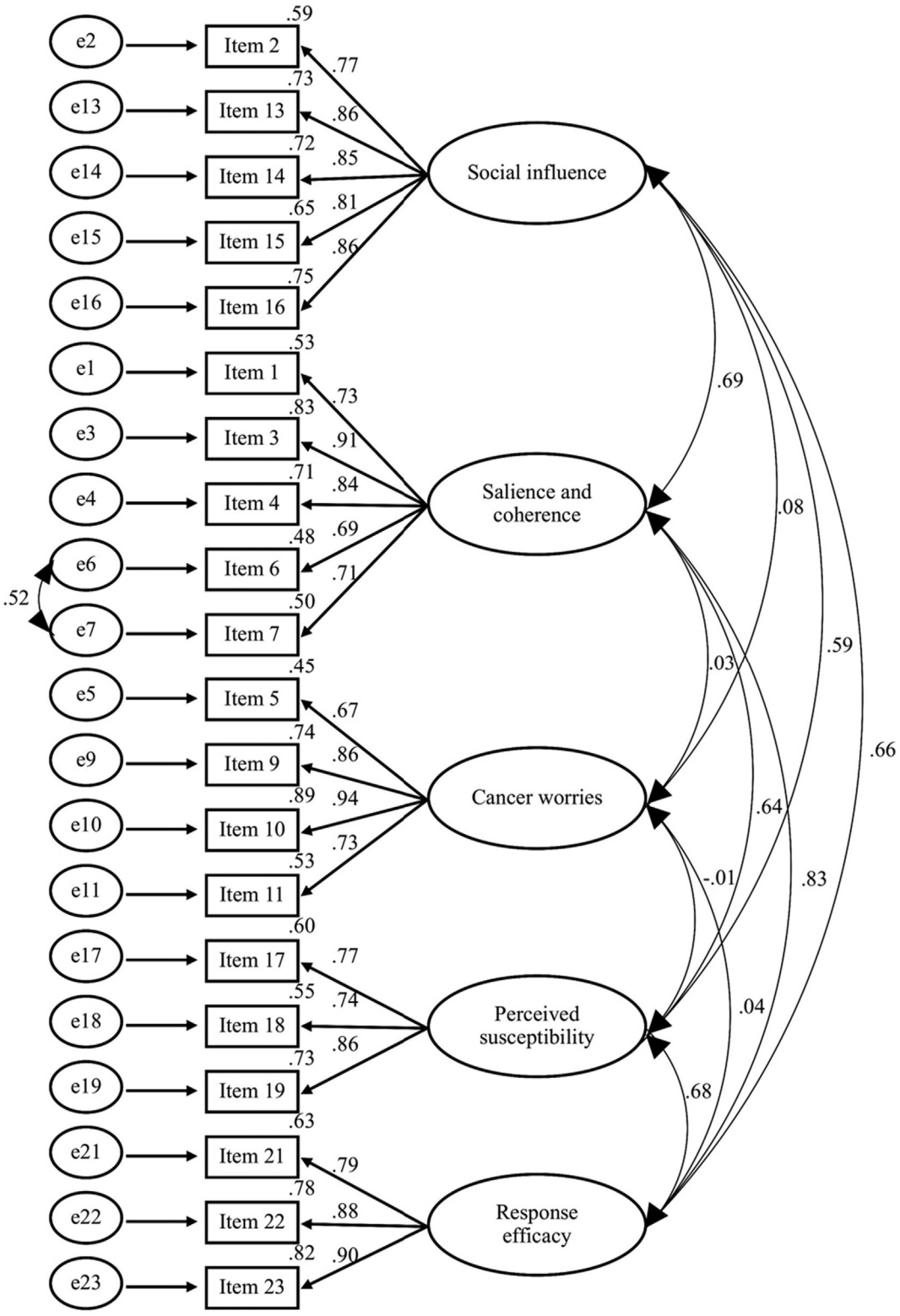

Figure 1. Five-Factor Model for the Chinese Preventive Health Model (PHM) Instrument.

validations, ranging from .56 for salience and coherence to .68 for perceived susceptibility among Caucasians, and African Americans [21]; and from .53 for social influence to .68 for perceived susceptibility among Australians [25]. The reason may be that these studies [21,25] were conducted in English-speaking countries and did not require adaptations. In contrast, this study adopted a systematic translation and adaptation process that maintained item, semantic, and conceptual equivalence, and added items that reflected culture-based perceptions of HCC screening, which might have led to the higher coefficients.

Table 4 *Average Variance Extracted (AVE), Composite Reliability (CR), Square Correlation between Subscales, and Known-group Analysis of the Chinese Preventive Health Model (PHM) Instrument.*

Latent Constructs	AVE	CR	Social Influence	Salience and Coherence	Cancer Worries	Perceived Susceptibility	Response Efficacy	Known-Group Analysis Median (IQR) or Mean (SD)		*t*/*Z* value	*p*
								Optimal HCC Screening Group	Suboptimal or Poor HCC screening Group		
Social influence	.69	.92	**.69**					3.87 (.46)	2.65 (.76)	−11.20	<.001
Salience and coherence	.61	.89	.48	**.61**				4.23 (.38)	2.91 (.49)	−12.51	<.001
Cancer worries	.65	.88	.01	.01	**.65**			3.83 (.69)	3.54 (.85)	−2.56	.010
Perceived susceptibility	.63	.83	.35	.41	.01	**.63**		3.84 (.54)	2.81 (.58)	−10.98	<.001
Response efficacy	.74	.90	.44	.68	.01	.47	**.74**	4.30 (.41)	3.02 (.54)	18.95	<.001

Limitations and strengths

Our study did not conduct a concurrent validity assessment because related scales for psychometric comparison are lacking. However, known-group validity was established based on the external criteria of HCC screening behavior. Second, although sample diversity was ensured by recruiting patients with hepatitis B with different indications for HCC screening, the generalizability of the results may be limited by convenience sampling of patients.

The study adopted a rigorous validation process. First, through committee-based translation, cognitive interviews, and expert consultations, instrument issues regarding comprehension, sensitive wording, wording clarity, question relevance, and cultural sensitivity were addressed. The systematic methodology guaranteed that the adapted PHM instrument had adequate construct, convergent, discriminant, and known-group validity and reliability to be administered to patients with hepatitis B.

Clinical implications

Currently, there is a gap between international guideline recommendations to improve HCC screening and the real-world utilization among high-risk populations. The adapted 20-item PHM instrument would facilitate clinical practices and studies in this area. First, it would help nurses and other health professionals to understand patient perception gaps regarding HCC screening, such as perceived HCC susceptibility. Thus, relevant education and tailored counseling can be provided to address the misbeliefs that preclude utilization. Second, it can also help researchers develop efficient strategies to improve HCC screening utilization and reduce HCC burden across high-risk regions. Since the five-factor structure is consistent with the original version, it would also permit comparisons of intervention effects between cross-cultural studies. Moreover, the three-step rigorous study process, especially the cultural adaptations through concept discussions and cognitive interviews, is also valuable for future cross-cultural validation of instruments in other countries.

Conclusions

This study applied a rigorous sequential process of translation, cognitive interviews, expert consultations, and cross-sectional surveys to ensure that the Chinese version of the PHM instrument is culturally sensitive, reliable, and valid in measuring psychosocial factors (social influence, salience and coherence, cancer worries, perceived susceptibility, and response efficacy) to HCC screening among patients with hepatitis B. Unpacking these psychosocial predictors is vital for health professionals and researchers to develop enhancive strategies to improve the globally underutilized HCC screening. The five-factor, 20-item adapted PHM instrument can be further tested among diverse samples with other HCC risks across practice settings, regions, and cultures to increase generalizability.

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Ethical consideration

The study received ethical approval from the Survey and Behavioral Research Ethics Committee of the Chinese University of Hong Kong (No.SBRE-20-072), and Medical Ethics Committee of the Henan Provincial People's Hospital (No.2020169).

Conflict of interest

The authors declare no conflicts of interest.

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Development and Validation of an Interprofessional Collaboration Scale for Home Health Care for the Frail Elderly

Keiko Tsukasaki,* Kaoru Kyota, Tomoya Itatani

Faculty of Health Sciences, Kanazawa University, Japan

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SUMMARY

Purpose: The purpose of this study was to develop an interprofessional collaboration (IPC) scale for home health care for frail elderly.
Methods: The first items of the IPC scale included collaboration members' attitudes, awareness, motivation, team strength, communication, relationships, information, care recipients' interests, effects, development, utilization of social resources, contributions to the community, and crisis management. The subjects were 512 care managers who work in home care support offices across Japan. They manage interprofessional collaboration in home health care for frail elderly who need care at 65 years old and above. The scale's construct validity, internal consistency, the validity of known groups, concurrent validity, and test-retest reliability (193 subjects) were examined.
Results: The final IPC scale's items consisted of four factors (37 items): the strength of interprofessional teams (16), the management of collaborative systems (7), effects of collaboration (8), and communication (6). Four factors explained 58.6% of the total explained variance. The modified model fit of the scale achieved acceptable levels. The Cronbach's α coefficient for all items was .97. The sum of communication factor in the cities/wards group was lower than those in the towns/villages group. There were differences between the sum and each factor with different levels of ease to collaborate. The intraclass correlation coefficient for all items in the first and second assessments was .875.
Conclusions: The validity and reliability of the IPC scale have been verified. This scale can be used to assess the IPC for home health care for frail elderly.

Introduction

Many developed countries are presently facing the challenges of an aging population, leading to an increase in the number of elderly people who require support and nursing care for health management every day. Japan has become a super-aging society in which the elderly account for more than 21.0% of the population, and the number of frail elderly people with impaired mental, physical, and cognitive functions has been rising [1]. Therefore, Japan has the urgent task of recruiting a variety of health professionals from medical, nursing, and welfare fields, among others, to develop efficient collaborative systems across the nation that can provide the elderly with high-quality support.

The World Health Organization declared ‘action on interprofessional education and collaborative practice’ to be an important strategy that is required to address the issue of the serious shortage of health professionals around the world [2]. Many countries have emphasized the importance of interprofessional collaboration and its promotion, as well as the implementation of education to help health professionals improve their collaboration skills [3,4].

In Japan, care managers are in charge of coordinating interprofessional collaboration for frail elderly people in the community who require health care. Care managers coordinate interprofessional collaboration among health professionals working in medical, nursing, and welfare facilities according to the healthcare insurance system and develop home care plans for each recipient to provide frail elderly the required home and nursing care services.

Community-based integrated care systems for the elderly that provide health/nursing care and daily support are being developed in many areas across Japan to create a society in which the elderly hoping to continue their community lives will be able to do so. Care managers are expected to serve as coordinators who facilitate collaboration among a variety of health professionals in such care systems. Therefore, they are aware of the obstacles of relationships with physicians, professional competency, relationships among

Keiko Tsukasaki: https://orcid.org/0000-0001-5429-4399
* Correspondence to: Faculty of Health Sciences, Kanazawa University, Japan. Fax: +81 76-234-4363.
E-mail address: tsukasak@staff.kanazawa-u.ac.jp

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other professionals, environmental constraints, and relationships with non-professionals [5]. These obstacles must overcome to strengthen interprofessional collaboration in their community.

Although previous studies conducted in many different countries have indicated the need for interprofessional collaboration to support the elderly living in the community, research that examines the effects of the collaborative activities has focused on limited areas [6]. In addition, no previous studies have presented sufficient evidence of the cost-effectiveness of collaborative activities [7].

Although it is necessary to conduct longitudinal assessments to examine the effects of collaborative activities [8], comparing collaborative effects is difficult. Because the elderly increasingly requires greater support as they become older, and systems and environments required to promote collaboration vary depending on the country, area, and era. However, if there is assessment scale of the functions of interprofessional teams, the functions of interprofessional teams in different systems, supportive environments, countries, and areas can be assessed and/or compared longitudinally and continuously.

Several scales have been developed to assess the functions of interprofessional teams that provide health care at different health levels in general hospitals, communities, and other such places. These scales include the assessment of inter-professional team collaboration scale (AITCS) [9], collaborative practice assessment tool (CPAT) [10], partnership self-assessment tool [11], and other scales with an emphasis on 'team climate' [12], 'the quality of team meetings' [13], and the sharing of decision making [14].

The concept of interprofessional collaboration to support the elderly with chronic diseases living in the community is evolving antecedent, attribute, and consequence but does not get consensus [15]. The functions of interprofessional collaboration required to provide home care for the elderly living in the community must be discussed in order to develop the criteria for their assessment.

This study aimed to define the concept and examine the functions of interprofessional collaboration required to support the health and lives of frail elderly people living in the community, in order to develop an interprofessional collaboration (IPC) scale for home health care for frail elderly. The IPC scale, developed in Japan, a super-aging society, will also be useful in many other countries that are facing the consequences of an aging population.

'Frail elderly' in this study refers to people aged 65 years and above who have been certified as requiring long-term care (people who need others to care for them) because of physical or mental problems or because aging interferes with their daily activities. In Japan, a long-term care insurance system allows those certified as needing long-term care, regardless of whether they live with their family, to receive public services. These include nursing care or home-visit nursing care from various organizations while living in their own home.

People who use such services need a home healthcare plan. Nevertheless, home care support offices are private organizations. These offices have staff members certified as care managers. They plan home health care regarding the necessary services for the frail elderly living at home. They also manage home health care so that various professionals from several organizations can collaborate to provide support.

Methods

Scale development

Conceptual framework

The definition of the concept of interprofessional collaboration required to provide home care for the frail elderly living in the community, and the development of the plans for the assessment index are described below.

To define this concept, reports pertaining to interprofessional collaboration were examined [3,4], and the differences between collaboration and similar concepts, including cooperation and liaisons, were analyzed. Interprofessional collaboration for providing home care is thus defined as 'collaboration among multiple professionals from different organizations who have expertise in each field, including mutual communication, the development of trusting relationships, and setting common goals to help the elderly users of home care services and their families live a high-quality life or fulfil their hopes.'

Preliminary items

Based on the definition above, personal and group interviews with nine health, medical, and welfare professionals were conducted. These professionals included care managers, home-visit nurses, nursing care workers, pharmacists, and physicians involved in activities that support the elderly in the community. They were asked about their experience regarding interprofessional collaboration as defined by the authors, including what they thought were important in promoting interprofessional collaboration. Based on their response, 58 items were identified as important elements for promoting interprofessional collaboration. These were divided into 10 areas, such as members' attitude, strength of teams, and communication.

Subsequently, a pilot survey with 24 care managers was conducted to examine the validity of the prototype, including its face validity, and a draft assessment index consisting of eight fields and 55 items was created.

Evaluation of the IPC scale

Setting and samples

The subjects were care managers working in home care support offices located in Japan's 47 prefectures. Of the 39,124 centers in the 47 prefectures (as of June 2016) [16], 1,962 centers were selected. A representative from each center was asked to participate in the study; the care manager from each center who most frequently collaborated with other health professionals responded to the originally developed questionnaire. The 1,962 centers were selected based on a stratified random sampling method, taking into consideration the ratio of the number of special administrative regions, ordinance-designated cities, core cities, and municipalities (1,761 as of October 2016). All 47 prefectures had at least one of these 1,962 centers.

Survey methods

Anonymous, self-completion questionnaire forms were sent to the subjects by mail, and they returned the completed forms to the researcher.

Survey period

The survey period was between July and August 2017.

