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Editorial

Research papers in the age of planetary health

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In recent years, the role of nursing has expanded beyond traditional healthcare to adopt a holistic approach that takes up such perspectives as environmental protection and sustainability. Hohashi (2023) defines planetary health as “an interdisciplinary field of study for understanding the interaction/transaction between the global environment and human health, and to build a sustainable future for the entire planet.” Humans are part of the global environment system, and the wellness of individuals (family members) and the well-being of families are related to the global environment, also making it an important concept in the field of nursing.

At present, the impact of environmental change and destruction, e.g. climate change, natural disasters, destruction of undeveloped woodlands near populated areas, etc., which are occurring on a global scale to affect individuals (family members) and families, is becoming increasingly critical. Planetary health transverses such fields as environmental issues, public health and economic development, and offers guidelines for promoting changes in awareness and behavior toward building a sustainable future. The *Lancet Planetary Health*, an open-access journal published in the U.K. since 2017, strives to deepen the understanding of planetary health and disseminate knowledge in order to propose remedial countermeasures.

The need also exists to consider new disaster response efforts from all angles. Japan is particularly prone to earthquakes. On January 1, 2024, a devastating earthquake struck the Noto Peninsula on the Sea of Japan, and now, more than a year later, the devastation can still be seen in many villages, where completely destroyed homes have been left abandoned. The author has been paying regular visits to the Noto Peninsula since immediately after the earthquake, and has been providing family nursing, his area of expertise, for nearly two months over the past year.

In the future, we welcome submissions of nursing research that relate to this era of planetary health, in the hope of providing an opportunity to reevaluate nursing on a new level, while contributing to the creation of new values.

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Review Article

Analyzing the “Toubyou-iyoku” concept to determine coping with illness among hospitalized children in Japan

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Abstract

This study aimed to clarify the concept of “Toubyou-iyoku”—a volition of the fight against illness—among hospitalized children. In Japan, patients undergoing treatment are sometimes described as having “Toubyou-iyoku” based on their positive attitudes toward their illness and treatment. When hospitalized, if affected children have a positive attitude toward fighting a disease, this can lead to positive changes after discharge. However, the conditions under which they can be motivated to fight diseases are unclear. To address this issue, Walker and Avant’s concept analysis method was used to analyze “Toubyou-iyoku.” The analysis yielded seven attributes: confronting the disease head-on, recognizing the disease, eagerly receiving treatment, focusing on treatment, endeavoring to overcome the disease, trying to remain calm and maintain composure, and keeping hope alive. These are seven antecedent requirements and eight consequences that do not move in one direction but rather circulate. Hence, supporting not only the antecedents (factors that influence the volition of the fight against illness) but also their individual attributes and consequences is necessary. Hospitalized children’s volition of the fight against illness was defined as their desire and hope to face illness and treatment, accept it with wavering feelings, and actively work to maintain treatment based on their innate ability to understand and cope with their illness and experiences associated with hospitalization.

Keywords

hospitalization, children, concept analysis, Toubyou-iyoku

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Introduction

In Japan, children with chronic diseases such as cancer often require extended hospitalization (≥6 months) for treatment. During hospitalization, they must live in a new environment, away from their familiar homes and schools, which poses a heavy burden on them. Many facilities offer in-hospital classes for elementary and middle school students while monitoring their treatment timing and physical condition;

however, learning is often delayed. In recent years, as elementary and junior high schools have moved online, students can take online classes at their schools without transferring to in-hospital classes. Nevertheless, as hospitalized children experience prolonged separation from their families and schoolmates, support is increasingly being provided from the time of hospitalization until their return to school.

