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#### Research Article

# Relationship between Unit-Level Nurses' Expectations from Nursing Assistant Roles and Individual Nursing Assistants' Information-Sharing Behaviors: A Multilevel Mediation Analysis



Masatoshi Saiki, 1, 4, \* Yukie Takemura, 2 Keiko Kunie 3, 4

- <sup>1</sup> Department of Advanced Clinical Nursing, Frontier Clinical Nursing, Graduate School of Nursing, Chiba University, Japan
- <sup>2</sup> Nursing Department, The University of Tokyo Hospital, Japan
- <sup>3</sup> Department of Nursing Administration, School of Nursing, Tokyo Women's Medical University, Japan
- <sup>4</sup> 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 investigate the relationship between the expectations of unit-level nurses from nursing assistants (NAs), frequency of individual NAs' information-sharing behaviors with nurses, and the effect of NAs' self-perceived roles on this relationship. NAs provide patient care along with nurses, and their information-sharing behaviors with nurses may be influenced by the expectations of the nurses

Methods: Nurses and NAs from 104 integrated community care (sub- and postacute) units were included in this Japanese cross-sectional study conducted from July to September 2018. Nurses' expectations from NAs and the NAs' self-perceived roles and information-sharing frequency were measured. Multilevel mediation analysis was performed for NAs' information-sharing behaviors, such as expressing, asking, providing linguistic responses, and providing feedback.

Results: Unit-level nurses' expectations from NAs were associated with the frequency of NAs' asking and responding behaviors with nurses (p < .05), mediated by the NAs' self-perceived roles. The frequency of NAs' expressing behaviors and feedback were also associated with their self-perceived roles (p < .001). Conclusions: High expectations of unit-level nurses from NAs led to better perception by NAs of their roles and led to better information-sharing behaviors. Educating nurses on NAs' roles may improve information-sharing between nurses and NAs that leads to safe and appropriate care to patients.

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#### Introduction

Nursing assistants (NAs) are often included as a part of a care delivery team. A systematic review of the activities of NAs revealed that NAs globally provide direct care, regardless of their specialty area [1]. NAs also provide patient care by themselves; therefore, they need to collaborate with the nurses. Sharing patient information and collaboration between nurses and NAs are critical to providing high-quality patient care [2,3]. Organizational research by Mesmer-Magnus et al. [4] reported that information-sharing within teams was a positive predictor of team performance [4].

Masatoshi Saiki: https://orcid.org/0000-0001-6247-965X; Yukie Takemura: https://orcid.org/0000-0003-2861-8673; Keiko Kunie: https://orcid.org/0000-0003-2951-0568

E-mail address: msaiki@chiba-u.jp

Similarly, appropriate information-sharing between nurses and NAs reportedly reduced patient fall rates [5]. Thus, facilitating information-sharing between nurses and NAs is important for quality care [6].

There is a global shortage of medical personnel, and to reduce costs at medical facilities, there has been an increased focus on personnel who can assist with nursing tasks without the need for specific qualifications [1,3,7]. Some tasks of NAs are complex and require high-level skills and are the same as those of nurses [1]. Therefore, promoting collaboration between nurses and NAs is essential for delivery of quality care. However, NAs are seldom considered as professionals or members of the healthcare team despite them providing direct patient care in healthcare settings [8,9].

To cope with the rapidly aging population in Japan, integrated community care units (sub- or postacute care units) have been established to help people live in the familiarity of their communities. Specifically, one or two integrated community care units

 $<sup>\</sup>ast$  Corresponding author. 1-8-1, Inohana, Chuo-ku, Chiba-shi, Chiba, 260-8672, Japan.

have been established in each hospital. Some patients in these units require rehabilitation and disease management, whereas others require acute treatment [10]. Most patients wish to return home or be admitted to a nursing home, but they require support with activities of daily living. Nurses and NAs work together to provide care, such as assistance with eating, toileting, and bathing.

In Japan, task shifting is being promoted to increase healthcare professionals' efficiency when completing tasks. In nursing tasks, NAs at some hospitals are certified care workers who have professionally learned about caregiving, whereas some NAs are unlicensed. NAs' tasks overlap those performed by nurses under the latter's supervision. Although NAs do not require some of the specific certifications as those required for certified care workers, they are expected to provide patients with care that is necessary for recuperative living, such as assistance with eating, toileting, and bathing, based on the training provided by hospitals. Therefore, in this study, we define an NA as a staff member who assists in providing basic patient care.

#### Nurses' expectations of the NA role

Although nurses and NAs have different roles, their tasks in direct patient care overlap. The role of the nurse is to assist in medical treatment, provide patient care, perform clinical decision making, and coordinate patient care [11], whereas the NA is providing direct patient care as well as care that does not involve direct contact with the patient to support the nurse's work.

Kalisch [12] indicated that nurses' leadership is a key element of an effectively functioning nursing team. To meet this goal, understanding the role of each team member is essential. Previous research has indicated that nurses and NAs have different perceptions of the NA role [2], which varies even among nurses [13,14]. The role of NAs is largely viewed from the perspective of the tasks they perform rather than how they function as members of a nursing team. In a previous study, Saiki et al. [15] focused on how NAs serve as a part of a nursing team and established a relationship between nurses' perceptions of the roles of NAs and their information-sharing behaviors with NAs. To promote interprofessional collaboration, all nurses in a unit must understand the role of NAs and convey their role expectations to the NAs. However, to the best of our knowledge, no study has quantitatively examined the relationship between the expectation of NAs by all members of a nursing unit and the individual NA's behaviors.

In Japan, registered nurses and assistant nurses (licensed practical nurses) are hired as professional nurses [16,17]. Registered nurses are licensed by the national government, whereas assistant nurses are licensed by the prefecture and legally perform their duties under the direction of a physician or nurse. Although registered nurses and assistant nurses have different legal work order systems, they perform almost identical tasks. To support the work of nurses and assistant nurses, NAs are employed, and there is no difference between nurses and assistant nurses in their relationship with NAs [39]. We treated both nurses and assistant nurses as nurses in this study.

#### NAs' information-sharing behaviors with nurses

A major part of an NA's role involves interacting with patients and observing minor changes in the patients' conditions [14,18]; NAs often note information about patients that can only be acquired by them [18,19]. However, nurses believe that NAs do not communicate such information at the time of delivering care [12]. Another study found that NAs are unable to ask nurses questions or fail to provide them with information about care [20]. Therefore, information-sharing, especially by NAs, may not be adequate.

In the field of healthcare, face-to-face communication is important for sharing information among employees [21]. According to Downs and Adrian [22], each person is a sender and receiver of information, with the receiver also providing feedback. The accuracy of the shared information increases when the receiver verifies the received information and provides feedback [22]. Therefore, nurses and NAs must improve their information-sharing behaviors, such as providing information, asking questions, verifying their understanding, and providing feedback. Accordingly, identifying strategies that improve NAs' information-sharing behaviors is essential.

#### Mediating effects of each individual NA's role perception

The hierarchical relationship between nurses and NAs makes it challenging for NAs to share information with nurses [9]. NAs were found to actively provide input and ask questions about care in units where team members are aware of the role of NAs [18]. Nurses' understanding of the role of NAs who work with them could be the key to improving NAs' information-sharing behaviors.

According to the role theory, an individual understands the role expectations of "specific others" and, subsequently, internalizes the role expectations of "generalized others" through role acquisition [23]. The "specific others" are also known as "significant others," and they influence the individual [24]. Previous studies have showed that the perception of the presence of nurses is a key factor in NA's behavior [20,25]. Saiki et al. [26] revealed that NAs' perception of the nurses' expectations from their roles was the key factor influencing how NAs participated in the nursing team. Therefore, NAs may internalize their roles from the role expectations of nurses and choose their own behaviors. We hypothesized that unit-level nurses' expectation from NAs mediates the role perceptions of NAs and improves their information-sharing behaviors with the nurses, which is an essential part of their jobs.

This study aimed to investigate the relationship between the expectations of unit-level nurses from NAs and the frequency of individual NAs' information-sharing behaviors with nurses and to assess the potential mediating effect of NAs' self-perceived roles in this relationship.

#### Methods

Study design and participants

This was a cross-sectional study on nurses, including registered nurses and assistant nurses, and NAs working in integrated community care units in Japan from July to September 2018. The number of nurses and NAs in each unit was 19.8 and 6.2, respectively [16].

All the nurses assigned to the included units were recruited, excluding only the frontline nurse managers of these units who were rarely expected to work with NAs. An earlier study reported that the stage of socialization at which the values and norms of an organization are acquired is approximately 6 months after employment [27]. It may have taken 6 months for NAs to be influenced by nurses; therefore, NAs who had worked in the unit for >6 months were targeted.

#### Data collection

Figure 1 presents the flowchart of participant recruitment. Data were collected from July to September 2018 by sending research requests to 182 hospitals randomly selected from Japan. We provided written explanation to the directors of the nursing departments of hospitals with at least one integrated community care unit requesting their participation. A survey was conducted at each

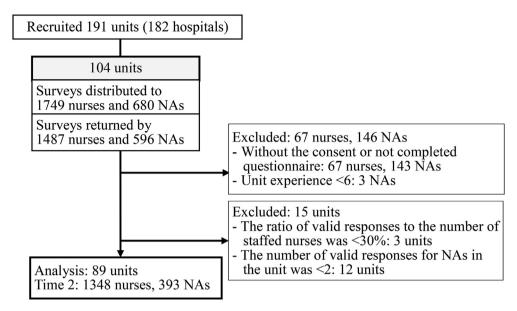


Figure 1. Participant Recruitment Flowchart.

hospital wherein each unit provided their consent and the units of the hospitals willing to participate were identified. Frontline nurse managers distributed the questionnaires to all nurses and NAs in their units. Collection boxes were placed in the units for 2 weeks, and the participants were instructed to seal their completed anonymous questionnaires in the unmarked opaque security envelopes provided and place the sealed envelopes in the collection boxes, which were returned to the researcher without checking the collection status. Overall, 1,787 nurses and 596 NAs from 104 units responded to the survey.

Inclusion criteria were participant consent to research and at least 6 months of unit experience for the NAs. The study excluded 67 nurses and 143 NAs with no research consent or with blank responses and 3 NAs with <6 months of experience. Nurses were treated as a unit-level variable. In order to ensure unit representativeness, we excluded three units with <30% valid responses from the number of nurses in each unit after checking participation. In addition, 12 units with <2 valid responses were excluded to assure variance in each unit for NAs. We assessed 1348 nurses and 393 NAs from 89 units for the final analysis.

#### Measurements

Nurses' expectations of the role of NAs and the NAs' perceptions of their role

Nurses' expectations from NAs and NAs' perceptions of their own role were measured using a perception scale for the role of NAs [28]. The scale comprises 16 items with the following four subscales: "improving patients' abilities through daily care," "caring for various patients using broad perspectives," "facilitating coordination and cooperation among team members," and "increasing the amount of information on patients among team members." We asked the nurses the following introductory question: "Do you expect NAs to take on this role in your unit?" For NAs, we provided the following introductory question: "Do you think the nurses in your unit expect you to take on each role?" The participants rated each item on a 5-point Likert scale from XX to XX. Cronbach's alpha coefficients of the subscales were 0.78-0.81 for nurses and 0.67–0.84 for NAs. As per the method approved by the author of the scale, the sum of the mean scores for each subscale was calculated and used as the NA role perception score (range: 5–20).

The indicators for evaluating the validity of the aggregation of nurses' expectations from NAs as a unit-level variable are as follows: ICC1 (intraclass correlation), 0.11; ICC2 (reliability of the means), 0.68; and  $r_{\rm wg}$  (measure of agreement within units), 0.93 [31]. We calculated the average of the nurses' scores in each unit, which was representative of the unit-level variable. A higher scale score was interpreted as a higher understanding of the NA's roles at the unit level and higher expectations for NAs in their own unit.

NAs information-sharing behaviors with nurses

We operationally defined information-sharing behaviors as verbal behaviors, including expressing, asking, linguistic response, and feedback. To assess the expressing and asking aspects of information-sharing, a subscale of a communication audit developed for Japanese care facilities was used [29], which comprised five items (e.g., information on patient condition). The participants were asked, "On average, how often do you express the following items to nurses?" for expressing and "On average, how often do you ask nurses for the following items?" for asking to evaluate the behavior toward the entire unit. Responses were rated on a 5-point Likert scale from 1 (never) to 5 (always).

To measure linguistic responses, the "linguistic response to the conversation" subscale of the revised version of the Listening Skills Scales was used [30]. Participants were presented with the following sentence: "Please choose the statement that best applies to your behavior when interacting with a nurse." This scale comprises seven items, e.g., not only listening but sometimes telling the other person what you thought or felt. Responses were rated on a 5-point Likert scale, with responses ranging from 1 (absolutely inappropriate) to 5 (absolutely appropriate).

The participants were asked how often they provided feedback to nurses regarding the information they received. The scale was developed in an earlier study on nurses and its reliability ( $\alpha$ =0.91) and content validity have been confirmed [15]. This feedback included the value of the information they received from nurses in terms of its validity; the importance of the information; and the possibility, result, and effects of the utilization of this information. The participants were asked "On average, how often do you provide feedback regarding the following items to nurses if you received any information from nurses?" This scale comprises five items (e.g., telling nurses that the information is important for the NA's job).

The responses were rated on a 5-point Likert scale from 1 (never) to 5 (always).

Cronbach's alpha coefficients for the information-sharing behaviors of telling, asking, linguistic response, and feedback were 0.89, 0.88, 0.90, and 0.93, respectively. We calculated the mean score of each of the four scales and used each for analysis. Higher scale scores are interpreted as higher frequency of each behavior.

Unit- and individual-level characteristics of the participants

Frontline nurse managers were asked about the number of nurses and NAs in their units. We calculated the ratio of NAs to nurses in the units. The greater the ratio of NAs to nurses, the more likely NAs were assumed to share information with nurses. Hence, we adopted the staff ratio as the unit-level control variable. Nurses and NAs were individually asked about their age, gender, marital status, employment status (permanent or part-time), and years of experience working at the hospital. NAs were also asked whether they were certified care workers. From the list of NAs' individual characteristics, we adopted employment status, hospital experience, and qualification of certified care workers as individual-level control variables, which were expected to be related to NAs' information-sharing behaviors toward nurses.

#### Ethical considerations

All participants were informed regarding the study purpose, methods, voluntary nature of participation, and privacy protections. We only analyzed the data of participants who provided consent. The unit identification given to each questionnaire was used only to connect each case between nurses and NAs. This study was approved by the Institutional Review Board of the Tokyo University, Approval no. 11582.

#### Statistical analyses

To examine how much of the overall variance in the dependent variables could be explained by the interclass variance, the ICCs were calculated using the null model. The ICCs for each dependent variable were as follows: 15.2% for expressing, 17.1% for asking, 3.1% for linguistic response, and 4.0% for feedback. Although the ICC typically ranges between 5.0% and 20.0% [31] and the ICC of the linguistic response and feedback were <5.0%, we adapted hierarchical linear modeling for all dependent variables as this study aimed to examine the effects of unit-level variables on individuals.

A random intercept model wherein the variance was allowed only in the intercept of each unit was used to analyze NAs' information-sharing behaviors as the dependent variable, and the restricted maximum likelihood method was used for estimation. Referring to methodological studies, we tested for cross-level mediation (2-1-1 model) [32,33]. We presented the proposed analytical model in Figure 2. First, we entered the nurses' expectations from NAs as a unit-level independent variable (Model 1). Second, we entered variables using Model 1 into Model 2, in which the individual NAs' role perception is the dependent variable. Third, we added individual NAs' role perceptions to Model 1 as a mediator variable (Model 3). Finally, we used bootstrapping with 20,000 Monte Carlo replications to examine the multilevel mediation effect [34]. Statistical analysis was performed using the "Ime4" package [35] in R Studio version 3.5.1 at a significance level of 5.0%. Monte Carlo confidence intervals (CIs) were calculated using the R web utility developed by Selig et al. [36].

#### Results

Participant data

Table 1 presents the demographic data of the participants. Means (standard deviations) for the four information-sharing behaviors of NAs were as follows: 3.48 (0.89) for expressing, 3.24 (0.77) for asking, 3.61 (0.65) for linguistic response, and 3.18 (0.87) for feedback (Table 2).

Relationship between nurses' expectations from NAs and the frequency of individual NAs' information-sharing behaviors with nurses

There was a statistically significant relationship between the unit-level nurses' expectations from NAs and the frequency of the following NA information-sharing behaviors: asking (Model 1b,  $\gamma_{02} = 0.14$ , p = .008) and linguistic response (Model 1c,  $\gamma_{02} = 0.08$ , p = .038). In contrast, expressing (Model 1a) and feedback (Model 1d) were not affected (Table 3).

Mediating effects of individual NAs' role perceptions

We investigated the mediating effects of the NAs' role perceptions on the abovementioned relationship (Table 3). Unit-level nurses' expectations from NAs correlated with the individual NA's role perceptions (Model 2,  $\gamma_{02}=0.69$ , p<.001). Furthermore, each individual NA's role perceptions correlated with the following two information-sharing behaviors: asking (Model 3b,  $\gamma_{40}=0.11$ , p<.001) and linguistic response (Model 3c,  $\gamma_{40}=0.08$ , p<.001); nurses' expectations from NAs no longer had a significant effect on individual NA's information-sharing. The 95% CIs calculated by

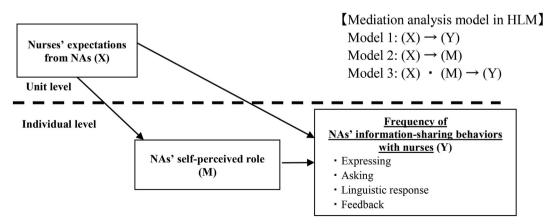


Figure 2. Proposed Analytical Model.

Table 1 Participant Characteristics.

Variables	Categories	Nurses	NAs
		(n = 1348)	(n = 393)
Gender <sup>a</sup>	Women	1228 (91.1)	336 (85.5)
	Men	80 (5.9)	31 (7.9)
	Missing	40 (3.0)	26 (6.6)
Marital status	Single	413 (30.6)	94 (23.9)
	Married	731 (54.2)	193 (49.1)
	Divorce or widowed	135 (10.0)	74 (18.8)
	Missing	69 (5.2)	32 (8.2)
Employment status	Permanent staff	1208 (89.6)	257 (65.4)
Position	Assistant nurse manager	140 (10.4)	_
Nurse qualification	Registered nurse	1196 (88.7)	_
•	Assistant nurse (licensed practical nurse)	152 (11.3)	_
NA qualification	Certified care worker	_ ` `	135 (34.4)
•	No qualifications	_	258 (65.6)

Note: an (%), NAs: Nursing Assistants.

 Table 2 Descriptive Statistics and Intercorrelations of the Individual-Level Variables.

Individual level	Mean	SD	1	2	3	4	5
NAs (n = 393)							
1 Hospital experience (years)	8.06	7.00					
2 NAs' perceptions of their role	13.76	2.88	.12**				
NAs' information-sharing behaviors							
3 Expressing	3.48	0.89	.04	.40***			
4 Asking	3.24	0.77	.12*	.46***	.67***		
5 Linguistic response	3.61	0.65	.13*	.36***	.42***	.50***	
6 Feedback	3.18	0.87	.03	.43***	.51***	.56***	.48***
Nurses $(n = 1348)$							
Nurses' expectations from NAs	14.08	2.26					

Note: \*p < .05; \*\*p < .01; \*\*\*p < .001. NAs: Nursing Assistants.

**Table 3** Results of the Multilevel Mediation Analyses Using Hierarchical Linear Modeling.

Variables	NAs' self-perceived roles			NA's info	rmation-sha	ring behavio	rs		
_	_	Expressing Asking			Linguistic response		Feedback		
	Model 2	Model 1a	Model 3a	Model 1b	Model 3b	Model 1c	Model 3c	Model 1d	Model 3d
Intercept (γ <sub>00</sub> )	12.38***	2.90***	3.05***	2.93***	3.07***	3.53***	3.64***	2.94***	3.12***
Unit-level control variable									
Staff ratios <sup>a</sup> $(\gamma_{01})$	1.96	0.96**	0.72*	0.27	0.06	-0.18	-0.35	0.31	0.07
Individual-level control variable									
Care worker qualification $(\gamma_{10})$	-0.30	0.01	0.03	-0.02	0.01	-0.02	0.00	-0.13	-0.10
Permanent staff <sup>c</sup> ( $\gamma_{20}$ )	0.41	0.24*	0.20*	0.17	0.13	0.09	0.06	0.18	0.13
Hospital experience ( $\gamma_{30}$ )	0.05**	0.00	0.00	0.01*	0.01	0.01**	0.01	0.00	0.00
Unit-level independent variable									
Nurses' expectations of the NA role ( $\gamma_{02}$ )	0.69***	0.09	0.02	0.14**	0.06	0.08*	0.04	0.08	-0.01
Individual-level mediating variable									
NAs' self-perceived role ( $\gamma_{40}$ )			0.11***		0.11***		0.08***		0.13***
Random effect									
Variance of Level-1 residual	7.00	0.65	0.61	0.50	0.44	0.41	0.36	0.72	0.62
Variance of Level-2 (intercept)	0.68	0.07	0.02	0.07	0.04	0.00	0.00	0.03	0.01
ICC	.09	.10	.03	.13	.08	.01	.00	.04	.02

Note: \*p < .05; \*\*p < .01; \*\*\*p < .01. NAs: Nursing Assistants.  $\gamma$  is the estimated coefficient for calculating the outcome. Entries presented are estimations of the hierarchical linear modeling regression coefficients.

The ICC of the null model for a mediating variable (NAs' self-perceived role) was 0.13, and those for the dependent variables (expressing, asking, linguistic response, and feedback) were 0.15, 0.17, 0.03, and 0.04, respectively. The nurses' expectations of the NA role at Level-2 and the NA s' self-perceived role at Level-1 were grand-mean

[Model 1]  $Y_{ij} = (\gamma_{00} + \gamma_{01} * Staff \ ratios _j + \gamma_{02} * Nurses' \ expectations of the NA role _j + u_{0j}) + \gamma_{10} * Care \ worker \ qualification_{ij} + \gamma_{20} * Permanent \ staff _{ij} + \gamma_{30} * Hospital \ experience$ 

[Model 2]  $M_{ij} = (\gamma_{00} + \gamma_{01} * Staff ratios_j + \gamma_{02} * Nurses' expectations of the NA role_j + u_{0j}) + \gamma_{10} * Care worker qualification_{ij} + \gamma_{20} * Permanent staff_{ij} + \gamma_{30} * Hospital experience$ 

 $_{ij} + r_{ij}$ . [Model 3]  $Y_{ij} = (\gamma_{00} + \gamma_{01} * Staff ratios_j + \gamma_{02} * Nurses' expectations of the NA role_j + u_{0j}) + \gamma_{10} * Care worker qualification_{ij} + \gamma_{20} * Permanent staff_{ij} + \gamma_{30} * Hospital experience$  $_{ij} + \gamma_{40}$  \* NAs' self-perceived role  $_{ij} + r_{ij}$ .

 $r_{ij}$ : The Level-1 error term,  $u_{0j}$ : The Level-2 error term. <sup>a</sup> The ratio of NAs to nurses in units.

 $<sup>^{</sup>b}\ \, ref=no.$ 

 $<sup>^{</sup>c} \ ref = part time.$ 

bootstrapping using Monte Carlo replication did not include zero; indirect effects were 0.08 (95% CI: 0.03–0.12) for asking and 0.05 (95% CI: 0.02–0.09) for linguistic response. The NAs' expressing and feedback behaviors correlated with their role perceptions (Model 3a,  $\gamma_{40} = 0.11$ , P < .001 and Model 3d,  $\gamma_{40} = 0.13$ , P < .001, respectively).

#### Discussion

To the best of our knowledge, this is the first study to quantitatively investigate the relationship between unit-level nurses' expectations from NAs and the frequency of NAs' informationsharing behaviors with nurses. In addition, we proposed a mechanism to explain how each individual NA's perceptions of their role mediate the relationship.

Unit-level nurses' expectations from NAs correlated with the frequency of NAs' information-sharing behaviors with nurses and mediating effect of NAs' self-perceived roles

We found that the frequencies of NAs' asking and linguistic response behaviors were high in units where nurses had high expectations from NAs. Previous qualitative studies have shown that understanding the roles of other personnel in interoccupational collaborations is essential for effective communication [6]. We quantitatively evaluated the effects of understanding their role on concrete information-sharing behaviors. The hypothesis was constructed on the basis of role theory and supported by quantitatively proving that the NAs' self-perceived roles fully mediated these relationships. In units where nurses understood NA roles and had high expectations, the NAs may expand their own role perceptions regarding patient care, which may encourage them to engage in information-sharing behaviors, such as asking and linguistic response. In terms of helping NAs understand their role on the unit, our results suggest that the understanding of the NA roles by unit nurses can change the individual NA role perception and elicit better communication behaviors. Moreover, a previous study found that some unit-level nurses understood the NA role, whereas others did not [2,14]. The results of this study indicated that an understanding of the NA role among all nurses on the units would facilitate communication with NAs, allowing for more informed clinical decision making and better care coordination.

In another study, nurses with positive perceptions of NA roles engaged in information-sharing with NAs [15]. Thus, the nurses' high expectations from NAs at the unit level indicate that nurses frequently share information with NAs, which may influence the NA's role perceptions and information-sharing behaviors. Another previous qualitative study reported that during medical record review sessions between nurses and NAs as they start working together, nurses play a directing and coordinating role, whereas NAs share their questions and ask for clarifications [18]. This indicates that the asking and linguistic response behaviors of NAs are important for efficient teamwork. Further, as NAs daily interact with and provide care to patients directly, the asking and linguistic responses of NAs will provide nurses with valuable information, resulting in safe, appropriate, and tailored patient care. This study highlighted the importance of nurses understanding the role of NAs in the unit environment for NAs to engage in asking and linguistic response behaviors.