Survey items

(1) Characteristics and ease of collaboration of subjects

The survey items included the names of the prefectures in which the healthcare institutions were located, administrative classification, sex, age, certificates other than care manager, period of

working as a care manager, the number of care recipients for whom they are responsible, frequency of meeting professionals from other healthcare institutions per month, frequency of participating in workshops on interprofessional collaboration per year, and ease of collaboration with other healthcare institutions and professionals (using a three-point scale).

(2) Items for the assessment of the functions of interprofessional collaboration

The following eight fields and 55 items of the draft were adopted: Field I: six items (Questions 1 to 6) related to attitudes toward and awareness of collaboration (understanding of/respect for the specialties of others and the recognition of the need for interprofessional collaboration); Field II: 11 items (Questions 7 to 17) related to the strength of teams (same goals for the activities of teams and roles within teams); Field III: nine items (Questions 18 to 26) related to communication and relationships (exchange of opinions and interaction with respect for other people's positions); Field IV: nine items (Questions 27 to 35) related to information (sharing/management of information and responsibility); Field V: six items (Questions 36 to 41) related to care recipients' interests (support centered on care recipients, satisfaction of care recipients and their families, and the status of their participation); Field VI: 10 items (Questions 42 to 51) related to the effects of collaboration (identification of problems to address and improve them through collaboration); Field VII: two items (Questions 52 and 53) related to the utilization of social resources and contributions to the community (status of the effective utilization of social resources and the level of contribution to the community through collaboration); and Field VIII: two crisis management-related items (Questions 54 and 55) pertaining to early identification of problems and responses in emergency situations.

Responses to each question were based on a seven-point Likert scale: 'Definitely yes' (7 points) to 'Definitely no' (1 point); the higher the collaborative function, the higher was the score.

Data analysis

Correlations between the scores for each question item to assess collaboration and the sum of these scores were analyzed and inter-item analyses were conducted. Question items were then selected based on the analysis results. Exploratory factor analyses using the maximum-likelihood method and promax rotation were performed, and the obtained factor structure was matched to the eight fields of the assessment index draft to examine the validity of the construct. Subsequently, Cronbach's α for each factor related to interprofessional collaboration and the question items was calculated to examine internal consistency.

Since there are differences in the social structures and resources of cities/wards and towns/villages because of their varying population sizes, the functions of collaboration in cities and wards may differ from those in smaller municipalities. The factors related to collaboration and the sum of the assessment scores for 'cities/wards' and 'towns/villages' groups were compared using χ^2 and t-tests.

High-level collaborative functions are considered to be associated with the ease of collaboration with other healthcare institutions and professionals. Therefore, the factors related to collaboration and the sum of the assessment scores were compared with different levels of ease using one-way analysis of variance and multiple comparison to examine the concurrent validity.

The second survey was conducted approximately 10 days after the first to calculate the intraclass correlation coefficient (ICC) for the first and second assessments.

SPSS Statistics Ver.22 and AMOS Ver.22 (IBM Corp., Armonk, NY, USA) and G*Power 3.1.9.1 (The G*Power Team, Heinrich-Heine-Universität, Düsseldorf, Germany) were used for the analyses. The significance level was 5.0%.

Ethical considerations

This study was approved by an Institutional Review Board of the institution to which the researchers belong. The participation of subjects was voluntary, and their submission of a completed questionnaire form was regarded as their consent to participate in the study. The subjects provided written consent to participate in the interviews and pilot surveys.

Results

A total of 564 care managers responded (response rate: 28.7%), and the 512 respondents who answered all of the questions contained in the assessment index draft were selected as the subjects for analysis (valid response rate: 90.8%). Of the 512 subjects, 194 responded to the re-test (response rate: 37.9%), and 193 valid responses were collected (valid response rate: 99.5%).

Subjects' characteristics

Of the 512 subjects, 43.8% and 56.3% worked in centers located in cities/wards and towns/villages, respectively. The majority of the participants were female (76.6%) and were in their 50s (39.1%). Furthermore, most were former qualified healthcare workers (56.8%). The mean period of working as a care manager was 9.4 years. The mean care ratio was one care manager to 30.9 elderly people. The care managers met health professionals from other institutions 4.4 times a month (mean) and participated in workshops on interprofessional collaboration 4.6 times a year (mean) (Table 1).

Construct validity

Correlation coefficients between each assessment score and the sum were 0.4 or higher. The correlation coefficient between one assessment score and the sum was 0.81 as a result of the inter-item correlation analysis and that question item was excluded to simplify the index.

Exploratory factor analysis was conducted based on the maximum-likelihood method and promax rotation; the number of factors was five, decided by using a scree plot. Factor analyses were conducted seven times until assessment items with a factor loading of 0.4 or lower (a total of 15 items) were excluded. As the eigenvalue of the fifth factor was lower than 1, an analysis involving four factors was conducted excluding two items (Field VIII) included in the fifth factor. There were no items with a factor loading of 0.4 or lower as a result of the analysis, and the four factors (37 items) were adopted. The contribution rates of the four factors were between 3.7% and 46.5%, and the cumulative contribution rate was 58.6%. Correlation coefficients among the factors were between 0.59 and 0.73, which suggest significant correlations (Table 2).

The first factor consisting of Fields I and II (16 items) included in the assessment index draft was titled 'Team strength.' The second factor consisting of Fields IV, VI, and VII (seven items) was titled 'Management of collaborative systems.' The third factor consisting of Fields V and VI (eight items) was titled 'Effects of collaboration.' The fourth factor consisting of Fields III and IV (six items) was titled 'Communication.'

Table 1 *Subjects' Characteristics.*

Items	Categories	Number (%)/M±SD
Administrative classification of areas in which the institutions were located N = 512	Cities/wards	224 (43.8)
	Towns/villages	288 (56.3)
Gender N = 508[a]	Men	119 (23.4)
	Women	389 (76.6)
Age N = 506[a]	In their 30s	53 (10.5)
	In their 40s	182 (36.0)
	In their 50s	198 (39.1)
	In their 60s	73 (14.4)
Certificates (multiple answers allowed) N = 512	Health care workers	291 (56.8)
	Participants who had completed training for new health care providers	114 (22.3)
	Nurses	89 (17.4)
	Social workers	76 (14.8)
	Other professionals (pharmacists, dietitians, etc.)	75 (14.7)
Time working as a care manager (years) N = 510[a]		9.41 ± 4.76
Number of care recipients under the care of the care managers (Number of recipients per care manager) N = 502[a]		30.86 ± 9.16
Frequency of meeting professionals from other institutions (per month) N = 509[a]		4.36 ± 3.34
Frequency of participating in workshops related to collaboration (per year) N = 492[a]		4.62 ± 6.38

Note. M = mean, SD = standard deviation.
[a] The number excludes subjects that did not answer this question.

Internal consistency

The Cronbach's α coefficient for all 37 items was 0.97, and those for each factor were between 0.88 and 0.95 (Table 2).

Validity of known groups

The mean of the sum of assessment scores for the six 'communication'-related items in the cities/wards group (n = 224) was 31.5 ± 5.7, which was lower than the mean of the sum in the towns/villages group (n = 288, 32.6 ± 5.0) (t = −2.33, p = .02, ES = 0.205, 1-β = 0.633). There were no significant differences between the other three factors and the sum of all items.

Concurrent validity

We used levels of ease in collaboration with other healthcare institutions and professionals to examine concurrent validity.

There were significant differences between the score for each factor and the sum of the three groups with different levels of ease to collaborate with other healthcare institutions. The results of the multiple comparisons indicated that scores for 'Definitely yes' were significantly higher than those for 'Yes' and 'No' (Table 3).

There were also significant differences between the score for each factor and the sum of the three groups with different levels of ease to collaborate with other healthcare professionals. Multiple comparisons of scores for each factor and the sum of scores for all items indicated that scores for 'Definitely yes' were the highest, followed by those for 'Yes' and 'No' (Table 4).

Test-retest reliability

The retest target was the 512 people who participated in the initial survey. It was conducted approximately 10 days after the initial survey. It was thought that the health conditions of the frail elderly or the content of interprofessional collaboration would not change significantly within 10 days. Further, participants needed to be given at least 10 days following the initial survey so that they would not feel overburdened. A total of 193 people responded to the retest and became the subject of analysis.

A re-test involving 193 subjects was conducted, and the ICC for all items in the first and second assessments was .875 [95.0% C I: .835–.906](p < .000); the ICCs for the first, second, third, and forth factors were .839 [95.0% CI: .786–.878] (p < .000), .824 [95.0% CI: .767–.868](p < .000), .816 [95.0% CI: .756–.861](p < .000), and .769 [95.0% CI: .693–.826](p < .000), respectively.

Discussion

This study aimed to develop the IPC scale consisting of four factors: "strength of teams," "management of collaborative systems," "effects of collaboration," and "communication." The study included care managers who coordinate interprofessional collaboration for the frail elderly living in the community and in need of health care from each prefecture in Japan. The construct validity, internal consistency, validity of known groups, concurrent validity, and test-retest reliability of the IPC scale were examined.

The contribution rate of the first factor (strength of teams) of the IPC scale was the highest (46.5%), which suggests that this factor is important in assessing the functions of collaboration. The first factor consisted of fields related to attitudes toward/awareness of interprofessional collaboration (having an understanding of/respect for the specialties of others and the recognition of the need for interprofessional collaboration) and the strength of teams (same goals for the activities of teams and roles within teams). As examples of previously developed indices to assess the functions of interprofessional collaboration, the AITCS, developed by Orchard et al. [9], consists of "cooperation" and "coordination," and the CPAT, developed by Schroder et al. [10], consists of "mission," "meaningful purpose," "goals," "general relationship," "team leadership," "general role responsibilities," and "autonomy." These items are similar to those that fall under the "strength of teams" factor in the present study. Even though the CPAT [10] consists of 56 items, the IPC scale developed in this study can intensively and simply assess the functions of interprofessional collaboration, including the "strength of teams" in home health care for the frail elderly in the community.

It has been pointed out that common interests among members of interprofessional teams promote collaboration [17] and that both "role clarification" and "collaborative leadership" are "competencies" required for collaboration [3]. Therefore, "common

Table 2 *Exploratory Factor Analysis to Develop an Index for the Assessment of the Functions of Interprofessional Collaboration to Provide Home Health Care (the maximum-likelihood method and promax rotation) (N = 512).*

Question items		Factor loading				Cronbach α coefficients	
		Factor 1	Factor 2	Factor 3	Factor 4	Each factor	All items
Q12	All members understand the effects of interprofessional collaboration and problems.	.922	.109	-.015	-.167	.954	.967
Q10	All members discuss how to set common goals, and cooperate with each other to fulfill them.	.889	.058	-.098	-.039		
Q9	All members discuss problems that have been identified in relation to the daily lives of care recipients.	.852	-.068	.002	-.008		
Q6	All members understand that interprofessional collaboration aims to improve the quality of support provided to care recipients.	.808	-.100	-.023	.020		
Q7	All members hope to support the lives of care recipients in collaboration with each other.	.776	-.127	.055	.034		
Q11	Roles for each member of the team have been clearly defined.	.765	-.106	.128	.020		
Q8	All members share a common understanding of the problems related to the daily lives of care recipients.	.746	-.126	.071	.091		
Q14	Members of the team, led by the leader, fulfill their roles.	.738	.101	.082	-.047		
Q5	All members recognize that it is necessary to collaborate with other professionals to solve problems.	.734	-.162	-.035	.101		
Q15	Members of the team support the leader.	.662	.214	-.036	-.037		
Q17	All members are learning about how to support provided for care recipients.	.640	.306	-.108	-.050		
Q16	All professionals in the team are allowed to dedicate themselves to provide support using their expertise and specialized skills.	.631	.051	.167	-.052		
Q2	All professionals in the team respect and trust the specialties of others.	.580	.075	-.116	.106		
Q13	The roles of the leader (coordinator) have been clearly defined.	.551	-.002	.158	.088		
Q4	All professionals in the team understand the types of support provided by others in the team and their effects.	.517	.111	-.048	.214		
Q1	All professionals in the team understand each others' expertise and specialized skills, and their functions are independent of each other.	.464	.097	-.093	.232		
Q49	The process for collaboration and methods for the assessment of results have been clearly defined.	.062	.806	-.035	-.010	.880	
Q53	Interprofessional collaboration is a community resource.	-.078	.777	-.009	-.020		
Q51	Members of the team exchange information, including what has been learned from interprofessional collaboration.	-.030	.747	.06	.000		
Q52	All professionals in the team effectively utilize social resources in the community.	-.083	.727	.095	-.011		
Q48	Procedures for collaboration are neither difficult nor a burden to perform.	.000	.681	-.037	.063		
Q50	Interprofessional teams can be organized by the professionals required to provide care for recipients on an as-required basis.	-.092	.669	.119	.123		
Q34	Members of the team discuss the measures required to address information leakage.	.088	.619	-.101	-.025		
Q37	Members of the team provide care recipients with the most appropriate care within a limited period of time.	-.105	.023	.871	-.035	.904	
Q36	Support to the life that the care recipients expect is provided.	-.052	-.063	.821	-.073		
Q42	Appropriate support is provided to respond to a variety of needs of the care recipients.	.016	.090	.769	-.014		
Q38	Explanations of the support provided to care recipients and their families are consistent.	.048	-.132	.715	.092		
Q39	Most care recipients and their families are satisfied with the support.	.018	.086	.709	-.088		
Q47	Interprofessional collaboration has the advantage of helping members of the team improve their knowledge and support skills.	.156	.122	.440	.084		
Q46	Collaboration helps members of the team reflect on their support activities and improve them.	.212	.075	.437	.113		
Q44	Collaboration helps professionals in the team address problems that need to be solved.	.192	.226	.413	.048		
Q22	Information about support can be shared even when conferences are not held by healthcare professionals.	-.017	-.006	-.048	.921	.921	
Q23	Members of the team keep in touch with each other.	.072	-.033	-.021	.876		
Q24	Members of the team can talk with each other to respond to changes in situations.	.012	-.001	.028	.825		
Q21	Members of the team exchange opinions on the types of support required by the care recipients.	.065	.130	-.016	.687		
Q20	Members of the team are acquainted with each other and understand the differences in their views.	.179	.096	-.102	.587		
Q27	Members of the team share necessary information regarding the daily lives of the care recipients.	.178	-.105	.268	.491		
	Contribution rate of factors (%)	46.5	4.8	3.7	3.7		
	Cumulative contribution rate of factors (%)		58.6				
	Factor correlation matrix 1	—	.664	.682	.731		
	2		—	.638	.586		
	3			—	.618		
	4				—		

Table 3 *Differences in the Scores of the Index for the Assessment of the Functions of Interprofessional Collaboration to Provide Home Health Care, Focusing on Different Levels of Ease to Collaborate with Other Institutions.*

	Is it easy to collaborate with other institutions?			One-way analysis of variance F value	Multiple comparison
	1 Definitely yes (n = 362) M±SD	2 Yes (n = 128) M±SD	3 No (n = 20) M±SD		
First factor: strength of teams (16 items; 112 points)	84.53 ± 12.74	74.55 ± 12.77	66.95 ± 11.98	42.47***	1 > 2,3
Second factor: management of collaborative systems (7 items; 49 points)	30.60 ± 7.21	26.54 ± 5.60	23.95 ± 5.44	23.48***	1 > 2,3
Third factor: effects of collaboration (8 items; 56 points)	42.00 ± 5.95	38.73 ± 6.16	34.85 ± 6.34	24.42***	1 > 2,3
Fourth factor: communication (6 items; 42 points)	33.28 ± 4.85	29.77 ± 5.20	26.45 ± 5.52	37.3***	1 > 2,3
All items (37 items; 259 points)	190.41 ± 26.69	169.59 ± 24.42	152.20 ± 25.73	45.2***	1 > 2,3

***p < .001.
Two subjects did not answer this question.
Note. M = mean, SD = standard deviation.

Table 4 *Differences in the Scores of the Index for the Assessment of the Functions of Interprofessional Collaboration to Provide Home Health Care, Focusing on Different Levels of Ease to Collaborate with Other Health Professionals.*

	Is it easy to collaborate with other health professionals?			One-way analysis of variance F value	Multiple comparison
	1 Definitely yes (n = 328) M±SD	2 Yes (n = 156) M±SD	3 No (n = 26) M±SD		
First factor: strength of teams (16 items; 112 points)	84.71 ± 12.79	76.74 ± 12.68	65.19 ± 12.07	42.63***	1 > 2,3 2 > 3
Second factor: management of collaborative systems (7 items; 49 points)	30.68 ± 7.24	27.31 ± 5.96	23.38 ± 5.15	23.39***	1 > 2,3 2 > 3
Third factor: effects of collaboration (8 items; 56 points)	42.05 ± 5.89	39.38 ± 6.17	35.04 ± 7.05	23.09***	1 > 2,3 2 > 3
Fourth factor: communication (6 items; 42 points)	33.48 ± 4.76	30.18 ± 5.14	26.35 ± 5.75	42.43***	1 > 2,3 2 > 3
All items (37 items; 259 points)	190.92 ± 26.51	173.62 ± 25.22	149.96 ± 26.06	45.88***	1 > 2,3 2 > 3

***p < .001.
Two subjects did not answer this question.
Note. M = mean, SD = standard deviation.

interests among members," "role clarification," and "collaborative leadership" were included under "strength of teams" in the present study. The results of our study also suggest that "strength of teams" is an important element to enhance interprofessional collaboration.