Prolonged hospitalization, separation from family and schoolmates, and facing illness affect children’s physical and

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mental health. Difficulties in life postdischarge and delays in learning affect the acquisition of self-belief (Maeda et al., 2004; Yamaji & Kuwata, 2015), leading to a backward-looking view of the illness and an attitude of “giving up” that negatively affects the participants’ quality of life (Currier et al., 2009; Phipps et al., 2007; Takei et al., 2013; Tonsing & Ow, 2018; Zebrack et al., 2010). Conversely, positive emotions and an optimistic outlook on the illness positively affect the participants’ quality of life and self-esteem (Currier et al., 2009; Dattilo et al., 2021; Kim, 2017; Kwak et al., 2021; Takei et al., 2013; Tonsing & Ow, 2018; Zebrack et al., 2010). The experience of illness can positively affect children’s socializing (Zebrack et al., 2010) and lead to positive changes, such as increased compassion toward children with illnesses other than their own (Servitzoglou et al., 2009).

In Japan, the positive attitude of patients undergoing treatment for an illness is sometimes described as “Toubyou-iyoku”—translated as the will or volition of the fight against illness. The term “Toubyou-iyoku” is a combination of “fighting disease” and “willingness, volition, desire, motivation.” Its exact definition is unclear. In the study of the illnesses of adult patients with cancer in Japan, there has been an increase in the number of illnesses with “kyosei” or “co-existence” as a specific concept since around 2000 (Kadobayashi, 2013). The idea that cancer is not something to fight but to be lived with together has been observed since this time. Nevertheless, in past literature on adult patients, the motivation to fight an illness has been discussed as something to be maintained or improved and is defined as a feeling of accepting the illness and treatment and facing one’s situation (Kameda & Inoue, 2009; Wada et al., 2018; Yamaguchi et al., 2007). However, this definition applies to adults and may not apply to hospitalized children. We examined literature from outside Japan to determine whether these studies mentioned children’s motivation to fight their illness during hospitalization. It has been stated that positive perceptions of illness positively affect children (Currier et al., 2009; Dattilo et al., 2021; Kim, 2017; Kwak et al., 2021; Takei et al., 2013; Tonsing & Ow, 2018; Zebrack et al., 2010), but it is unclear whether children’s positive approach is the same as their willingness to fight the disease. Hence, we wondered whether “Toubyou-iyoku” might have a different meaning for hospitalized children in Japan and other countries. In Japan, long-term hospitalization is common because of the universal health insurance system and subsidies for medical expenses for children with chronic diseases. However, in other countries, because of differences in medical insurance, short-term hospitalization and home care may be combined, and the hospitalization environment varies during treatment. If the volition of fighting an illness is a way of facing it, then a positive attitude toward the illness, coping, resilience, and adaptation may be close to it, al-

though these cannot be said to comprise “Toubyou-iyoku.” As children’s attitudes toward illness, treatment, and hospitalization may differ across countries and cultures, this study aimed to clarify the concept of “Toubyou-iyoku”—what it means, what influences it, and ways in which it influences hospitalized children in Japan.

Methods

Concept Analysis Model

A concept analysis model was adopted because of its usefulness in redefining ambiguous concepts in theory and clearly defining concepts that have been overused or remain ambiguous and common in nursing practice (Walker & Avant, 2008, pp. 51-52). The concept “Toubyou-iyoku” is often used, but what constitutes it is unclear. Hence, it was examined and analyzed in a continuous or iterative manner using Walker and Avant’s eight stages: (1) selecting a concept, (2) determining the aims or purposes of the analysis, (3) identifying all uses of the concept, (4) defining attributes, (5) identifying a model case, (6) creating additional cases, (7) identifying antecedents and consequences, and (8) defining empirical referents.

Data Collection

We searched the Japanese literature. Original articles were searched for the keyword “Toubyou-iyoku” using Ichushi-Web and CiNii Research. To ensure that the concepts covered did not change over time and to include as much literature as possible, the period covered was broad and included literature from the year of search availability to April 2021. Of the 195 original articles extracted, references that did not clearly mention children in the title and abstract, or did not mention children in the hospital, were excluded. We extracted 32 references. After carefully reading the articles and excluding 4 references that did not mention children, 28 references were retained. The 28 documents were analyzed (Figure 1). All included literature was nursing literature. The literature was published from 1985 to 2020. Diseases in children described in the included literature were not limited (Table 1). The target literature was read repeatedly to extract attributes, antecedent requirements, and consequences. The researcher and three coresearchers analyzed and discussed the literature separately, especially literature with the most descriptions of “Toubyou-iyoku” (Saiki-Craighill et al., 2004; Tahara, 1990). The remaining literature was analyzed by the researcher, and the extracted content was manually described on a self-made coding sheet.