Relationship between NAs' role perceptions and NA expressing and feedback to nurses

The frequencies of NAs' expressing and feedback to nurses did not correlate with unit-level nurses' expectations from NAs. This finding differed from our hypothesis, but the difference is understandable. Regarding NAs' expressing, an earlier study reported that NAs promptly share patient information with nurses when NAs strongly feel like a part of the nursing team [11]. In other words, NAs may express themselves to nurses if they see themselves as a part of the nursing team, regardless of the nurses' expectation of NAs. Another study reported that although nurses and NAs recognize the importance of information-sharing between the two groups of healthcare professionals, a heavy workload in a healthcare unit hinders this sharing [2]. Therefore, increasing the role perceptions of individual NAs may enable NAs to communicate important patient information to nurses even in a busy environment. However, only some behaviors of NAs will not result in effective information-sharing.

In terms of NAs' feedback, NAs convey the value and usefulness of information received from nurses as perceived by the NAs. It can be assumed that NAs evaluate the information they receive from nurses when required; therefore, NAs' feedback highly depends on their individual intention to establish a relationship with nurses. A previous study found that NAs who are aware of their role in the unit engaged in more discussions with nurses regarding patient care [37]. When NAs are strongly aware of their role, the frequency of their feedback to nurses is expected to increase.

Clarifying the roles of nurses and NAs alone often leads to "it's not my job" syndrome, which hinders true collaboration [38]. Nurses and nurse managers must understand that NAs are members of the nursing team that is involved in patient care and not just individuals who simply perform tasks. Moreover, it is necessary to provide encouragement and opportunities for NAs to share their intentions and thoughts regarding patient care with nurses.

Our results suggest that improving unit nurses' understanding of NAs' roles can change NAs' communication behavior. NAs' own role perceptions were associated with their information-sharing behaviors, and the relationship between unit-level nurses' expectations of NAs differed according to the type of information-sharing behavior, indicating a need for both nurses and NAs to increase awareness regarding NAs' roles. NAs are important collaborative partners for nurses in providing quality healthcare with limited resources. A previous study indicated that less communication between nurses and NAs can lead to a lack of leadership in the nursing team [12]. If information-sharing between nurses and NAs increases, nurses can demonstrate better leadership qualities. In addition, when NAs better understand their own roles, nurses can delegate and direct tasks based on shared goals, which may enable a more effective and appropriate provision of nursing care. Future research is needed to develop interventions to increase awareness regarding the role of NAs among nurses and NAs, as well as to identify leadership steps that individual nurses can take to promote collaboration.

#### Limitations

There are some limitations to our study. First, informationsharing by NAs that did not coincide with actual behaviors of NAs may have remained unnoticed because a questionnaire survey was used rather than direct observation. Second, not all nurses in each unit completed the questionnaire; therefore, the unit-level scores may not be sufficiently representative. Third, in this study, nurses included registered nurses and assistant nurses, and NAs included certified care workers and unlicensed NAs; therefore, the differences in the perceptions of the NA role and the frequency of information-sharing behaviors based on their qualifications may have influenced the results. Finally, we captured only one aspect of the communication behavior of NAs (i.e., the frequency of behavior). The elements of communication include frequency of behavior, accuracy of information, and timing [22]. It is necessary to conduct further studies that capture communication from multiple aspects.

#### **Conclusions**

In units where nurses have high expectations from NAs, NAs frequently engaged in asking and linguistic responses with the nurses. Thus, nurses' expectations from NAs were important for improving information-sharing by NAs. Furthermore, the effects of nurses' expectations from NAs were mediated by the NAs' selfperceived roles. Increasing awareness of NA roles by nurses and NAs may be an effective educational intervention to improve information-sharing between nurses and NAs.

#### **Conflicts of Interest**

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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#### Research Article

# Dignity and Related Factors in Patients with Cancer: A Cross-Sectional Study



Yu-Chi Li,<sup>a</sup> Yin-Hsun Feng,<sup>b, c</sup> Shu-Ching Ma,<sup>d, e</sup> Hsiu-Hung Wang<sup>a, \*</sup>

- <sup>a</sup> College of Nursing, Kaohsiung Medical University, Taiwan
- <sup>b</sup> Department of Nursing, Chung Hwa University of Medical Technology, Taiwan
- <sup>c</sup> Division of Hematology and Oncology, Department of Internal Medicine, Chi-Mei Medical Center, Taiwan
- <sup>d</sup> Nursing Department, Chi-Mei Medical Center, Taiwan
- <sup>e</sup> Southern Taiwan University of Science and Technology, Taiwan

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#### SUMMARY

*Purpose*: Dignity is a basic human right that is related to psychological distress factors in patients with cancer such as depression and demoralization. Hence, the dignity issue is of great importance to healthcare professionals. The present study aimed to advise healthcare professionals regarding the related distress factors of dignity in patients with cancer by investigating its relationship with patients' demographics, disease characteristics, and psychological distress.

Methods: This was a cross-sectional study design. A convenience sample of 267 patients with cancer from a medical center was recruited into this study. Each patient completed demographics and disease characteristics questionnaires, the Patient Dignity Inventory Mandarin Version, the Demoralization Scale Mandarin Version (DS-MV), and the Patient Health Questionnaire-9 (PHQ-9). Data were analyzed with SPSS 22.0 software.

Results: Dignity was significantly correlated with age, demoralization, and depression. Cancer patients aged 65 or above were more likely to have a lower sense of dignity. In the present study, the sensitivity and specificity of the Patient Dignity Inventory Mandarin Version for demoralization (DS-MV $\geq$ 30) were 84.8% and 79.1% and for depression (PHQ-9 $\geq$ 10) were 73.8% and 70.9% in patients with cancer with an aggregate score of 35 or above.

Conclusions: Dignity is significantly correlated with personal demographic characteristics and psychological distress in patients with cancer. The results provide reference data for healthcare professionals to understand and enable dignity in patients with cancer and aid in the development of methods that promote their dignity.

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#### Introduction

Cancer is a life-threatening disease. The number of patients with cancer worldwide is estimated to be 18.1 million [1], and since 1982, cancer has been the number one cause of death in Taiwan [2]. Patients with cancer experience physical symptoms as well as psychological distress such as fear of relapse, depression,

Yu-Chi Li: https://orcid.org/0000-0002-1467-5290; Yin-Hsun Feng: https://orcid.org/0000-0002-8660-0685; Shu-Ching Ma: https://orcid.org/0000-0003-2128-173X; Hsiu-Hung Wang: https://orcid.org/0000-0001-6055-5401

E-mail address: hhwang@kmu.edu.tw

demoralization, despair, loneliness, loss of autonomy, and fear of becoming a burden to others [3]. Previous research has shown that the psychological distress patients with cancer experience are related to dignity [4,5]. A severe loss of dignity can lead to a desire for early death [3,6].

Dignity is an intrinsic human feature and is related to personal values, freedom, responsibility, and capability [7]. It arises from interpersonal interactions, in which social constructionism plays a role [8]. Dignity can thus be classified as either fundamental or absolute, or personal or relative [9]. Fundamental or absolute dignity is a universal concept, having its roots in human rights, proclaiming that all humans have value regardless of status and situation, and this does not change under any circumstances [9]. Personal or relative dignity, however, is subject to change. It can be affected by

 $<sup>\</sup>ast$  Corresponding author. College of Nursing, Kaohsiung Medical University, No. 100 Shih-Chuan  $1^{\rm st}$  Road, San-Ming District, Kaohsiung, 80708, Taiwan

culture, society, and education; it can also be threatened by a healthcare system or lack thereof [10,11]. Everyone hopes to maintain their dignity in all settings and circumstances, including when they seek medical help at healthcare institutions. Previous studies on patient dignity have pointed out that provision of dignified care is closely related to the patient's sense of dignity [12], although being physically weak or challenged, capabilities of patients with cancer might be impaired, leading to an imbalance between health and human rights. In addition, if healthcare professionals do not pay attention to their needs, patients could feel that their dignity has been violated [12,13]; accordingly, protecting the dignity of patients with cancer is a priority for healthcare professionals.

The dignity of patients with cancer is related to personality and psychological distress [5,13,14]. Depression falls under psychological distress, affecting approximately 45.0% of patients with cancer [15]. Compared with the general public, patients with cancer are three or four times more likely to have depression. In severe cases, they may commit suicide [16,17]. Depression is a mood-related disorder; its diagnostic criteria include sadness or feeling down, loss of enthusiasm or joy for daily activities, and recurrent listlessness almost daily for more than 2 weeks. There may also be accompanying symptoms such as lowered self-esteem, guilt, sleeplessness, change in appetite, inability to focus, changes in activity, and suicidal thoughts [18]. Demoralization is also a common psychological state found in patients with cancer, characterized by a sense of misery and doubts over one's own capability [19].

Characteristics of demoralized patients include feeling incapable, helpless, having a sense of failure, feeling like an outcast, despairing, and even considering giving up [20,21]. A systematic review of 10 studies has shown that 13-18.0% of patients with cancer feel demoralized [22]. Three systematic reviews list the following as some of the demoralization-related factors: poor health, poor control over physical or psychological symptoms, decreased quality of life, unemployment and economic pressure, decreased social skills, singlehood, and social rejection or isolation [22-24]. In addition, compared with depression, demoralization has stronger correlation with suicidal thoughts or behavior [25–27]. These findings highlight that demoralization is indeed significant. As a result, sometime in the last 10 years, demoralization was included in the Diagnostic and Statistical Manual of Mental Disorders (DSM) [20]. Our review of existing literature revealed that the dignity of patients with cancer is almost always discussed alongside demoralization or depression [5,28,29]. The Patient Dignity Inventory (PDI) indicates lower sense of dignity with higher scores [14]. According to previous studies, the dignity of patients with cancer with demoralization and depression were positively significantly correlated [28-31], which means that the higher the sense of low dignity, the higher the level of demoralization and depression in patients with cancer.

However, what do dignity scores really mean to patients with cancer and healthcare professionals, and what is the threshold that indicates that the patient may be demoralized or depressed? Existing literature barely addresses these questions. Building on the literature reviewed, the present study examined the relationship between the dignity of patients with cancer in Taiwan and demoralization and depression; it also focused on the cut-off point pertaining to their dignity.

#### Methods

Study design, setting, and sample

This was a cross-sectional study design and convenience sampling from a medical center in Southern Taiwan. Participants were recruited between June 2016 and February 2017, and the inclusion criteria were (1) having a diagnosis of cancer; (2) being 20 years of

age or greater; (3) being mentally alert, clear; (4) having no history of diagnosis of depression or other psychiatric disorders; (5) being able and willing to provide written informed consent; and (6) being able to express their own opinions and complete the questionnaires. Participants were excluded if (1) they had organic diseases of the brain, as diagnosed by a physician; (2) they were delirious or unconscious; (3) they had depression or other emotional problems; and (4) they were unable to speak and read Mandarin Chinese. This study was approved by the Institutional Review Board of the Chi Mei Medical center, Approval no. 10411-003.

#### Variables and instruments

Demographics and disease characteristics

Participants' demographics included gender, age, marital status, number of children, education, occupation, monthly income, cohabitation status, religious beliefs, tumor site, cancer stage, and disease characteristics.

#### Dignity

The original English version of the Patient Dignity Inventory (PDI) was developed by Chochinov et al. in 2008. It is mainly used to measure the degree of dignity in patients with cancer over the past few days [32]. This study used the Mandarin Version of Patient Dignity Inventory (PDI-MV) for measuring dignity. The PDI-MV was translated from the original English version by Li et al. in 2018 [28]. It is a 25-item self-report questionnaire, with each item rated on a 5-point Likert scale (from 1 = not a problem to 5 = an overwhelming problem). Higher scores indicate lower levels of dignity. Cronbach's  $\alpha$  coefficient for the PDI-MV was .95. In construct and criterion-related validity, the PDI-MV significantly correlated with the Mandarin Version of the Demoralization Scale (DS-MV) (r=.58, p<.010), with the Patient Health Questionnaire-9 (PHQ-9) (r=.54, p<.010), and with the Rosenberg Self-Esteem Scale (RSES) (r=-.30, p<.010) [28]. In this study, Cronbach's  $\alpha$  for the PDI-MV was .95.

#### Demoralization

The original English version of the Demoralization Scale (DS) was developed by Kissane et al. in 2004. It was used to assess the levels of demoralization over the past 2 weeks [33]. This study used the Mandarin Version of Demoralization Scale (DS-MV) for measuring demoralization. The DS-MV was translated from the original English version by Hung et al. in 2010 [34]. It is a 24-item self-report questionnaire, with each item rated on a 5-point Likert scale (from 0 = strongly disagree to 4 = strongly agree). Scores higher than 30 indicated significant demoralization [34]. Cronbach's  $\alpha$  coefficient for the DS-MV was .90. In construct and criterion-related validity, the DS-MV significantly correlated with the Beck Hopelessness Scale (BHS) (r = .66, p < .001), with the PHQ-9 (r = .65, p < .001), and with the McGill Quality of Life Scale-Taiwan (MQOL-T) (r =  $-.68,\,p$  < .001) [34,35]. In this study, Cronbach's  $\alpha$  for the DS-MV was .85.

#### Depression

The original English version of the PHQ-9 was developed by Kroenke et al. in 2001. It was used to assess the degree of depression over the past 2 weeks [36]. This study used the Mandarin Version of PHQ-9 for measuring depression. The Mandarin version of PHQ-9 was translated from the original English version by Liu et al. in 2011 [37]. It is a 9-item self-report questionnaire; with each item rated on a 4-point Likert scale (from 0 = not at all to 3 = almost every day). The PHQ-9 score higher than 10 had a sensitivity of 86.0% and a specificity of 94.0% for major depression. Cronbach's  $\alpha$  coefficient for the PHQ-9 was .80 [37]. In construct and criterion-related validity, the PHQ-9 significantly correlated with the

Patient Health Questionnaire-15 (PHQ-15) (r=.65, p<.010), with the World Health Organization-five Well-Being Index (WHO-5) (r=-.38, p<.050), and with the short form of the Beck Depression Inventory-13 (BDI-13) (r=.70, p<.010) [38]. The PHQ-9 used in the study had a Mandarin version with good reliability and validity. In this study, Cronbach's  $\alpha$  for the PHQ-9 was .96.

#### Data collection

The study protocol was approved by the Institutional Review Board (IRB number: 10411-003). Informed consent and confidentiality were obtained from all the participants. Consent letters for the use of the PDI-MV, DS-MV, and PHQ-9 were obtained for this study. The study obtained the permission from a medical center of Southern Taiwan to contact the participants and conduct the study. The participants were recruited through a face-to-face interview by a research assistant using the self-report questionnaires with standard instructions. A research assistant, who possessed a license to practice nursing and had been the deputy head nurse in the hematology and oncology division for three years, was trained to administer the questionnaires and ensured rigor during administration and data retrieval from the medical charts. The research assistant checked the list of newly admitted patients with cancer in the inpatient information system every day, screened those meeting enrollment criteria, and confirmed with the attending physician. Subsequently, the research assistant went to the ward to recruit patient one by one and face-to-face based on the list of participants who were eligible for inclusion in this study. The research assistant explained the purpose and procedure of the study to patient, and obtained patient's informed consent in writing, after which the questionnaire survey was conducted. The research assistant used easy-tounderstand words, and appropriate volume, speed, and tone to explain the study objectives and processes for the patients. The explanation method of the research assistant was appropriate to the patient's educational level and cultural background, and allowed sufficient time for the patients to consider the pros and cons of participating in the study. If the patient was unable to select the questionnaire options, the research assistant would read out the questions one-by-one and complete the scale based on the patient's answers. Patient autonomy was respected during the completion of the questionnaire and patients were allowed to withdraw or stop at any time during the study. The research assistant was present throughout the administration of the questionnaires to answer any questions that the participant had. Appropriate support, which included support from the attending physician, was provided in a timely manner if the patient experienced emotional distress.

#### Data analysis

All statistical analyses were performed using SPSS version 22.0 (IBM Corporation, Armonk, NY, USA). Descriptive statistics were used to present variable distributions, which included frequencies, scores, percentages, means, and standard deviations. Inferential statistics were used for the correlation analysis between the independent variables, such as sociodemographic and clinical characteristics, and the dependent variable, a sense of dignity. These tests included an independent t-test, one-way analysis of variance, Pearson's correlation, and receiver operating characteristic (ROC) curve.

#### Results

#### Participant's demographics

A total of 267 participants were included in the study. Demographic data and disease characteristics of the participants

are shown in Table 1. The mean of PDI-MV total score was 35.69 (range = 25–93). Regarding demographic and clinical characteristics, the following groups had the mean of PDI-MV total scores higher than the mean of the whole sample: patients who aged 65 years or older (M = 37.65, t = 3.13, p = .002), patients who were demoralization (M = 47.12, t = 8.93, p < .001) and patients who had depression (M = 43.66, t = 5.57, p < .001), there were statistically significant difference between the groups. While women (M = 36.02), single patients (M = 36.26), patients who had children (M = 35.71), had a college level or higher education (M = 38.58), were employed (M = 37.10), had a monthly income more than NTD 40,000 (M = 38.58), lived with family (M = 35.79), had religious beliefs (M = 35.91), had breast cancer (M = 37.84), had leukemia

**Table 1** Participants Characteristics and Bivariate Correlations with Dignity (N = 267).

			, , ,	I = 267).
Variable	n (%)	M ± SD	t/F/r	P
Dignity (PDI-MV) (mean ± SD = 35.69	± 12.30, ran	ge 25-93)		
Gender		,	-0.42	.674
Men (reference)	137 (51.3)	$35.38 \pm 13.02$		
Women	, ,	36.02 ± 11.54		
Age (mean $\pm$ SD = 57.43 $\pm$ 11.51, range	,	_	.14	.021
21–87)				
≥65 (reference)	153 (57.3)	$37.65 \pm 12.85$	3.13	.002
<65		$33.06 \pm 11.05$		
Marital status	, ,		-0.45	.655
Married (reference)	198 (74.2)	$35.49 \pm 12.32$		
Single		36.26 ± 12.30		
Children	, ,	_	0.01	.993
Yes (reference)	141 (52.8)	$35.71 \pm 12.62$		
No		$35.66 \pm 11.96$		
Education	, ,		1.97	.050
College or above (reference)	55 (20.6)	$38.58 \pm 14.43$		
Below college		$34.94 \pm 11.60$		
Occupation	( ,		0.86	.392
Yes (reference)	70 (25.5)	$37.10 \pm 13.96$		
No		$35.21 \pm 11.68$		
Monthly income (NTD)	107 (7110)	30.21 ± 11.00	1.07	.293
>40000 (reference)	31 (11.6)	$38.58 \pm 16.53$		
≤40000		$35.31 \pm 11.62$		
Cohabitation status	250 (00.1)	30.31 ± 11.02	0.39	.698
Live with family (reference)	240 (89.9)	35.79 ± 12.25	0.55	.050
Alone		$34.81 \pm 12.96$		
Religious belief	27 (10.1)	34.01 <u>1</u> 12.30	0.67	.501
Yes (reference)	223 (83.5)	35.91 ± 12.62	0.07	.501
No		$34.55 \pm 10.58$		
Tumor site	TT (10.5)	34.33 ± 10.30	2.00	.812
Breast	38 (14 2)	37.84 ± 12.90	2.00	.012
Reproductive	, ,	$35.42 \pm 9.21$		
Leukemia		$36.50 \pm 14.77$		
Digestive tract		$34.67 \pm 11.96$		
Lung		$31.23 \pm 6.89$		
Urology		$32.75 \pm 7.71$		
Head and neck		$42.79 \pm 17.60$		
Others		$34.50 \pm 15.02$		
	4 (3.4)	34.30 ± 13.02	-0.07	.941
Cancer stage	79 (20.2)	25.60 . 12.12	-0.07	.541
I-II stage (reference)		$35.60 \pm 13.12$ $35.72 \pm 11.98$		
III-IV stage Disease characteristics	169 (70.6)	33.72 ± 11.96	0.68	.497
	170 (62.7)	26.00 . 12.76	0.08	.497
Initial diagnosis (reference)		$36.08 \pm 12.76$ $35.01 \pm 11.49$		
Recurrence	97 (30.3)	35.01 ± 11.49		. 001
Demoralization (DS-MV) (mean $\pm$ SD =			.55	<.001
$23.84 \pm 10.37$ , range 0–68)	CC (247)	47.10 10.00	0.00	001
Scoring ≥30 (reference)		$47.12 \pm 12.69$	8.93	<.001
Scoring <30	201 (75.3)	$31.94 \pm 9.57$	40	. 001
Depression (PHQ-9) (mean $\pm$ SD = 5.65			.49	<.001
± 4.52, range 0–24)	CD (DD C)	40.00 40.50		001
Scoring ≥10 (reference)		$43.66 \pm 12.79$	5.5/	<.001
Scoring <10	203 (70.8)	33.28 ± 11.10		

Note. Means and SDs refer to scores on the Patient Dignity Inventory Mandarin version. NTD = new Taiwan dollars; PDI-MV = Patient Dignity Inventory Mandarin version; DS-MV = Demoralization Scale Mandarin version; PHQ-9 = Patient Health Questionnaire-9; M = mean; SD = standard deviation.

(M=36.50), had head and neck cancer (M=42.79), had stage III–IV tumors (M=35.72), patients for whom it was the initial diagnosis (M=36.08), there were no statistically significant difference between the groups (Table 1).

#### Bivariate correlations with dignity

Bivariate correlations were used to examine the relationship between ratio variables and dignity. Significant correlations were found between dignity and age (r=.14, p=.021), demoralization (r=.55, p<.001), and depression (r=.49, p<.001) (Table 1). Specifically, patients aged 65 or older having demoralization and depression were more likely to have lower dignity.

#### Mean item scores of the PDI-MV

The PDI-MV items with the highest mean scores were item 8 "worrying about my future," (M = 1.78, SD = 0.97), item 3 "experiencing physically distressing symptoms," (M = 1.73, SD = 0.83), item 7 "feeling uncertain about my illness and treatment" (M = 1.67, SD = 0.81), and item 18 "feeling that I am a burden to others" (M = 1.67, SD = 0.82) (Table 2).

#### Cut-off point of the PDI-MV

Figures 1 and 2 show the receiver operating characteristic (ROC) curve and area under the curve (AUC) of the PDI-MV (total score) for detecting the presence of demoralization and depression. The results show that when the best cut-off point of PDI-MV was at 36, the AUC, sensitivity, and specificity for demoralization (DS-MV  $\geq$  30) were .86, 84.8%, and 79.1%, respectively. When the best cut-off point was 35, the AUC, sensitivity, and specificity for depression (PHQ-9  $\geq$  10) were .77, 73.8%, and 70.9%, respectively (Table 3).

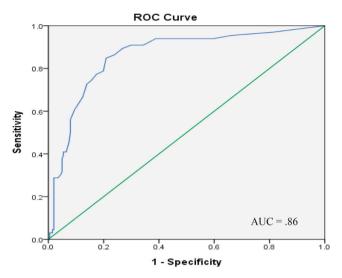


Figure 1. The Receiver Operating Characteristics (ROC) Curves of PDI-MV for Demoralization.

#### Discussion

This study examined the dignity of patients with cancer in Taiwan and related psychological distress factors. We found that the higher the PDI-MV aggregate score, the lower the sense of dignity and the greater the problem—the PDI-MV average aggregate score was 35.69 and the average itemized score was 1.43. These scores are higher than those obtained in a study conducted in Italy (M=21.01) [29] and lower than those obtained in studies conducted in Germany (M=51.60) [14], Spain (M=38.80) [39], and Iran (average itemized score = 1.94) [40]. The patients with cancer studied in those studies were similar to the present study's participants in terms of the disease's basic attributes, type, stage, and treatment methods. Notably, previous studies have pointed out that when the Patient Dignity Inventory itemized scores were

**Table 2** The Item Mean Scores of Patient Dignity Inventory Mandarin Version (PDI-MV) (N = 267).

Number	Item	$M \pm SD$	Rank
1	Not being able to carry out tasks associated with daily living	1.26 ± 0.69	21
2	Not being able to attend to my bodily functions independently	$1.20 \pm 0.59$	22
3	Experiencing physically distressing symptoms	$1.73 \pm 0.83$	2
4	Feeling that how I look to others has changed significantly	$1.40 \pm 0.68$	11
5	Feeling depressed	$1.59 \pm 0.80$	9
6	Feeling anxious	$1.62 \pm 0.82$	6
7	Feeling uncertain about my illness and treatment	$1.67 \pm 0.81$	3
8	Worrying about my future	$1.78 \pm 0.97$	1
9	Not being able to think clearly	$1.34 \pm 0.67$	17
10	Not being able to continue with my usual routines	$1.43 \pm 0.76$	10
11	Feeling like I am no longer who I was	$1.60 \pm 0.83$	8
12	Not feeling worthwhile or valued	$1.37 \pm 0.76$	15
13	Not being able to carry out important roles	$1.39 \pm 0.68$	14
14	Feeling that life no longer has meaning or purpose	$1.36 \pm 0.70$	16
15	Feeling that I have not made a meaningful and lasting contribution during my lifetime	$1.29 \pm 0.68$	20
16	Feeling I have unfinished business	$1.61 \pm 0.86$	7
17	Concern that my spiritual life is not meaningful	$1.40 \pm 0.74$	12
18	Feeling that I am a burden to others	$1.67 \pm 0.82$	4
19	Feeling that I don't have control over my life	$1.63 \pm 0.93$	5
20	Feeling that my illness and care needs have reduced my privacy	$1.33 \pm 0.73$	18
21	Not feeling supported by my community of friends and family	$1.06 \pm 0.39$	24
22	Not feeling supported by my health care providers	$1.05 \pm 0.33$	25
23	Feeling like I am no longer able to mentally fight the challenges of my illness	$1.40 \pm 0.67$	13
24	Not being able to accept the way things are	$1.33 \pm 0.60$	19
25	Not being treated with respect or understanding by others	$1.19 \pm 0.50$	23
Total score		$35.69 \pm 12.3$	
Range		25-93	

Note. Used with permission from Li et al. [28].