The second factor, "management of collaborative systems," consisted of fields related to information (measures to cope with information leakage), the effects of collaboration (establishment of interprofessional teams, procedures for collaboration, and methods for the assessment of collaboration), utilization of social resources, and contribution to the community. Some of these items are similar to "community linkages and coordination of care," the assessment item adopted by the CPAT [10]. To improve the quality of the functions of collaboration, it is necessary to reflect on what has been learned from collaboration in the community through cooperation with community residents and effectively utilize the community's social resources.

The third factor, "effects of collaboration," consisted of the fields related to the interests of care recipients (most appropriate support centered on care recipients and their satisfaction) and the effects of collaboration (including appropriate support, addressing problems experienced by professionals, and self-reflection by professionals and their improvement). The field of care recipients' interests is considered to be one aspect of "patient involvement," item included in the CPAT [10]. Certain features of "the effects of the improvement of members of interprofessional teams" have been adopted by the partnership self-assessment tool developed by Weiss et al. [11]. This suggests that the IPC scale developed in this study can assess the effects of interprofessional collaboration on both the users of healthcare services and health professionals.

The fourth factor, "communication," consisted of the fields of communication and relationships (including the exchange of opinions and efforts to maintain communication) and information (including information sharing). "Communication" is a core competency for interprofessional collaboration [4]. The importance of team climates or interactions among team members and communication for interprofessional collaboration has also been pointed out [12]. Moreover, "communication" has been suggested to be an important aspect for the assessment of collaborative functions in home health care for the frail elderly in the community by the IPC scale developed in the present study. Assessment items "partnership" from AITCS [9] and "communication and information exchange" from CPAT [10] are similar to "communication" factor in the assessment index developed in the present study. However, the AITCS [9] consists of a large number of items, whereas the IPC scale developed in the present study can intensively and simply assess the functions of interprofessional collaboration.

The sum of scores for the six items of the communication factor in the cities/wards group was significantly smaller than that in the towns/villages. This suggests that it is necessary to promote communication among health professionals to improve collaboration among those living in large cities. Healthcare and educational institutions have paid attention to methods for the improvement of skills to communicate with other professionals [18,19]. Although meeting people in person is important as a communication

method, it is often difficult for all members of an interprofessional team working in a large city to meet to discuss matters face to face. Therefore, it is necessary to develop effective communication methods using information and communication technology.

Enhancing interprofessional collaboration is an important issue facing many countries today. Various nations seek to develop indices to assess interprofessional collaboration and its competency. Since the necessary collaboration would vary depending on the supply and demand of health care or on each country's healthcare system, it is essential to create indices that reflect such differences. The attitudes and values required of team members may also differ depending on each occupation's role, education, and culture.

The Norwegian version of the interprofessional collaborative competency attainment survey (ICCAS) [20] was developed, and its validity was confirmed [21]. Thus, ICCAS has been translated and used in many countries. ICCAS comprises five areas: communication, collaboration, roles and responsibilities, a patient-centered approach, and conflict management and team functioning [21]. In addition, the Italian version of the Chiba Inter-professional Competency Scale (CICS29) [22] was created, and its validity was confirmed [23]. CICS29 consists of six areas: attitude and belief, team management, actions, respect for patients, improved team cohesion, and role [22].

The IPC scale is similar to ICCAS and CICS29 concerning evaluating the organizational strength as a collaborative team, members' roles, and communication. However, the IPC scale differs from them in that it emphasizes whether collaboration is conducive to providing support to the elderly so that they would be able to maintain their preferred ways of community life. Thus, rather than solving immediate problems that are the subjects' primary concerns, it evaluates the attitudes of team members as they work with the subject to consider countermeasures jointly. In addition, the IPC scale emphasizes the process of collaboration in conducting the evaluation. This is because collaborative teams seek to support the frail elderly and become a new resource for the local community.

The IPC scale was developed with the cooperation of Japanese care managers. Thus, its validity must be confirmed before using it in other countries. However, the authors believe that it will also be helpful to evaluate the collaboration of care teams outside Japan as they help the frail elderly maintain their home life.

Most of the previous indices for the assessment of interprofessional collaboration were designed to assess general collaborative teams, and they often include items unnecessary for the assessment of collaborative functions required to provide home health care to the elderly. Furthermore, they have an excessive number of items or can only assess limited fields. The IPC scale developed in this study, which is specialized for the assessment of the functions of interprofessional teams that provide home health care for the frail elderly living in the community, only has a small number of items and can comprehensively assess collaborative functions required for home health care.

Study limitations and challenges

The response rate to the present survey was 28.7%, and the subjects may have only included those who were interested in professional collaboration. Furthermore, as the reliability and validity of the assessment index were supported by care managers, it is necessary to examine whether or not the index can be used by other professionals. This survey was conducted in 2017. Thus, it is necessary to conduct another survey to validate the results of this survey and confirm the factor structure.

A longitudinal assessment of collaborative functions using the IPC scale in the homes of the frail elderly living in the community in need of health care will be conducted. A comparison of the functions of interprofessional teams in Japan and other countries will also help improve the quality of interprofessional collaboration in many different countries.

Conclusions

The new IPC scale for the assessment of the functions of interprofessional collaboration to provide home health care for the frail elderly living in the community consists of four factors: “strength of teams,” “management of collaborative systems,” “effects of collaboration,” and “communication,” comprising 37 items in total. This scale indicated that the reliability and validity were good. It is easy to implement the factors of IPC. This scale can be used to assess the IPC for home health care for frail elderly.

Consent for publication

The authors and participants all consent to the publication of the article.

Ethics approval and consent to participate

This study was approved by Medical Ethics Committee of Kanazawa University (No. 751). Participation was voluntary, and submission of a completed questionnaire form was regarded as consent to participate in the study. The subjects consented to participate in the interviews and pilot surveys in written form. The data of the participants were kept confidential and used for the academic research only.

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Conflict of interest

The authors declare no conflict of interest.

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Research Article

Effects of a Sociodrama-based Communication Enhancement Program on Mothers of Children with Neurodevelopmental Disorders: A Pilot Study

Sun Joo Jang, Jong-Sook Han, Myoung Hee Bang, Jung-Won Ahn*

Red Cross College of Nursing, Chung-Ang University, South Korea

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SUMMARY

Purpose: The incidence and prevalence of neurodevelopmental disorders have rapidly increased, indicating an urgent need for assistance through parenting interventions. This study aimed to evaluate the effects of a sociodrama-based communication enhancement program on mothers of children with neurodevelopmental disorders.
Method: A non-randomized controlled experimental study design was employed. The experimental and control groups had 16 and 18 participants, respectively. The once-a-week six-session intervention was conducted from September to November 2017, in South Korea. The effects of group, time, and group-by-time interactions among the groups were verified using generalized estimating equations with an autoregressive correlation structure.
Results: There was a significant decrease in the parenting burden, alongside a significant improvement in parent-child communication and parenting competence in the experimental group compared to the control group.
Conclusion: The sociodrama-based communication enhancement program was found to positively influence the parenting burden, communication, and parenting competence of mothers of children with neurodevelopmental disorders. These findings suggest that sociodrama-based programs may be an effective intervention strategy for parents of children with neurodevelopmental disorders. The sociodrama-based communication enhancement program can be applied to decrease parenting burden and improve parent-child communication and parenting competence. Through continuous parenting interventions, an improvement in expressive language and an increase in the attachment behaviors of children with neurodevelopmental disabilities could be expected.

Introduction

Neurodevelopmental disorder is a broad term for diseases related to physical, learning, verbal, or behavioral impairment and includes autism spectrum disorder (ASD), intellectual disability (ID), and attention deficit hyperactivity disorder (ADHD) [1]. A recent study, based on a nationwide sample, revealed that the incidence and prevalence of developmental disorders have increased two- and four-fold, respectively, in the last 15 years [2], indicating an urgent need for assistance through parenting interventions.

Parents of children with neurodevelopmental disorders experience psychosocial distress and economic burden, difficulties in performing their parental role [3], and severe parenting stress [4]. Children with disabilities require additional sustained and diverse care compared to healthy children, which can result in multidimensional experiences regarding both parenting stress and parenting reward (i.e., feeling indispensable in the family) [5]. According to a recent survey, 90.3% of the primary caregivers for young children with disabilities in Korea were mothers; consequently, the latter are at a greater risk of parenting burden [6]. A previous study defined the parenting burden of children with neurodevelopmental disorders involving psychological distress,

Sun Joo Jang: https://orcid.org/0000-0002-7655-1744; Jong-Sook Han: https://orcid.org/0000-0003-2720-8779; Myoung Hee Bang: https://orcid.org/0000-0001-6824-6814; Jung-Won Ahn: https://orcid.org/0000-0001-5389-3189
* Corresponding author.
E-mail addresses: icedcoffee@hanmail.net, jshan@cau.ac.kr, mhbang72@cau.ac.kr, jwahn@cau.ac.kr

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anxiety, depression, and a loss of freedom [7]. This is because parents of children with neurodevelopmental disorders experience more significant stress than those of children with other disabilities, due to the lack of services available to meet the needs of their children when they become adults, making them feel that they have a lifelong responsibility as parents [8].

Maladaptive and atypical behaviors frequently seen in children with neurodevelopmental disorders cause parenting stress and depression, both of which are negatively associated with parenting competency [9,10]. Studies on interventions for parents of these children indicated that techniques such as skills training, parenting education, and parenting coaching could provide parents with knowledge, with parent-led interventions enhancing parenting competence and self-efficacy; these interventions were found to help parents' psychological well-being and mitigate their caregiving burden [11,12]. Specifically, parenting interventions for parents of children with neurodevelopmental disorders were effective in lowering caregiving stress and improving parenting competence [13,14]. Since parents of children with neurodevelopmental disorders were found to experience more parenting burden than those of children with other disabilities [15,16], it is crucial to rigorously diagnose childcare problems and provide tailored assistance to meet the specific needs of these families.

Communication is a bidirectional process of building and maintaining relationships among family members through symbolic interactions that create and share meaning [17]. The quality and intimacy of parent-child relationships are developed through communication [18]. Specifically, effective communication can alleviate the parenting burden for parents of children with disabilities, acting as an important factor affecting parent-child relationships [19]. Indeed, a previous study showed that parents of children with neurodevelopmental disorder face difficulties when interacting with their children [20]. Parent–child interaction and communication skills are important factors influencing the outcomes of parent-training programs [21]. Thus, interventions emphasizing parent–child communication may have positive implications for the development of children [20].

Jacob Moreno first developed sociodrama, a deep action method using group relationships, in 1953. Alongside research on sociodrama interventions for families in vulnerable situations [22], this method is used as an intervention in other scenarios, for example, as a teaching method to enhance the communication skills of healthcare personnel, including oncologists [23], those caring for terminal patients and intensive care unit doctors [24]. Sociodrama can facilitate the learning of roles, ideas, concepts, and behaviors through socioeducational experiences [25]. In the field of nursing, sociodrama has been applied in two ways. Sociodrama has been used as a psycho-pedagogical method in nursing education [26,27] by facilitating learning engagement [27]. In addition, it has been implemented as a therapeutic method [28,29]. These methods are in line with two types of sociodrama: one for educational purposes in a learning group and one for therapeutic purposes in a client group [25]. The sociodramatist should understand the psychological and pedagogical context when working with individuals [25]; in this regard, a nurse can be the right person to conduct sociodrama as a psycho-pedagogical method in nursing education or as a therapeutic method in clinical settings.

Sociodrama helps participants experience emotional liberation and catharsis by developing a better understanding of themselves, their circumstances, and the roles of others in those circumstances, further encouraging them to express their feelings [30]. When prioritizing the mental health of teen mothers, SmithBattle et al. (2017) emphasized the importance of interventions to alleviate their psychological distress and tested the effects of behavioral group therapy to train them in life skills [31]. Similarly, in one study using sociodrama with mothers of students with special needs [28], sociodrama was effective in lowering parenting stress and improving parenting self-efficacy. In the last 20 years, most intervention studies that have aimed to enhance the interactions of parents, teachers, and caregivers of children with developmental disorders [32], have used didactic instruction, video monitoring/modeling, group debate, feedback, and coaching. Interventions can be more effective when they include realistic scenarios [22,30]; however, in previous studies, reflecting the actual situation was not sufficient, and interventions targeting parents of children with neurodevelopmental disorders were extremely rare.

Comprehensively examining the results of previous studies, parent–child communication can affect the parenting burden and parent-training program's effectiveness [19,21]. In addition, sociodrama is known to alleviate the parenting burden and improve parent–child communication as well as parenting competence by facilitating the learning of roles and behaviors [25,28]. Thus, to mitigate the parenting burden and enhance communication skills and parenting competence among parents of children with neurodevelopmental disorders, there is a need to develop and implement sociodrama-based intervention programs that are tailored to the difficulties experienced by this group, including elements of their personal situations. Therefore, the objective of this study was to develop a sociodrama-based program to enhance communication (SCEP) for parents of children with neurodevelopmental disorders, and investigate the effects of this program on caregiving burden, parent-child communication, and parenting competence. The hypotheses of this study were as follows:

H1. The parenting burden within the experimental group will be significantly decreased after the SCEP when compared to that in the control group.

H2. The parent–child communication in the experimental group will be significantly improved after the SCEP when compared to that in the control group.

H3. The parenting competence in the experimental group will be significantly improved after the SCEP when compared to that in the control group.