The described contents were analyzed inductively for each attribute, antecedent requirement, and consequence. To ensure the validity and truthfulness of the analysis, the results were shared among the researchers, and opinions were exchanged.

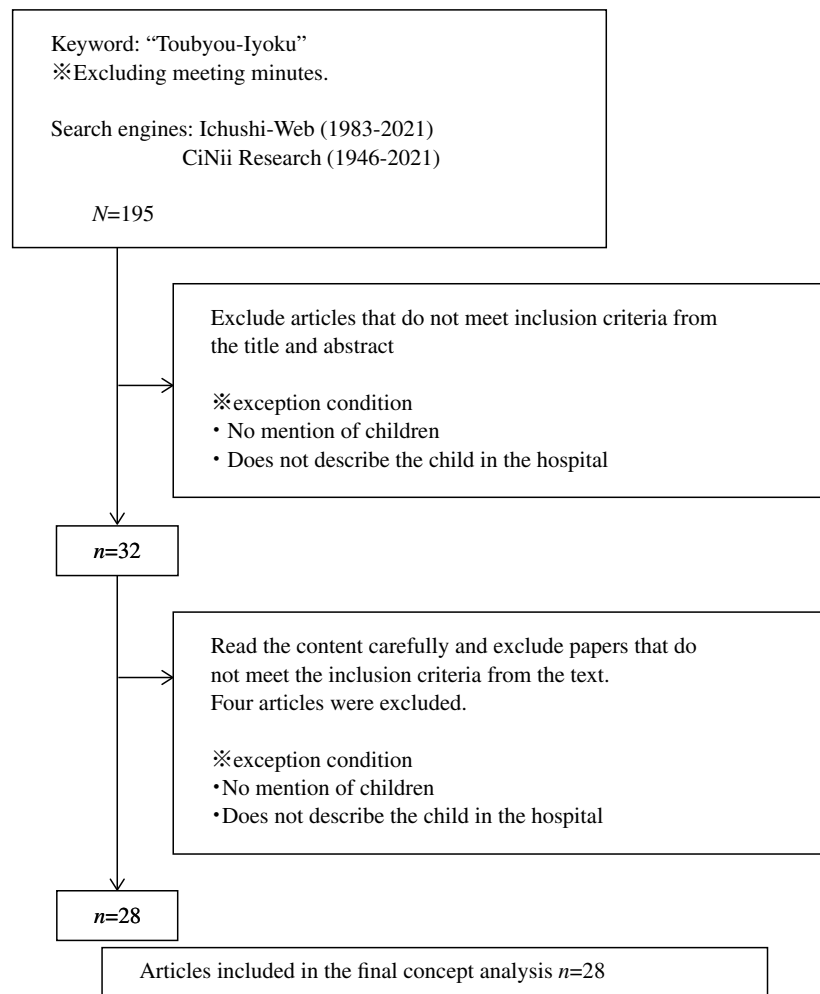


Figure 1. Data sources.

Results

Concept Selection

The “Toubyou-iyoku” for children in the hospital was selected. Clarifying the internal structure of hospitalized children will help explain the state in which they can be said to have “Toubyou-iyoku.” Additionally, clarifying what influences children’s “Toubyou-iyoku” and what happens when they gain it will contribute to their support; hence, this concept was selected.

Identifying All Uses of the Concept

“Toubyou-iyoku” is a compound of “fighting illness” and “motivation.” According to a large dictionary of the Japanese language (Shougakukan, 2007), “toubyou” means “fighting against an illness or striving for medical treatment for a certain period, with a strong will to cure an illness,” whereas “iyoku” means “the will to do so.” “Willingness” is defined as being inclined or favorably disposed in mind to do something, the will to actively try to do something, and a desire in one’s heart to willingly do so. It is the active and

proactive work of the will to select a certain goal from various motives. In the field of nursing, it is defined as “the desire to bring about the will to act” (Nagai & Tamura, 2013), and in the field of education, it is used with various connotations, such as the will to learn.