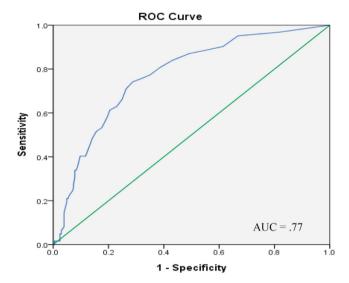


Figure 2. The Receiver Operating Characteristics (ROC) Curves of PDI-MV for Depression.

greater than 3, this indicates that the patient has dignity-related issues [41]. In the present study, none of the itemized scores were greater than 3, but the aggregate score showed a significant correlation with demoralization and depression. Therefore, we recommend looking at aggregate scores along with itemized scores to understand the overall state of patient dignity, and this should minimize the possibility of psychological distress in patients from being overlooked. Dignity scores might differ across countries due to varying cultural backgrounds, social structures, and contextual expression [42,43]; nonetheless, it can be concluded from previous studies that dignity-related issues in patients with cancer have garnered much attention.

The present study also found that dignity and age were significantly correlated, which is in line with the findings of the studies conducted in Italy [29] and Iran [40]. In the present study, two groups were observed: patients with cancer aged below and above 65. We found that patients with cancer aged above 65 had significant dignity-related issues. Previous studies have mentioned that elderly people feel that they have nothing to contribute and are not valued if they have cancer or any other disease or weakness, so they feel a greater lack of recognition and even being ignored, with these self-perceived behaviors posing the greatest threats to dignity in elderly patients with cancer [44]. It is therefore crucial to maintain the dignity of elderly patients with cancer in healthcare settings, be it through the healthcare professionals paying attention to their language, attitude, and behaviors, or the environment and facilities. The key is to ensure that the elderly patients with cancer feel valued and recognized and see their life as meaningful.

In the present study, the top three PDI-MV questions with the highest itemized scores were Q8 (worried about the future), Q3 (experiencing physical discomfort), and Q7 (feeling uncertain about the disease and treatment). The results are similar to those of the studies conducted in Germany [31], Spain [39], and Italy [29]. As medicine continues to advance, the odds of cancer survival are also

increasing. Having cancer is no longer considered a hopeless and fatal situation. That said, patients with cancer will still feel anxious and uncertain about their future; the pain they experience is not limited to the physiological condition. Accordingly, we recommend that healthcare professionals share the disease progression and treatment process with the patients in detail and also encourage them to express their views about the future. This will help reduce their uncertainty and psychological distress and boost their hopes for the future.

Furthermore, the present study came to a similar conclusion as have most studies on dignity, demoralization, and depression: the dignity of patients with cancer is significantly correlated with demoralization and depression [29,30]; it even went a step further, discovering that at a threshold of 36, the sensitivity and specificity for demoralization (DS-MV  $\geq$  30) were 84.8% and 79.1%, respectively, and when the threshold was 35, the sensitivity and specificity for depression (PHQ-9  $\geq$  10) were 73.8% and 70.9%, respectively. Previous studies lack in-depth analyses on the dignity threshold scores for demoralization and depression, and therefore, no comparison can be made; moreover, these studies merely point out that patients suffer from dignity-related issues when each itemized score is equal to or greater than 3 (a problem) [41] and do not analyze the aggregate score. Although the PDI-MV cut-off point of 35 and 36 in the present study did not reach the "a problem to overwhelming problem" level (>75-125), these cut-off points had higher sensitivity and specificity for depression and demoralization in patients with cancer in Taiwan.

This is an important finding. We hope that the PDI-MV can be used to detect early signs of dignity-related issues in patients with cancer and also be applied as a preventive screening tool for psychological distress. For healthcare professionals, diagnosing demoralization or depression is challenging, especially because the side effects of cancer treatments are similar to the symptoms of demoralization and depression. We recommend that healthcare professionals pay more attention toward patients with cancer with a PDI-MV aggregate score of 35 or more as they may have developed psychological distress due to dignity-related issues (such as demoralization or depression); implementing additional psychological assessments or counseling for such patients will allow healthcare professionals to better understand their psychological state and offer appropriate treatment and care.

Negative associations such as perceiving cancer as fatal and equating growing old with nearing the end of life, can directly threaten patient dignity. If healthcare professionals share such negative attitudes, they will not be able to provide dignified care to patients. Therefore, the dignity of patients with cancer should receive greater educational attention and social recognition in the healthcare sector. Healthcare professionals have to advocate for a dignified healthcare environment. This applies to their language, attitude, and behaviors, as well as medical and care facilities.

#### Limitation

This study had several limitations. First, a cross-sectional design was used, making causal inferences impossible to determine. Second, although an effective sample size was used for the analysis, there were insufficient samples for understanding and

**Table 3** The Cut-off Point of Patient Dignity Inventory Mandarin Version (PDI-MV) for Demoralization and Depression.

Item	AUC	Cut-off points	Sensitivity	Specificity	SE	р	95% CI	Cronbach's α
Demoralization (DS-MV $\geq$ 30)	.86	36	84.8	79.1	0.03	<.001	0.81-0.92	.91
Depression (PHQ-9 ≥ 10)	.77	35	73.8	70.9	0.03	<.001	0.70-0.83	.85

comparing dignity for every type of cancer diagnosis. Third, we only included cases from one medical center, and the collected data were from a period of time indexed 5 years ago (2017); therefore, the study results cannot be generalized to all patients with cancer.

#### Conclusion

This study found that dignity in patients with cancer was correlated with age, demoralization, and depression. Healthcare professionals could use the PDI-MV to routinely monitor dignity changes in patients with cancer, understand how they view dignity and dignity-related distress, encourage them to speak out regarding their personal views, and provide suitable care measures based on local backgrounds and cultural habits. This will increase dignity in patients, alleviate dignity-related distress, and reduce adverse outcomes. Future studies should examine dignity in chronic diseases, major illnesses, terminal illnesses, and long-term care to enable clinical caregivers or competent authorities to better meet the needs of the patients.

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#### **Conflict of interest**

No conflict of interest has been declared by the authors.

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#### Research Article

# Early Sedation Depth and Clinical Outcomes in Mechanically Ventilated Patients in a Hospital: Retrospective Cohort Study



Jeong Mi Hwang,<sup>1</sup> Su Jung Choi<sup>2,\*</sup>

- <sup>1</sup> Department of Nursing, Samsung Medical Center, Republic of Korea
- <sup>2</sup> Graduate School of Clinical Nursing Science, Sungkyunkwan University, Republic of Korea

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#### S U M M A R Y

Purpose: This study aimed to identify the early sedation depth in the first 48 hours of mechanical ventilation and its relationship to clinical outcomes to promote the transition to light sedation. Methods: This retrospective single-center cohort study was conducted in two medical intensive care units (MICUs) at a general tertiary hospital, using a standardized sedation protocol. To investigate the early sedation depth, the Sedation Index was used, which can indicate changes over the first 48 hours. Patients were divided into three groups based on tertiles of Sedation Index. The primary outcome was mortality at 30, 90, and 180 days. The secondary outcomes included length of stay in the ICU and ventilator-free days. Kaplan-Meier analysis and multivariable Cox regression were conducted to compare factors influencing mortality.

Results: This study included 394 patients. The deepest sedation group showed more severe illness, delirium, and deeper sedation at admission (p < .001). The survival curve decreased as sedation increased, even within the light sedation levels. In the deepest sedation group, 30-day mortality (hazard ratio [HR] 2.11, 95% confidence interval [CI] 1.33-3.34), 90-day mortality (HR 2.00, 95% CI 1.31-3.06), and 180-day mortality (HR 1.77, 95% CI 1.17-2.67) increased. The length of stay in the ICU and ventilator-free days did not show statistical differences.

Conclusions: These results indicate that early deep sedation is a modifiable factor that can potentially affect mortality. The protocol for inducing the transition into light sedation must comply with recommendations to improve clinical outcomes.

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#### Introduction

Sedating a patient under mechanical ventilation is important for promoting stability and safety to aid in managing pain, agitation, and delirium, as well as preventing increased oxygen consumption due to desynchronization with mechanical ventilation [1-3]. However, the appropriateness of sedation therapy is being questioned after reports of negative outcomes due to the prolonged application of mechanical ventilation under deep sedation [4-6]. Thus, the practice guidelines for sedation of critical patients under mechanical ventilation released by the U.S. Society of Critical Care Medicine advise maintaining light sedation, which is sufficient to facilitate treatment [7,8].

It has recently been reported that deep sedation within the first 48 hours of mechanical ventilation is a major factor that increases mortality in hospitals, even considering the patient's characteristics, such as severity of illness [1,9-11]. Furthermore, deeply sedated patients tend to experience less pain [1], but more subsequent delirium [9] and have an increased length of stay in the intensive care unit (ICU) [1,10] and longer ventilation times [1,10,11]. Although this modifiable factor can improve clinical outcomes [1], many patients still undergo deep sedation at the beginning of their treatment [12,13]. In Korea, efforts have been made to comply with the sedation protocol [14] and adjust medication use [15,16] to transition to light sedation. Nevertheless, >50% of patients remain under deep sedation for the first 5 days under mechanical ventilation [16]. There is a lack of data on the association between sedation level and clinical outcomes such as early sedation depth and mortality.

Jeong Mi Hwang: https://orcid.org/0000-0002-8457-5252; Su Jung Choi: https:// orcid.org/0000-0003-2171-7441

Correspondence to:

E-mail address: sujungchoi@skku.edu

Deep sedation, as defined by the Richmond Agitation—Sedation Scale (RASS), an instrument for measuring sedation depth [17], is typically classified as a RASS score of  $\leq -3$  points [13]. However, the RASS score of the patient varies considerably over time [4] and has positive and negative values. Thus, calculating the sedation depth in the first 48 hours following mechanical ventilation is difficult [9]. To deal with methodological problems, the Sedation Index was regarded as a representative value of early sedation depth to reflect changes over the first 48 hours of ventilation instead of a single point in time [9]. To ascertain the current situation in this study, the Sedation Index was investigated in patients admitted to two medical ICUs (MICUs) at a general tertiary hospital in Korea that followed a standardized sedation protocol. In addition, the association of Sedation Index with clinical outcomes, including mortality, was analyzed. This study was aimed to examine the recent practice of sedating critically ill patients and provide basic data for transitioning to a light sedation protocol.

#### Methods

#### Study design

This retrospective cohort study used data from the electronic medical records of an university-affiliated hospital Seoul, South Korea. To identify the effects of early deep sedation on the clinically important outcomes of patients under mechanical ventilation, all patients in the database were admitted to two MICUs and received mechanical ventilation from July 2018 to December 2019. This hospital follows a standardized sedation protocol (the Pain, Agitation, and Delirium [PAD] Protocol) [14], with the nursing staff periodically measuring the patients' sedation depth using the RASS [17].

#### **Participants**

Patients aged older than 18 years old who underwent endotracheal intubation followed by mechanical ventilation were included. Endotracheal intubation was performed in the emergency room, general ward, operating room, radiology room, or ICU of the study hospital. The criteria for initiation of mechanical ventilation were based on the actual time of intubation. The exclusion criteria were as follows: mechanical ventilation lasting less than 48 hours, not consenting to provide personal information, history of endotracheal intubation at another hospital, fewer than three RASS assessments during the first 48 hours under mechanical ventilation, reduced consciousness due to separate sedation or neurological injury from cardiovascular resuscitation, stroke, or other reasons; receiving extracorporeal membrane oxygenation (ECMO) for the heart or lungs; and history of ICU admission twice or more.

#### Demographics and clinical characteristics

Age, sex, admission route, patient diagnosis, and Simplified Acute Physiology Score (SAPS) III [18] were collected. The SAPS III is a validated scoring system for predicting hospital mortality that considers patient characteristics before ICU admission, reasons for ICU admission, and existence of physiologic derangement at ICU admission [18]. After admittance to the ICU, the doctor recorded the patient's unique SAPS III score.

#### Sedation depth

Early sedation depth refers to the Sedation Index in the first 48 hours of mechanical ventilation: the higher the Sedation Index, the deeper the early sedation depth. The Sedation Index is the sum of negative RASS scores divided by the total number of RASS measurements [9]. The RASS is reliable instrument for assessing the quality and degree of sedation and agitation in adult ICU patients [7,17] and has a high quality of psychometric evidence such as interrater reliability, convergent or discriminant validation [7]. The individual RASS values, indicating the sedation depth at a specific time, were the data that the nurse measured every shift or, additionally, if changed. The participants were divided into three groups based on the tertiles of Sedation Index: the first tertile indicates the group with the lightest sedation level, whereas the third tertile indicates the group with the deepest sedation level. Under the central limit theorem, when the number of participants in each group was greater than 30, the normal approximation was regarded adequate [19]. However, the individual RASS score at the point of admission could not be expressed by the Sedation Index; a single RASS of -3 or lower was categorically classified as deep sedation, from -2 to +1 as light sedation, and +2 and higher as agitation [20].

#### Prevalence of pain and delirium

During the first 48 hours of mechanical ventilation, the presence of pain and delirium was recorded. Pain and delirium in critically ill adults are recommended to measure by using reliable and valid assessment method [7,8]. For patients who can express pain, the Numeric Rating Scale (NRS) is a valid and feasible pain scale [7,8,21]. For whom unable to report pain, the Critical Care Pain Observation Tool (CPOT) is useful because it has high interrater reliability and discriminant and criterion validity for all ICU adults except patients with brain injury [7,22]. Pain was recorded as yes in the presence of the NRS score >4, or the CPOT score >3 at least once during the early phase of ventilation. Delirium was assessed using the Confusion Assessment Method-ICU (CAM-ICU), which has very good psychometric properties of validity and high interrater reliability [7]. The presence of at least one positive result was considered delirium during the first 48 hours of ventilation. But RASS scores of -4 or lower and +3 or higher were excluded because they could not be assessed in the CAM-ICU. Pain and delirium data were assessed by the bedside ICU nurse every shift or, additionally, if changed.

#### Sedative variables

Information on medications administered as analgesics and sedatives during the first 48 hours of ventilation was also collected. They were sorted by type (analgesics or sedatives) and infusion method (intermittent or continuous administration).

#### Outcome

Clinical outcomes related to early sedation depth included the following. The primary outcome was mortality over 30, 90, and 180 days. Patients were followed-up until hospital day 180 or death. Secondary outcomes included length of stay in the ICU and ventilator-free days [23]. Length of stay in the ICU refers to the total period from admission to discharge from ICU. Ventilator-free days are defined as the number of days in which spontaneous breathing is possible continuously for more than 48 hours without mechanical ventilation assistance [23]. If the patient is successfully weaned from mechanical ventilation within 28 days, ventilator-free days are calculated by subtracting the number of days applied to the mechanical ventilation from 28 days [23]. If the patient died before 28 days or required mechanical ventilation for 28 days or more, ventilator-free days are zero [23].

#### Fthical consideration

This study was approved by the Institutional Review Board of the Samsung Medical Center, Approval no. 2020-06-099. The need for informed patient consent was waived because of the study's retrospective nature. This study was performed in accordance with the relevant guidelines and regulations of the IRB. One researcher then examined and collected electronic medical records.

#### Statistical analysis

The collected data were analyzed using SPSS WIN 25.0 (SPSS Inc., Chicago, IL, USA), with a significance level of .05, and a 95% confidence interval as follows: continuous variables were presented as average and standard deviation, and categorical variables as frequency and percentage. The patient demographics, clinical characteristics, sedative variables, and clinical outcomes according to the Sedation Index were analyzed using one-way analysis of variance, chi-squared test, or Fisher exact test. A post-hoc test was performed using Bonferroni correction. Kaplan-Meier analysis was conducted to compare the survival period according to the early sedation depth. To analyze the factors influencing mortality, a multivariable Cox regression analysis was conducted (backward likelihood ratio test was used to select variables). The confounding variables were age, sex, admission route, SAPS III, patient diagnosis, RASS at admission, Sedation Index, prevalence of pain and delirium, and analgesics and sedatives with intermittent or continuous administration. To account for numerous confounding variables, multivariable Cox regression included covariates with a p value 0.05 in univariable Cox regression. Significant predictors were defined as covariates with a multivariable Cox regression p value 0.05.

#### Results

Demographics, clinical characteristics, and sedative variables according to Sedation Index

Among the 1,287 patients who were aged more than 18 years and received mechanical ventilation via endotracheal intubation, 970 received mechanical ventilation for ≥48 hours. Of these, 28 patients refused to provide their personal information, 84 had undergone endotracheal intubation in other hospitals, 2 had fewer than three RASS assessments during the first 48 hours under mechanical ventilation, 124 had reduced consciousness due to separate sedation or neurological injury from seizures, cardiovascular resuscitation, stroke, or other reasons, 43 were under ECMO for the heart or lung, and 295 patients had been admitted to the ICU for two or more reasons. After excluding these 576 patients, data from 394 patients were used for analysis. The mean early sedation depth in the entire cohort was 1.35. Dividing this into three groups based on tertiles, the Sedation Index of the first tertile with the lightest sedation ranged from 0.00 to 0.83, with 130 patients (0.54  $\pm$  0.23); the second tertile's Sedation Index ranged from 0.84 to 1.50, with 136 patients (1.13  $\pm$  0.20); and the Sedation Index of the third tertile with the deepest sedation ranged from 1.51 to 5.00, with 128 patients  $(2.40 \pm 0.77)$  (Figure 1).

The demographics, clinical characteristics, and sedative variables of the patients in the early phase of ventilation in terms of Sedation Index are shown in Table 1. Age, sex (male), ICU admission route, and patient diagnosis did not differ significantly between the groups. More than 50% of patients admitted to ICU had cancer, followed by respiratory, neurological, and digestive system diseases. The SAPS III was  $58.64 \pm 14.62$  points in the first tertile,  $62.13 \pm 15.53$  points in the second tertile, and  $68.25 \pm 15.94$  points in the third tertile, increasing as the sedation deepened; there were

significant differences between the third tertile and first and second tertile groups (p < .001); 73.8% of the first tertile group was lightly sedated at admission, and only 17.7% were deeply sedated. On the other hand, 50.8% of the third tertile group showed light sedation at admission, and 43.8% showed deep sedation (p < .001).

Pain prevalence decreased from the first to the third tertile (30.8 vs. 18.8%, p=.021). Delirium prevalence was 65.4% in the first tertile, 83.8% in the second tertile, and 89.8% in the third tertile, increasing as sedation deepened, showing significant differences (p < .001).

Intermittent analgesics were most frequently used in the second tertile (92.6%, p = .033). Fentanyl was used the most in all groups and showed significant differences among the three groups (p = .022). Continuous analgesic prescribed most was remifentanil in all three groups, but statistically significant difference between groups was only shown in hydromorphone among continuous analgesics (p = .004). No significant differences were found between the three groups in the use of intermittent sedatives, and ketamine was used the most. The use of midazolam showed significant differences among the three groups (p = .011). Continuous sedatives were used by 60.2% of the third tertile, with a significantly higher usage rate than the first tertile (38.5%) and the second tertile (39.0%) (p < .001). Although the continuous infusion of midazolam, ketamine, and propofol showed significant differences among the groups per medication, there were no significant differences in the use of dexmedetomidine among the three groups.

#### Clinical outcomes according to Sedation Index

The clinical outcomes of patients in the first 48 hours of ventilation in accordance with the Sedation Index are shown in Table 2. The primary outcome was the mortality rate. The 30-day mortality (p < .001), 90-day mortality (p = .004), and 180-day mortality (p = .013) increased as sedation deepened, indicating statistical differences. The results of the Kaplan–Meier analysis of 30-, 90-, and 180-day mortality are shown in Figure 2. Throughout all periods, the survival curve indicated a significant difference between the first tertile and the second and third tertiles, and the survival curve between the second and third tertiles was not statistically significant. The secondary outcome was length of stay in the ICU and ventilator-free days, neither of which revealed statistically significant differences within the groups (Table 2).

#### Relationship between factors influencing mortality

To analyze the factors influencing mortality and how the Sedation Index predicted mortality, multivariable Cox regression was performed, and the results are shown in Table 3. Multivariable Cox regression incorporated factors with a p value of 0.05 in univariable Cox regression to account for various confounding variables of age, sex, admission route, SAPS III, patient diagnosis, RASS at admission, Sedation Index, prevalence of pain and delirium, and analgesics and sedatives with intermittent or continuous administration. The admission route, SAPS III, use of intermittent morphine, delirium prevalence, and Sedation Index were the variables associated with 30-day mortality in univariable Cox regression. Addition to variables above, patient's diagnosis and use of intermittent ketamine were plus added for predicting the 90- and 180-day periods, and use of continuous fentanyl for the 180-day mortality in univariable Cox regression. Significant predictors were determined to be variables with a multivariable Cox regression p value of 0.05. Delirium prevalence and use of continuous fentanyl among the initial covariates in the univariable cox analysis were excluded from the final model to predict all period of mortality.

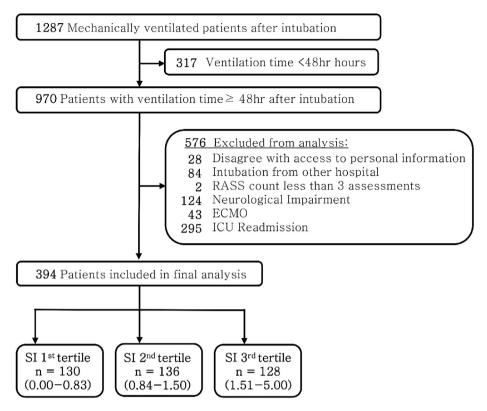


Figure 1. Patient Inclusion Flow Diagram.

Note: RASS = Richmond Agitation Sedation Scale; ECMO = extracorporeal membrane oxygenation; SI=Sedation Index.

The Sedation Index tertiles were identified as independent predictors of mortality. In the second tertile group, compared to the first one, the risk of death increased by 1.73 times at 30 days (p = .018), 1.61 times at 90 days (p = .020), and 1.46 times at 180 days (p = .052). In the third tertile group, mortality was 2.11 times higher than the first tertile at 30 days, 2.00 times at 90 days, and 1.77 times at 180 days (p < .01). As the SAPS III increased, all types of mortality increased (p < .01). While intermittent ketamine usage only increased the risk of death by 1.47 times at 90 days, intermittent morphine usage more than doubled the mortality rate across all time periods. When patient was admitted to the intensive care unit via the general ward compared to the emergency room, mortality at 90 and 180 days increased higher by 1.53 times (p < .05) and 1.61 times (p < .01), respectively. The risk of death at 90 and 180 days decreased, however, when the patient had a neurological diagnosis compared to a respiratory diagnostic by 0.35 times and 0.28 times, respectively (p < .05).

#### Discussion

This retrospective cohort study attempted to improve early sedation strategies in critical patients by analyzing early sedation depth, which has been reported to be related to mortality in patients under mechanical ventilation.

The average Sedation Index of the entire patient cohort was 1.35 points, with two-thirds of the participants scoring 0.00–1.50 points. The patients in this study maintained a lighter sedation depth overall compared with the results of other study where the average Sedation Index was 2.42 points and the distribution of two-thirds of the participants ranged from 0.00 to 3.25 [9].

Also, the participants in this study showed less pain prevalence, about 30% or less. According to previous studies, 40–70% of

patients admitted to ICU are known to experience moderate to severe pain [24,25]. More than 30% of patients complained of pain even during rest, and this number was more than 50% during various nursing treatments [26]. The use of the standardized sedation protocol (PAD Protocol) is cited as the reason for maintaining light sedation while controlling pain properly. It is estimated that pain in mechanically ventilated patients was properly controlled by assessing pain every shift and administering analgesic first. In all groups, intermittent analgesic fentanyl was used in at least 80% of cases. The benefit of fentanyl-based analgosedation is that it is known to help the transition to light sedation by reducing pain and unnecessary use of sedatives [27]. The continuous analgesic remifentanil is chiefly used, which is also effective for maintaining light sedation [28]. The frequent use of ketamine, a sedative with analgesic effects, could have led to lower pain as the sedation deepened, even though the analgesic dosage decreased [29,30]. In particular, benzodiazepine midazolam usage was substantially lower in all groups, regardless of Sedation Index. This low use could have influenced the fact that there was no difference in the length of stay in the ICU and ventilator-free days among the three groups in this study [20,31].

However, despite the low use of benzodiazepine, delirium occurred frequently in this study's patients, even in the first tertile, with the lowest occurrence (65.4%) compared with 38.8% in previous study [9], and it was the highest in the deepest sedation (third tertile). Delirium is assumed to occur due to various risk factors, including the use of mechanical ventilation, age, emergency room admission, and medical history of dementia [8]. The risk of delirium increased 6.27 times when under mechanical ventilation [32]. This study targeted only patients undergoing mechanical ventilation. In contrast with the previous study [9], the admission rate in the emergency rooms and the average age in this study showed higher,

**Table 1** Demographics, Clinical Characteristics and Sedative Variables of Patients in the First 48 Hours of Ventilation according to Sedation Index (N = 394).