Methods

Design

This study used a non-randomized controlled experimental pretest-posttest design. The Transparent Reporting of Evaluations with Non-randomized Designs guidelines were followed throughout the manuscript [33].

Participants and data collection

The participants were the mothers of students with neurodevelopmental disorders (ID, ASD, and ADHD) living in A— City (a major city located to the north of the Korean capital city, with a population of 460,000), South Korea. With the cooperation of the A— City Office of the Education's Institute for Special Education, the parents of students with special needs were notified of the program's contents, aims, and procedures, and individuals who consented to participate were included in the study. Data collection was performed between September 28 and November 10, 2017. According to the research assistant's instructions, the participants completed self-reported questionnaires both on the first day of the study and after six weeks. The participants were non-randomly allocated to the experimental and control groups. To minimize potential bias induced due to non-randomization, we first matched

individuals according to their key general characteristics: (1) for parents: age, level of education, household income; (2) for children: sex, disability type, presence of multiple disabilities, severity of disability. After the process of matching, the two decided groups were randomly assigned to the experimental and control groups, respectively.

Participants were selected according to the following inclusion criteria: (1) being primary caregivers of children with neurodevelopmental disorders and (2) being well literate. According to a longitudinal study following up participants from the age of six to adulthood [34], the deep-seated nature of neurodevelopmental disorders persists from childhood into adulthood. Therefore, we did not restrict the age range of the children during recruitment. The exclusion criteria were (1) individuals with restricted movement and (2) primary caregivers of children with impairments other than neurodevelopmental disorders.

Using G*Power 3.1.9.7 with conditions of F-test, analysis of variance, repeated measures, and within-between interaction (effect size f = 0.30, power = 0.90, $\alpha = .05$) [35], both groups required 32 participants. Considering a potential dropout rate of 20.0%, a total of 40 participants were enrolled, with 20 participants each in the experimental and control groups. Four participants from the experimental group and two from the control group dropped out immediately after registration due to personal scheduling issues, resulting in 16 and 18 participants in the experimental and control groups, respectively, for the final analysis (Figure 1).

The sociodrama-based communication enhancement program

The control group received nursing intervention as usual, consisting of counseling and psycho-education. The experimental group received usual care except for the SCEP, which happened once a week for six weeks. The SCEP was initially based on the nonviolent communication model (NVC) [36] and previous literature that used sociodrama with mothers of students with special educational needs [28]. However, in a previous study, parents of children with physical disability and emotional disturbance were also included as participants [28]. The SCEP was developed specifically to reflect the parent–child communication needs based on interviews with three parents of children with neurodevelopmental disorders. Thus, this pilot study served to develop the most significant tailored nursing intervention for parents raising children with neurodevelopmental disorders and finalize it, confirming the applicability of this program as an effective nursing intervention. To verify the validity of the program, a panel of two experts from the Korean Association for Psychodrama and Sociodrama, two mental health nursing professors, one counseling expert, and one school counselor from an Institute for Special Education reviewed and modified it, after which the content validity of the final program was analyzed.

The study authors have been teaching mental health nursing and communication at a college of nursing for the past few years. Author 2 is particularly an expert in sociodrama as she has received

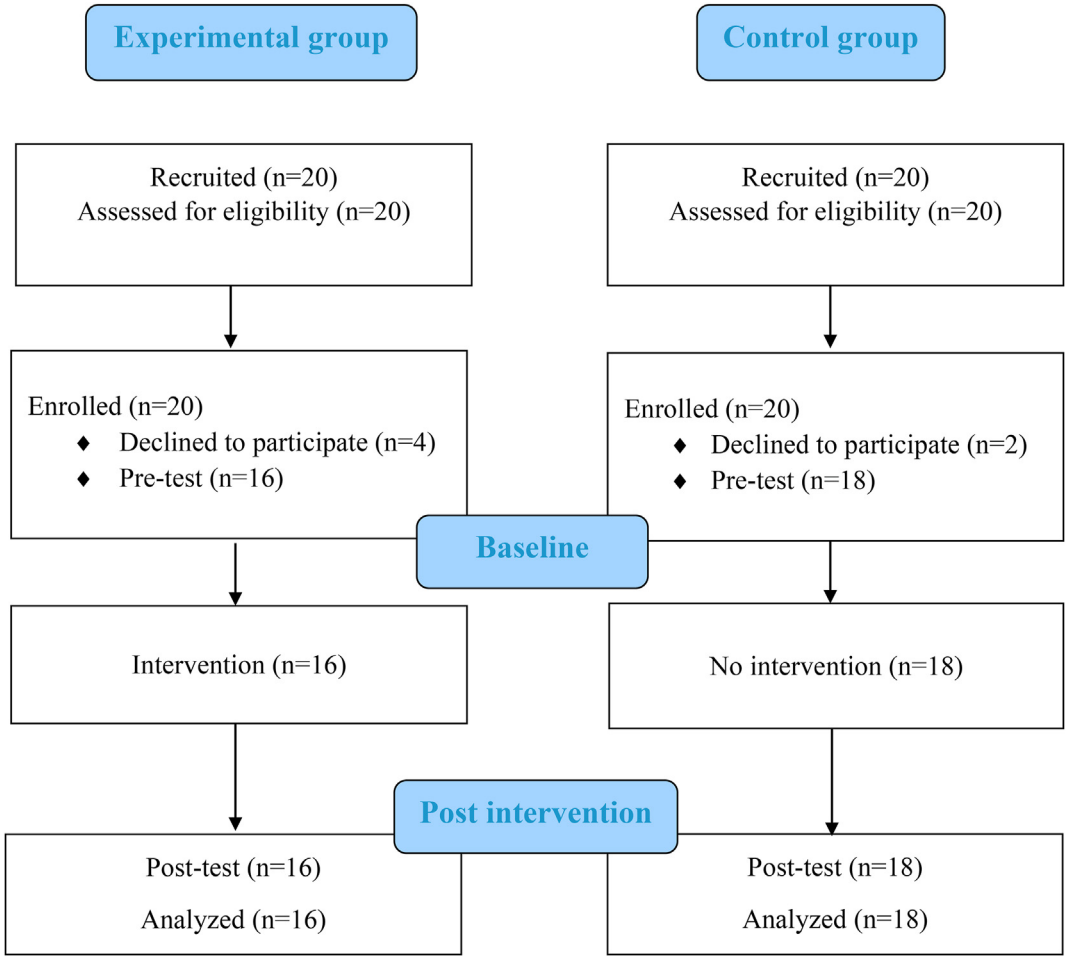

Figure 1. Flow chart of the participants' recruitment and participation.

over 500 hours of professional education as a member of the Korean Association for Psychodrama and Sociodrama, having conducted sociodrama programs for over seven years. For intervention adherence and fidelity, one of the researchers (author 2) administered the program for 150 minutes per session, with one session per week, for six sessions in a seminar room. The interventions were delivered through group sessions and the group size comprised 16 participants altogether.

The program composition enabled participants to understand and learn observations, feelings, needs, and requests—the four components of the NVC model [36]. In addition, sociodrama was used to encourage participants to express their emotions, recognize parent-child needs, and practice the communication skills they had learned. The sociodrama process consisted of warming up, enactment, and sharing phases. After determining common topics related to communication difficulties with the participants' children with disabilities, a scenario was chosen. During the enactment phase, participants voluntarily adopted a role and were instructed to express their emotions and solve the problem through their behaviors. In the sharing phase, participants could share their emotions with each other. The drama process was improvised based on spontaneous interactions among the participants.

The first session focused on building motivation for the program, as well as trust and intimacy among the participants. The second session focused on identifying the needs of the participants and their children in conflicting situations. The third and fourth sessions encouraged participants to differentiate between their thoughts and feelings and understand and empathize with their own needs and those of their children and families. The fifth session encouraged participants to communicate compassionately by reaffirming the meaning of family and value of existence. The sixth session encouraged participants to find true happiness and meaning in life by using the technique of "family sculpting." Participants were asked to complete a questionnaire before and after the program. Those who attended all six sessions were awarded a

Table 1 *Sociodrama-based Communication Enhancement Program.*

Session	Themes	Goals	Contents
1	Opening mind	To motivate participation and build intimacy and trust among group members	1. Program orientation and lecture (60 min) 2. Sociodrama 1) Warming up (20 min) 2) Sociodrama enactment (50 min) - Practice in generic scenarios (role reversal) 3) Sharing (20 min)
2	Resolving Conflict	To explore each other's needs	1. Life sharing (20 min) 2. Lecture on anger and needs (30 min) 3. Sociodrama 1) Warming up (15 min) 2) Sociodrama enactment (60 min) - Conflict situations with family members (child) (doubling, voices, role reversal, soliloquy) - Finding own and child's needs in a conflict scenario (15 min) 3) Sharing feelings and evaluation (15 min)
3	Expressing myself	To distinguish thoughts and feelings	1. Life sharing (20 min) 2. Lecture on thoughts and feelings (30 min) 3. Sociodrama 1) Warming up (15 min) 2) Sociodrama enactment (60 min) - Problematic situations with family members (spouse) - Using communication skills to resolve problems (doubling, voices, role reversal, soliloquy) 3) Sharing feelings and evaluation (15 min)
4	Enhancing communication I	To practice empathetic listening and speaking	1. Life sharing (20 min) 2. Lecture on listening and speaking (30 min) 3. Sociodrama 1) Warming up (15 min) 2) Sociodrama enactment (60 min) - Child's problematic behavior - Understanding and empathizing with the needs of child/spouse/oneself (doubling, voices, role reversal, monologue) 3) Sharing feelings and evaluation (15 min)
5	Enhancing communication II	To practice sympathetic communication	1. Life sharing (20 min) 2. Lecture on sympathetic communication (30 min) 3. Sociodrama 1) Warming up (15 min) 2) Sociodrama enactment (60 min) - Connecting one's own needs and feelings with those of child - Applying empathic listening - Sculpting and reconstituting of the family 3) Sharing feelings and evaluation (15 min)
6	Building a happy family	To find the meaning of life and happiness	1. Life sharing (20 min) 2. Lecture on the meanings of life and happiness (30 min) 3. Sociodrama 1) Warming up (15 min) 2) Sociodrama enactment (60 min) - Family photo 3) Sharing feelings and evaluation (15 min)

certificate and took part in a graduation ceremony. Table 1 illustrates a summary of the themes, goals, and contents of each session in the program.

Measures

Parenting burden

The parenting burden scale comprises 28 questions regarding physical burden (five questions), emotional burden (seven questions), social burden (10 questions), and economic burden (six questions) [37]. Participants responded to each question on a scale of 1 ("Never") to 5 points ("Always"), with higher scores indicating higher parenting burden. In a study that measured the parenting burden of parents of children with neurodevelopmental disorders using the same instrument, the Cronbach's α was .95 [38], and it was .92 in the present study. Six professionals (two psychiatric-mental health advanced practice nurses, two professors in child health nursing, and two professors in mental health nursing) verified the content validity. The scale-level content validity index (S-CVI)/average for each item was .97, and the S-CVI/universal for each item was .82.

Parent–child communication

Communication ability was measured using the Parent–Adolescent Communication Scale [39]. It has two subscales: open communication (10 items) and problematic communication (10 items). Each item was rated on a self-report Likert scale from "Never" (1 point) to "Always" (5 points). While this scale was developed to measure parent-adolescent children communication, it has also been used in measuring parent-child communication [28,29]. Open communication refers to communication that enables family cohesion and adaptability to a functional level (i.e., clear and unambiguous messages, empathy, reflective listening, and supportive speech) [39]. In contrast, problematic communication refers to closed and dysfunctional communication, which does not occur smoothly due to reluctance in parent–child interaction, with an experience of more critical expressions [40]. Higher open communication scores indicate more positive parent-child communication in which the parent and child can interact freely and express their opinions. Higher problematic communication scores indicate more negative parent–child communication. The Cronbach's α was .88 at the time of development of the Korean version of the scale and .78 in the present study. Six professionals verified the content validity. The S-CVI/average for each item was .96, and the S-CVI/universal for each item was .85.

Parenting competence

Parenting competence was measured using the Parenting Sense of Competence scale [41]. It consists of 16 questions on parenting efficiency (nine questions) and parenting satisfaction (seven questions). Each question is scored on a Likert scale from 1 ("Strongly disagree") to 5 points ("Strongly agree"), with higher scores indicating better parenting competence. In terms of the instrument's reliability, Cronbach's α was .74–.76 in a recent study on the mothers of children with neurodevelopmental disorders [42] and .76 in the present study. Six professionals verified the content validity. The S-CVI/average for each item was .96, and the S-CVI/universal for each item was .81.

Ethical considerations

This study was approved by the institutional review board at the authors' affiliated institution (No. 1041078-201709-HRSB-175-01). The study protocol was registered at the Clinical Research Information Services (registration number: KCT0006412) and is available online. Before participation in the SCEP, participants who had received the program application and provided prior written consent, voluntarily consenting to participate, were selected. They were informed that they could withdraw from the study at any time, and that they would not experience any disadvantage as a result. In addition, the participants pledged to protect the privacy of all other participants to ensure that any knowledge gained during the program would remain private.

Data analysis

Data were analyzed using the IBM SPSS/WIN 26.0 Program. Pre-homogeneity between the experimental and control groups was analyzed using the chi-squared test, Fisher's exact test, and t-test. Based on the results of normality testing, parametric tests indicating normal distributions were used for communication ability and parenting self-efficacy, and non-parametric tests indicating non-normal distributions were used for parenting burden. The effects of group, time, and group-by-time interactions among the groups were verified using generalized estimating equations with an autoregressive correlation structure. Generalized estimating equations were used because our data were repeatedly measured, clustered, and correlated, but the generalized estimating equations approach did not assume the independence and homogeneity of variance [43]. To clarify effect size, Cohen's criteria [44,45] was adapted: Cohen's d = 0.2 (small), d = 0.5 (medium), and d = 0.8 (large).

Results

Homogeneity test of participants' general characteristics and dependent variables

In this study, all the participants were mothers, and the mean ages of mothers and children were 42.62 (SD 6.29) and 12.38 (4.26) years, respectively. As for the diagnosis of children, 61.8% had ID and the rest had ASD. Table 2 illustrates the results of the homogeneity tests for the general characteristics and dependent variables at pre-intervention between the experimental and control groups. There were no significant differences with respect to age, education level, income, gender of child, age of child, diagnosis of child, or severity of child's disease, and the two groups were comparable in terms of all dependent variables.

Verification of the effects of the SCEP

The effects of the SCEP were tested using generalized estimating equations. Table 3 and Figure 2 compare the parenting burden, parent–child communication, and parenting competence between the experimental and control groups pre-intervention, as well as the changes post-intervention.