Attributes of Children’s Volition in Fighting Illness during Hospitalization

The content of the attributes was extracted from the target literature, and the results yielded seven categories: confronting the disease head-on, recognizing the disease, eagerly receiving treatment, trying to focus on treatment, endeavoring to overcome the disease, trying to remain calm and maintain composure, and keeps hope alive.

Confronting the Disease Head-on

This category includes two subcategories. “Confronting the disease and its treatment” was extracted from *confronting one’s own disease* (Hirose & Yoshino, 1990; Mori, 2020; Yamamura, 2006) and *confronting chemotherapy and painful procedures with strong side effects* (Hirose & Yoshino,

Table 1. Articles selected for inclusion.

	Author	Title	Target	Illness	Research methods
1	Mori et al. (2020)	Koukousei no gantiryō niokeru gakusyuusien no jyuuyousei [The importance of cancer treatment learning support for high school students]	High school student	Hematological malignancy and solid tumor	Intervention research
2	Nagae et al. (2018)	Daigakubyōin de tenkai shita doubutukaizairyōhou dōnyūugo 3 nendenseika [Animal-assisted therapy developed in a university hospital – Initial 3-year experience and results]	4–92 years old (19 under 20)	Various	Intervention research
3	Matsumi et al. (2016)	Syouni nesssyō kanja kango no 1 keikenrei kangōkeikaku no rituan ni okeru hattatudankai kouryō no jyuuyousei [A report of a pediatric burn case – The importance of child-centered rehabilitation and nursing]	8 years old	Burns	Case study
4	Nagoya et al. (2013)	Syounizōketukisyūyō de nyūinntiryō sita keiken wo motu kodomo ga genseikō no yujin ni taisite idaku omoi [The feelings of children with hematologic malignancy for friends at a local school]	12–18 years old	Pediatric hematopoietic tumors	Questionnaire interview
5	Kawasaki et al. (2008)	Gakudōki ni manseisikkan wo rikan sita daigakusei no sizentaiken no yuuyousei ni kansuru kenkyū [A study of the therapeutic utility of nature experience among college students with chronic diseases during childhood]	College students experiencing chronic illness	Asthma, atopic dermatitis, heart disease, etc.	Questionnaire
6	Lee et al. (2006)	The potential of play activities for children with cancer at a hospital – Case study of children in a hospital	2–13 years old	AML (acute myeloid leukemia) and rhabdomyosarcoma	Case study
7	Yamamura (2006)	Nyūin shiteiru gakudōki no kodomo ga kangōshi ni jyōhouteikyō wo motometatokino taiō ni kansuru kenkyū [A study of nurses' methods for managing information requests from hospitalized schoolchildren]	Nurses	Respiratory and blood diseases	Interview survey
8	Saiki-Craighill et al. (2005)	Syounigan senmoni no kodomo heno truth-telling ni kansuru isiki to jittai: Byōmeikokuti no jyōkyō [Attitudes and practices of pediatric oncologists when truth-telling to children: The situation among Japanese oncologists when telling children about their diagnoses]	Pediatric oncologist	Childhood cancer	Questionnaire
9	Hamasuna et al. (2004)	Massyōketukansaiyōkyō wo okonau gakudōki no ji heno kōkateki na syōtēnnyō wo kokoromite tankimokuhyō wo setteisita kominike-syon wo thūjite [Providing effective treatment assistance to school-aged children undergoing peripheral blood stem cell transplantation through communication with short-term goals]	First-grade elementary school	Neuroblastoma	Case study
10	Inoue et al. (2004)	Jakunensei kansetu riumati no saishin no tiken to kea no jissai jirei ni miru kango no jissai sainen wo kurikaesu ji no tōbyōyōkyō wo sasaeru kango [The latest knowledge and practical care for juvenile rheumatoid arthritis: Nursing practice in case studies to support the fight against the disease in children with repeated reflagration]	17 years old	Systemic juvenile rheumatoid arthritis	Case study
11	Saiki-Craighill et al. (2004)	Tōbyōyōkyō to iu na no tōkyōrisō byōmeikokuti wo uketa syounigan no kodomo no tōbyōutaiken [Fighting an illness as a long marathon: How do children manage cancer after they receive their diagnosis?]	11–18 years old, siblings, doctors, and nurses	ALL (acute lymphoblastic leukemia), CML (chronic myelogenous leukemia), and malignant lymphoma	Interview
12	Tanaka et al. (2003)	Manseisikkan wo motu nyūinchu no kodomo no iyoku wo sasaerumono [What supports the motivation of hospitalized children with chronic illnesses?]	7–16 years old	Chronic disease	Interview
13	Nagao et al. (2002)	Kyūseikotsuziseihakkeubyōkanja nitaishuru tōbyōyōkyō heno enjyō kanjasaido chiryōyōteihyō no sakusei wo kokoromite [Helping patients with acute myelogenous leukemia fight disease: An attempt to create a patient-side treatment schedule]	Unknown	AML	Questionnaire
14	Nagasaki (2000)	Shisyūnki ni aru ji no identity to tōbyōyōkyō wo sasaeru kango akuseisikkan wo kakaeruji no body image no henka kara manandakoto [Nursing care to support adolescents' identity and motivation to fight disease: Lessons learned from body image changes in children with malignant disease]	11 years old	Malignant lymphoma	Case study
15	Kasai (2000)	Zensisyūnki niaru gasyōanseityū no kanji heno enjyō tōbyōyōkyō wo sasaerutameni knngosya ga hatasubeki yakuwari toha [Assistance to a preadolescent bedridden patient: What role does nurses play in supporting patients' motivation to fight the disease?]	10 years old	Lumbar spondylolysis	Case study
16	Nakano (1996)	Manseijyōtai no kodomo no tōbyōyōkyō wo takameru kangōhō no keakōdō no jittai [Nurses' caring behaviors to support fighting behaviors in children with chronic illness]	Nurses	None	Questionnaire
17	Yamamoto et al. (1993)	Insurinhiizongata tōnyōbyōji no jikokanri ni mukete no enjyō tōbyōyōkyō ni kakeru shisyūnki no 1 jirei wo tōshite [Helping children with insulin-independent diabetes achieve self-management through a case study of an adolescent who lacks motivation to fight the disease]	17 years old	Noninsulin dependent diabetes	Case study