Variable	SI $1^{st}$ tertile <sup>a</sup> ( $n=130$ )	SI $2^{nd}$ tertile $(n=136)$	SI $3^{rd}$ tertile <sup>c</sup> ( $n=128$ )	$X^2$ or F	p	Post-hoc
	N (%)/M±SD	N (%)/M±SD	N (%)/M±SD			
Age(y)	63.61 ± 14.19	63.67 ± 15.90	65.50 ± 14.22	0.68	.506	
Gender, Men	87 (66.9)	92 (67.6)	85 (66.4)	0.05	.977	
Admission route	, ,	, ,	, ,			
ER	53 (40.8)	56 (41.2)	52 (40.6)	4.18	.375 <sup>†</sup>	
Ward	71 (54.6)	78 (57.4)	75 (58.6)			
Other	6 (4.6)	2 (1.5)	1 (0.8)			
SAPS III $(n = 354)$	$58.64 \pm 14.62$	62.13 ± 15.53	$68.25 \pm 15.94$	11.54	<.001**	a,b < c
Patient diagnosis	_	_	_			,
Respiratory	19 (14.6)	19 (14.0)	13 (10.2)	6.91	.547	
Cancer	73 (56.2)	73 (53.7)	76 (59.4)			
Neurology	7 (5.4)	8 (5.9)	13 (10.2)			
Gastrointestinal	6 (4.6)	8 (5.9)	9 (7.0)			
Other	25 (19.2)	28 (20.6)	17 (13.3)			
RASS at admission	` ,	` ,	` ,			
Light sedation	96 (73.8)	83 (61.0)	65 (50.8)	20.57	<.001**	
Deep sedation	23 (17.7)	43 (31.6)	56 (43.8)			
Agitation	11 (8.5)	10 (7.4)	7 (5.5)			
Pain prevalence‡	40 (30.8)	45 (33.1)	24 (18.8)	7.71	.021*	
Delirium prevalence§	85 (65.4)	114 (83.8)	115 (89.8)	26.03	<.001**	
Analgesic, intermittent	114 (87.7)	126 (92.6)	105 (82.0)	6.83	.033*	
Fentanyl	114 (87.7)	126 (91.9)	103 (80.5)	7.67	.022*	
Morphine	5 (3.8)	5 (3.7)	5 (3.9)		1.000	
Pethidine	4 (3.1)	6 (4.4)	2 (1.6)		.442	
Hydromorphone	1 (0.8)	0 (0.0)	1 (0.8)		.547	
Analgesic, continuous	118 (90.8)	120 (88.2)	108 (84.4)	2.50	.287	
Remifentanil	110 (84.6)	112 (82.4)	94 (73.4)	5.68	.058	
Fentanyl	21 (16.2)	21 (15.4)	21 (16.4)	0.05	.976	
Hydromorphone	6 (4.6)	11 (8.1)	21 (16.4)	10.87	.004**	
Sedative, intermittent	89 (68.5)	85 (62.5)	86 (67.2)	1.17	.556	
Ketamine	85 (65.4)	79 (58.1)	70 (54.7)	3.21	.201	
Propofol	3 (2.3)	2(1.5)	3 (2.3)		.824	
Midazolam	1 (0.8)	0 (0.0)	5 (3.9)		.011*	
Sedative, continuous	50 (38.5)	53 (39.0)	77 (60.2)	16.01	<.001**	
Ketamine	30 (23.1)	30 (22.1)	50 (39.1)	11.73	.003**	
Dexmedetomidine	24 (18.5)	28 (20.6)	22 (17.2)	0.51	.774	
Propofol	4 (3.1)	2 (1.5)	25 (19.5)	35.82	<.001**	
Midazolam	0 (0.0)	0 (0.0)	5 (3.9)		.003**	

Note: ER = emergency room; RASS = Richmond Agitation—Sedation Scale; SAPS III = Simplified Acute Physiology Score III; SI = Sedation Index.

40.0% vs. 27.9% and 64.0 vs. 58.4 years, respectively, and could thus represent risk factors for the occurrence of delirium. Moreover, unlike a previous study that only investigated a patient's delirium between -2 and +1 of RASS [9], this study included all patients between -3 and +2 of RASS. It is assumed that this inclusion reflects hypoactive delirium, the primary subtype of delirium occurring in the ICU [33,34]. According to a systematic literature review of subtypes of delirium [34], the prevalence of hypoactive delirium is high in groups with increased severity of disease or mechanical ventilation. Considering that patients in the third tertile group had high severity of illness with a ventilator, it is estimated that the incidence of delirium was the highest since hypoactive type delirium was reflected more than the others.

Although RASS at admission did not affect mortality, it showed a tendency to affect early sedation depth during the first 48 hours. Patients with deep sedation in early phase of mechanical ventilation were more subsequently deeply sedated during the first 2 ICU days [12]. Hence, medical staff must accurately assess and constantly monitor early sedation depth to prevent unnecessary

**Table 2** Clinical Outcomes of Patients in the First 48 Hours of Ventilation according to Sedation Index (N = 394).

Variable	SI $1^{st}$ tertile $(n = 130)$	SI 2 <sup>nd</sup> tertile (n = 136)	SI $3^{rd}$ tertile $(n = 128)$	X <sup>2</sup> or F	p
	N (%)/M±SD	N (%)/M±SD	N (%)/M±SD		
Mortality					
30-day mortality	32 (24.6)	58 (42.6)	67 (52.3)	21.37	<.001**
90-day mortality	48 (36.9)	70 (51.5)	73 (57.0)	11.19	.004**
180-day mortality	56 (43.1)	75 (55.1)	78 (60.9)	8.63	.013*
Length of stay, ICU	$11.65 \pm 9.68$	$13.58 \pm 13.63$	$12.42 \pm 8.69$	1.06	.349
Ventilator- free days	19.59 ± 7.75	18.72 ± 7.63	$18.59 \pm 6.99$	0.68	.507

Note: SI = Sedation Index.

p < .01. p < .001.

<sup>&</sup>lt;sup>a</sup> SI 1<sup>st</sup> tertile group.

<sup>&</sup>lt;sup>b</sup> SI 2<sup>nd</sup> tertile group.

<sup>&</sup>lt;sup>c</sup> SI 3<sup>rd</sup> tertile group

<sup>†</sup> Fisher exact test.

<sup>‡</sup> Pain was recorded as yes in the presence of the Numeric Rating Scale (NRS) score ≥4, or the Critical Care Pain Observation Tool (CPOT) score ≥3 at least once.

<sup>§</sup> Delirium was recorded as yes when at least one Confusion Assessment Method-ICU (CAM-ICU) was positive.

<sup>\*</sup> p < .01.

<sup>\*\*</sup> p < .001.

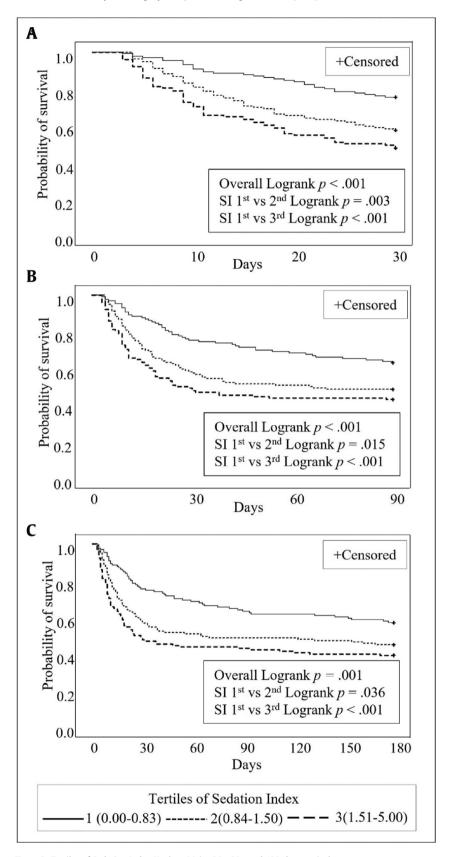


Figure 2. Tertiles of Sedation Index Kaplan—Meier 30-, 90-, and 180-day survival curve. Note: The log rank p values of comparing with groups are values applied with Bonferroni correction.

**Table 3** Multivariable Cox Regression Analysis of Relationship Between Factors Influencing 30-, 90-, and 180-day Mortality (N = 354).

Variable		30-day			90-day			180-day	
	HR	95% CI	р	HR	95% CI	p	HR	95% CI	p
Sedation Index									
1 <sup>st</sup> tertile (=Ref)	1.0			1.0			1.0		
2 <sup>nd</sup> tertile	1.73	1.10 - 2.72	.018*	1.61	1.08 - 2.39	.020*	1.46	1.00 - 2.14	.052
3 <sup>rd</sup> tertile	2.11	1.33-3.34	.001**	2.00	1.31-3.06	.001**	1.77	1.17 - 2.67	.007**
SAPS III	1.02	1.01-1.03	<.001**	1.02	1.00 - 1.03	.006**	1.02	1.01-1.03	.004**
Admission route									
ER (=Ref)				1.0			1.0		
Ward				1.53	1.09 - 2.16	.015*	1.61	1.16 - 2.24	.005**
Other				1.97	0.70 - 5.59	.201	1.73	0.61 - 4.88	.302
Patient diagnosis									
Respiratory (=Ref)				1.0			1.0		
Cancer				1.24	0.75 - 2.07	.403	1.12	0.70 - 1.81	.631
Neurology				0.35	0.13 - 0.95	.039*	0.28	0.10 - 0.74	.010*
Gastrointestinal				0.88	0.38 - 2.03	.762	0.71	0.31 - 1.61	.411
Other				0.81	0.43 - 1.51	.499	0.69	0.39 - 1.25	.226
Morphine, intermittent	2.37	1.14-4.89	.020*	2.17	1.09 - 4.31	.028*	2.28	1.19 - 4.40	.013*
Ketamine, intermittent				1.47	1.05 - 2.05	.025*	1.35	0.99 - 1.85	.062
Delirium prevalence							1.40	0.94 - 2.08	.100

Note: CI = confidence interval; ER = emergency room; HR = hazard ratio; Ref = reference.

Multivariable Cox regression incorporated factors with a p value of 0.05 in univariable Cox regression of 30, 90, and 180 days to account for various confounding variables of age, sex, admission route, SAPS III, patient diagnosis, RASS at admission, Sedation Index, prevalence of pain and delirium, and analgesics and sedatives with intermittent or continuous administration.

deep sedation. Admission route was not associated with the Sedation Index, but, in line with previous research [9.35], the patients in this study also showed increased 90- and 180-day mortality when admitted from a ward compared to emergency room. Patients who remained in the ward for a longer period may have an opportunity to be exposed to infection, nutritional deficiencies, and other conditions [35]. Therefore, it is necessary to consider the possibility that patient characteristics may vary depending on the source of admission, which may have an impact on mortality. Even though patient's diagnosis was mainly cancer and morphine administration was less observed in this study, there was association between morphine use and morality in all period. Morphine can increase mortality for patients with acute heart failure [36] or ARDS [37], and its evidence remains controversial [36,37]. Thus, it is necessary to use morphine carefully in consideration of each patient's disease.

The 30-, 90-, and 180-day mortality rates tended to significantly increase as the sedation deepened, and this tendency was identical to a previous study [9]. However, the participants in this study differed in that there was a decrease in the survival curve even in the first and second tertile groups with light sedation although the difference in SAPS III that affected the mortality between the two groups was not statistically significant. In the current circumstances, in which the definition of light sedation and deep sedation is not clear [8] unless deep sedation is required for therapeutic purposes, it suggests that maintaining the patient in a lighter sedation may play a role in improving mortality of patients with mechanical ventilation. However, no statistical significance was confirmed in the survival curve between the second and third tertile. This lack of significance could have been due to a difference in SAPS III scores, strongly affecting mortality between the two groups.

A limitation of this study is that there could be other factors that influenced the clinical outcomes during the early phase of ventilation. For example, there were no data on the reason for mechanical ventilation at the time of hospitalization or the setting value of the ventilator. In addition, the medication administration dosages were not considered and medication administration during intubation was not excluded from total medication usage during the first 48 hours of ventilation. Furthermore, it is difficult to state that this research is representative of treatment in Korea, given that it was conducted in only one tertiary general hospital that already had a standardized sedation protocol. The details of protocols may vary from hospital to hospital, and inconsistent protocols may affect the transition of the patient to light sedation, which may be another bias in evaluating the effect of sedation status on clinical outcomes. Therefore, a study was conducted in a single hospital where standardized sedation protocols were applied. In the future, it will be necessary to conduct the study in multiple institutions with a uniform sedation protocol.

Despite these limitations, the results from this study are consistent with the previous study [9] and indicate that early deep sedation in critically ill patients on mechanical ventilation is associated with mortality. It should be noted that early sedation depth is a modifiable variable among those known to be related to mortality [1,9,11]. Compared with the general treatment as directed by the doctor, nurses play a crucial role in reducing mortality in the ICU and mitigating sedation-related adverse effects by maintaining an appropriate sedation depth for the patient [38,39]. Since the early stage of mechanical ventilation is a phase when a doctor diagnoses a patient and determines the treatment direction, the patients' sedation depth may be considered relatively less important. The patient's target sedation level should be set. The nurse at the bedside can adjust the sedative medication dose without delay [38] and make a faster clinical decision to guarantee a light sedation in keeping with the patient's condition during the early phase of ventilation. Also, the nurse' protocol management skills can be improved with adequate educational intervention [39]. Thus, nurses must endeavor to accomplish early light sedation by performing a standardized sedation protocol.

#### Conclusion

This study confirmed that early sedation depth during the first 48 hours of mechanical ventilation is a modifiable factor that can potentially affect the mortality of patients. Considering bedside

<sup>\*</sup> *p* < .01.
\*\* *p* < .001.

nurses play a leading role in controlling the sedation depth of critical patients, the protocol for inducing the transition into light sedation must be geared toward improving clinical outcomes of patients with mechanical ventilation. Additional studies on enhancing sedation depth in the first 48 hours are warranted.

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#### **Conflict of interest**

The authors have declared no competing interests.

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#### Research Article

# The Moderated Mediating Effects of Nutrition and Physical Activity Between Fatigue and Quality of Life in Childhood Cancer Survivors



Wei-Wen Wu,<sup>1, 2, \*</sup> Cheng-Shi Shiu,<sup>3</sup> Chia-Chun Tang,<sup>1, 2</sup> Shiann-Tang Jou,<sup>4, 5</sup> Huey-Ling Chen<sup>4, 6</sup>

- <sup>1</sup> School of Nursing, College of Medicine, National Taiwan University, Taipei, Taiwan
- <sup>2</sup> Department of Nursing, National Taiwan University Hospital, Taipei, Taiwan
- <sup>3</sup> Department of Social Work, National Taiwan University, Taipei, Taiwan
- <sup>4</sup> Department of Pediatrics, National Taiwan University Children's Hospital, Taipei, Taiwan
- <sup>5</sup> Department of Medicine, College of Medicine, National Taiwan University, Taipei, Taiwan
- <sup>6</sup> Department and Graduate Institute of Medical Education and Bioethics, College of Medicine, National Taiwan University, Taipei, Taiwan

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#### SUMMARY

*Purpose:* The aim of this study was to investigate the associations between nutrition, physical activity, fatigue, and quality of life (QoL) among childhood cancer survivors. The specific purpose was to examine whether nutrition mediated and physical activity moderated the relationship between fatigue and QoL in this population.

Methods: A pooled sample of 120 childhood cancer survivors was recruited at pediatric oncology wards and ambulatory settings between August 2020 and May 2021. We collected data on participants' demographic characteristics, fatigue, nutritional status, physical activity, and QoL. We then adapted Hayes Process Macro to examine the mediating and moderating effects of nutrition and physical activity on the relationship between fatigue and QoL.

Results: In models adjusted for age and sex, (1) the simple mediation analysis identified the mediating effect of nutrition on the relationship between fatigue and QoL; and (2) the mediation and moderation analysis identified that the direct effect of nutrition between fatigue and QoL was significant when adding (a) physical activity and (b) fatigue × physical activity. There were significantly decreasing trends in physical activity at 1 standard deviation below the mean and at the mean, but not at 1 standard deviation above the mean.

Conclusions: Our findings demonstrate that nutrition mediated and physical activity moderated the relationship between fatigue and QoL. This highlights an opportunity to enhance QoL among childhood cancer survivors through healthy lifestyle interventions. To ensure that future interventions address children's needs and promote the greatest impact, such interventions should include nutrition and physical activity components that involve nurses, pediatric oncology physicians, nutritionists, and physical therapists.

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#### Introduction

For children aged 1 through 14 years in high-income countries such as Taiwan and the United States, cancer is the second leading

Wei-Wen Wu: https://orcid.org/0000-0002-6439-5369; Cheng-Shi Shiu: https://orcid.org/0000-0003-3121-4389; Chia-Chun Tang: https://orcid.org/0000-0001-8239-6632; Shiann-Tang Jou: https://orcid.org/0000-0003-1483-0403; Huey-Ling Chen: https://orcid.org/0000-0002-4074-5838

E-mail address: weiwen@ntu.edu.tw

cause of death [1,2]. Due to advances in cancer treatment, the 5-year survival rate has dramatically improved over the past 60 years, from less than 25.0% to more than 80.0% [3]. The term "childhood cancer survivors" indicates people who were first diagnosed with cancer under the age of 18. A children diagnosed with cancer is considered to be a childhood cancer survivor from the time of diagnosis until the end of life [4]. However, despite treatment advances, childhood cancer survivors continue to experience short- and long-term adverse effects [5]. This has turned research attention from "how to survive" to "how to live with cancer well."

<sup>\*</sup> Corresponding author. School of Nursing, College of Medicine, National Taiwan University, Taiwan.

For childhood cancer survivors, cancer-related fatigue (CRF) is one of the most distressing adverse effects [6]. CRF is both more severe than fatigue in healthy people and less likely to be relieved by sleep or rest [7]. While CRF typically improves after treatment is completed, it continues to affect long-term survivors [6]. Persistent CRF not only negatively correlates with nutritional status [8.9] and physical activity [10], it also negatively interferes with quality of life (OoL) [11]. These findings support that fatigue causes these declines, but these associations have not been examined by a single study. Because CRF negatively correlates with nutritional status [8,9] in childhood cancer survivors, and nutritional status positively affects QoL [12,13], we hypothesize that nutrition mediates the relationship between CRF and QoL. In addition, we hypothesize that physical activity moderates the relationship between CRF and QoL, given that physical activity significantly reduces CRF in childhood cancer survivors [14] and significantly enhances QoL in healthy children [15], while fatigue also significantly affects QoL in childhood cancer survivors [11].

Systemic inflammation may be one explanation for these associations. Both CRF [16] and malnutrition [17] are known to activate pro-inflammatory cytokines. This results in systemic inflammation, which creates a catabolic situation and leads to worse QoL in people with cancer [18,19]. Physical activity plays a significant role in reducing the inflammatory protein at sites of inflammation [20]. Thus, proper nutrition and physical activity may have the potential to inhibit the systemic inflammation reaction [21–23].

Evidence has shown that a healthy lifestyle, consisting of proper nutrition and physical activity, improves the relationship between fatigue and QoL [24,25]. However, research into optimizing childhood cancer survivors' QoL through healthy lifestyle has been limited. The prior research evaluating QoL in association with lifestyle factors has focused primarily on physical activity [24]. Research studies that integrate nutrition, within a single study, to examine the associations between nutrition, physical activity, fatigue, and QoL for childhood cancer survivors are extremely limited. In view of the potential manageability of nutrition and physical activity behaviors, such a study could be important to facilitating timely development of healthy lifestyle interventions for this population.

Aim

The aim of this study was to investigate the associations between nutrition, physical activity, fatigue, and QoL among childhood cancer survivors. Specifically, our purpose was to examine whether (a) nutrition mediated and (b) physical activity moderated the relationship between fatigue and QoL for childhood cancer survivors.

#### Methods

Design, setting, and sample

This correlational study was conducted in accordance with the STROBE guidelines. A pooled sample of 120 childhood cancer survivors were recruited at pediatric oncology wards and ambulatory settings in a university-based hospital in Taiwan that is well-known for pediatric oncology care. Participants were recruited between August 2020 and May 2021, using the following inclusion criteria: (1) age between 3 and 18 years; (2) inpatient receiving active treatment in pediatric oncology/hematology wards, outpatient receiving active treatment in ambulatory settings, or survivor (having completed cancer treatment) now receiving care in ambulatory settings; and (3) ability to understand the study information. We used G-Power version 3.1.9 (Franz Faul, Universität

Kiel, Germany) to compute sample size a priori. Although a generally accepted power is .80 [26], higher power is more desirable if it is practically feasible [27]. A minimum of 108 participants would be needed to reach a sufficient power (90.0%), alpha error (.05), and effect size (0.15).

#### Ethical considerations

This study was approved by the institutional review board of the National Taiwan University Hospital, Approval no. 202001023RINA. Upon agreeing to participate, the child participants provided informed assent and their parents provided informed consent. Once the formal consents were received from the participants and their parents (guardians), all of the measures would be collected. All participants were also informed they had the right to withdraw from the study at any time for any reason.

#### Procedure

A research assistant approached participants who met the inclusion criteria, along with their parents (guardians), and explained the research aims and procedures. Those who agreed to participate were given a set of questionnaires that included a demographic survey, the Pediatric Quality of Life Inventory Multidimensional Fatigue scale (PedsQL-MFS), the Exercise Involvement Scale, and the Pediatric Quality of Life Inventory 3.0 Cancer Module (PedsQL-C). Both a parent and a research assistant were present when children answered the study questionnaires in case assistance was needed. After completing questionnaires, they were brought to the examination room for evaluating the nutritional status (phase angle) measured by a bioelectrical impedance analysis (BIA) device (InbodyS10, Biospace Co., Seoul, Korea).

#### Measures

**Demographics.** Survey items collected demographic data on participants' age, sex, cancer diagnosis, treatment status, years in current treatment status, and body mass index (BMI). The survey also collected data on the child's, father's, and mother's education level.

**Fatigue.** We used the Mandarin version of the PedsQL-MFS to measure fatigue. This scale was developed to assess fatigue among children with cancer aged 2 to 18 years [28]. It is an 18-item 5-point Likert scale from 0 (never) to 4 (almost always). There are three dimensions: general fatigue (6 items), sleep/rest fatigue (6 items), and cognitive fatigue (6 items). In this study, children 7 years and younger used the proxy-reported versions of the scale for their age group (2–4 years and 5–7 years), and those aged 8 to 18 years used the self-report version. Total scores were transformed on a scale from 0 to 100. Based on the PedsQL-MFS manual, higher scores indicate less fatigue, but we reversed the direction so that higher scores indicated greater fatigue, which seemed more intuitive. Studies have demonstrated the PedsQL-MFS's excellent reliability and validity among children with cancer [28–31]. The Cronbach αs in the current study were between .72 and .93 across the three age

**Nutritional status.** BIA is a method for acquiring body composition parameters (e.g., phase angle, body fat, muscle mass) that has the advantages of being noninvasive, safe, easy to use, and offering immediate results [32]. Phase angle represents cellular integrity, inflammation, nutritional status, and immune status [33] and has been recommended as a prognostic tool for nutritional screening of children [34–36]. To complete the phase angle measures with the InbodyS10 device, participants had to fast for at least 2 hours, empty their bladder, measure their height and body weight with

minimal clothing, and rest for at least 10 minutes before the BIA measurement. During measurement, eight electrodes were attached to hands and feet (this process took around 2 minutes).

Phase angle values have a pattern that holds regardless of gender: values increase progressively from the first years of life until 18 years of age, stabilize from age 19 until 48 years of age, and then decrease progressively thereafter [37]. The phase angle reference values for boys are 5.60° for 3- to 5-year-olds, 6.00° for 6-to 12-year-olds, 6.40° for 13- to 15-year-olds, and 7.30° for 16- to 18-year-olds. Reference values for girls are 5.40° for 3- to 5-year-olds, 5.90° for 6- to 12-year-olds, 6.30° for 13- to 15-year-olds, and 6.40° for 16-to 18-year-olds [37]. Higher scores within the relevant age strata indicate better nutritional status [36]. We set a cutoff point for poor nutritional status at less than 4.00°, which is the same cutoff used for adults with cancer [38].

**Physical activity.** We used a three-item Exercise Involvement Scale to evaluate participants' degree of physical activity in the prior week [39]. The item regarding exercise frequency ("During the last week, how many times did you engage in exercise?") has six graded response options ranging from 1 (zero) to 6 (5 or more times a week); higher scores indicate more frequent exercise. The item regarding exercise intensity ("During the past week, how much effort did you put into exercising each time?") also has six graded responses: 1 (extremely easy), 2 (very easy), 3 (easy), 4 (a little hard), 5 (very hard), and 6 (extremely hard); higher scores indicate greater amount of effort invested in exercise. The item regarding exercise duration ("During the past week, how much time did you spend exercising per time?") again has six graded responses, starting at 1 (0–10 minutes) and increasing in 10minute intervals to 6 (51-60 minutes); higher scores indicate longer average duration. The equation is as follows: exercise involvement = exercise frequency  $\times$  (exercise intensity + exercise duration). Again, higher scores indicate higher levels of physical

**Quality of life.** QoL was measured using the Mandarin version of the PedsQL-C. This scale was developed to assess the QoL of children with cancer aged 2 to 18 years [40]. There are eight dimensions: pain and hurt, nausea, procedural anxiety, treatment anxiety, worry, cognitive problems, perceived physical appearance, and communication. Scale items use a 5-point Likert scale from 0 (never) to 4 (almost always). PedsQL-C has 25 items for children aged 2 to 4 years, 26 items for those aged 5 to 7 years, and 27 items for those aged 8 to 18 years. Total scores were transformed on a scale from 0 to 100, with higher scores indicating better QoL. Studies have demonstrated the PedsQL-C's excellent reliability and validity among children with cancer [11]. The Cronbach αs in the current study were between .75 and .91 across the three age groups.

#### Statistical analysis

All statistical analyses were performed using SPSS 20.0 (SPSS Inc., Chicago, IL). We used frequency and percentage to analyze participants' categorical demographic characteristics; we used mean and standard deviation to characterize the interval/ratio demographic characteristics and main variables. Pearson correlation analysis was used to examine the bivariate correlations between fatigue, nutrition, physical activity, and QoL.

Hayes Process Macro with SPSS was used for the analysis [41]. First, to identify the simple mediation, we examined whether nutrition mediated the relationship between fatigue and QoL [41]. Once the simple mediation was identified, we identified the mediation and moderation in Model 5 by examining whether both nutrition mediated and physical activity moderated the relationship between fatigue and QoL [41]. Because previous studies have

pointed out gender and age differences in phase angle [37,42], we controlled for covariates (age and sex) in all model analyses. Finally, we plotted the conditional effects of physical activity at low (1 standard deviation below the mean value of physical activity), moderate (mean value of physical activity), and high (1 standard deviation above the mean value of physical activity) levels.

#### Results

#### Descriptive analysis

Of the 124 participants who agreed to participate and completed all measures, 4 were excluded due to poor-quality BIA measurements. This resulted in 120 included participants (96.8%; 77 boys and 43 girls). The descriptive analyses of participants' age, sex, diagnosis, BMI status, and child's, father's, and mother's education levels are summarized in Table 1.

The mean (SD) scores in fatigue, nutrition, physical activity, and QoL were 22.48 (15.51), 4.32 (0.75), 28.65 (13.75), and 79.14 (14.29), respectively (see Table 2). We calculated the percentage of participants with a phase angle less than 4.00° to obtain a 38.3% prevalence of poor nutrition.

#### Bivariate analysis

Each pair among the four variables was significantly correlated (r range, -.60 to .38), except for the pair of nutrition with physical activity (r = .16; see Table 2). This indicated that although the two modifiable factors (nutrition and physical activity) were not

Table 1 Demographic Characteristics of Participants.