Parenting burden

The experimental group that participated in the program exhibited a significant reduction in parenting burden compared to that in the control group, supporting hypothesis 1. As revealed in the generalized estimating equations analysis results in Table 3, the main effects of group and time were not significant, but the group × time interaction effect was significant (Wald's test = 4.90, p = .027). The analysis showed that the parenting burden of the experimental group decreased significantly more (−.25 − .04 = −.29, i.e., a decrease by .29 points) than that of the

Table 2 *Homogeneity Test of General Characteristics (N = 34).*

Characteristics	Categories	Exp. (n = 16)	Cont. (n = 18)	χ^2 or t	*p*
		n (%) or M ± SD	n (%) or M ± SD		
Age (years)		42.56 ± 5.10	42.67 ± 7.34	0.05	.962
Level of education	≤ High school	10 (62.5)	13 (72.2)	3.66	.545
	≥ College	6 (37.5)	5 (27.8)		
Income of household[a]	Low	8 (50.0)	9 (50.0)	0.17	>.999
	Average	5 (31.3)	6 (33.3)		
	High	3 (18.7)	3 (16.7)		
Gender of child	Men	11 (68.8)	9 (50.0)	1.23	.268
	Women	5 (31.2)	9 (50.0)		
Age of child (years)		12.31 ± 4.25	13.00 ± 3.38	0.53	.603
Type of disability	Autism spectrum disorder	7 (43.8)	6 (33.3)	0.39	.725
	Intellectual disability	9 (56.2)	12 (66.7)		
Multiple disabilities[a]	Yes	12 (75.0)	14 (77.8)	0.04	.849
	No	4 (25.0)	4 (22.2)		
Severity of disabilities[a]	Mild	4 (25.0)	4 (22.2)	0.62	.799
	Moderate	10 (62.5)	10 (55.6)		
	Severe	2 (12.5)	4 (22.2)		
Number of children without disabilities[a]	0	5 (31.2)	2 (11.1)	2.10	.349
	1	9 (56.2)	13 (72.2)		
	2	2 (12.6)	3 (16.7)		
Parenting burden		2.69 ± 0.57	2.71 ± 0.66	0.07	.945
Communication	Open communication	3.38 ± 0.64	3.18 ± 0.53	1.19	.233
	Problematic communication	2.66 ± 0.70	2.45 ± 0.63	1.07	.284
Parenting competence[b]		3.24 ± 0.35	3.03 ± 0.49	1.21	.226

Exp = Experimental group; Cont = Control group; SD = standard deviation
[a] Fisher's exact test,
[b] Mann-Whitney U test.

Table 3 *Effects of the Program on Family Burden, Communication, and Parenting Competence (N = 34).*

95% Wald CI							
	B	SE	Lower	Upper	Wald χ^2	*p*	ES (d)
Parenting burden							0.32
Group[a]							
Exp	−0.02	0.20	−0.42	0.38	0.01	.930	
Time[a]							
Baseline	0	0					
Post intervention	0.04	0.08	−0.13	0.20	0.22	.637	
Interaction of group and time[a]							
Baseline	0	0					
Post intervention	−0.25	0.11	−0.48	−0.03	4.90	.027	
Open communication							0.98
Group[a]							
Exp	0.20	0.20	−0.18	0.59	1.06	.302	
Time[a]							
Baseline	0	0					
Post intervention	−0.08	0.06	−0.21	0.04	1.81	.179	
Interaction of group and time[a]							
Baseline	0	0					
Post intervention	0.35	0.13	0.10	0.61	7.32	.007	
Problematic communication							0.01
Group[a]							
Exp	0.21	0.22	−0.22	0.65	-.92	.337	
Time[†]							
Baseline	0	0					
Post intervention	0.11	0.08	−0.05	0.27	1.80	.179	
Interaction of group and time[a]							
Baseline	0	0					
Post intervention	−0.21	0.13	−0.46	0.05	2.58	.108	
Parenting competence							0.95
Group[a]							
Exp	0.21	0.14	−0.07	0.48	2.18	.140	
Time[a]							
Baseline	0	0					
Post intervention	−0.06	0.05	−0.15	0.03	1.80	.180	
Interaction of group and time[a]							
Baseline	0	0					
Post intervention	0.21	0.09	0.02	0.39	4.91	.027	

Exp: Experimental group, ES: effect size (Cohen's d), p value: generalized estimating equations model adjusted for covariates.
[a] Reference: control group for group effect; baseline values for time effect; and baseline values of control group for interactions.

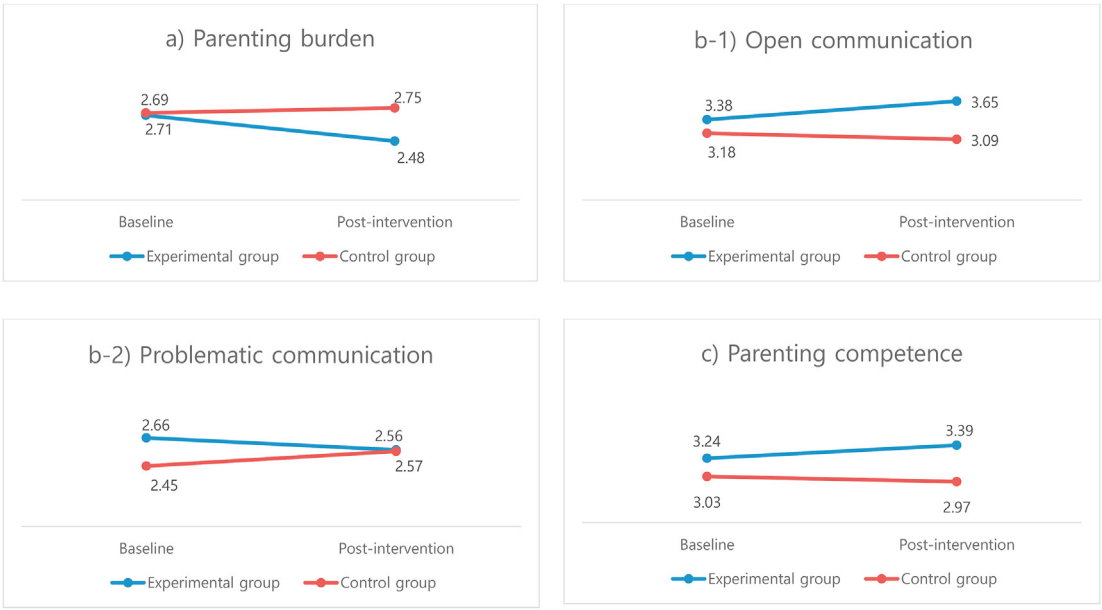

Figure 2. Outcome changes in group comparison; effect of the program on (**a**) parenting burden, (**b**-1) open communication, (**b**-2) problematic communication, and (**c**) parenting competence. The estimated mean is shown.

control group (i.e., an increase by .04 points). This difference in change reflected a small effect size (Cohen's d = .32).

Parent–child communication

The experimental group exhibited a significant increase in open communication scores between the parent and child compared to the scores for the control group. As revealed in the generalized estimating equations analysis results in Table 3, the main effects of group and time were not significant, but the group × time interaction effect was significant (Wald's test = 7.32, $p = .007$). The analysis showed that open communication of the experimental group improved significantly more [.35 − (−.08) = .43; i.e., an increase of .43 points] than did that of the control group (i.e., a decrease of .08 points). The effect size was .98, indicating a large effect. Although the experimental group exhibited a decrease (−.21 − 0.11 = −.32; i.e., a decrease of .32 points) in problematic communication compared to that in the control group, the difference was not significant (Wald's test = 2.58, $p = .108$); therefore, hypothesis 2 was partially supported in that the SCEP could improve the parent–child communication solely in terms of open communication.

Parenting competence

The experimental group exhibited a significant increase in parenting competence scores compared to the scores for the control group, supporting hypothesis 3. As revealed in the generalized estimating equations analysis results in Table 3, the main effects of group and time were not significant, but the group × time interaction effect was significant (Wald's test = 4.91, $p = .027$). The analysis showed that the parenting competence of the experimental group improved significantly more [.21 − (− .06) = .26; i.e., an increase of .26 points) than did that of the control group (i.e., a decrease of .06 points). The effect size was .95, indicating a large effect.

Discussion

In the present study, an SCEP was implemented for the primary caregivers of children with neurodevelopmental disorders, and the effects of the program were analyzed. This sociodrama-based communication enhancement program was tailored to reduce parenting burden and enhance communication and parenting competence, which comprise the biggest problems for parents of children with neurodevelopmental disorders. In the group sociodrama sessions, based on the NVC model of Rosenberg and Eisler (2003) [36], the participants observed each other; expressed their needs, feelings, and requests in the corresponding phases; and learned to understand and express their conflicts as a caregiver.

After the SCEP, participants exhibited a significant decrease in parenting burden (effect size, Cohen's d = .32). Although no previous study has indicated the direct effects of a sociodrama intervention on overall parenting burden, sociodrama was effective in reducing depression in a study on the mothers of students receiving special needs education [28], encouraging participants to perceive, control, and express their own anxiety [46]. Similarly, sociodrama was efficient in alleviating parents' negative emotions, such as anger, anxiety, and sadness, in a study on the parents of patients with schizophrenia [47]. In a study on the mothers of children with neurodevelopmental disorders, an action methods-based program reduced the mothers' anxiety and depression [31], and informal support from people in their surroundings reduced parenting burden for the parents of children with neurodevelopmental disorders [7]. Given that Robinson et al. (2016) claim that psychological distress, such as anxiety and depression, is included in the properties of parenting burden [7], the results of the present study can be considered consistent with those of previous studies. The SCEP was administered as part of a parent-focused planning approach. In line with previous research [48], this program was able to help participants unload their parenting burden by encouraging them to express their emotions and difficulties verbally, thereby sharing their experiences with other parents. The fact that the participants were all caregivers of children with developmental disorders stimulated interactions within the group, providing an outlet for them to share real-life experiences [49], thereby alleviating their parenting burden. These findings were also partially supported by a study in which informal support, rather than formal support from the government, was effective in reducing parenting burden for parents of children with neurodevelopmental disorders [7].

The SCEP was also found to be effective for developing communication ability (in particular, the open communication) in parents of children with neurodevelopmental disorders. Parents of children with developmental disorders have extremely diverse and complex communication needs because they experience many interaction-related difficulties while performing various roles throughout their lives, such as supporting their child's communication development, effectively fulfilling their role as parents, and helping their child form social relationships [18,21]. Since communication education consists more of observation and feedback than lecture-based instruction, it is essential to encourage and assist learners to find their own solutions through interactions within a group [50]. Family-mediated communication programs enhance open communication, and unimpeded communication within the family enhances children's communication development, self-esteem, problem-solving ability, and stress management, reducing behavioral and emotional problems in parents of children with ASD [51,52]. In one prospective longitudinal study [53], an intervention conducted with primary caregivers of children with neurodevelopmental disorders resulted in an improvement in the children's long-term language outcomes through the caregivers being more responsive during their communication with them. Furthermore, parenting interventions have been found to increase maternal synchronization with the child's speech or behavior, improve the child's expressive language [52], and increase attachment behaviors [35].

The upbeat ambience created by interventions using action methods, including sociodrama, assists individuals in achieving self-reflection during group programs, helping them become more aware of problems [49]. Similarly, the SCEP may have been effective since sociodrama was used to develop communication skills by helping parents specifically express needs and recognize their children's needs in situations of conflict, differentiate between thoughts and feelings, and listen effectively. Therefore, the authors believe that programs using sociodrama can enhance patient–child communication, ultimately helping children with neurodevelopmental disorders adapt to life situations. In terms of future long-term care plans for individuals with neurodevelopmental disorders, one might consider expanding the scope of participants beyond mothers being the only primary caregivers, by including fathers and siblings, to promote cooperation with the primary caregiver's perspective rather than the overseer's perspective [54].

The parenting competence scores of the participants in this study were slightly lower than those reported in previous studies for mothers or both parents of children with developmental disorders [42,55,56] and slightly higher than those reported for parents of typically developing children [54,57]. The SCEP was found to be effective in improving the parenting competence of parents of children with neurodevelopmental disorders. This was because the SCEP was based on sociodrama, which is known to alleviate parenting burden by facilitating the learning of roles and behaviors [25]. This is consistent with the results of a previous study that reported a significant increase in parenting self-efficacy after a sociodrama intervention for the mothers of adolescents receiving special needs education [28].

In a previous study [15], parenting competence was analyzed in parents of children with various disabilities and parents of children with ID showed far lower parenting competence than those of children with other disabilities. Among the participants in the present study, there was a high proportion of parents of children with ID. Thus, if SCEPs are tailored for parents of children with ID and actively utilized in intervention strategies for mental health nursing practice, they could help improve the particularly low parenting competence observed in this population.

Nevertheless, this study had several limitations. Although Nawalana et al. (2020) reported differences in parenting efficiency depending on the extent of the child's disability [15], this could not be incorporated in the current study. In future studies, we propose that participants should be divided into groups based on the severity of their disability to enable enhanced individualized care. In this study, all the participants included mothers as primary caregivers. This reflected the tendency of mothers to be the primary caregivers for children in Korea. In addition, the present study was conducted in a single large city in South Korea and, as it was a non-randomized controlled trial, there was a possibility of selection bias. Besides, there were no participants who were the parents of children with ADHD in this study. Therefore, the generalizability of our results is limited. Finally, owing to the small sample size in our study, it was not feasible to compare effects depending on the children's level of development. In future studies on parents of children with neurodevelopmental disorders, randomized controlled trials and longitudinal studies should be performed to overcome these limitations. We also propose intervention studies that differentiate between participants based on their child's level of development. Through continuous parenting interventions such as SCEPs, an improvement in expressive language and increase in attachment behaviors of children with neurodevelopmental disabilities could be expected. Studies to confirm long-term outcomes are encouraged.

Conclusion

As the number of children diagnosed with neurodevelopmental disorders increases so does the demand for mental health nurses to conduct interventions for these children and their parents. Our findings indicate that SCEPs that alleviate the parenting burden, and enhance parent–child communication and parenting competence, should be applied in mental health nursing environments. These findings suggest that sociodrama-based programs may be an effective intervention strategy for parents of children with neurodevelopmental disorders.

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Ethical approval

The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Institutional Review Board of Chung-Ang University (Approval No. 1041078-201709-HRSB-175-01). The study protocol was registered at the Clinical Research Information Services (registration number: KCT0006412) and is available online.

Data availability statement

The data presented in this study are available on request from the corresponding author and with permission of the Institutional Review Board of Chung-Ang University.

Conflict of interest

The authors had no conflicts of interest to disclose.

Author contributions

Conceptualization, S.J.J., J.H, M.H.B, J.A.; methodology, S.J.J. and J.A; formal analysis, S.J.J. and J.A.; investigation, J.H. and S.J.J.; data curation, S.J.J. and J.A.; writing—original draft preparation, S.J.J., J.H, M.H.B, and J.A.; writing—review and editing, S.J.J. and J.A.; project administration, J.H, M.H.B, and J.A; All authors have read and agreed to the published version of the manuscript.