Variables	Mean (S	D) or n (%)
Age	8.01	(3.93)
Gender		
Men	77	(64.2)
Women	43	(35.8)
Diagnosis		
ALL	65	(54.2)
AML	11	(9.2)
NHL	7	(5.8)
HL	4	(3.3)
Neuroblastoma	12	(10.0)
Brain tumor	4	(3.3)
Others <sup>a</sup>	17	(14.2)
BMI status		
Underweight	13	(10.8)
Healthy weight	69	(57.5)
Overweight or obesity	38	(31.7)
Child's education		
Below elementary	42	(35.0)
Elementary	57	(47.5)
Junior high	12	(10.0)
Senior high or above	9	(7.5)
Father's education		
Junior high	7	(5.8)
Senior high	31	(25.9)
Associate or bachelor's degree	59	(49.2)
Master's degree or PhD	22	(18.3)
Missing	1	(0.8)
Mother's education		
Junior high	6	(5.00)
Senior high	26	(21.6)
Associate or bachelor's degree	66	(55.0)
Master's degree or PhD	20	(16.7)
Missing	2	(1.7)

Note.  $^{a}$ Others included bladder cancer, hepatoblastoma, kidney cancer, and retinoblastoma; ALL = acute lymphocytic leukemia; AML = acute myeloid leukemia; BMI = body mass index; NHL = non-Hodgkin's lymphoma; HL = Hodgkin's lymphoma; SD = standard deviation.

**Table 2** Variable Descriptions and Pearson Correlations.

Variables	Range	Mean	SD	Fatigue	Nutrition	Physical activity	QoL
1. Fatigue	0.00-69.44	22.48	15.51	r = 1.00	<i>r</i> = −.19*	r =34**	r =60**
2. Nutrition	2.60-6.50	4.32	0.75		r = 1.00	r = .16	r = .29**
3. Physical activity	2.00-60.00	28.65	13.75			r = 1.00	r = .38**
4. QoL	37.96-100.00	79.14	14.29				r = 1.00

Note. QoL = quality of life; SD = standard deviation.

correlated with each other, each was individually correlated with both fatigue and QoL.

Simple mediation analysis

After adjusting for age and sex, simple mediation analysis found both a significant total effect ( $\beta=-.55,\,95\%$  confidence interval [CI -0.69 to -0.42) and a significant direct effect ( $\beta=-.52,\,95\%$  CI -0.66 to -0.39) of nutrition on the relationship between fatigue and QoL. We further examined the indirect effect and found that the 95% CI (-0.08 to -0.00) did not include zero. This indicated that after adjusting for age and sex, nutrition partially mediated the adverse effect of fatigue on QoL (see Figure 1).

Mediation and moderation analysis (Model 5)

In the mediation and moderation analysis, after adjusting for age and sex, the direct effect of nutrition on the relationship between fatigue and QoL was significant ( $\beta=-.39$ , 95% CI -0.55 to -0.24) when adding physical activity ( $\beta=.21$ , 95% CI 0.05 to 0.37) and fatigue  $\times$  physical activity ( $\beta=.01$ , 95% CI 0.00 to 0.02). This indicates that all paths in Model 5 were significant (p<.050) and that suggests that physical activity qualified as a moderator between fatigue and QoL when controlling for nutrition (see Figure 2).

Conditional moderating effect on the direct effect of fatigue on QoL

Figure 3 demonstrates how the conditional moderating effect of physical activity affected the relationship between fatigue and QoL after controlling for nutrition. There were significantly decreasing trends in the coefficients of conditions of physical activity at 1 standard deviation below the mean (low physical activity) ( $\beta=-.56,~95\%$  CI-0.72 to -0.40) and at the mean (moderate physical activity) ( $\beta=-.39,~95\%$  CI-0.55 to -0.24). There was no significantly decreasing trend in condition of physical activity at 1 standard deviation above the mean (high physical activity) ( $\beta=-.23,~95\%$  CI-0.47 to 0.01). These results indicate that fatigue was negatively and significantly correlated with QoL among children with low and moderate levels of physical activity.

#### Discussion

Our study identified the associations between nutrition, physical activity, fatigue, and QoL among childhood cancer survivors. Responding to the specific purpose, our finding identified the mediating role of nutrition between fatigue and QoL, which indicates that enhancing children's nutrition could reduce the adverse effect of fatigue on QoL. This is supported by prior studies [13,43].

When we compare the mean phase angle of our study sample with the estimated reference values for healthy children's phase angles in Germany [37], it appears likely that our participants had worse nutritional status. In addition, our use of the cutoff point for poor nutritional status in adults with cancer [38] resulted in more

than one-third of study participants categorized as in poor nutritional status. This is a high proportion of malnutrition among children with cancer and is similar to prior findings [44]. Altogether, these findings highlight the importance of routinely assessing nutritional status for childhood cancer survivors. The goal would be to detect malnutrition early and thus provide timely nutrition interventions to prevent poor nutrition hindering their growth and development [45].

However, there is currently no standardized nutrition assessment in clinical practice for children with cancer [46]. Using a BIA device to acquire phase angle would be a good start. There may be differences in phase angle between populations, and population-specific reference values may be required [42]. As of now, though, published reference values of phase angle for children are lacking. Establishing reference values for healthy children in Taiwan or in other countries with similar ethnic and cultural backgrounds is needed. These reference values can then serve as a basis for phase angle evaluations in the clinical setting to identify childhood cancer survivors—or children with other diseases—whose nutritional status should be closely watched.

Responding to the specific purpose, our finding identified the moderating role of physical activity between fatigue and QoL. This indicates that physical activity may be the variable that affects the strength of the relation between fatigue and QoL. We found that fatigue has an adverse effect on QoL among children who engaged in low and moderate levels of physical activity. In contrast, fatigue had no adverse effect on OoL among those who engaged in a high level of physical activity. These findings indic ated that physical activity might protect childhood cancer survivors from the adverse effect of fatigue and lead to a good and stable QoL. This inference is supported by prior findings that physical activity has a positive effect on QoL in childhood cancer survivors [24,47]. However, an opposite finding was reported by a systematic review and metaanalysis: that physical activity did not moderate QoL [48]. That finding could be associated with participants not following the instructions of physical activity programs due to lack of time, motivation, exercise skills, exercise partners, poor health status, or reluctance to sweat [49,50]. For example, Kim's study found that only 5.0% of participating childhood cancer survivors met physical activity guidelines [49]; Sims's study reported that average increases in participants' activity levels post-intervention only reached 4.47 minutes per day [50]; and Wu's study indicated that children undergoing cancer treatment do not achieve the recommended level of physical activity suggested by the Children's Oncology Group [51,52]. In addition, children entering adulthood are known to follow a natural behavioral pattern of gradually becoming more physically inactive [53]. We conclude that childhood cancer survivors need additional assistance to be physically active.

Evidence indicates that among children undergoing cancer treatment in hospitals, personalized physical activity programs are associated with better QoL, in both physical and psychological dimensions [47]. A similar finding in adult cancer survivors indicates that supervised physical activity has significantly greater effects on QoL than unsupervised activity [54]. Based on these findings, we

<sup>\*</sup>p < .05, \*\*p < .01.

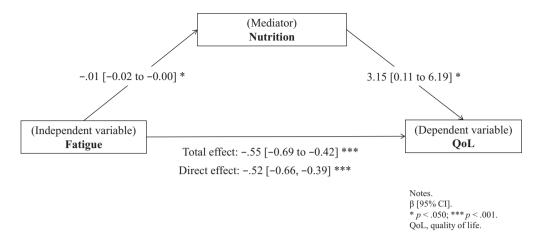


Figure 1. Simple Mediation Analysis after Controlling for the Covariates of Sex and Age.

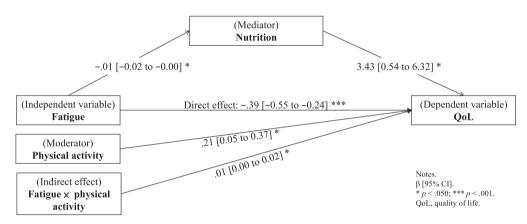


Figure 2. Mediation and Moderation Analysis for Conditional Direct Effect after Controlling for the Covariates of Sex and Age (Model 5).

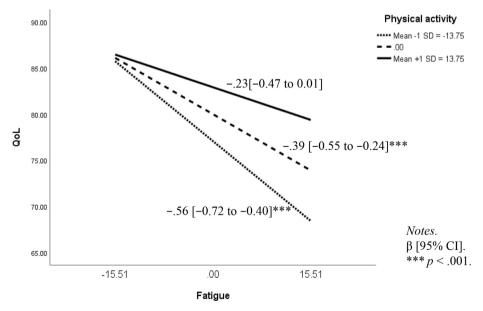


Figure 3. Conditional Moderating Effects of Physical Activity on the Effects of Fatigue on Quality of Life after Controlling for the Covariates of Sex and Age.

infer that personalized and supervised physical activity programs can help childhood cancer survivors reach the minimum intensity, frequency, and duration of activity suitable for improving OoL.

In summary, our study clearly addresses the importance of healthy lifestyle behaviors. A healthy lifestyle consists of proper nutrition and adequate physical activity, both of which are essential to reduce fatigue and enhance QoL for childhood cancer survivors. Yet cancer treatment and its effects directly limit children's opportunities to engage in healthy nutrition and physical activity. Children are known to be at a developmental stage of adopting and consolidating health behaviors [55]. Long-term cancer treatment at a young age may lead these children to get used to an unhealthy lifestyle during critical stages of developing behavioral patterns [56]. Evidence indicates that small and optimal changes in children's lifestyle behaviors can result in obvious improvements to children's health outcomes [47]. Thus, timely correction of such behaviors is important. Such intervention can help these children continue a healthy lifestyle into adulthood.

#### Limitations

Our use of a convenience sample from one medical center may limit this study's generalizability. Also, we used a standard value to identify malnutrition that is based on an adult population [38]; further research to identify appropriate phase angle reference values and cutoff points for malnutrition among children is needed.

#### **Implications**

We observed a high prevalence of malnutrition in our study participants. Clinical practice for childhood cancer survivors should include regular screening of phase angle: at diagnosis, throughout therapy, and into survivorship. A phase angle cutoff point for malnutrition among children needs to be established. In addition, future research is needed to identify unhealthy lifestyle factors and then to develop healthy lifestyle interventions. Such interventions must include adequate frequency, intensity, and duration of physical activity as well as sufficient nutrition to facilitate meaningful changes in lifestyle factors. Clinical dietitians, physical therapists, and pediatric oncology nurses should work as a team to promote healthy nutrition and physical activity among children with cancer.

#### **Conclusion**

Our study demonstrates the importance of both nutrition and physical activity in reducing the adverse effect of fatigue on QoL. This highlights an opportunity to enhance QoL among children with cancer through healthy lifestyle interventions. Healthy lifestyle behaviors need to be promoted throughout children's entire treatment trajectory and in survivorship. Future interventions should include nutrition and physical activity components and should involve nurses, pediatric oncology physicians, nutritionists, and physical therapists to ensure that the interventions address children's needs and promote the greatest impact.

#### **Conflict of interest**

The authors have no conflicts of interest relevant to this article to disclose.

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#### Research Article

### Patient Safety Culture and Speaking Up Among Health Care Workers



Seung Eun Lee,<sup>1,\*</sup> V. Susan Dahinten,<sup>2</sup> Ja-Kyung Seo,<sup>3</sup> InYoung Park,<sup>4</sup> Mi Young Lee,<sup>4</sup> Hye Sung Han<sup>4</sup>

- <sup>1</sup> Mo-Im KIM Nursing Research Institute, College of Nursing, Yonsei University, Seoul, South Korea
- <sup>2</sup> School of Nursing, University of British Columbia, Vancouver, Canada
- <sup>3</sup> Department of Psychology, Yonsei University, Seoul, South Korea
- <sup>4</sup> Division of Quality Improvement, Yonsei University Gangnam Severance Hospital, Seoul, South Korea

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#### SUMMARY

*Purpose:* Although previous research showed the importance of safety culture on health care workers' speaking up behaviors, it is not clear how particular safety culture domains are associated with the speaking up behaviors of hospital staff. Also, researchers have suggested that health care workers' speaking up behaviors vary by profession, but there has been limited research into such differences. Thus, this study examined differences in perceptions of patient safety culture and the promotive and prohibitive speaking up behaviors of health care workers by profession and investigated the relationships between patient safety culture and the two types of speaking up behaviors.

*Methods:* A descriptive correlational study was conducted using secondary data collected through an online survey of health care workers at a private, nonprofit, tertiary-level teaching hospital in South Korea. The sample (N = 831) consisted of nurses (54.0%), physicians (13.0%), and other licensed and unlicensed hospital personnel (33.0%). Analyses of variance were conducted to examine differences in study variables by profession. Hierarchical regression analyses were conducted to evaluate the effects of the seven patient safety culture factors on promotive and prohibitive voice after controlling for tenure and profession.

*Results:* Perceptions of safety culture and promotive voice behaviors were higher for physicians compared with nurses. Communication openness, reporting patient adverse events, and unit supervisors' and hospital managements' support for patient safety were significant predictors of both types of voice behaviors.

Conclusion: Hospital administrators and unit managers should create a supportive environment where staff feel free to voice their concerns and suggestions. They should also pay attention to the varying perspectives held by different groups of hospital workers and their different voice behaviors. Knowing which dimensions of patient safety culture are most strongly related to health care workers' voice behaviors can guide patient safety improvement activities in health care organizations.

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# Seung Eun Lee: https://orcid.org/0000-0002-4173-3337; V. Susan Dahinten: https://orcid.org/0000-0002-5469-922X; Ja-Kyung Seo: https://orcid.org/0000-0002-5065-8383; InYoung Park: https://orcid.org/0000-0003-2981-3921; Mi Young Lee: https://orcid.org/0000-0002-5747-6611; Hye Sung Han: https://orcid.

Introduction

Patient safety has been recognized as a critical health care issue for almost two decades, but approximately one in 10 patients is still harmed while receiving hospital care in high-income countries [1]. Evidence has suggested that the willingness of staff to speak up proactively to improve patient safety is vital as it can not only prevent errors such as medication errors [2] but also provide opportunities for learning and improvements to health care systems [3]. Other terms that have been used to describe the concept of speaking up include employee voice behavior [4], safety voice [5], and assertive communication [6]. One of the most widely used

org/0000-0001-8745-394X

<sup>\*</sup> Correspondence to. Mo-Im KIM Nursing Research Institute, College of Nursing, Yonsei University 50-1 Yonsei-ro, Seodaemun-gu, Seoul 03722, South Korea E-mail address: leese@vuhs.ac

definitions of speaking up in health care is "the raising of concerns by health care professionals for the benefit of patient safety and care quality upon recognizing or becoming aware of the risky or deficient actions of others within healthcare teams" [7], and thus, much empirical attention has been paid to problem-focused voice in health care research. However, organizational literature has suggested that there are two aspects to speaking up: promotive and prohibitive voice [8,9].

Promotive voice refers to employees' expressions of ideas or suggestions with the intention of improving existing work practices and procedures [8]. Prohibitive voice refers to employees' expressions of concerns regarding existing work practices, incidents, or behaviors that they consider to be damaging to the organization [8]. Both types of voice behaviors are critical within health care organizations for improving patient safety and quality of care. Speaking up has been recognized as an important predictor of patient safety outcomes, particularly in acute care hospital settings [10], and it is widely agreed that health care workers should speak up to express concerns or to challenge questionable behaviors and actions in the provision of care [11]. However, health care workers often choose to remain silent rather than voicing their suggestions or concerns even when they have witnessed patient safety threats, possibly because of fear of conflict, retribution, and reprisal [7,12]. To encourage health care workers to speak up, it is essential to identify factors associated with their speaking up behaviors.

One important factor that has been found to be related to the speaking up behaviors of health care professionals is safety culture [3]. Safety culture, a subset of an organizational culture, is defined as "the shared values, attitudes, and behaviors within an organization that direct attention toward patient safety and the minimization of patient harm" [13]. Because safety culture is a complex and multidimensional concept that comprises factors such as leadership, teamwork, learning culture, and communication [14], it is important to examine which dimensions of safety culture are most strongly related to the speaking up behaviors of health care workers [3]. Furthermore, researchers in previous studies have argued that different patterns of relationships between safety culture dimensions and different types of speaking up behaviors exist, but the links have not been well examined with various Korean health care workers [10]. Thus, it is necessary to identify how particular antecedents are associated with promotive and prohibitive behaviors of hospital staff in Korean health care contexts.

Previous literature on speaking up in health care also suggests that health care workers' speaking up behaviors can vary by profession (i.e., physicians, nurses, other health care workers) [3]. However, there has been limited research into such differences, and to our knowledge, no research has been conducted with Korean health care workers. Examining differences in perceptions of safety culture and speaking up behaviors among health care workers is especially important in an environment where seniority-based hierarchies are prevalent across society, in addition to the significant power differentials between physicians and other health care workers, all of which could affect the speaking up behaviors of health care workers [15,16]. In a culture with a seniority strongly determined by age or job longevity and power differentials between professions, speaking up could be more challenging for health care workers [15,16]. Moreover, as the concepts of both speaking up and patient safety culture originated in Western culture [15], it is important to examine how the concepts and their relationships are perceived by health care workers in Korean health care contexts.

In view of the limitations of previous research, this study examined (1) the differences in perceptions of patient safety culture and speaking up behaviors (i.e., promotive and prohibitive voice) by profession; and (2) the relationship between patient

safety culture and the two types of voice among health care workers after accounting for tenure and profession.

#### Methods

Design and sample

This descriptive correlational study was conducted using secondary data collected at a private, nonprofit, tertiary-level teaching hospital with a total capacity of over 700 beds in Seoul, South Korea. The deidentified data were provided by a quality improvement manager of the hospital. This hospital has assessed perceptions of patient safety culture among their employees every 2 years to identify areas of strength and weakness with the goal of enhancing patient safety and quality of care throughout the organization. In January 2021, survey invitations comprising a secure online link were emailed to all hospital staff as part of one such biannual safety culture assessment in accordance with the Agency for Healthcare Research and Quality's instructions [17]. Participation in the study was voluntary, and a total of 915 responses were received. As a relatively small number of managers in various disciplines completed the survey, in this study, we only used data from staff employees, and the final sample size for this study was 831.

In prior patient safety culture studies, Korean health care professionals have reported that a punitive culture is prevalent in their organizations [18]. Because this could hinder the honest reporting of patient safety issues, in the original survey, demographic information such as age and gender of subjects that could be used to identify respondents was not included in the questionnaire. Because the original survey was part of biannual patient safety culture assessment in the hospital, participation was voluntary, and consent was implied by survey completion. Ethics approval for this secondary data analysis study was obtained from the Institutional Review Board of the Yonsei university health system (#4-2021-0297).

#### Measures

#### Outcome variables

The 10-item, 2-dimension scale developed by Liang et al. [8] was used to measure health care workers' ratings of their *promotive and prohibitive voice behaviors* on a 5-point response scale, ranging from 1 (strongly disagree) to 5 (strongly agree). A sample item for promotive voice is "I make constructive suggestions to improve the unit's operation." An example item for prohibitive voice is "I dare to point out problems when they appear in the unit, even if that would hamper relationships with other." The scale has shown good psychometric properties in previous research [8]. For this study sample, Cronbach's  $\alpha s$  for promotive and prohibitive voice were 0.92 and 0.88, respectively. Exploratory factor analysis with principle components analysis supported the two-factor model, which explained 74.1% of the variance; factor loadings ranged from 0.58 to 0.85. The mean subscale scores were computed with higher scores indicating higher levels of promotive and prohibitive voice.

#### Safety culture variables

Eight patient safety culture factors (i.e., subscales) were measured using the Korean version of Hospital Survey on Patient Safety Culture 2.0 (K-HSOPSC 2.0), which has demonstrated its good reliability and validity [19]. The K-HSOPSC was adapted based on the Agency for Healthcare Research and Quality's Hospital Survey on Patient Safety Culture version 2.0 [20]. The number of items and an example item of the eight subscales are as follows. Organizational learning—continuous improvement was measured using three items; an example is "This unit regularly reviews work

processes to determine if changes are needed to improve patient safety." Response to error was assessed using four items, and a sample item is "In this unit, staff feel like their mistakes are held against them." Supervisor/clinical leader support for patient safety was measured using three items, and "My supervisor, manager, or clinical leader seriously considers staff suggestions for improving patient safety" is an example item. Communication about error was assessed using three items, and a sample item is "We are informed about errors that happen in this unit." Communication openness was assessed using four items, and "In this unit, staff are afraid to ask questions when something does not seem right" is a sample item. Hospital management support for patient safety was measured using three items, and "The actions of hospital management show that patient safety is a top priority" is a sample item. Teamwork was measured using three items, and an example is "In this unit, we work together as an effective team." Reporting patient safety events was measured using two items, and an example item is "When a mistake is caught and corrected before reaching the patient, how often is this reported?"

With possible scores ranging from 1 to 5 (for strongly disagree to strongly agree, or never to always), higher scores indicate a more positive perception of safety culture. For this study sample, Cronbach's alphas for the patient safety culture subscales were 0.68 (organizational learning), 0.77 (response to error), 0.78 (supervisor/clinical leaders support for patient safety), 0.84 (communication about error), 0.72 (communication openness), 0.71 (hospital management support for patient safety), 0.70 (teamwork), 0.84 (reporting patient adverse events), 0.92 (promotive voice), and 0.88 (prohibitive voice), all of which exceeded the minimum threshold of 0.60 [21].

#### Demographic variables

Information on profession, hospital tenure, and unit tenure were collected.

# Data analysis

The study variables were screened for normality, homoscedasticity, and linearity before investigating their relationships. None of the study variables had exceeded the absolute value of 2 for skewness and kurtosis, indicating that the data did not significantly deviate from normality. Regression diagnoses, including residual plots and quantile-quantile plots, were further conducted to assess linearity and homoscedasticity. The plots showed no evidence of substantial deviations from regression assumptions. Descriptive statistics were used to summarize sample characteristics and study variables by group. Pearson bivariate correlations were computed for hospital tenure, unit tenure, patient safety culture dimensions, and voice behavior variables to examine their relationships. Next, a series of analyses of variance with post hoc tests was conducted to examine mean differences in study variables by profession. Post hoc tests using Bonferroni or Duncan methods were performed on the three professional groups to identify which particular group differences were significant. Hierarchical multiple regression analyses were then conducted to evaluate the effects of the eight patient safety culture factors on promotive and prohibitive voice, after controlling for hospital and unit tenure, and profession due to their probable associations with the outcome variables [8,22,23]. Statistical analysis was conducted with SPSS version 25 (Armonk, NY: IBM Corp), with a statistical significance level set at p < 0.05.

#### Results

Sample characteristics

The sample comprised 831 health care workers. As in previous safety culture studies, we categorized professions into three groups: nurse, physician, and others [24,25]. As shown in Table 1, about half (54.2%) of the sample were nurses, 12.5% were physicians, and the remaining participants (33.3%) were a mixture of unlicensed (e.g., transporter) and licensed (e.g., pharmacist, physical therapist, and laboratory technician) personnel. Physicians reported the shortest hospital tenure, whereas nurses reported the shortest unit tenure.

Differences in patient safety culture and speaking up by profession

Analyses of variance results indicated that were significant differences across professions for all eight patient safety culture dimensions and for promotive and prohibitive voice behaviors (Table 2). Post hoc analyses showed that, on average, physicians' scores were higher than nurses' scores for 8 of the 10 variables. The exceptions were reporting patient safety events and prohibitive voice, where only the others group was significantly higher than the nurse group.

Relationships between patient safety culture and speaking up

Table 3 presents the bivariate correlations between the key study variables. Hospital and unit tenure and all eight patient safety dimensions were positively associated with both promotive and prohibitive voice. Organizational learning and communication openness were most strongly associated with promotive voice (r=0.41 and 0.39, respectively), whereas communication openness and teamwork were most strongly associated with prohibitive voice (r=0.43 and 0.41, respectively).

Before conducting hierarchical multiple regression analyses, variance inflation factors between the predictor variables were examined. Variance inflation factors ranged from 1.09 to 2.36, all below the cut-off value of 10, indicating no potential multicollinearity. Moreover, the Durbin—Watson statistics of each model was approximately 2 (i.e., 1.95 for promotive voice and 1.90 for prohibitive voice), indicating that there exists no evidence of autocorrelation in the residuals from these two regression models.

Tables 4 and 5 present the results for the two-step hierarchical multiple regression analyses that were conducted for promotive voice and prohibitive voice. Hospital and unit tenure and profession were entered in Model 1 as control variables. Profession was dummy coded with nurses serving as the reference group. The eight safety culture factors were entered in Model 2.

The regression analyses yielded some differences in the predictors that were associated with promotive versus prohibitive voice. In Model 1, neither hospital tenure nor unit tenure was significantly associated with promotive voice, whereas hospital

**Table 1** Sample Characteristics (N = 831).

	Nurses (n = 450, 54.2%)	Physicians ( <i>n</i> = 104, 12.5%)	Other professions ( $n = 277, 33.3\%$ )	All $(n = 831)$
Hospital tenure (yr), mean (SD) ( $n = 766$ ) Unit tenure (yr), mean (SD) ( $n = 766$ )	12.41 (9.51) 5.28 (5.54)	6.18 (6.10) 5.65 (5.96)	13.30 (11.64) 6.63 (7.94)	11.92 (10.16) 5.77 (6.50)
Offit tenure (yr), mean (3D) ( $n = 700$ )	5.28 (5.54)	3.03 (3.90)	0.03 (7.94)	3.77 (0.30)

**Table 2** *Mean Differences in Patient Safety Culture Dimensions and Voice Behaviors by Profession (N* = 831).

Variable	Nurses <sup>a</sup> ( $n = 450$ ), mean (SD)	Physicians <sup>b</sup> ( $n = 104$ ), mean (SD)	Others <sup>c</sup> ( $n = 277$ ), mean (SD)	F	p	Post hoc analyses (Bonferroni or Dunnett's tests)
Patient safety culture		_				
Organizational learning	3.26 (0.68)	3.65 (0.66)	3.49 (0.63)	19.74	< 0.001	a < b, c
Response to error	2.82 (0.71)	3.39 (0.71)	3.13 (0.75)	32.73	< 0.001	a < c < b
Supervisor/clinical leader support for patient safety	3.65 (0.66)	3.90 (0.67)	3.72 (0.72)	5.82	0.003	a < b
Communication about error	3.27 (0.75)	3.61 (0.87)	3.06 (0.86)	17.84	< 0.001	c < a < b
Communication openness	3.18 (0.62)	3.51 (0.76)	3.18 (0.72)	11.00	< 0.001	a, c < b
Hospital management support for patient safety	2.86 (0.72)	3.45 (0.89)	3.24 (0.69)	39.35	<0.001	a < b, c
Teamwork	3.50 (0.67)	3.91 (0.69)	3.70 (0.73)	18.00	< 0.001	a < c < b
Reporting patient adverse events	3.31 (0.87)	3.53 (0.95)	3.55 (0.96)	6.98	0.001	a < c
Promotive voice	3.13 (0.68)	3.41 (0.84)	3.33 (0.65)	11.08	< 0.001	a < b, c
Prohibitive voice	3.19 (0.65)	3.34 (0.76)	3.33 (0.60)	5.26	0.005	a < c

Note. Welch's *F* test and Dunnett's *post hoc* test were conducted for Communication openness, hospital management support for patient safety, teamwork, reporting patient adverse events, promotive voice, and prohibitive voice because the assumption of equal variance was not satisfied.

SD = standard deviation.

**Table 3** Correlations of Patient Safety Culture Dimensions and Voice Behavior (N = 831).

Variable	1	2	3	4	5	6	7	8	9	10	11	12
1. Hospital tenure (yr)	_											
2. Unit tenure (yr)	0.57**	_										
3. Organizational learning	-0.14**	-0.10**	_									
4. Response to error	-0.16**	-0.06	0.60**	_								
5. Supervisor/clinical leader support for patient safety	-0.22**	-0.13**	0.56**	0.56**	_							
6. Communication about error	-0.25**	-0.12**	0.24**	0.18**	0.32**	_						
7. Communication openness	-0.17**	-0.08*	0.46**	0.45**	0.52**	0.63**	_					
8. Hospital management support for patient safety	-0.06	-0.02	0.54**	0.56**	0.39**	0.09**	0.33**	_				
9. Teamwork	-0.14**	-0.10**	0.63**	0.55**	0.57**	0.28**	0.48**	0.43**	_			
10. Reporting patient adverse events	0.05	0.07	0.31**	0.28**	0.27**	0.32**	0.41**	0.29**	0.29**	_		
11. Promotive voice	0.08*	0.12**	0.41**	0.36**	0.36**	0.23**	0.39**	0.36**	0.37**	0.32**	_	
12. Prohibitive voice	0.14**	0.12**	0.37**	0.36**	0.38**	0.24**	0.43**	0.34**	0.41**	0.34**	0.71**	_

<sup>\*</sup>p < 0.05. \*\*p < 0.01.

**Table 4** Hierarchical Multiple Regression Models for Promotive Voice (N = 764).

Predictors		Mod	del 1			Mod	del 2	
	В	SE	β	p	В	SE	β	р
Hospital tenure (yr)	<0.01	<0.01	0.04	0.325	0.01	<0.01	0.12	0.003
Unit tenure (yr)	0.01	0.01	0.08	0.070	0.01	< 0.01	0.09	0.014
Profession <sup>a</sup>								
Physicians	0.28	0.08	0.14	< 0.001	0.05	0.07	0.02	0.483
Others	0.18	0.06	0.12	0.001	0.08	0.05	0.05	0.123
Patient safety culture								
Organizational learning					0.16	0.05	0.15	0.001
Response to error					0.05	0.04	0.05	0.264
Supervisor/clinical leader support for patient safety					0.09	0.04	0.08	0.047
Communication about error					0.05	0.04	0.05	0.197
Communication openness					0.17	0.05	0.16	0.001
Hospital management support for patient safety					0.10	0.04	0.11	0.004
Teamwork					0.05	0.04	0.05	0.235
Reporting patient adverse events					0.07	0.03	0.10	0.007
$R^2$ (change in $R^2$ )	0.04 (0.0	4)			0.30 (0.2	7)		
Adjusted $R^2$	0.03	,			0.29	,		
F(p)	7.18 (<0	.001)			27.03 (<0	.001)		
F change (p)	7.18 (<0	,			35.65 (<0	,		

*Note.* SE = standard error.

tenure was significantly related to prohibitive voice. In Model 2, hospital and unit tenure became statistically significant for promotive voice, whereas hospital tenure stayed as a significant predictor for prohibitive voice. Profession was statistically significant when entered in Model 1 for both promotive and prohibitive voice, indicating that physicians and others had higher scores than nurses, but the regression coefficients became

nonsignificant in Model 2 when safety culture factors were entered.

Five of the eight safety culture factors were uniquely predictive of promotive voice, and five were uniquely predictive of prohibitive voice. After controlling for tenure and profession, communication openness ( $\beta = 0.16$ , B = 0.17, p = 0.001) was the strongest predictor of promotive voice, followed by organizational learning ( $\beta = 0.15$ ,

a Reference: nurses.

**Table 5** Hierarchical Multiple Regression Models For Prohibitive Voice (N = 764).

Predictors		Mod	del 1			Mo	del 2	
	В	SE	β	p	В	SE	β	p
Hospital tenure (yr)	0.01	<0.01	0.13	<0.01	0.01	<0.01	0.21	<0.001
Unit tenure (yr)	< 0.01	< 0.01	0.04	0.352	0.01	< 0.01	0.05	0.184
Profession <sup>a</sup>								
Physicians	0.19	0.07	0.10	0.010	-0.03	0.06	-0.02	0.619
Others	0.11	0.05	0.08	0.036	0.02	0.04	0.01	0.666
Patient safety culture								
Organizational learning					0.01	0.04	0.01	0.802
Response to error					0.07	0.04	0.08	0.074
Supervisor/clinical leader support for patient safety					0.09	0.04	0.10	0.020
Communication about error					0.03	0.03	0.04	0.379
Communication openness					0.22	0.04	0.23	< 0.001
Hospital management support for patient safety					0.08	0.03	0.10	0.012
Teamwork					0.13	0.04	0.14	0.001
Reporting patient adverse events					0.08	0.02	0.12	0.001
$R^2$ (change in $R^2$ )	0.03 (0.0	03)			0.34 (0.3	31)		
Adjusted R <sup>2</sup>	0.03				0.33			
F(p)	6.38 (<0	0.001)			32.20 (<0	0.001)		
F change (p)	6.38 (<0	0.001)			43.67 (<0	0.001)		

*Note.* SE = standard error.

 $B=0.16,\ p=0.001$ ), hospital management support for patient safety ( $\beta=0.11, B=0.10, p=.004$ ), reporting patient adverse events ( $\beta=0.10, B=0.07, p=0.007$ ), and supervisor/clinical leader support for patient safety ( $\beta=0.08, B=0.09, p=0.047$ ), based on the values of the standardized coefficients. For prohibitive voice, communication openness ( $\beta=0.23, B=0.22, p<0.001$ ) was the strongest predictor, followed by teamwork ( $\beta=0.14, B=0.13, p=0.001$ ), reporting patient adverse events ( $\beta=0.12, B=0.08, p=0.001$ ), hospital management support for patient safety ( $\beta=0.10, B=0.08, p=0.012$ ), and supervisor/clinical leader support for patient safety ( $\beta=0.10, B=0.09, p=0.020$ ) based on the values of the standardized coefficients.

# Discussion

This study examined differences in perceptions of patient safety culture and two types of voice behaviors (i.e., promotive and prohibitive voice) among health care workers by their profession (nurse vs. physician vs. other health care workers). We also investigated the relationships between patient safety culture and the outcomes after accounting for hospital and unit tenure and profession of study participants. Knowing which dimensions of patient safety culture are most strongly related to health care workers' voice behaviors and differences in perceptions by profession can guide patient safety improvement activities in health care organizations.

In the present study, on average, nurses' scores were lower than physicians' scores for all safety culture variables and promotive voice. The exceptions were prohibitive voice and reporting patient adverse events, where only the others group was significantly higher than the nurse group. This finding is consistent with results from a Taiwanese study [26] and two studies in Swiss hospitals [27,28], showing that physicians reported higher levels of patient safety culture than nurses. These findings call for attention as nurses are in a unique position to monitor patient care and the hospital environment on a 24-hour basis, and thus, their perceptions of safety culture and patient safety may be more accurate or comprehensive than perceptions by other hospital personnel [28,29]. However, prior research [5] has shown that nurses are unwilling to speak up because of their feelings of ineffectiveness and powerlessness and embedded expectations that are related to the power dynamics and authority gradients in health care environments. Regardless of the type of voice behavior, it would be particularly challenging for health care workers in the lower levels of a hierarchy to voice their suggestions or concerns in countries where hierarchy, collectivism, and obedience are cultural values [15,16]. Thus, hospital administrators and nurse managers should make an effort to create an environment that supports and empowers nurses to voice their ideas and concerns [28].

This study found that all eight patient safety culture dimensions were positively associated with health care workers' promotive and prohibitive voice, similar to a recent US study where researchers found that those who had positive views on safety culture reported always voicing their concerns about patient safety [3]. The results from the hierarchical multiple regression analyses in the present study indicate the importance of communication openness, reporting of adverse events, and unit supervisors' and hospital managements' support for patient safety as important predictors of both types of voice behaviors. When health care workers perceive that the hospital leaders value patient safety and support open communication and reporting culture, they are more likely to make constructive suggestions (promotive voice) and voice their concerns (prohibitive voice) to improve operations in their unit or hospital, as well as patient safety. Other literature [30-32] has also suggested that supervisors' and hospital management's support for patient safety and communication openness would foster health care workers' engagement in behaviors that contribute to patient safety. Also, a culture that supports error reporting would provide opportunities to learn from mistakes, which enables continuous organizational learning [33]. Therefore, unit managers and hospital leaders should create an environment that is supportive for error reporting and receptive to employee input, for example, by inviting staff suggestions and concerns, actively listening to them, showing appreciation, and responding appropriately to such input [34,35]. Also, managers should understand that employee voice is not necessarily a voice of complaint but often indicates a desire to contribute to improvements in the organization [36] and thus should encourage their staff to speak up.

#### Limitations

To our knowledge, this study is the first to examine differences in perceptions of patient safety culture and promotive and prohibitive voice behaviors among health care workers by professions

<sup>&</sup>lt;sup>a</sup> Reference: nurses.

and to investigate the associations between patient safety culture and the two types of voice behaviors in a Korean health care context. Although it contributes to the sparse literature on the relationship between an organizational characteristic (i.e., organizational safety culture in the present study) on employee voice [3,9], several limitations should be noted. First, the use of data from a single health care organization limits the generalizability of our study findings, and we cannot draw causal inferences when using cross-sectional data. We recommend that future studies aim to confirm the findings from this present study with by sampling from multiple health care settings and striving for a higher response rate. Second, because all data were collected using self-report questionnaires, the data are inherently subjective. Third, although we controlled for hospital and unit tenure, and profession due to their probable associations with promotive and prohibitive voice [8,22,23], unknown or unmeasured factors (e.g., assertiveness) could have contributed to the relationships found in the present study. Finally, we were not able to use data from managers due to relatively small sample size. However, as previous international literature suggests that health care workers' perceptions of patient safety culture [37,38] and speaking up behaviors can vary by position (i.e., staff vs. managers) [27], future research should examine whether similar differences can be found in Korean health care contexts.

#### Conclusion

This study provides new knowledge on patient safety culture and voice behaviors among health care workers. We found that, overall, nurses reported significantly less positive perceptions of patient safety culture and lower levels of promotive voice than other hospital personnel. This finding suggests that hospital administrators should pay attention to the varying perspectives held by different groups of hospital workers and their different behaviors. Considering only the average level of responses to surveys measuring patient safety culture or voice behaviors may obscure differences by profession, which have important implications for appropriate interventions. It was also notable that promotive voice and prohibitive voice were influenced by different patient safety culture dimensions, indicating that the two types of voice should be examined separately, and different interventions might be needed for each. Finally, as shown in this study, it is important for hospital leaders and unit supervisors to consider staff suggestions, address patient safety concerns, and support speaking up culture to encourage all members in health care organizations to voice their concerns and make constructive suggestions, which are all essential for improving patient safety.

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#### **Conflict of Interest**

The authors have no conflicts of interest to declare.

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## Research Article

# Effect of Animal-Assisted Therapy (AAT) on Social Interaction and Quality of Life in Patients with Schizophrenia during the COVID-19 Pandemic: An Experimental Study\*



Chieh-An Shih, Man-Hua Yang<sup>2, \*</sup>

- <sup>1</sup> National Taiwan University, Taiwan
- <sup>2</sup> National Yang Ming Chiao Tung University, Taiwan

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#### SUMMARY

*Purpose:* Most patients with schizophrenia exhibit low willingness to return to society because of negative social experiences. The COVID-19 pandemic led to severe social isolation for schizophrenia patients. However, animal-assisted therapy (AAT) can improve individuals' empathy, social functions, and quality of life. The study aimed to evaluate the effectiveness of AAT in improving social interactions and quality of life in patients with chronic schizophrenia during the COVID-19 pandemic.

Methods: An experimental study was conducted, with six institutions for psychiatric rehabilitation in Taiwan as the case institutions. Patients in these institutions were randomly allocated to the experimental group, which received 60 minutes of AAT once a week for 12 weeks, or the control group, which engaged in routine discussion groups and watched short films about animals. Comparisons between the two groups were made before and after the intervention on social function, social adaptive function, and quality of life. Data were collected before the intervention (T1), immediately after the intervention (T2), and 3 months after the intervention (T3).

Results: Comparison between groups showed that social functioning was significantly higher in the experimental group than in the control group at T2. However, there was no sign of improvement in social adaptive functions of the experimental group. The experimental group exhibited significantly higher quality of life than the control group at T2 and T3.

Conclusions: There was an impact of COVID-19 on the studied effects. AAT improved social functioning and quality of life in patients with chronic schizophrenia. The effect on quality of life lasted only up to 3 months after the intervention. AAT should be promoted for use as a community-based rehabilitation tool in patients with chronic schizophrenia.

Trial registration: Chinese Clinical Trial Registry, ChiCTR2200061715. https://www.chictr.org.cn.

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#### Introduction

The restoration of patients suffering from psychiatric disorders to society has been a crucial topic given recent trends toward deinstitutionalization. Patients with psychiatric disorders who

Chieh-An Shih: https://orcid.org/0000-0001-5603-2667; Man-Hua Yang: https://orcid.org/0000-0002-1554-4639

E-mail addresses: happytiger8899@gm.ym.edu.tw, mhyang@nycu.edu.tw

receive long-term institutional treatment may experience an impaired quality of life and face challenges in returning to and living in society [1]. The possession of beneficial social skills is crucial for patients with psychiatric disorders to return to a community and may improve their quality of life and increase their satisfaction with social support. However, during their return to society, patients with psychiatric disorders may be less willing to interact with others because of their previous experiences with stigmatization and ostracism [2,3]. In particular, patients with schizophrenia experience discrimination and misunderstanding most frequently. Patients who take medication regularly may still exhibit residual psychotic symptoms. When others do not understand their disease condition, they can easily misunderstand and

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<sup>\*</sup> Correspondence to: Man-Hua Yang, No. 155, Sec. 2, Linong St., Beitou Dist., Taipei City 112, Taiwan.

**Table 1** Framework of the 12 Week Animal-Assisted Therapy Program.

Goal	Proposal content
Building relationship	Week 0 Introducing the group  1. Introduce the content of the group activity to the participants  2. Finish the distribution and measurements of the pretest questionnaires  Week 1 Meet the puppies  1. Introduce the participants to each other and start building relationship  2. Increase participants' willingness to continue engaging in these activities  Week 2 Get to know the puppies—"touching"  1. Guide the participants to try to get along with the service dogs  2. Guide the participants to touch the service dogs to induce their confidence of making social connections and also build trust between each other
Brief interaction	<ol> <li>Week 3 Get to know the puppies—"stand up, sit down"</li> <li>Stimulate the participants' sense of autonomy by establishing simple instructions to the service dogs</li> <li>The success of establishing instructions to the service dogs impacts the participants by increasing their confidence in their problem solving skills</li> <li>Week 4 "embrace and admire"</li> <li>The service dogs will lay down beside the participants, making the participants feel secure and trusted</li> <li>Reflecting on the participants' emotional dilemmas by sharing one's thoughts and listening to others' advices</li> <li>Week 5 "Take a walk together"</li> <li>From walking the service dogs, the participants get to improve their social interaction skills</li> <li>The activity can increase the participants' physical flexibility and also increase their ability to get along with other people</li> <li>Week 6 Feeding</li> <li>Increase the participants' feeling of being able to control matters and boost their confidence by the sense of accomplishment after feeding process to the service dogs</li> <li>Let every participant experience the achievement felt through feeding and commanding</li> </ol>
Deeper interaction	Week 7 Groom and talk  1. Train the participants' communication and social interaction skills through group activities and talking to each other  2. Foster the participants' confidence during social interactions  Week 8 Repeat week 1–7  1. Hold competitive games to help increase the participants' confidence, sense of accomplishment, and self-efficacy  2. Increase the time of physical activities to train the participants' physical coordination and flexibility through group activities  Week 9 Go through the tunnel together  1. Improve interactive skills between both participants and service dogs through group activities  2. The use of competitive games can provoke the participants' aggressiveness and increase their sense of accomplishment and confidence, hence accumulate their feelings of self-efficacy  Week 10 Touching puppies without seeing  1. Increase the participants' awareness to others' sound and concentrate through the game  2. The participants are able to feel other people physically by touching the service dogs, at the same time practice the appropriate way to control their strength during physical interactions with others  Week 11 Depict the puppy in their most beautiful way  1. Deepen the impression of other participants and the service dogs through painting  2. By holding a group talk session, the participants can share their inner thoughts, receive feedback, and encourage each other  Week 12 Wave goodbye  1. Enhance positive emotions when the participants think back about the memories of group activities  2. Stimulate harmonious relationship between the participants by group activities

become upset with the patients. The patients thus face setbacks in interpersonal relationships, experience distress, and feel a sense of worthlessness and helplessness [3]; these factors can lower their intention to engage in social interaction [4,5]. When patients with schizophrenia exhibit increased levels of loneliness and social isolation, they are likely to develop illusions and delusions [6]. Social isolation is not only a critical predictor of both positive and negative symptoms but also a risk factor for suicidal behavior and intention [7,8]. Since the outbreak of the COVID-19 pandemic in 2019, human interactions have decreased significantly, worsening the social isolation of schizophrenia patients. Ma et al. [9] conducted a study on schizophrenia patients dwelling in psychiatric facilities and concluded that, after their close contact with COVID-19 patients, there was an obvious increase in social isolation compared to those who did not interact with COVID-19 patients, showing that COVID-19 leads to severe mental burden.

To improve the social interaction skills of patients with schizophrenia, professionals in healthcare institutions should establish stable and positive therapeutic relationships with patients before initiating treatment. However, interpersonal relationships are subjective experiences, even for well-trained professionals; unconditional acceptance of a relationship with other people cannot be achieved easily. Relationships with animals, however, can mitigate this difficulty. The enthusiasm of dog could motivated and engaged participants and help improving participants' social interaction despite their age and diseases [10]. Animal-assisted therapy (AAT) involves the appropriate introduction of animals that satisfy certain criteria into healthcare scenarios with the guidance and assistance of professionals to achieve goal-oriented intervention measures [11]. Animals show unconditional acceptance and companionship, thereby helping reduce depression and anxiety symptoms in older adults [12] and aiding teenagers in understanding their behavioral problems and increasing empathy [13]. Among studies concerning the use of AAT to help patients with psychiatric disorders, Calvo et al. [14] conducted a randomized clinical trial to study the application of AAT to patients with schizophrenia. The results revealed that patients in the experimental group not only improved significantly in terms of both positive and negative symptoms but also exhibited fewer negative symptoms and problematic behaviors, such as social withdrawal after discharge from the hospital. Chang et al. [15] conducted 24 weeks of AAT group activity for patients with schizophrenia and recorded the therapeutic process with respect to 20 patients. The content analysis results indicated that positive activity design and social interaction among participants created supportive group atmospheres, improved participants' willingness to challenge themselves, and increased their self-efficacy. These research results

**Table 2** *Demographic Data* (N = 90).

Variables	Participants ( $n = 90$ )	Experiment group $(n = 45)$	Control group $(n = 45)$			
	n (%)	n (%)	n (%)	$\chi^2$	p	
Gender				0.04	.833	
Women	45 (50.00)	23 (51.11)	22 (48.89)			
Men	45 (50.00)	22 (48.89)	23 (51.11)			
Marriage				0.05	.829	
Single	55 (61.11)	28 (62.22)	27 (60.00)			
Married/divorced	35 (38.89)	17 (37.78)	18 (40.00)			
Educational level	, ,	, ,	, ,	0.00	.999	
Below high school	58 (64.44)	29 (64.44)	29 (64.44)			
University or above	32 (35.56)	16 (35.56)	16 (35.56)			
Religious belief	, ,	, ,	, ,	0.73	.677	
No	6 (6.67)	4 (8.89)	2 (4.44)			
Yes	84 (93.33)	41 (91.11)	43 (95.56)			
Employment	, ,	, ,	, ,	0.56	.455	
No	69 (76.67)	33 (73.33)	36 (80.00)			
Yes	21 (23.33)	12 (26.67)	9 (20.00)			
Family visiting	, ,	, ,	, ,	4.87	.027*	
No	16 (17.78)	4 (8.89)	12 (26.67)			
Yes	74 (82.22)	41 (91.11)	33 (73.33)			
Experiencing side effects	, ,	` ,	` ,	1.11	.292	
No	45 (50.00)	25 (55.56)	20 (44.44)			
Yes	45 (50.00)	20 (44.44)	25 (55.56)			
	$M \pm SD$	$M \pm SD$	$M \pm SD$	t	р	
Age	50.2 ± 9.6	49.5 ± 9.5	51.0 ± 9.7	-0.74	.459	
Age of morbidity	$30.6 \pm 11.0$	29.7 ± 11.1	$31.4 \pm 10.9$	-0.75	.457	

Note: M (SD) Continuous variables used Independent t test; n (%) Categories variables used Chi-square test or Fisher's exact test; \*p < .05.

suggest that AAT can substantially improve the physical conditions, psychological status, and quality of life of patients with schizophrenia.

To date, only a limited amount of research has been conducted concerning the application of AAT to patients with schizophrenia. In particular, the social interaction between patients with schizophrenia and other individuals has rarely been explored during the COVID-19 pandemic. Most relevant studies have focused on positive and negative symptoms, depression and anxiety, and quality of life. The objective of the present study was to explore the effectiveness of AAT with respect to improving the social interaction and quality of life of patients with chronic schizophrenia during the COVID-19 pandemic.

#### Methods

#### Research site and recruitment

This longitudinal, single-blind experimental study mainly recruited participants from institutions for psychiatric rehabilitation in northern Taiwan. A small psychiatric rehabilitation institution generally has an average of 15-30 residents in Taiwan. This study needed to recruit 4-6 institutions. A lot-drawing method using Microsoft Excel was employed to provide a random selection of all institutions for participant recruitment. After approvals were obtained from six institutions by the selection list, coin tosses were used to assign an institution randomly to the experimental or control group, with three institutions per group. Participants of the control group and the experimental group were not in contact throughout the intervention, avoiding interference to the results. The intervention activities in both groups involved the participation of researchers, and animals were featured in the intervention activities of both groups. Participants and institution personnel were blinded to the grouping. Recruitment took place between January 29 and February 7, 2021. The researchers introduced and highlighted the benefits of the objectives and contents of the study to residents at the institutions' activity halls. Individuals who satisfied the inclusion criteria were recruited after signed consent forms were obtained.

The researchers wanted to investigate the changes over time. Referencing Olsen et al. [16]'s research design. Data were collected before the intervention (T1), immediately after the intervention (T2), and 3 months after the intervention (T3).

# Inclusion and exclusion criteria for participant recruitment

The inclusion criteria were as follows: patients diagnosed with schizophrenia according to the *Diagnostic and Statistical Manual of Mental Disorders*, 5th edition; patients who resided in the institution for psychiatric rehabilitation throughout the research period (at least 3 months); patients with ages between 20 and 65 years; and patients who were able to listen to, speak, and write Mandarin or Taiwanese. The exclusion criteria were patients with cognitive impairment, alcoholism, brain injury, mental retardation, personality disorders, or allergies to or fears of dogs.

# Sampling

The study used G-power to calculate the sample size. Utilizing the work of Virués-Ortega et al. (2012) on the meta-analysis of AAT on elderly populations and patients with psychiatric disorders, outcome indicators including depression, anxiety, and behavior disturbances. The range of the effect size is 0.29–0.34 [17] and is small to medium ES [18]. The criteria set by this study are rigorous, while ES was set at 0.25, with  $\alpha$  being set at 0.05 and power at 0.8. Repeated-measures statistical tests were used at three time points. The total sample size was 86 participants. To account for possible withdrawals, this study recruited 90 patients. After the study has concluded, doing post hoc power analysis by G-power and we found that the calculating power is 81.9%.

# Research ethics

This study was reviewed by the Institutional Review Board of National Yang Ming ChiaoTung University, Approval no. YM109184F. Participants were informed that they could withdraw any time without affecting their rights. All personal data

**Table 3** Effectiveness of AAT on Social Function (MHSFS), Social Adaptive Function (SAFS) and Quality of Life (WHOQOL) among Patients with Schizophrenia (N = 90).