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Research Article

A Study of the Educational Needs of Clinical Nurses Based on the Experiences in Training Programs for Nursing COVID-19 Patients

Jeong-Won Han,[1] Jaewon Joung,[2] Ji-Soon Kang,[3] Hanna Lee[4,*]

[1] College of Nursing Science, Kyung Hee University, Republic of Korea
[2] College of Nursing, Research Institute of Nursing Science, Jeonbuk National University, Republic of Korea
[3] Department of Nursing, Hansei University, Republic of Korea
[4] Department of Nursing, Gangneung-Wonju National University, Republic of Korea

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SUMMARY

Purpose: This study aimed to explore the experience of clinical nurses regarding training programs for critically ill patients with coronavirus disease 2019 (COVID-19) and their educational needs.
Methods: Qualitative data were analyzed using content analysis, and quantitative data were analyzed according to Borich's formula. Data for the study were collected in March 2021 from 16 nurses who had completed a nursing program for critically ill patients with COVID-19 and were working at three hospitals designated for COVID-19.
Results: Participants' experiences were classified into three major categories, namely "Participation experiences and perceptions of the training program," "Recommendations for improving the training program," and "Perceptions of working in an infectious environment," and 10 subcategories. According to Borich's formula, the most pressing educational needs in respiratory and non-respiratory nursing, respectively, were for "nursing care for patients on extracorporeal membrane oxygenation" and "application of continuous renal replacement therapy and caring for patients."
Conclusion: To prepare for the periodic emergence of communicable infectious diseases throughout the world and cultivate nursing staff to care for critically ill patients, it is necessary to develop nursing education programs with content corresponding to nurses' needs. This study can be used as base data for cultivating nursing staff for critically ill patients with communicable infectious diseases in keeping with clinical nurses' educational needs and basic educational materials for nursing students.
Trial registration: CRIS, KCT0006359. Registered 20 July 2021 - Retrospectively registered, https://cris.nih.go.kr/cris/

Introduction

Coronavirus disease 2019 (COVID-19) is a viral disease that was first reported in Wuhan, Hubei Province, China. On December 1, 2019, the World Health Organization [1] declared COVID-19 a pandemic, prompting countries around the globe to respond to their respective national emergencies; however, the number of confirmed cases has been continuously rising, and the emergence of new and more dangerous COVID-19 variants worldwide is a growing concern. The clinical manifestations of COVID-19 vary from being asymptomatic to having fever, cough, shortness of breath, diarrhea, and many other symptoms. The symptoms are mild in the initial stage, can progress to severe symptoms, and may lead to death [2,3]. COVID-19 is particularly deadly in the case of elderly, immunocompromized, and comorbid patients, and in some cases, advanced interventions such as extracorporeal membrane oxygenation (ECMO) and mechanical ventilation are required [4]. Therefore, it is necessary to increase the number of healthcare personnel who can manage critically ill COVID-19-related patients [2,3].

The Korean government has designated national hospitals and built more intensive care units (ICUs) to manage critically ill

Jeong-Won Han: https://orcid.org/0000-0002-4893-8327; Jaewon Joung: https://orcid.org/0000-0001-9466-3240; Ji-Soon Kang: https://orcid.org/0000-0001-5650-1013; Hanna Lee: https://orcid.org/0000-0002-9835-4717
* Correspondence to: Hanna Lee, Department of Nursing, Gangneung-Wonju National University, Republic of Korea.
E-mail address: hannalee@gwnu.ac.kr

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COVID-19-related patients [4,5]. To supply nursing staff for their care, the government has deployed trainees who have completed relevant training courses [6]. However, cultivating nursing staff for critically ill COVID-19-related patients is time consuming, and in-depth educational programs are needed, specifically training programs suited to the novel circumstances including medical personnel movement management, cleaning wards, and wearing protective equipment. Hence, the supply of nurses who can care for critically ill COVID-19-related patients is inadequate [5]. Critically ill COVID-19-related patients should be provided with special nursing care from the basic level of personal hygiene to life-saving treatment for 24 hours [7]; at this point in time, nursing personnel who can provide nursing care for severe COVID-19-related cases are integral.

Since caring for critically ill patients is difficult for nurses experiencing it for the first time, several problems, such as maladjustment and low self-confidence, may arise [8,9]. These may affect the quality of nursing care provided to critically ill patients and lead to excessive work-related stress, as well as increased turnover rates for nurses [10]. A study conducted by the Ministry of Health and Welfare involving experienced nurses caring for COVID-19 patients in Korea reported that nurses viewed themselves as lacking knowledge about COVID-19 patients and that they felt pressured and overwhelmed in response to the demand to provide nursing care for critically ill patients without sufficient nursing experience regarding patients with respiratory communicable infectious diseases, leading to an increase in emotional and psychological stress [11]. The uncertainty that characterizes infectious diseases increases healthcare professionals' stress, anxiety, and depression [12] and decreases sleep quality [13]. In such circumstances, if a sufficient number of nursing staff is secured through systematic educational programs related to the care of critically ill patients with respiratory communicable infectious diseases, healthcare personnel can comply with the regulations for controlling viral spread with regard to infected patients through training involving wearing personal protective equipment (PPE) and nursing practice simulation [14], and they can perform all medical procedures calmly because of the reduced pressure, which may decrease the risk of additional infections. Given these results, it is necessary to address in depth the content of educational programs aimed at training nurses to care for critically ill patients by obtaining sufficient knowledge about COVID-19 and the skills required for managing it.

Nurses' practical education requirement becomes evident when they need to perform nursing practice on a professional level, feel insufficient or face difficulty in nursing, or want to improve their expertize by obtaining up-to-date knowledge and skills [15]. Considering that respiratory infectious diseases, such as Middle East respiratory syndrome (MERS) followed by COVID-19, occur repeatedly, it is important to identify nurses' educational needs to prepare nursing staff to care for critically ill patients.

Therefore, this study explores two aspects of educational needs. First, we will explore subjects' participation experiences with education for nursing critically ill COVID-19-related patients with respiratory infectious diseases based on the study question "What nursing education characteristics and content are required to adequately prepare for nursing critically ill patients?" Second, we confirm the participants' objective educational needs. On this basis, we aim to use the results as base data to improve clinical nurses' competency in nursing critically ill COVID-19-related patients and identify strategies that meet the social requirements of nursing personnel who care for critically ill patients.

Methods

Study design

This study used mixed methods research design [16], combining focus group interviews (FGIs) as the qualitative element and a survey as the quantitative element. The qualitative results reflecting the participants' experiences in the existing training programs were supplemented with a quantitative study to identify the participants' objective educational needs.

Study participants

Eighteen study participants were recruited from among nurses who completed a training program for critically ill patients with COVID-19 who were working at three hospitals designated for COVID-19 in Gyeonggi Province. Two people were excluded from the study because they withdrew due to the side effects of COVID-19 vaccination; thus, 16 people participated in the study. Six participants belonged to A hospital, six to B, and four to C, and FGIs were conducted with them at their respective hospitals. They all received training at government-designated teaching hospitals from September 2020 to February 2021, after which they returned to their hospital where they currently care for confirmed cases of COVID-19. Perspectives on the proper number of focus group participants differ in the literature. This study adopted the opinion [17] that the desirable number is six to ten participants per group. Given practical considerations related to group dynamics and participants' high interference tendency, there were at least three participants per group.

Data collection

Data were collected from March 4 to March 11, 2021. A list of COVID-19-designated hospitals located in Gyeonggi Province was obtained to gather participants, and participant recruitment advertisements were posted on three hospitals' online bulletin boards after obtaining approval from the respective heads of department among those hospitals implementing education programs for critically ill patients with COVID-19. Participants who saw the advertisements and voluntarily expressed their interest in participating in the study were selected, and FGIs were scheduled in advance according to the participants' availability. Considering the risk of COVID-19 infection, three FGIs were conducted using Zoom video conferencing. Each group meeting lasted approximately one hour. FGIs were led by a researcher with extensive FGI and qualitative research interview experience, and other researchers participated as assistant facilitators. Before the interviews, consent to study participation was reconfirmed, and interview guidance was provided. By voluntary agreement, interviews were recorded and transcribed. Group interviews were conducted until content saturation was reached, and it was determined that no new content could be derived through the team meetings. Researchers developed a guide to general interview questions to maintain the flow of the interview in keeping with the clarified purpose. Related ad-hoc interview questions were also used. The main guiding questions were as follows:

- Please describe your experience of participating in the nurse training program for critically ill patients with communicable infectious diseases.
- What did you like about participating in the nurse training program for critically ill patients with communicable infectious diseases?

- What did you dislike about participating in the nurse training program for critically ill patients with communicable infectious diseases?
- What changes did you notice after participating in the nurse training program for critically ill patients with communicable infectious diseases?

At the end of the FGIs, the participants completed a 10–15-minute questionnaire aimed at investigating general characteristics and educational needs related to critically ill patients with communicable infectious diseases. The questionnaire consisted of 16 items about nursing critically ill patients with respiratory diseases, 20 items about nursing critically ill patients with non-respiratory diseases, and six items about infection control. There were 42 items based on guidelines and books about the management of critically ill patients, and a survey was conducted on effective learning methods for each item [7,18–20].

Data analysis

The qualitative data collected were analyzed using inductive content analysis, following Elo and Kyngas' suggestions [21]. The inductive method is useful when data from previous studies on research phenomena are insufficient or knowledge about phenomena is segmented. The interviews revealed the participants' experiences of nursing education programs aimed at shaping dedicated personnel to care for critically ill patients with COVID-19. This study aimed to identify and categorize common factors to generalize their experiences. Based on content analysis, words and phrases were chosen as the unit of analysis in the preparation phase. Following the stages of open coding, category formation, and abstraction in the organizing phase, the specific data analysis procedure was as follows: First, transcribed data were read several times to grasp the fundamental content and flow of the interview as a whole; second, the transcript was read and marked up to arrange repeated words and phrases in order to extract codes; third, researchers examined the arranged codes together and categorized them through grouping and comparison according to the characteristics; fourth, the categorized content was confirmed and repeatedly perused and re-classified to grasp the meaning and relevance; and fifth, through deduction of abstract categories reflecting the key categorized interview content and the relevance, a description of a phenomenon in keeping with the purpose of the study was derived. Regarding the rigor of the study, following Lincoln and Guba [22], credibility was established directly with the participants by confirming the meanings derived from the transcribed conversations, and validity was verified through transcripts indicating that our participants had clearly recounted their experiences. Neutrality was ensured through meetings among the researchers to avoid biases and personal judgements; these meetings were held in consultation with a qualitative researcher. In addition to the FGIs, 16 participants were surveyed about their educational needs in nursing programs related to dedicated critical care. Questionnaires were analyzed as follows. Regarding the subjects' general characteristics, frequencies, percentages, and standard deviations were verified. The educational needs related to nursing patients with respiratory infectious diseases were analyzed using the Wilcoxon signed rank test and Borich's formula. According to Borich [23], educational needs can be deduced through a discrepancy analysis of current and desired levels. In this study, using Borich's formula for needs, after subtracting the subject's performative self-confidence from the importance of each item, the difference was multiplied by each item's average importance and then divided by the total number of cases to calculate the needs. Based on this value, the larger the needs coefficient, the higher the demand priority.

Ethics approval and consent to participate

The institutional review board reviewed and approved the study (IRB approval no.). Informed consent was obtained from all the subjects involved in the study. Written informed consent was obtained from the patients for publication of this article.

Results

Study participants' general characteristics

All study subjects were women (100.0%), and their mean age was 31.94 ± 6.21. Regarding marital status, there were five (31.3%) married women and 11 (68.8%) unmarried women. Regarding education, three (18.8%) had an associate's degree and 13 (81.3%) had a bachelor's degree. Regarding work, one nurse (6.3%) was working in an emergency room (ER), six nurses worked in an ICU (37.5%), and nine (56.3%) worked in a COVID-19 ward. The total duration of clinical experiences was 8.90 ± 6.21 years, and the duration of experience in the current department was 1.09 ± 1.27 years. The sources of COVID-19-related information were the hospital website's homepage (6 nurses, 37.5%), the Korea Disease Control and Prevention Agency (5 nurses, 31.3%), mass media (2 nurses, 12.5%), and the Internet (7 nurses, 43.8%) (Table 1).

Content analysis for focus group interviews

Participants' experiences regarding nursing programs aimed at shaping dedicated critical care nurses were classified into three major categories and ten subcategories (Table 2).

Category 1. Participation experiences and perceptions of the training program

This category concerns the overall structure and characteristics of training as well as post-training changes in participants.

Disorganized program arrangement in early stage. Due to the onset of the COVID-19 pandemic in early 2020, the nursing personnel shortage was highlighted, and a nursing program aimed at shaping dedicated critical care nurses commenced as an improvement measure at the national level. However, during the initial training period, there were some problems, including indecision regarding the ratio of theoretical education to practical training in the

Table 1 *General Characteristics of the Participants.*

	Gender	Age (year)	Marital Status	Education level	work department	Total clinical career (year)
1	Women	34	Single	Bachelor degree	COVID-19 ward	7.02
2	Women	37	Married	Bachelor degree	COVID-19 ward	16.00
3	Women	48	Married	Bachelor degree	COVID-19 ward	25.00
4	Women	34	Single	Bachelor degree	COVID-19 ward	10.00
5	Women	30	Single	Associate degree	ICU	8.00
6	Women	36	Married	Bachelor degree	ICU	13.10
7	Women	35	Married	Associate degree	COVID-19 ward	14.00
8	Women	27	Single	Bachelor degree	COVID-19 ward	3.10
9	Women	27	Single	Bachelor degree	ER	5.00
10	Women	28	Single	Bachelor degree	COVID-19 ward	4.03
11	Women	27	Single	Associate degree	COVID-19 ward	3.00
12	Women	26	Single	Bachelor degree	ICU	5.00
13	Women	29	Single	Bachelor degree	ICU	7.00
14	Women	40	Married	Bachelor degree	ICU	15.00
15	Women	26	Single	Bachelor degree	ICU	3.00
16	Women	27	Single	Bachelor degree	COVID-19 ward	4.09

COVID-19 = coronavirus disease-2019, ICU = intensive care unit.

education plan, preceptors' lack of experience with the relevant content, and the absence of a practical training protocol. During the first round of training, practical training was provided exclusively for 4 weeks. This was changed to 1 week of theoretical instruction and 3 weeks of practical training. This was further modified to an even split, consisting of 2 weeks of theoretical instruction and 2 weeks of practical training, and it is this arrangement that has been implemented so far. The nursing staff of tertiary hospital ICUs were deployed in great numbers to COVID-19 nursing departments. As a result, many new personnel were assigned to the ICUs where this study's participants practiced, and the absence of an education protocol made it difficult to administer the program. Many participants expressed their dissatisfaction with practical training and thought that it would be more effective to increase the amount of theoretical instruction. Although the training included scenario-based simulation practice, it seems that the preparation offered was insufficient for the participants to effectively apply the content of the program.

> *First, there was a lot of trial and error. Those who first participated in the training had clinical practice almost exclusively, and I joined for the second session on clinical practice and theory together. The time dedicated to theory was absolutely adequate, but as for clinical practice, we only observed, and the preceptors were not well prepared, so it was not that helpful. It seems that they had not quite decided what to teach and what to practice*. (1-1).

> *There were many new nurses. The preceptors were busy teaching them, so there was no one for us to ask …* (1-2).

> *(For simulation practices), I understand that the intention was for us to practice, like in the actual situation, wearing protective clothing. However, the situation was not clearly set, and it was disorganized. I wish that it had been better organized*. (3-1).

Progressing to systematic arrangement of the training program. Although programs varied by educational institutions, the training program gradually became more organized through trial and error over successive rounds. Nurse educators and doctors delivered theoretical lecturers, and critical care content was included. The theoretical portion of the program gave participants opportunities to practice what they learned through lectures and on site. Participants could familiarize with content by assessing and operating devices first-hand. Participants also received one-on-one training with a preceptor according to their duty roster, and the preceptors made efforts to thoroughly educate participants with the aid of a checklist.

> *For the first 2 weeks, we had theoretical sessions, and during the following 2 weeks of practice sessions, the preceptor explained how to operate a ventilator, even though I did not get to do it myself and shared various patient cases. I think I understood to some degree.* (2-1).