Variables		Control group ( $n = 45$	)	Experimental group $(n = 45)$				
	T <sub>1</sub>	T <sub>2</sub>	T <sub>3</sub>	T <sub>1</sub>	T <sub>2</sub>	T <sub>3</sub>		
Social function $M \pm SD$ Social adaptive function $M \pm SD$ Quality of life $M \pm SD$	54.09 ± 13.80 11.87 ± 7.67 78.38 ± 11.89	55.18 ± 14.34 10.51 ± 8.21 81.02 ± 16.82	54.81 ± 12.97 10.16 ± 7.46 75.16 ± 13.81	$50.56 \pm 11.89$ $11.56 \pm 7.66$ $79.33 \pm 13.40$	$52.80 \pm 11.93$ $9.87 \pm 7.69$ $86.42 \pm 17.98$	46.07 ± 14.36 9.30 ± 8.73 86.64 ± 15.92		
Social function $t^1/t^2$ Social adaptive function $t^1/t^2$ Quality of life $t^1/t^2$		2.45* -2.52* 1.85	1.20 -2.95** -1.83		4.12** -4.18** 4.10**	-1.85 -1.60 3.08**		
		В		SE		$P_{adj}$		
Group (reference: control group) Experimental group Time (reference: baseline)	-2.88	3 <sup>a</sup> /-0.34 <sup>b</sup> /1.23 <sup>c</sup>	2.8	4 <sup>a</sup> /1.71 <sup>b</sup> /3.26 <sup>c</sup>	.116 <sup>a</sup>	/.649 <sup>b</sup> /.021* <sup>c</sup>		
T2 T3		0 <sup>a</sup> /-1.36 <sup>b</sup> /2.64 <sup>c</sup> 1 <sup>a</sup> /-1.91 <sup>b</sup> /-3.48 <sup>c</sup>		9 <sup>a</sup> /0.40 <sup>b</sup> /1.40 <sup>c</sup> 30 <sup>a</sup> /1.13 <sup>b</sup> /2.48 <sup>c</sup>		** <sup>a</sup> /<.01** <sup>b</sup> /<.01** <sup>c</sup> /.043* <sup>b</sup> /.536 <sup>c</sup>		
Group × time (reference: control gr Experimental group × T2 Experimental group × T3	oup × baseline)	$5^{a}/-0.33^{b}/4.44^{c}$ $7^{a}/-0.52^{b}/11.06^{c}$	0.5	55 <sup>a</sup> /0.57 <sup>b</sup> /1.98 <sup>c</sup> 33 <sup>a</sup> /1.59 <sup>b</sup> /3.50 <sup>c</sup>	.043*	a <sup>a</sup> /.671 <sup>b</sup> /. 044* <sup>c</sup> a <sup>a</sup> /.734 <sup>b</sup> /.007** <sup>c</sup>		
Family visiting Yes vs. No		7 <sup>a</sup> /0.14 <sup>b</sup> /-1.56 <sup>c</sup>		4 <sup>a</sup> /2.00 <sup>b</sup> /3.60 <sup>c</sup>		/.841 <sup>b</sup> /.578 <sup>c</sup>		

Note: T1: baseline; T2: postintervention; and T3: post 3 months follow-up.

were coded for privacy protection. All data were used for research purposes only.

#### Research instruments

# Demographics

Demographic data included sex, age, education level, marital status, employment, religion, and age of diagnosis. The demographic data were used as control variables to understand the intervention effectiveness of AAT on residents' social interaction and quality of life.

# Mental health-social functioning scale (MHSFS)

This study used the MHSFS developed by Song [19] to measure participants' social competence and abilities in daily life. The MHSFS comprises 36 items across 7 subdimensions, namely, social/ withdrawal, interpersonal communication, independence-ability, independence-performance, entertainment, sociality, and occupation/employment. Each item is scored from 0 to 3, except for items in the "occupation/employment" subdimension. The total score ranges between 0 and 100. Higher scores indicate better social functioning. The MHSFS exhibited good internal consistency with respect to patients with psychiatric disorders; Cronbach's  $\alpha$ coefficient of the overall dimension was 0.80. MHSFS can be filled by patients with psychiatric disorder or their caregivers [19], for this study to reach the same level of evaluative criteria, it would be filled by the regular institutional staff. The scale was completed by institutional staff who evaluated the social functioning of residents over the last 3 months.

# Social adaptive function scale (SAFS)

This study used the SAFS developed by Li and Tsai [20] to measure participants' day-to-day living abilities, social functioning, and occupational abilities. SAFS is used by mental health workers to assess patients with psychiatric disorder's social life. The scale was completed by institutional staff. The SAFS contains 15 items and is scored on a 4-point (0 to 4) Likert scale. Higher scores indicate worse adaptive functions. Cronbach's  $\alpha$  coefficients of each factor

were 0.88 for day-to-day living abilities, 0.90 for social functioning, and 0.90 for occupational abilities. The internal consistency of the scale was 0.94.

Taiwanese version of the world health organization quality of life brief version WHOQOL-BREF

The WHOQOL-BREF, Taiwanese version [21], the scale is measuring participants' subjective feelings toward their life quality, was completed by participants. This questionnaire consists of four dimensions: physical, psychological, social, and environmental. It contains 28 items, each of which is scored on a 5-point Likert scale. Higher scores indicate better quality of life. Cronbach's  $\alpha$  coefficients of the dimensions ranged between 0.70 and 0.77. The overall Cronbach's  $\alpha$  coefficient of the questionnaire was 0.91, suggesting good internal consistency [22].

# AAT program

This study developed a 12-week AAT program, with one 60 min session of group activity per week. The program was designed considering the labor and economic cost and was also based on previous studies [15]. The intervention program was implemented through support groups to help participants develop their skills in social interaction and emotional expression (Table 1). The expert validity of the intervention was determined by five nurses and social workers who had more than 3 years of experience providing clinical care in the Psychiatry Department and by two AAT experts. The scale-level content validity index was calculated to be 0.976, implying that the overall program demonstrated good content validity.

The AAT program proceeded as usual, being held in the reception hall. Activities were carried out by the researchers and social workers, along with the participation of two service dogs and two professional AAT therapists. The dogs had received training for at least 3 months and were amicable. The AAT therapists had undergone at least 6 months of dog-related training and professional courses and had experience providing services to people with disabilities. The control group participated in discussion groups once per week, sharing their thoughts about life; these activities

 $t^1$ : baseline and postintervention comparison;  $t^2$ : baseline and post 3 months follow-up comparison.

 $P_{adj}$ : P-value must be adjusted for the multiple comparisons by Bonferroni.

<sup>\*</sup>p < .05; \*\*p < .01.

a Social function.

<sup>&</sup>lt;sup>b</sup> Social adaptive function.

<sup>&</sup>lt;sup>c</sup> Quality of life.

were led by the researchers and social workers. For the blinding of the participants, short films about animals were provided for the members of the control group to watch. Videos of cute animal documentaries were 10–15 minutes length each. Participants will then share their thoughts afterward. The intervention duration and frequency were identical for both groups.

#### Data analysis

All statistical analyses were conducted using SPSS V23.0 (IBM Corporation, Armont, NY, USA). Participants who did not attend the first and last sessions or were absent for  $\geq 2$  sessions were excluded from the analysis. Data are presented as the mean (M)  $\pm$  standard deviation (SD) or frequency (n) and percentage (%). Chi-square tests and independent-samples t tests were used to compare demographic variables between the two groups. The effectiveness of the intervention with respect to social functioning, social adaptive functions, and quality of life was compared using paired t tests for within-group comparisons and a generalized estimating equation (GEE) for between-group repeated comparisons. According to "Goodness of fit," the best QIC value is "unstructured" correlation structure in the study. Using the matrix, a GEE analysis was conducted.

#### Results

The research period for this study was from January 31, 2021, to September 12, 2021. A total of 98 residents met the inclusion criteria, eight of whom refused to participate in the study. Ninety participants completed the study and were included in the data analysis.

# Participant demographics

The experimental group and the control group each consisted of 45 participants. The participants of two groups have even gender distribution. The mean age in experimental group was 50.2 years and 49.5 years in control group. Table 2 shows that both groups had no significant differences in terms of eight demographic attributes, including sex, marriage, and education. Participants in the experimental group received significantly more family visits than those in the control group (p = .03).

# Effectiveness of MHSFS

Within-group comparison (Table 3): In the experimental group, the MHSFS scores of participants were significantly higher at T2 (M=52.80, SD=11.93) than at T1 (M=50.56, SD=11.89) (p<.01), but the MHSFS scores at T3 (M=46.07, SD=14.36) were not significantly different from those at T1 (p>.05). Participants in the control group had significantly higher MHSFS scores at T2 (M=55.18, SD=14.34) than at T1 (M=54.09, SD=13.80) (p<.05), but their MHSFS scores at T3 (M=54.81, SD=12.97) were not significantly different from those at T1 (p>.05). The results revealed that both groups improved their social functioning after the intervention; however, this effect was not permanent.

Repeated measurements were conducted with respect to both groups. At T2, MHSFS scores increased significantly, indicating improved social functioning in both groups. The interaction of group  $\times$  time indicated that the MHSFS scores of the experimental group at T2 were significantly higher than those of the control group at T1 (B=1.16, p<.05). However, the MHSFS scores of the experimental group decreased significantly at T3 (B=-5.37, p<.05). The results suggested that the social functioning of the experimental group improved significantly immediately after the

intervention; however, their social functioning decreased significantly 3 months after the intervention. Inclusion of the only dissimilar demographic variable between the two groups—family visits—into the analysis did not yield a significant difference.

#### Effectiveness of SAFS

Within-group comparison (Table 3): In the experimental group, the SAFS scores of participants at T2 (M=9.87, SD=7.69) were significantly lower than those at T1 (M=11.56, SD=7.66) (p<.01). However, the decrease in SAFS scores at T3 (M=9.30, SD=8.73) did not indicate a significant difference (p>.05). The control group had significantly lower SAFS scores at T2 (M=10.51, SD=8.21) and T3 (M=10.16, SD=7.46) than at T1 (M=11.87, SD=7.67) (both p<.05). Thus, social adaptive functions improved in both groups after the intervention, and the effectiveness of the intervention on the control group persisted 3 months after the intervention.

Repeated measurements were conducted with respect to both groups (Table 3). At T2 and T3, SAFS scores decreased significantly (p < .01 and p < .05, respectively), indicating that both groups achieved significant improvement in terms of their social adaptive functions. The interaction of group  $\times$  time indicated that the experimental group did not achieve a significant decrease in SAFS scores at T2 and T3 as compared with the control group (p > .05). The results suggested that the experimental group did not exhibit a significant difference in terms of the level of improvement in their social adaptive functions as compared with that of the control group. Inclusion of the demographic variable of family visits into the analysis did not yield a significant difference.

#### Effectiveness of WHOQOL-BREF

First, a within-group comparison was conducted (Table 3). The WHOQOL scores of the experimental group at T2 (M=86.42, SD=17.98) and T3 (M=86.64, SD=15.92) were significantly higher than their scores at T1 (M=79.33, SD=13.40) (both p<.01). The WHOQOL scores of the control group increased at T2 (M=81.02, SD=16.82) and decreased at T3 (M=75.16, SD=13.81); however, none of these differences were significant (all p>.05). The results revealed that the quality of life of the experimental group improved significantly after the intervention and that such improvement persisted for 3 months.

Repeated measurements and comparisons of the experimental and control groups were conducted. At group, WHOQOL scores of the experimental group were significantly higher compared with the control grop. At T2, WHOQOL scores increased significantly, indicating improved quality of life in both groups. The interaction of group  $\times$  time indicated that the experimental group exhibited a significant difference in terms of the level of increase in their WHOQOL scores at T2 and T3 compared with the changes exhibited by the control group (p < .05). The inclusion of the demographic variable of family visits did not yield a significant difference in terms of quality of life.

# Discussion

The objective of this study was to explore the positive effects of AAT for patients with chronic schizophrenia. The research results see great improvements in social function, experimental group at postintervention, but a clear downward trend 3 months after the intervention. However, we saw no great improvements in both social adaptive function and experimental group at postintervention until 3 months later. In terms of the quality of life, the experimental group saw significant improvement at postintervention until three months later. The positive effects on social

function and quality of life meant that through animal interactions schizophrenia patients can build social skills and improving their quality of life. Meanwhile, the lack of improvement in social adaptive function is unprecedented considering previous studies [23,24], and there will be related discussed on said topic.

The effects on social function in our study, there was no significant difference in the social function between the experimental group (M = 54.09) and control group (M = 50.56) in the pretest. meaning that the two groups have the same social function level. At T2, both groups exhibited increased social functioning scores. The control group might have been subjected to the Hawthorne effect [25]. During the AAT activities, researchers participated in the activities of both groups to maintain blindness. The control group engaged in routine discussion groups and watched short films about animals, which were not part of their original discussion group. This change may have caused residents to believe that they were of an experimental group and affected their postintervention behavioral performance, thereby leading to a significant effect. In repeated measurements and comparisons between the two groups, the T2 scores of social functioning exhibited by the experimental group increased significantly compared with those of the control group. The intervention effectiveness indicated that the AAT intervention improved participants' social functioning. O'Haire et al. [23] used 8 weeks of AAT to improve the social functioning of people with autism spectrum disorder. Wesenberg et al. [24] demonstrated AAT to 17 dementia patients, and we saw great increase in patients' social interaction and positive emotion (pleasure). The results of that study revealed that AAT not only improved patients' social skills but also reduced their social withdrawal. During the AAT process used in the present study, interactions between residents and service dogs helped residents understand their internal emotional changes and develop a trusting and interactive relationship with the dogs. Consequently, residents could practice the capabilities required to develop mutual trust and social skills with people, thereby increasing their social functioning. However, at T3, the social functioning of the experimental group decreased significantly, possibly because of the effects of the COVID-19 pandemic. After May 2021, the Taiwan Center for Disease Control announced that no visitors were allowed to enter hospitals, nursing centers, and institutions for psychiatric rehabilitation, including family members. During the study, the researchers found that compared to the control group, the participants in the experimental group received visits from family significantly more frequently. However, the no-visiting regulation was established during T2 to T3. For participants in the experimental group whose family did not visit, the lack of social interactions could lead to the degeneration of their social function. There is negative influence to social function when patients with Schizophrenia lack familial support [26]. The situation is shown and proved by previous experimental results by Ma et al. [9]. At the same time, to reduce contact between residents of psychiatric rehabilitation and other people, two of the institutions in the experimental group limited the outdoor time of residents (no such limitations were reported by the other four institutions); residents decreased their amount of time spent on outdoor activities and lacked normal social interactions with others in the institutions. Since MHSFS scores were calculated using staff's evaluation of the residents' social life over the last 3 months, the scores of the experimental group decreased significantly. The results were similar to those reported by studies of COVID-19. The pandemic reduced social interaction and social support [27]. Thus, the present study assumed that the results were caused by the limitation of residents' interactions by institutions to mitigate the effects of the pandemic.

The social adaptive functions of the experimental group improved significantly at T2 compared to T1, which corresponds to

the results found by Chang et al. [15]. However, no significant improvement was noted at T3, possibly because of the larger SD (8.37) of the T3 sores in experimental group, which indicated marked inter-individual differences. This result may be explained by the stricter pandemic prevention measures implemented by two of the institutions in the experimental group. Some residents remained in their rooms by themselves most of the time. The staff evaluation of the residents' day-to-day living abilities at T3 changed from "active completion" to "needs reminders by others." When the social interaction of institutional residents is reduced, their social adaptive functions can easily decrease [28]. The between-group comparison results revealed that the experimental group did not exhibit significant improvement at T2 and T3. There are other reasons that could have influenced the effect of the intervention—social function and social adaptation are both subjective perceptions, leading to the potential for different perceptions due to their analysis from different aspects. For instance, it is very challenging for residents and experts to evaluate social adaption and communication about the forced migration issue from their perspectives; hence, subjective perceptions need to be evaluated [29]. In addition, Ortega et al. [30] performed a follow-up on social function for a year after the first onset of psychosis and used a selfreport questionnaire. Considering the objectiveness of the evaluation, the MHSF and SAFS in this study were completed by institutional staff. The study was limited by the lack of consideration on differences in perceptions that would influence the results, so it is recommended that researchers collect information from both participants and staff for reference in future studies.

The quality of life of participants in the experimental group at T2 and T3 significantly improved compared with preintervention. The quality-of-life scores of the experimental group at T2 and T3 were significantly higher than those of the control group. The results implied that AAT not only benefited participants immediately after the intervention but also had persistent effects 3 months after the intervention. The positive effect on quality of life described in other studies were also proven [16,31]. Moreover, the quality of life of the experimental group was not affected by the pandemic. Smolarczyk-Kosowska et al. [32] explored the effects of a rehabilitation program on patients with psychiatric disorders during the COVID-19 pandemic and identified positive effects on their emotions and quality of life that are consistent with the results of the present study. The present study used AAT to improve the quality of life of patients with schizophrenia significantly. During the AAT process, group activities and the development of supportive environments, including physiological, psychological, social, and environmental aspects, were fundamental factors influencing the quality of life of patients with psychiatric disorders [15]. Thus, the present study identified the positive effects of AAT with respect to improving the quality of life of patients with chronic schizophrenia.

During the COVID-19 pandemic, the regulations established by institutions to mitigate the effects of the pandemic affected residents' social functioning and social adaptive functions. These regulations were environmental factors that could not be eliminated, and they serve as limitations for the present study. Another limitation was randomization in one institution and each group. The effects of intervention is easily influenced by the environment of the institutions, random assignment is a method that can be considered in future studies.

#### Conclusion

Because of the COVID-19 pandemic, institutions for psychiatric rehabilitation established stricter regulations that interfered with the results of this study. The AAT program effectively improved the social interaction and quality of life of patients with chronic

schizophrenia. In the case of the quality of life, the effectiveness of the intervention lasted for only up to 3 months after the intervention. Nevertheless, the proposed intervention program can assist patients with chronic psychiatric disorders in returning to social life and can serve as a reference for personnel working in community institutions for psychiatric rehabilitation. This intervention can help improve patients' physiological and psychological health, strengthen their social functioning and social adaptive functions, and promote their return to a healthy life.

# Data availability

The data that support the findings of this study are openly available in ResMan clinical trial management public platform at http://www.medresman.org.cn, Reg number ChiCTR2200061715.

#### **Author contributions**

Study conception and design: Chieh-An Shih, Man-Hua Yang. Data collection: Chieh-An Shih. Data analysis and interpretation: Chieh-An Shih, Man-Hua Yang. Drafting of the article: Chieh-An Shih, Man-Hua Yang. Critical revision of the article: Man-Hua Yang.

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#### **Conflicts of interest**

The authors declare that we do not have any commercial or associative interest that represents a conflict of interest in connection with the work submitted.

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# Research Article

# Personal Factors and Clinical Learning Environment as Predictors of Nursing Students' Readiness for Practice: A Structural Equation Modeling Analysis



Taewha Lee, Su Jeong Lee, Yea Seul Yoon, Hyunju Ji, Sookhee Yoon, SangA Lee, Yoonjung Ji, 3, \*

- <sup>1</sup> Mo-Im Kim Nursing Research Institute, College of Nursing, Yonsei University, Republic of Korea
- <sup>2</sup> Hyejeon college, Nursing Division, Republic of Korea
- <sup>3</sup> Brain Korea 21 FOUR Project, College of Nursing, Yonsei University, Republic of Korea
- <sup>4</sup> Severance Hospital, College of Nursing, Yonsei University, Republic of Korea
- <sup>5</sup> Department of Nursing, Semyung University, Republic of Korea
- <sup>6</sup> Manning College of Nursing and Health Sciences, University of Massachusetts Boston, USA

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#### SUMMARY

*Purpose*: It is essential to ensure the readiness for practice among undergraduate nursing students since the purpose of such education is to cultivate competent nurses who deliver high-quality and safe nursing. Astin's theory of student involvement suggests that this is affected by their personal factors and learning environment.

Methods: We conducted a cross-sectional study between November 16, 2020 and December 21, 2020 which examined personal factors and aspects of the clinical learning environment among senior nursing students (n=838) enrolled across 54 nursing schools in Korea. The participants were asked to fill out a self-administered online survey, which assessed demographic characteristics, self-esteem, depression, work-life balance, clinical learning environment, anxiety during clinical practicum, and readiness for practice. Readiness for practice was measured using the Casey-Fink Readiness for practice survey. We used structural equational modeling to test our hypothetical model.

Results: The nursing students' readiness for practice was significantly affected by their self-esteem, work-life balance satisfaction, and clinical learning environment. Anxiety during clinical practicum directly influenced their readiness for practice.

*Conclusion:* Increasing self-esteem and work-life balance satisfaction, and improving their clinical learning environment by providing sufficient educational and clinical support, could help facilitate the transition from nursing schools to real-world practice for nursing students.

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# Introduction

Nursing students constitute a future healthcare workforce that will be tasked with safeguarding the health and well-being of all people. The cultivation of competent nurses is critical, particularly owing to the high prevalence of global health crises such as the COVID-19 pandemic. Preparing nursing students for clinical practice is a goal shared by nursing educators and administrators in clinical practice and academia [1]. Enabling nursing students to adapt to clinical practice remains a significant challenge, given the global shortage of nurses exacerbated by the high turnover rate of new graduate nurses. The RN Work Project—a 10-year panel study

E-mail address: jiyoonjung0113@gmail.com

Taewha Lee: https://orcid.org/0000-0003-2568-3074; Su Jeong Lee: https://orcid.org/0000-0001-8146-3151; Yea Seul Yoon: https://orcid.org/0000-0002-4434-3932; Hyunju Ji: https://orcid.org/0000-0002-8427-939X; Sookhee Yoon: https://orcid.org/0000-0003-4677-4899; SangA Lee: https://orcid.org/0000-0003-3340-1313; Yoonjung Ji: https://orcid.org/0000-0001-7447-9833

<sup>\*</sup> Correspondence to: Yoonjung Ji, PhD, Mo-Im Kim Nursing Research Institute, Brain Korea 21 FOUR Project, College of Nursing, Yonsei University, 50-1 Yonsei-ro, Seodaemun-gu, Seoul 03722, South Korea.

of new nurses in the United States—reported that ~17.5% of new nurses leave their first job within one year [2]. In Korea, the turnover rate of new nurses was 33.6% in 2011 and increased to 44.5% in 2019 [3].

In addition, most of the current nursing students and new graduate nurses belong to Generation Z and, thus, have significantly different generational characteristics and values compared to more experienced nurses [4]. A new generation of students—Generation Z, born between the mid-1990s and ending around 2012 [5]—is entering nursing programs and the workplace [6]. Surrounded by technology, Generation Z is known to be pragmatic; immature in social and interpersonal skills; individualistic; displays a desire for convenience and immediacy; cares about emotional, physical, and financial safety [7]. These characteristics result in lower self-esteem [8], higher depression [9], and greater importance of work-life balance (WLB) [10] than in older generations.

For new graduates, being ready for practice involves possessing the attributes that enable them to succeed in their workplace [11]. Readiness for practice is an essential element of undergraduate nursing programs as its primary objective is to cultivate competent nurses who deliver high-quality and safe nursing care [12]. However, students whose hands-on education is limited to clinical experience are often unprepared for clinical work [13]. The prevalence of perceived unpreparedness among nursing students leads to their maladaptation to practice and high turnover rates for new nurses [14]. To respond to this concern, the American Association of Colleges of Nursing suggested that educational programs should prioritize the adaptation of nursing students to the actual clinical field [15].

Previous research has shown that the readiness for practice of nursing students is associated with diverse factors, including their individual characteristics, psychosocial status, and clinical learning environment. A recent scoping review of 17 studies on nursing education conducted from 2000 to 2017 showed that the readiness for practice of nursing students was primarily influenced by personal and educational factors [16]. Personal factors included their backgrounds and feelings, whereas educational factors involved their professional competencies. Individual characteristics, including age [17,18], sex [17], and previous health care experience [19], were associated with their practice readiness. Self-esteem [20], depression [21], and anxiety during clinical practicum [22] were also related to their readiness for clinical practice. Nursing students who had negative emotions such as fear and anxiety toward clinical practicum experienced insecurity about working as a nurse and lacked professional confidence [7]. The clinical learning environment is integral since it supports the development of the professional competence of students, which in turn influences their readiness for practice. The quality of the practice sites and clinical supervision [17,23], feedback and support from faculty and clinical preceptors [15,23], and clinically centered hands-on training [24] were associated with an improvement in the professional competence of students.

Most previous studies regarding readiness for practice in nursing students were conducted in the Western culture, as described above, to develop an instrument [15] exploring the current status and associated factors [18,24]. On the other hand, research on practice readiness in Korea is scarce, focusing only on nursing competence of graduating nursing students and the role transition of senior nursing students [25]. Although lower readiness for practice is an important predictor of negative outcomes, such as maladaptation [26], turnover [27], and transition shock [28] among new nurses, few studies have comprehensively examined the factors affecting readiness for practice among nursing students [22,29].

The factors that reflect the unique characteristics and values of the new generation of students have also not been explored. Most of the current nursing students and new graduate nurses belong to Generation Z. These individuals are known to be pragmatic, individualistic, and lacking in social and relationship skills, which increases their risk of experiencing isolation, anxiety, insecurity, and depression [7]. The persistently high turnover rates of new nurses warrant innovative actions to improve their readiness for practice [6]. The aim of this study was, therefore, to examine the associations of personal factors with readiness for practice among senior nursing students in Korea. The specific factors of interest included self-esteem, depression, and satisfaction with WLB, clinical learning environment, and anxiety during clinical practicum.

Hypothesized model

A hypothesized model was derived from Astin's theory [30] of student involvement.

Astin's [30] student involvement theory research discusses students' college experiences and how these experiences play a role in changing and developing students over time. With numerous factors influencing academic achievement and social involvement through these experiences. Astin used the critical elements of student inputs (I), the educational environment (E), and student outcomes (O) to create a model for identifying such variables. In this model, "input" variables refer to the characteristics of students on school entry. The "environment" refers to the college context, including institutional aspects or student experiences while attending college. Finally, "outcome" refers to students' academic performances or degree attainment. One notable example is the work of Thomas et al. [31] who utilized Astin's I-E-O model to examine the relationship between personal behavioral and emotional health (e.g., depression, anxiety, and antisocial behavior) as input factors and the school environment factors (e.g., social support, student organization participation) to student retention from a large urban university. Their quantitative study revealed that increased depressive symptoms, antisocial behaviors, lower social support, and school participation were consistently related to decreased college retention. Consequently, Thomas et al. [31] have provided vital insight into how factors such as personal characteristics can benefit college students while challenging individuals to consider which environments may affect their retention.