> *During 2 weeks of theoretical sessions, we attended a lecture in the hall in the morning and went to the site in the afternoon, where a nurse educator re-explained what we learned in the morning and let us practice it ourselves. As a preceptor taught us for the remaining two weeks, it was very systematic.* (2-2).

Table 2 *Analysis of Focus Group Interview.*

Category	Subcategory
Participation experiences and perceptions of the training program	Disorganized program arrangement in early stage
	Progressing to systematic arrangement of the training program
	Inadequate hands-on clinical practice
	Perceived self-efficacy in critical care after training
	Motivation by nurses with expertize
Recommendations for improving the training program	Inclusion of specific institutional practice
	More hands-on practice and simulation training
	Inclusion criteria for trainee selection
Perceptions of working in an infectious environment	Anxiety and fear about the work
	Burden of wearing personal protective equipment

Inadequate hands-on clinical practice. Since the participants did not belong to the institutions (hospitals) where the clinical practice sessions were held, they could not perform nursing care directly, and practice was mainly through observation. Moreover, despite the program's aim of cultivating dedicated critical care nurses for COVID-19, the participants expressed dissatisfaction regarding limited opportunities to practice nursing patients with COVID-19. Although they acknowledged that direct contact with COVID-19 patients would entail an infection risk and the need for intensive care, they noted that such contact would be necessary to meaningfully experience the operation of a COVID-19 ward.

> *It was not helpful because I only observed during practice. It was more valuable, and I learned a lot from the ICU where I was first assigned after I returned to the hospital after training.* (2-3).

> *I was assigned to the SICU [surgical intensive care unit], where there were many neurosurgical patients. In fact, patients with COVID-19 have many respiratory problems, but I only cared for neurosurgical patients for 2 weeks. I could provide critical care, but I could not practice the important aspects of caring for patients with COVID-19.* (2-4).

Perceived self-efficacy in critical care after training. Medical equipment such as continuous renal replacement therapy (CRRT) and ECMO were new to nurses without ICU experience; however, training improved their understanding of how to use the equipment, as they were able to practice setting up and preparing it in person, as well as observe how to apply it to various patients. This was also a good opportunity to clarify medications with which they were previously unfamiliar. Consequently, overall nursing competency for critical care improved, including assessment of the nervous system, in addition to the respiratory system. Participants became more communicative with their colleagues as a result, and the quality of patient care improved, leading to increased self-confidence in nursing.

> *I was unfamiliar with ventilators, but learning about them and operating one by myself during training helped me a gain a clear understanding of how to use them. I was roughly aware of what would happen based on theoretical knowledge" if applicable, but I gained a clearer understanding of what the figures mean when operating the CRRT.* (1-3).

> *I have worked only in the ward in the hospital, so I did not provide actual care for patients. However, after training, I [now] know how to look after the patients.* (2-5).

> *I am less fearful than before, and I have a little more self-confidence. My fear of machines dissipated a lot, and now I can interpret their output. In that respect, I think I have changed significantly.* (3-2).

Motivation by nurses with expertize. Participants were motivated by expert nurses, the program educators' expertize and passion, the teamwork spirit between medical staff in emergency situations, and the nurse preceptors' management of material resources in

preparation for emergency situations. They reflected on their nursing practice so far and attempted to apply what they had learned after returning to their workplaces.

> *The nurse educators really looked like professionals, and even though I have been working in the clinical field for a long time, I thought I still had so much to improve [on], so I felt ashamed of myself. I was a lot more motivated.* (1-1).

> *She was very experienced [from working] at another hospital. After perusing my experience, she skipped content that would have been redundant and explained the theory first, about procedure, with which I was unfamiliar and then, I got the chance to practice it after she gave me a demonstration of how to do it. She is so impressive because she actively taught me in this way.* (3-2).

> *In the practice session, there was a nurse who was really good at organizing and cleaning up. She organized everything in the ward for use in emergency situations. So, now I am also organizing staff in my ward.* (1-3).

Category 2. Recommendations for improving the training program

The second category concerns participants' post-training opinions regarding the need to improve future training, as well as trainees' perceptions of the actual situation as soon-to-be critical care nurses.

Inclusion of specific institutional practice. Participants were disinterested in medical equipment and practices that had not yet been established at their workplace. In cases where some participants' home institutions were equipped with some of them, product type varied; hence, there was an adjustment period. Participants therefore demanded customized training to reflect their work environment. On the other hand, since the education program was administered by an external institution, there were problems such as having to practice in the pediatric intensive care unit (PICU) even though some participants did not have pediatric intensive patients at their institution. Therefore, regarding education delivery methods, it was suggested that it would be more efficient if nurse educators could visit the institution where the trainees belong and provide content tailored to their respective work environments, rather than having trainees visit a site other than their institution. In addition, participants also said that when they received training at another institution, it was difficult to care for critically ill patients immediately after returning to their own, and sufficient time should be provided for them to adjust to a preceptor.

> *My hospital is not equipped with CRRT or ECMO yet, so even though I have learned about these, there is nowhere to apply it. That's a shame. Now, I am aware of it only theoretically. If that equipment is introduced in my hospital later, I think I [will] need to learn to use them from scratch again.* (2-1).

> *In the practice session, some of us were assigned to the PICU. It is very rare to see pediatric patients in my hospital. We just practiced for no reason because there is almost no opportunity to apply such knowledge after returning.* (2-2).

> *Because the systems are completely different between the hospital where I received training and the one where I am working, it seems like it would take far more than a month or two to apply what I learned in training in the field. However, as I cannot receive training forever, I think that after practicing in the external institution for about a month as I am doing now, I will need time to adapt to the field again. After grasping the bigger concept, I think we should focus on the finer details after returning.* (2-2).

More hands-on practice and simulation training. Given that critically ill patients' status changes frequently and rapidly, it was found that the current mainly observation-based 4-week theoretical and practical training program was limited in terms of its ability to enhance participants' adaptability and coping skills in the field. Despite their theoretical understanding after training, many participants doubted whether they had acquired the actual practical skills to care for critically ill patients. In addition, the need for simulation training was mentioned as a means to increase the program content's practical applicability.

> *If participants in training receive content that is applicable in practice, then nurses will know how to take care of critically ill patients. We need to be trained on how to cope with situations according to the test results and the status of patients*. (1-4).

> *We know the alphabet from A to Z, but it is difficult to speak in English. I know how to turn the machines on and off, but I think it takes more time and effort to apply such things and cope with unexpected situations.* (3-3).

> *Currently, nursing students' simulation training involves a demonstration with a simulator. It will be helpful for us to repeat such practice and apply it to different situations.* (1-2).

Inclusion criteria for trainee selection. Trainees either participated in training voluntarily or upon recommendation from a manager at their workplace, such as a head nurse. Institutions recommended personnel for training based on their ICU work experience and the trajectory of their nursing career. Voluntary participants felt the need to acquire additional knowledge and more advanced methods when their hospital was designated for patients with COVID-19. Post-training, participants could cope well with emergency situations. They also created ripple effects by educating other nurses when they returned to work. Such personnel should have sufficient (5–10 years or more) experience in nursing practice and be motivated to receive training.

> *Since the hospital where the practice sessions are held is large and well organized, it would be good if nurses with about five years of nursing experience or those with an intermediate position or higher receive training and can teach junior nurses what they learned upon return.* (2-2).

> *Motivation seems to be the most important factor. Nurses with no interest have nothing to gain despite [the] opportunities [they are] given, but it will be a good opportunity for motivated nurses to learn a lot if the hospital provides the opportunities.* (3-2).

Category 3. Perceptions of working in an infectious environment

The third category concerns perceptions of caring for critically ill patients that should be considered when developing future training program content.

Anxiety and fear about the work. Participants received training during the relevant period, but even thereafter, they were still not accustomed to caring for critically ill patients and feared mishandling situations due to the inability to predict changes in patients' condition.

> *I received training, but I will be under a lot of pressure to save patients' lives under conditions to which I am not fully accustomed. I am anxious about communication, such as knowing what exactly to do as a nurse in charge, giving instructions to acting nurses, and reporting to doctors.* (1-1).

I have no idea when the patient's condition changes. Because I am not good at coping with such situations, I feel anxious in that sense. This is not anxiety about caring for patients. This may be because I am not good at dealing with rapidly changing situations. (3-4).

Burden of wearing personal protective equipment. Nurses caring for critically ill patients with COVID-19 must wear PPE. However, participants had difficulty working while wearing PPE because the equipment acted as a major physical obstacle. On the other hand, anticipating emergency cases in which there is inadequate time to put on PPE, they expressed their views about ethical dilemmas related to PPE.

I cannot hear well in PPE. During emergencies, I need to move quickly. So, I am afraid that because I [could] mistakenly hear a doctor's prescription, I may give [a patient] an incorrect drug or do something wrong, causing harm to a patient. (1-2).

Of course, I am afraid of performing cardiopulmonary resuscitation in general, but in the case of COVID-19, we need to do it in Level D PPE. Therefore, it is inevitable that we get slower at doing everything. Because communication is not easy and movement, for example, to get something is slowed down, we need more staff. It is difficult, even for experienced people. Therefore, it will be especially difficult for inexperienced nurses. (2-2).

When emergencies occur, we run. However, in that situation, if we go there without wearing PPE, we cannot protect ourselves, and if we put on PPE, it takes more than 10 minutes. However, as you know, timing is very important. I am really concerned about what I should do in a situation like that. (1-3).

Analysis of educational needs using Borich's formula

The results of the analysis of the subjects' educational needs for critical care are presented in Table 3. Regarding the subjects'

Table 3 *Analysis of Critical Care Educational Needs and Priority.*

Content	Importance M±SD	Confidence M±SD	z	*p*	Borich score	Borich priority
Respiratory nursing						
Anatomy and physiology of the respiratory system	4.31 ± 0.80	3.44 ± 0.51	3.27	.001	3.77	13
Physical assessment of the respiratory system	4.31 ± 1.01	3.44 ± 0.51	2.56	.010	3.77	13
Oxygen therapy (including high-flow oxygen therapy)	4.63 ± 0.71	3.88 ± 0.61	2.26	.023	3.47	16
Nursing care for the patient with dyspnea	4.69 ± 0.79	3.81 ± 0.65	2.95	.003	4.10	11
Nursing care of patients on intubation	4.50 ± 1.03	3.63 ± 0.71	2.37	.017	3.94	12
Understanding a mechanical ventilator	4.75 ± 0.57	3.25 ± 0.57	3.38	.001	7.13	4
Nursing care of patients on mechanical ventilators	4.75 ± 0.68	3.19 ± 0.75	3.47	.001	7.42	3
Nursing care of a patients on extubation	4.50 ± 0.89	3.31 ± 0.79	2.55	.011	5.34	8
Application of the prone positioning	4.00 ± 1.26	3.13 ± 1.02	1.81	.069	3.50	15
Tracheostomy management	4.31 ± 0.87	3.06 ± 0.77	2.98	.003	5.39	7
Understanding of a diagnostic test for pneumonitis and its treatment	4.44 ± 0.72	3.38 ± 0.61	2.98	.003	4.71	10
Understanding of a diagnostic test for ARDS and its treatment	4.38 ± 1.08	3.13 ± 0.61	2.83	.005	5.47	6
Understanding of Aspergillus co-infections	4.38 ± 0.88	2.94 ± 0.68	3.23	.001	6.29	5
Understanding of ECMO	4.25 ± 1.06	2.44 ± 1.15	2.70	.007	7.70	2
Nursing care for patient on ECMO	4.25 ± 0.93	2.00 ± 0.81	3.24	.001	9.56	1
Understanding of ABGA and acid-base imbalance	4.69 ± 0.62	3.56 ± 0.62	3.28	.001	5.27	9
Non-respiratory nursing						
Anatomy and physiology of the circulatory system	4.38 ± 0.80	3.19 ± 0.65	3.09	.002	5.47	7
Physical assessment of the circulatory system	4.44 ± 0.89	3.19 ± 0.65	3.33	.001	5.82	5
Understanding of ECG	4.50 ± 0.81	3.00 ± 0.63	3.21	.001	6.75	3
Defibrillator application	4.63 ± 0.71	3.50 ± 0.89	3.16	.002	5.49	6
Understanding of a diagnostic test for acute coronary syndrome and its treatment	4.38 ± 0.88	2.94 ± 0.85	3.13	.002	6.29	4
Understanding of CPR	4.50 ± 0.96	3.38 ± 0.80	3.08	.002	5.34	8
Nursing care of patients with shock	4.44 ± 1.03	3.31 ± 0.70	2.33	.019	5.27	9
Anatomy and physiology of the digestive system	4.31 ± .060	3.56 ± 0.62	2.65	.008	3.50	15
Physical assessment of the digestive system	4.25 ± 0.68	3.38 ± 0.71	2.81	.005	3.98	14
Understanding of a diagnostic test for digestive system diseases and its treatment	4.13 ± 0.88	3.44 ± 0.51	2.11	.035	3.09	17
Nutrition management	4.06 ± 1.06	3.69 ± 0.60	2.38	.166	1.78	20
Anatomy and physiology of the kidney system	4.19 ± 0.91	3.13 ± 0.71	3.32	.001	4.71	11
Physical assessment of the kidney system	4.13 ± 1.08	3.06 ± 0.77	2.50	.012	4.64	12
Understanding of CRRT	4.31 ± 1.08	2.69 ± 0.87	2.83	.005	7.55	2
CRRT application and nursing care	4.38 ± 1.07	2.31 ± 0.70	3.23	.001	9.30	1
Thrombosis prevention	4.13 ± 1.08	3.06 ± 0.85	2.47	.013	4.38	13
Anatomy and physiology of the nervous system	4.25 ± 0.93	3.13 ± 0.71	3.16	.002	5.05	10
Physical and consciousness assessment of the nervous system	4.19 ± 1.04	3.44 ± 0.72	2.19	.028	3.40	16
Nursing care for stroke patient	4.13 ± 1.20	3.44 ± 0.72	1.96	.049	3.09	17
Nursing care for delirium patient	4.06 ± 1.23	3.38 ± 0.71	2.65	.008	2.79	19
Infection control						
Understanding of respiratory infectious diseases	4.69 ± 0.60	3.81 ± 0.65	3.35	.001	4.10	2
Application of PEE in each nursing situation	4.63 ± 0.80	3.75 ± 0.68	2.50	.012	4.05	3
Aerosol-generating procedures (AGPs)	4.44 ± 0.89	3.31 ± 1.01	2.02	.003	4.99	1
Disposal of infectious waste	4.38 ± 0.80	4.06 ± 0.44	1.66	.096	1.37	6
Disinfection of medical devices and hospital rooms of quarantined patients	4.44 ± 0.89	4.13 ± 0.34	1.38	.166	1.39	5
Nursing care of a patient after death	4.19 ± 1.10	3.81 ± 0.75	1.30	.193	1.57	4

CPR = cardio-pulmonary resuscitation; CRRT = Continuous renal replacement therapy; ECG = electrocardiogram; ECMO = Extracorporeal membrane oxygenation; M = Mean; SD = Standard deviation.

educational needs for respiratory nursing, for all items except application of the prone position ($p = .069$), the importance and level of the subjects' self-confidence in their current performance showed a statistically significant difference ($p = .05$). Within the framework of Borich's needs, five items were identified; in descending order, starting with the most urgent, these were: nursing care for patients on ECMO, understanding ECMO, nursing care for patients on artificial ventilators, understanding artificial ventilation, and Aspergillus co-infection. Regarding the educational needs for non-respiratory nursing, for all items except nutrition management ($p = .166$), the importance and level of subjects' self-confidence in their current performance showed a statistically significant difference ($p = .05$). Within the framework of Borich's needs, the following five items were the most urgently needed: application of CRRT and nursing care for such patients, understanding CRRT, understanding electrocardiogram (ECG), understanding diagnostic testing for acute coronary syndrome and its treatment, and physical assessment of the circulatory system. Regarding educational needs for infection control, a statistically significant difference ($p = .05$) was found in the importance and level of current performative self-confidence for the following items: understanding respiratory infectious diseases ($p = .001$), application of PPE to various nursing situations ($p = .012$), and aerosol-generating procedures ($p = .003$), except for the disposal of infectious waste ($p = .096$), disinfection of medical devices and quarantined patients' hospital rooms ($p = .166$), and post-mortem patient care ($p = .193$). In addition, based on Borich's needs, the following items were, in descending order, the most urgently needed: erosol-generating procedures, understanding respiratory infectious diseases, and application of PPE to various nursing situations. The results for the trainees' learning methods are shown in Table 4.

Discussion

This study aims to explore participation experiences with COVID-19 training program and clinical nurses' educational needs on this area. The findings have a few implications.

First, based on the FGIs, regarding their training experience, the participants thought that the critical care nursing program was initially poorly organized but noted that this improved over time. Moreover, there were educational infrastructural shortcomings, even at the hospitals where the training was conducted, because of the voluminous increase in the number of critically ill patients due to COVID-19 and a shortage of critical care nurses. Accordingly, the participants did not view the early-stage programs as effective. However, with successive training sessions and progressive systematization, the participants eventually expressed satisfaction with the content. A study [9] on nursing experiences with patients with confirmed COVID-19 diagnoses involving Iranian nurses emphasized the importance of supplying trained nursing personnel prepared to cope with pandemic situations. This study also highlighted the importance of systematic education programs and manpower supply-and-demand planning to prepare for medical crizes. In addition, in this study, it was necessary for the participants to practice providing nursing care for patients with confirmed COVID-19 diagnoses; however, the risk of infection and efforts toward strict infection control made it difficult to proceed with such practice. Nevertheless, the ability to cope with various situations involving respiratory infectious diseases is essential for dedicated nursing personnel responsible for caring for critically ill patients with respiratory diseases, unlike other communicable infectious diseases. Therefore, to overcome such situations, it will be necessary to develop diverse simulation training programs using high-fidelity simulation or virtual reality so that trainees can practice providing critical care for confirmed COVID-19 cases in the program setting.

Second, the content of the FGIs conducted as part of this study showed that pre-training, the participants feared caring for confirmed COVID-19 patients, but their fear declined after training, and their competency as dedicated nurses for critically ill patients improved. They were also found to be stimulated by expert nurses. A study conducted in China [24] on nurses caring for confirmed COVID-19 patients reported that nurses without prior experience caring for patients with infectious diseases or critically ill patients feared performance of such nursing care and experienced stress as a result. A study [11] conducted in Korea involving nurses experienced with caring for confirmed COVID-19 patients also reported psychological pressure among the nurses because they were assigned to critical care with insufficient experience caring for infected patients. Similarly, the participants in this study also expressed feelings of fear before training and a decline in self-confidence. However, the study results showed that nursing education for critically ill patients improved the subjects' self-confidence in terms of nursing assessment, drug administration, and use of medical equipment. This indicates that nursing programs for critically ill patients with infectious diseases are an effective method to enhance nursing competency for critical care and the quality of nursing care.

Third, the content of the FGIs conducted in this study revealed the need for customized education to suit participants' clinical settings, education that increases practical applicability, and proper trainee selection. In particular, participants suggested that it would be more effective if nurse educators could visit the institutions where the trainees work and provide education tailored to their respective working environments, rather than having participants attend external institutions for training. As previously mentioned, the Korean government has designated hospitals for COVID-19 and established more ICUs [5], as well as rapidly launching educational programs to secure dedicated nursing personnel to care for critically ill patients [6]. However, it is thought that there is a limit to increasing the supply of dedicated nursing staff for critical care at each hospital through the current critical care nursing programs because every hospital's system and settings are different, and critically ill patient care requires the use of various medical equipment. In addition, there was a demand for simulation of the required educational content. Given that simulation education improves clinical performance and knowledge more than conventional educational methods, the scope of nursing education for students is expanding [25,26]. However, hospitals face challenges acquiring expensive simulation facilities and equipment, and scenario development, training for educators, and operation and management also present difficulties [20]. Therefore, regarding training programs for nursing critically ill patients with communicable infectious diseases, it is necessary to share and develop simulation equipment to deliver training practice and content through systematic connections between hospitals and schools in the long term. Government support will be needed to establish a simulation center for healthcare personnel through school–work links.

Fourth, the nurses reported that because they were unaccustomed to caring for critically ill patients and could not predict the situations in which they would be placed, they feared providing such care. Previous studies [8,9] have reported that healthcare personnel described caring for confirmed COVID-19 patients as more difficult and stressful than caring for other patients. This study also showed that caring for critically ill patients with infectious diseases is intense and highly stressful, although the subjects received related training. However, a previous study [24] on nurses working in isolation wards revealed a case in which nurses who had worked in another ward were assigned to the isolation ward, indicating that it intensive cases for the acquisition

Table 4 *Analysis of Critical Care Educational Methods.*

Content	Lecture N (%)	Lecture + practice N (%)	HFS N (%)	VR N (%)	Others N (%)
Respiratory Nursing					
Anatomy and physiology of the respiratory system	12 (75.0)	1 (6.3)	1 (6.3)	2 (12.5)	0 (0.0)
Physical assessment of the respiratory system	6 (37.5)	2 (12.5)	6 (37.5)	1 (6.3)	1 (6.3)
Oxygen therapy (including high-flow oxygen therapy)	6 (37.5)	3 (18.8)	5 (31.3)	2 (12.5)	0 (0.0)
Nursing care for the patient with dyspnea	6 (37.5)	1 (6.3)	3 (18.8)	6 (37.5)	0 (0.0)
Nursing care of patients on intubation	3 (18.8)	2 (12.5)	8 (50.0)	3 (18.8)	0 (0.0)
Understanding a mechanical ventilator	8 (50.0)	3 (13.8)	1 (6.3)	4 (25.0)	0 (0.0)
Nursing care of patients on mechanical ventilators	5 (31.3)	2 (12.5)	4 (25.0)	5 (31.3)	0 (0.0)
Nursing care of a patients on extubation	5 (31.3)	3 (13.8)	5 (31.3)	3 (13.8)	0 (0.0)
Application of the prone positioning	3 (13.8)	2 (12.5)	8 (50.0)	3 (13.8)	0 (0.0)
Tracheostomy management	3 (13.8)	2 (12.5)	9 (56.3)	1 (6.3)	0 (0.0)
Understanding of a diagnostic test for pneumonitis and its treatment	14 (87.5)	1 (6.3)	1 (6.3)	0 (0.0)	0 (0.0)
Understanding of a diagnostic test for ARDS and its treatment	14 (87.5)	1 (6.3)	1 (6.3)	0 (0.0)	0 (0.0)
Understanding of Aspergillus co-infections	13 (81.3)	1 (6.3)	1 (6.3)	1 (6.3)	0 (0.0)
Understanding of ECMO	9 (56.3)	3 (13.8)	1 (6.3)	3 (13.8)	0 (0.0)
Nursing care for patient on ECMO	2 (12.5)	5 (31.3)	4 (25.0)	5 (31.3)	0 (0.0)
Understanding of ABGA and acid-base imbalance	12 (75.0)	0 (0.0)	2 (12.5)	2 (12.5)	0 (0.0)
Non-Respiratory Nursing					
Anatomy and physiology of the circulatory system	14 (87.5)	1 (6.3)	1 (6.3)	0 (0.0)	0 (0.0)
Physical assessment of the circulatory system	8 (50.0)	1 (6.3)	6 (37.5)	0 (0.0)	1 (6.3)
Understanding of ECG	8 (50.0)	2 (12.5)	3 (13.8)	3 (13.8)	0 (0.0)
Defibrillator application	0 (0.0)	7 (43.8)	7 (43.8)	2 (12.5)	0 (0.0)
Understanding of a diagnostic test for acute coronary syndrome and its treatment	10 (62.5)	1 (6.3)	2 (12.5)	3 (13.8)	0 (0.0)
Understanding of CPR	1 (6.3)	3 (13.8)	7 (43.8)	5 (31.3)	0 (0.0)
Nursing care of patients with shock	9 (56.3)	1 (6.3)	2 (12.5)	4 (25.0)	0 (0.0)
Anatomy and physiology of the digestive system	13 (81.3)	0 (0.0)	2 (12.5)	1 (6.3)	0 (0.0)
Physical assessment of the digestive system	10 (62.5)	2 (12.5)	2 (12.5)	1 (6.3)	1 (6.3)
Understanding of a diagnostic test for digestive system diseases and its treatment	14 (87.5)	0 (0.0)	2 (12.5)	0 (0.0)	0 (0.0)
Nutrition management	13 (81.3)	2 (12.5)	1 (6.3)	0 (0.0)	0 (0.0)
Anatomy and physiology of the kidney system	14 (87.5)	1 (6.3)	1 (6.3)	0 (0.0)	0 (0.0)
Physical assessment of the kidney system	10 (62.5)	1 (6.3)	3 (13.8)	1 (6.3)	1 (6.3)
Understanding of CRRT	10 (62.5)	3 (13.8)	2 (12.5)	1 (6.3)	0 (0.0)
CRRT application and nursing care	0 (0.0)	7 (43.8)	4 (25.0)	5 (31.3)	0 (0.0)
Thrombosis prevention	14 (87.5)	0 (0.0)	2 (12.5)	0 (0.0)	0 (0.0)
Anatomy and physiology of the nervous system	14 (87.5)	0 (0.0)	2 (12.5)	0 (0.0)	0 (0.0)
Physical and consciousness assessment of the nervous system	7 (43.8)	2 (12.5)	5 (31.3)	1 (6.3)	1 (6.3)
Nursing care for stroke patient	10 (62.5)	1 (6.3)	3 (13.8)	2 (12.5)	0 (0.0)
Nursing care for delirium patient	12 (75.0)	1 (6.3)	1 (6.3)	2 (12.5)	0 (0.0)
Infection control					
Understanding of respiratory infectious diseases	14 (87.5)	1 (6.3)	1 (6.3)	0 (0.0)	0 (0.0)
Application of PEE in each nursing situation	11 (68.8)	1 (6.3)	2 (12.5)	2 (12.5)	0 (0.0)
Aerosol-generating procedures (AGPs)	11 (68.8)	1 (6.3)	2 (12.5)	2 (12.5)	0 (0.0)
Disposal of infectious waste	13 (81.3)	1 (6.3)	1 (6.3)	1 (6.3)	0 (0.0)
Disinfection of medical devices and hospital rooms of quarantined patients	13 (81.3)	1 (6.3)	1 (6.3)	0 (0.0)	1 (6.3)
Nursing care of a patient after death	9 (56.3)	0 (0.0)	5 (31.3)	2 (12.5)	0 (0.0)

CPR = cardio-pulmonary resuscitation; CRRT=Continuous renal replacement therapy; ECG = electrocardiogram; ECMO = Extracorporeal membrane oxygenation; HFS=High fidelity simulation; M = Mean; SD=Standard deviation; VR=Virtual simulation.

of infection control, self-protection, and communication skills for self-improvement would be helpful as a turning point in career development. In conclusion, nurses are professionals with a sense of duty and a drive for self-improvement. Therefore, if systematic education programs can be provided to regularly and adequately meet subjects' needs amid a national crisis, the burden of nursing care for critically ill patients may lighten, and even when pandemic infectious diseases occur in the future, there will be a sufficient supply of critical care nurses.

Fifth, in this study, the subjects' educational needs for critical care were analyzed using Borich's formula. The results showed that demand was the highest for ECMO and mechanical ventilation among the educational needs for respiratory nursing, while for non-respiratory nursing, there was high demand for CRRT and ECG application. This corresponds to the results of a study [20] in which educational needs were investigated in ICU nurses through analysis of the importance of nursing practice, performance frequency, and level of difficulty. In that study, the subjects' most urgent educational needs were related to high-risk equipment such as ECMO, ventricular assistance devices, artificial pacemakers, and intra-aortic balloon pumps.

To provide such education, educational institutions should be equipped with medical devices at the relevant hospitals, and these devices should be readily available. Since long-term education and experience with a diverse cross-section patients are necessary, the government and nursing educators should contemplate appropriate

educational programs. In terms of infection control, the most pressing needs were erosol-generating procedures, understanding respiratory infectious diseases, and situational PPE application. Therefore, it is necessary to organize educational programs that reflect these results. In the case of patients with respiratory infectious diseases in particular, there are various issues, including situational PPE application. Clinical nurses face many challenges in nursing practice. Amid the current COVID-19 pandemic crisis, it will be necessary to standardize guidelines for nursing patients with respiratory infectious diseases across several countries through collaborative efforts, instead of using standardized nursing guidelines limited to one nation. In addition, because this study's subjects wanted training regarding the use of high-risk equipment, training should be delivered mostly as practice or based on high-fidelity simulation or virtual reality, necessitating collaborative efforts to develop appropriate programs.

This mixed-methods study's significance lies in its in-depth investigation of nurses' educational needs for nursing critically ill patients. We have made suggestions based on the results obtained. First, it can be seen that a nursing education program for critically ill patients with infectious diseases is an effective means to enhance nurses' critical care capacity and improve the quality of nursing care. Therefore, various educational programs have been established, and research to verify their effectiveness is suggested. Second, the participants highlighted the merits of educational nurses receiving national-centered education followed by education tailored to their home institution's specific working environment. Therefore, it is necessary to build a network to nurture nursing education, specifically supporting tailored education at individual hospitals. Third, content that it is difficult to deliver in the nursing education program for patients with infectious diseases needs to be developed as part of a simulation education program.

The limitations of this study are as follows. It is common to calculate the number of samples based on the t-test for the Borish education need assessment equation. In the case of embedded design among mixed methods research, embedded data plays a secondary role and be supplemental to the primary dataset. As a mixed method study was conducted with same 16 nurses, calculation for the minimum sample size, validation of the reliability and validity of the newly developed tool were omitted in this study. In addition, this study involved nurses at government-designated COVID-19 hospitals, it is necessary to also identify the educational needs of nurses who care for confirmed COVID-19 patients in the wider clinical field. Repeated future studies on educational needs should therefore be conducted by expanding the subjects to include various types of hospitals.

Conclusion

Changes in the medical industry due to COVID-19 demand changes in, including the expansion of, nurses' roles, an increase in the quality of nursing care, and a high level of knowledge and skills. Such demands emphasize the need to acquire new knowledge and skills for critical care. A number of participants in this study saw the need for critical care education and noted that training improved critical care nursing competency. Therefore, it is necessary to develop educational programs for nursing critically ill patients to meet learners' needs, enhance the educational effect of nursing programs for critical care, and supply healthcare personnel to satisfy social needs.

Ethical consideration

The institutional review board reviewed and approved the study (GWNUIRB-2021-12).

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Consent for publication

Not applicable.

Availability of data and materials

The data presented in this study are available on request from the corresponding author.

Conflict of interest

The authors have no competing interests to declare.

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