We identified factors related to individual psychological and emotional health in line with the supposition that the effect of school environment factors on persistence is influenced by individual-level factors in the I-E-O model [30]. Consistent with the model, some entering characteristics are demographic and academic backgrounds, same as most previous studies [32,33], while others represent student values, beliefs, and attitudes [31,34]. Assessing nursing student's personal characteristics, including psychological health, can help nursing programs understand how the educational environment affects students' readiness for practice in a more integrated manner. Therefore, in this study, input referred to personal factors, including their self-esteem, depression, and satisfaction with WLB. Environment referred to their clinical learning environment and anxiety regarding clinical practice. Outcomes include their readiness for practice. We hypothesized that these personal factors affect readiness for practice through their clinical learning environment and anxiety during clinical practicum (Figure 1).

# Methods

Design and participants

In this cross-sectional study, a total of 842 senior nursing students from 54 nursing schools with 4-year baccalaureate programs

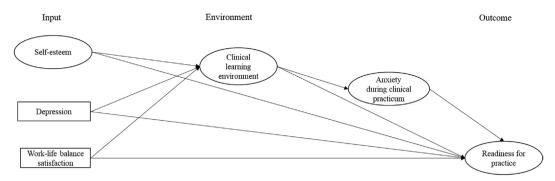


Figure 1. Hypothesized Model.

participated. Inclusion criteria were (1) senior nursing students aged 20–29 years to include Generation Z students (generally referring to those born between 1997 and 2012) [5], (2) expected to graduate in February 2021, and (3) expected to take the national nurse licensure examination in 2021. Data of four participants were excluded due to incomplete responses or the inclusion criteria not being met, and our final sample thus comprised 838 participants. The sample size used for the structural equation modeling (SEM) in the study was calculated based on the condition that the ratio of the sample size to the parameters should be no less than 10:1 [35]. Therefore, the total sample size was suitable for testing a model with 49 free parameters, which would necessitate the inclusion of at least 490 participants.

#### Measurements

A self-administered questionnaire with 81 items was used. After getting authors' approval for all measures of the study, a committee translation [36] was performed for the measures being used for the first time in Korea—the Casey-Fink Readiness for Practice Survey (CFRPS). The committee translation recommended by the Guidelines for Best Practice in Cross-Cultural Surveys was performed [37]. After the committee translation, cognitive interviews were conducted with 12 nursing students with clinical experience to evaluate the cultural relevance and semantic homogeneity of the translated questionnaire and the response-related complexity of its questions [38]. The survey instrument was finalized after the complicated/ambiguous sentences and questions that were difficult to answer were revised. The Korean version of the readiness for practice survey comprised 20 items (Supplementary Figure 1).

#### Demographic characteristics

The general characteristics queried included participants' age, gender, type of nursing school, other degrees, school locations, the reason for joining nursing school, and employment expectations.

#### Personal factors

Self-esteem was measured using the Korean version [39] of Rosenberg's Self-Esteem Scale [40], which consists of 10 items. The Cronbach's  $\alpha$  was .85 at the time of the instrument's development [39] and .80 in this study. Each item was rated on a 4-point Likert scale that ranged from 1 (strongly disagree) to 4 (strongly agree). The overall mean is considered the scale score, and higher scores indicated higher levels of self-esteem. The overall mean score of self-esteem was used for the correlation analysis with other variables. In the SEM, item parceling was performed using the "item-to-construct balance" technique to obtain more stable parameter

estimates and better model fit. Item parceling was used by averaging item scores in each parcel and generating parcel scores as indicators of latent variables [41]. There were three-item parcels of self-esteem, all of which were confirmed to be valid through confirmatory factor analysis (CFA).

Depression was measured using the Short Form of the Normal Depression Scale for Individual Screening (SFNDS), which consists of five items [42]. The Cronbach's  $\alpha$  was .81 at the time of the instrument's development [42] and .80 in our study. Each item was rated on a 5-point Likert scale that ranged from 1 (strongly disagree) to 5 (strongly agree), and the total score (range, 5–25) was calculated by adding the scores of each item. A score of 5–17 is considered normal, whereas  $\geq$ 18 indicates dysfunctional depression. The total score of the five items was used in the correlation analysis. We used the total score as an observed variable in the SEM.

WLB was assessed using two items—one for WLB proportion and the other for WLB satisfaction. WLB proportion was measured using the WLB Charter by the Japanese Cabinet [43]. In this study, the WLB proportion was determined by calculating the ratio of the percentage of time spent on work to the percentage of time spent on private life. WLB satisfaction was measured using a 4-point Likert scale that ranged from 1 (not at all satisfied) to 4 (very satisfied) developed [44]. Higher scores indicated greater WLB satisfaction. The participants were asked, "How satisfied are you with your current WLB?" The WLB satisfaction score was used in the correlation analysis and SEM as an observed variable.

# Environment factor

The clinical learning environment was evaluated using a modification of the Korean version of the Clinical Learning Environment, Supervision and Nurse Teacher Scale (CLES + T) [45]. The Korean version was developed with 33 items and seven subdomains that were adapted from the original CLES + T [46], an instrument that is used internationally to evaluate clinical learning environments in undergraduate nursing education. Given the purpose of this study, we used 13 items from three subdomains: pedagogical atmosphere in the ward, supervisory relationship, and role of nurse teacher. Each item was rated on a 5-point Likert scale that ranged from 1 ("entirely disagree") to 5 ("entirely agree"), and higher scores indicated that the students perceived their clinical learning environment to be more positive. The Cronbach's alpha of the Korean version of the CLES + T for the overall scale was .94, and the subscales ranged from .78 to .94. [45]. The Cronbach's  $\alpha$  was .96 for the total scale and .83 to .88 for the subscales in the present study. The overall mean score was used for the correlation analysis with other variables. As a latent variable in the SEM, clinical learning environment had three indicators, corresponding to the overall mean scores of the three subscales.

Anxiety during clinical practicum was assessed using the Korean version [22] of the clinical experience assessment form [47]. The Korean version was developed with 16 items and three subdomains. Given the purpose of this study, we used 12 items from two subscales (communication and procedural aspects, and interactions with faculty) to measure the perceptions of anxietyprovoking situations during clinical practicum in nursing students. The Cronbach's alpha of the Korean version of the clinical experience assessment form for the overall scale was .82, and the subscales were not reported. [47]. The Cronbach's  $\alpha$  was .89 for the total scale and .76 to .86 for the subscales in the present study. Each item was rated on a 5-point Likert scale ranging from 1 ("strongly disagree") to 5 ("strongly agree"), and higher scores indicated greater anxiety levels about clinical practicum. The mean score for this factor was calculated and used in the correlation analysis. As a latent variable in the SEM, anxiety during clinical practicum had two indicators, corresponding to the average scores of the two subscales.

#### Outcomes

Readiness for practice was assessed using the comfort/confidence section of the CFRPS [15]. This 20-item self-report questionnaire was used to measure the confidence and comfort to providing nursing care among the participants. The questionnaire contained four subscales: clinical problem solving, learning techniques, professional identity, and trials and tribulations. The instrument underwent committee translation and was validated through a CFA. Based on the validation result, we used the four original subscales, and the items were rated on a 4-point Likert scale that ranged from 1 ("strongly disagree") to 4 ("strongly agree"). The mean of all items was considered scale score, and a higher score indicated better readiness for practice. The Cronbach's  $\alpha$  for the overall scale was .69 and the subscales ranged from .50 to .80 at the time the instrument was developed [15]. The Cronbach's  $\alpha$  was .89 for the total scale and .50 to .76 for the subscales in the present study. The overall mean scores of the readiness for practice were used for the correlation analysis with the other variables. As a latent variable in the SEM, readiness for practice had four indicators: the mean scores of the four subscales.

## Data collection

For data collection, we selected nursing schools using convenience sampling and asked them to distribute the study flyer online and offline to their students. Students interested in the study participated by accessing the New Nurse e-cohort study website (http://newnurse.or.kr). All participants were asked to complete the survey after carefully reading the explanation on the first page of the online survey link, stating the purpose and content of the study, non-collection of personally identifiable information, confidentiality, and anonymity, and right to withdraw from research participation. Each participant was provided with a small incentive of approximately \$16. Data were collected using the online survey, which took 10-20 minutes to complete. The item non-response rate was minimized because the online survey did not proceed to the next question until the current one was answered. The data collection was conducted from November 16, 2020 to December 21, 2020.

#### Data analysis

SPSS Version 26.0 (SPSS Inc., Chicago, IL, USA, 2019) was used to conduct statistical testing, including a description of the data, correlation analysis, and the calculation of reliability estimates. To

explore the impact of personal factors, and clinical learning environment on the readiness for practice among senior nursing students, SEM as implemented in AMOS Version 26.0 was used to test the model hypothesized in this study.

In this study, univariate normality was satisfied, and even if multivariate normality was not satisfied, parameter estimation was performed with the maximum likelihood method according to the report that the estimated parameters are reliable if the maximum likelihood method is used [48]. Maximum likelihood estimation was used to estimate the model, and the bootstrap resampling technique was used in the SEM to obtain more stable and valid standard errors of the estimates. Multivariate normality reported a multivariate kurtosis value of 32.712 in AMOS, and multivariate normality was not satisfied because it exceeded the critical value. Path analysis was used to identify both the direct and indirect effects in the model. The direct, indirect, and total effects of the variables in the model are presented in Supplementary Table 1. The model fit was assessed using the following indices, i.e., relative chisquare  $(x^2/df)$  test <5.00 [49], comparative fit index (CFI)  $\geq 0.90$ [50], root mean square error of approximation  $\leq 0.08$  [49], and standardized root mean square residual  $\leq$  0.08 [51]. A *p*-value <.05 was considered statistically significant.

#### Ethical consideration

This study was approved by the Institutional Review Board of Yonsei University Medical Center (Approval No: Y-2020-0138). All participants received information about the study, which guaranteed their confidentiality and underlined that their participation was voluntary and could be terminated at any time.

#### Results

Students' general characteristics

Of the total of 842 participants, 838 were used for the final analysis, excluding two born before 1997 and two with careless responses. The average age of the participants was  $22.9 \pm 1.4$ , and women students accounted for 90.6% of the sample (Table 1). In total, 82.6% of the participants were enrolled in university, and only 4.4% of them were pursuing a second degree. The high employment rate after graduation (39.5%), as well as academic interest and aptitude (33.9%), were the major reasons for the participants joining nursing schools. Most (88.4%) of the students are expected to be employed. A majority (54.2%) of the participants spent >50.0% of their time on work (Table 1).

#### Descriptions and factor loadings of study variables

The participants' perceived readiness for practice was at a moderate level ( $2.86 \pm 0.31$ ) (Supplementary Table 2). In total, 86.8% of the participants responded to questions on the CFRPS with "agree" or "strongly agree," which indicated that they were ready for practice. Learning technique and professional identity were the subdomains with the highest scores ( $2.94 \pm 0.54$  and  $2.94 \pm 0.43$ , respectively), whereas trials and tribulations received the lowest ( $2.73 \pm 0.35$ ). Self-esteem was at a moderately high level ( $3.23 \pm 0.45$ ). The mean score of depression among students was  $10.85 \pm 4.12$ , and only 7.0% of the students were assessed to be experiencing dysfunctional depression (scores >18). The participants displayed a moderate level of WLB satisfaction ( $2.82 \pm 0.63$ ).

The students perceived their clinical learning environment as moderate (3.14  $\pm$  0.67). Role of nurse teacher (3.79  $\pm$  0.82) was the subdomain that received the highest score, whereas pedagogical atmosphere in the ward (2.82  $\pm$  0.81) received the lowest score.

**Table 1** Students' Demographic Characteristics (N = 838).

Characteristics	Mean $\pm$ SD or $n$ (%)
Age (year)	22.9 ± 1.4
21–23	648 (77.3)
≥24	190 (22.7)
Gender	
Women	759 (90.6)
Men	79 (9.4)
Type of school	
University	692 (82.6)
College	146 (17.4)
Second-degree students	
Yes	37 (4.4)
No	801 (95.6)
Location of school	
Capital area	425 (50.7)
Urban	204 (24.3)
Rural	209 (25.0)
Reason for joining nursing school	
High employment rate after graduation	331 (39.5)
Academic interest and aptitude	284 (33.9)
Suggestions of family and friends + Social perception and reputation	123 (14.7)
Depending on SAT score + Aiming to get into	100 (11.9)
medical or dental schools	
Expected employment	
Yes	741 (88.4)
No	97 (11.6)
WLB proportion	
Balance (50:50)	156 (18.6)
Life-oriented imbalance (spent above	228 (27.2)
50% of time on private life)	
Work-oriented imbalance (spent above 50% of time on work)	454 (54.2)

Note. SAT = Scholastic aptitude test; WLB = Wok-life balance.

Their anxiety during clinical practicum was at a moderate level  $(2.84 \pm 0.70)$ .

Students felt more anxious about communication and the procedural aspects related to patients ( $2.90\pm0.89$ ) compared to interactions with faculty ( $2.81\pm0.71$ ). The CFA results are reported in Supplementary Table 2. The values of the factor loadings ranged from .440 to .874 (>.40), showing that the latent variables were measured comprehensively by their observed indicator variables [46].

# Correlations of study variables

A correlation matrix was prepared before testing the hypothesized model (Supplementary Table 3). Self-esteem (r=.42, p<.001), WLB satisfaction (r=.34, p<.001), and clinical learning environment (r=.40, p<.001) were positively correlated with readiness for practice. In contrast, depression (r=-.23, p<.001) and anxiety during clinical practicum (r=-.50, p<.001) were negatively associated with readiness for practice. Their correlation coefficients were less than .70, which is the criterion for questioning multicollinearity [52]. The Variance inflation factor (VIF) value of 1.7 or less confirmed no multicollinearity between all variables.

#### Test of the hypothetical model and parameter estimates

The modified model's goodness of fit with the research variables was  $x^2/df = 4.888$  (<.001), GFI = 0.950, CFI = 0.941, and root mean square error of approximation= 0.068. Thus, the modified model fit the data. Through the modifications, the difference between the Chi-square of the hypothesized model and the third modified model [ $x^2 = 98.281$  (411.118 - 312.837), df = 3 (67 - 64)] is larger

than 18.55 and in the range of p=0.005, the modified model may be considered significant and be adopted in place of the hypothesized model [53], and also, CFI improved from .918 to .941 (Supplementary Table 1). A fully adjusted model that controlled for all the participant characteristics (age, gender, type of school, second degree students, location of school, reason for joining nursing school, expected employment) was also tested, and the effects among the study variables were consistent with the unadjusted hypothetical model. For simplicity, we have reported the unadjusted results in this paper. The final model is presented in Figure 2. After checking the modification indices, within-factor correlated measurement was allowed, and the model fit indices improves compared to the previous model.

Tables 2 and 3 summarize the final model's standardized direct, indirect effect, and total path estimates. There were significant direct and indirect effects associated with the personal factors, environment factors, and readiness for practice. Higher self-esteem ( $\beta$  = .29, p < .001), higher WLB satisfaction ( $\beta$  = .12, p < .001), and better clinical learning environment ( $\beta = .30$ , p < .001) were directly associated with better readiness for practice. Conversely, lower anxiety during clinical practicum was directly related to better readiness for practice among nursing students ( $\beta = -.36$ , p < .001). In addition, higher self-esteem ( $\beta = .19$ , p < .001) and higher satisfaction with WLB ( $\beta = .25$ , p < .001) were associated with a better clinical learning environment. The clinical learning environment significantly influenced the nursing students' readiness for practice through anxiety during clinical practicum. A better clinical learning environment was associated with lower anxiety during clinical practicum ( $\beta = -.37$ , p < .001), which resulted in better readiness for practice. Self-esteem indirectly influenced readiness for practice through clinical learning environment, anxiety during clinical practicum sequentially ( $\beta = .02$ , p = .001). Selfesteem also indirectly influenced readiness for practice through clinical learning environment ( $\beta = .06$ , p = .001). WLB indirectly influenced readiness for practice through clinical learning environment, anxiety during clinical practicum sequentially ( $\beta = .03$ , p < .001). WLB also indirectly influenced readiness for practice through clinical learning environment ( $\beta = .08$ , p = .001). Depression had no direct or indirect effect on readiness for practice. The model estimated a 49.7% variance in the readiness for practice of nursing students.

#### Discussion

The findings of this study generally supported our hypothesized model, even though some paths were not significant. We observed that readiness for practice was directly and indirectly affected by self-esteem, WLB satisfaction, and clinical learning environment.

Anxiety during clinical practicum also directly influenced readiness for practice. These findings provided a more comprehensive picture of how personal factors and clinical learning environment are related to the readiness of nurses for practice, driven by anxiety during clinical practicum. However, given the weak-to-moderate effects of the examined variables, further research is needed to explore more factors related to readiness for practice among nursing students.

We used the comfort and confidence section of the CFRPS after the validation process to measure readiness for practice, new graduate nurses have reported that a lack of clinical confidence impedes their transition to clinical practice [1]. While other researchers changed the subscales or number of items [18,29] of the CFRPS to suit the context of their study, we used the four original subscales with 20 items each to facilitate global comparisons. The Korean senior nursing students displayed a moderate level of readiness, which was similar to, or slightly lower than, those

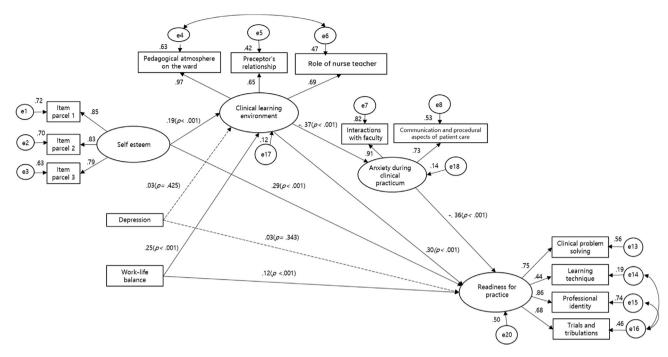


Figure 2. Final Model with Standardized Coefficients. Note: The dashed lines with arrows represent non-significant relationships (p > .05).

observed in previous studies that used the same instrument [18,23,29]. In terms of the subscales, nursing students were more confident in their professional identity and learning technique and less confident about addressing their trials and tribulations. The results of this study were similar to those of previous studies, which indicated that nursing students reported higher scores in professional attributes but lowest in time management, prioritization, and management of multiple patients [1,15,23]. These results can inform teaching strategies, including simulation education to complement clinical practicum, strengthen academic-clinical partnerships, and promote readiness for entry-level practice [1].

Our findings further revealed that as personal factors, both self-esteem and WLB satisfaction had a specific indirect effect on readiness for practice through the clinical learning environment and the anxiety during the clinical practicum. This finding is supported by the previous study, which reported that lower self-esteem has significant adverse effects on perceiving both themselves and the clinical learning environment, provoking defensive behavior and poor communication, resulting in negative clinical practicum achievements among nursing students [20,54]. These results suggest that the self-esteem level of nursing students needs to be identified before delivering clinical practicum. In addition,

improving WLB satisfaction is a potential strategy to improve readiness for practice. Dissatisfaction with WLB causes problems such as anxiety, stress, and depression, which negatively affect the academic performance of students [55]. Given that Generation Z prioritizes WLB, which seems to be commensurate to their academic achievement [56]. WLB satisfaction is an important factor that reflects the characteristics of Generation Z and influences their academic achievement. Educational institutions should thus strive to increase WLB satisfaction in order to improve readiness for practice among students.

On the contrary, depression had no significant effect on readiness for practice, which is a different result from the study by Ruz et al. [57], where the lower the depression of nursing students, the higher their academic achievement. This might be related to self-selection bias. Due to the nature of voluntary participation of the subjects, it is believed that students with depression are not likely to respond to the survey. According to a systematic review by Tung et al. [58], the prevalence of depression among nursing students is 34.0%. However, only 7% of the participants in the study had dysfunctional depression, which meant that most students do not experience depressive symptoms. A possible reason for this result is that there is a possibility of assessing depression inaccurately in

**Table 2** Direct, Indirect, and Total Effects of Variables in the Final Model (N = 838).

Endogenous variables	Predicting variables	Predicting variables Standardized direct effect			ardized ct effect	Standardized total effect		SMC
		β	р	β	р	β	р	
Clinical learning environment	← Self-esteem	.19	<.001			.19	<.001	.122
	← Depression	.03	.425			.03	.425	
	← Work-life balance satisfaction	.25	<.001			.25	<.001	
Anxiety during clinical practicum	← Clinical learning environment	37	<.001			37	<.001	.135
Readiness for practice	← Self-esteem	.29	<.001	.08	.001	.37	.001	.497
•	← Depression	.03	.343	.01	.416	.04	.214	
	←Work-life balance satisfaction	.12	<.001	.11	.001	.23	.001	
	← Clinical learning environment	.30	<.001	.13	.001	.43	.001	
	← Anxiety during clinical practicum	36	<.001			36	<.001	

**Table 3** *Specific Indirect Effects of Readiness for Practice* (N = 838).

Path	В	β	р	95% CI
Self-esteem → Clinical learning environment → Anxiety during clinical practicum → Readiness for practice	0.02	0.02	0.001	[.006, .029]
Self-esteem → Clinical learning environment → Readiness for practice	0.03	0.06	0.001	[.016, .060]
Work-life balance → Clinical learning environment → Anxiety during clinical practicum → Readiness for practice	0.02	0.03	<.001	[.009, .025]
Work-life balance $\rightarrow$ Clinical learning environment $\rightarrow$ Readiness for practice	0.03	0.08	0.001	[.020, .050]

practice although SFNDS has been a relatively reliable and proven tool. Whether the dysfunctional depression identified using the SFNDS is consistent with the actual clinical diagnosis has not fully established [42]. Hence, further studies are needed to confirm the practical usefulness of the SFNDS.

A notable finding of this study was that, among all variables, the clinical learning environment had the most significant effect on the readiness for practice. Specifically, the clinical learning environment had a direct effect on the readiness for practice for nursing students; moreover, it indirectly affected the readiness for practice through the anxiety during clinical practicum. The more positively the students perceived their clinical learning environment, the lower their anxiety during clinical practicum, which in turn indicated better readiness. Similar to our findings, another study reported high rates of attributable to unfamiliar new clinical conditions during clinical practicum [59]. A poor clinical learning environment causes nursing students to worry and diminishes their confidence, reducing the efficiency of their clinical practice education [2]. Thus, the educational environment in the clinical setting is critical, as students should be nurtured as professional nurses and be given the opportunity to integrate their knowledge into practice [60]. In addition, among the sub-domain of CLES + T, " role of nurse teacher" had the highest scores, which means the better the nursing faculty's relationship with the practice setting and ability to integrate theory and practice, the more positive the students' perception of the clinical learning environment. This result is consistent with Saarikoski's study [46], suggesting that the nurse teacher should take effort to ensure the continuity of theory and practice with open communication and commitment between students, teachers, and staff nurses in clinical teaching. Further, a partnership between the nursing school and the hospital is needed to provide better clinical education to the students in a consistent and exemplary manner. In Korea, due to the rapid increase in the number of nursing schools over the last 10 years [61], numerous nursing schools find it difficult to secure clinical practicum sites and qualified preceptors for training students [62]. In addition, the provision of a good learning experience is hindered within the current hospital environment due to high turnover rate of patients, limited access to medical records, and increased awareness regarding the rights and safety of humans [63]. This situation provokes anxiety, depression, and burn-out among students and deteriorates the quality of their clinical education [62,63].

The last notable finding was that anxiety during clinical practicum had directly affected readiness for practice among students. This is in consistent with the results of previous studies, which reported that high levels of anxiety during clinical practicum negatively affect the clinical performance and successful adaptation and retention to practice of students [22]. Incorporating pre-clinical knowledge and skill development sessions through simulation education [64] is effective in decreasing anxiety among students. Most nursing students in Korea are provided simulated education because simulation hours are accepted as 10.0% of the compulsory 1,000 clinical hours by the Korean Accreditation Board of Nursing Education [65]. Given that anxiety during clinical practicum can be mediated through various methods, the persistent attention and efforts of educators are needed to ameliorate this anxiety and improve readiness for practice among students.

This study has several limitations. First, our findings must be viewed with caution as most participants were female and from universities located in urban areas due to the convenient sampling method employed. Second, we measured readiness for practice using a self-administered survey based entirely on the students' perspectives. Readiness for practice should be evaluated by the student, nursing faculty, and nurse educators in practice as they have different lenses through which they view practice readiness. Additionally, this study was cross-sectional, limiting our understanding of the influence of personal and environmental factors on readiness for practice based on the I-E-O model [30]. A longitudinal study may be conducted to better explore relationship between factors and understand the association between analyzed variables. Lastly, we modified the standardized instruments with multiple subdomains into shorter versions to suit the purpose of our study. This may have hindered us from attaining an in-depth understanding of the concepts and limited the comparisons that could be made with other studies that explored readiness for practice. While the readiness for practice instrument maintained the same construct as the original instrument, Cronbach's alpha value was .5 in learning techniques, one of the sub-domains, which was not ideal but was acceptable [66]. Although this is the same result as the original instrument when developed, a psychometric test for the Korean student nursing population is proposed in follow-up studies to secure validity and reliability.

# Conclusions

Our findings suggest that taking personal factors into account, improving their clinical learning environment, and providing sufficient educational and clinical support could enable nurses to establish better professional values and readiness for practice. In addition, considering the characteristics of Generation Z, where individual values and characteristics are becoming increasingly important, the cooperation among nursing schools, teaching hospitals, and clinical learning institutions toward providing clinical learning curricula reflecting generational characteristics can effectively improve readiness for practice among nursing students. This would effectively help ensure readiness for practice so that graduates can transition to professional nurses.

#### **Author contribution**

Taewha Lee, guided the research plan from the beginning to the completion, participated in the entire process until the completion of the research, and revised and developed the manuscript.

Yoonjung Ji, all processes including research plan preparation, data collection, result analysis, discussion writing, manuscript writing, and submission.

Yea Seul Yoon participated in research plan preparation and data collection.

Hyunju Ji participated in research plan preparation and data collection.  $\,$ 

SangA Lee participated in discussion writing and manuscript writing.

Sookhee Yoon participated in statistical analysis, result analysis and writing the result of the manuscript.

Su Jeong Lee participated in research plan preparation.

#### Conflict of interest

There are no conflicts of interest to declare.

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#### Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.anr.2023.01.003.

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