Table 1. Articles selected for inclusion (continued).

	Author	Title	Target	Illness	Research methods
18	Nakao (1992)	Hakketubyoukanja no to-tarukea gakugyoutojyou ni aru seinennihakketubyoukanja no kango toubyouiyoku wo sasaete [Total care of patients with leukemia nursing care of adolescent patients with leukemia during their studies: Supporting their motivation to fight their disease]	16 years old	ALL	Case study
19	Hibi et al. (1992)	Manseisikkankanji no seruhukeakakuritu heno enjo hakketubyoukanji no toubyouiyoku wo sasaerutame no enjo tiryoukyohi wo sita jirei wo toushite [Assistance in establishing self-care for chronically ill children: Assistance in supporting the motivation of children with leukemia to fight their disease through refusal of treatment]	10 years old	ALL	Case study
20	Miyamoto et al. (1992)	Manseisikkankanji no seruhukeakakuritu heno enjo kanji no jiritu wo unagasi toubyouiyoku wo jizoku surutameno enjo sinsin no tanren ya jikokontoro-ruhou nadono kuhuu wo tousite [Assistance in establishing self-care for chronically ill children: Promoting independence and sustaining motivation to fight illness through mental and physical exercises and self-control methods]	11 years old	Asthma	Case study
21	Abe (1991)	Syouni koukarori-yuekihou IVH kannri ga chouki ni oyonda kanji no kango toubyouiyoku wo jizoku saserutameno kuhuu to kango [Pediatric high-calorie infusion nursing care of children with long-term IVH management: Devices and assistance to sustain motivation for fighting disease]	5 years old	Congenital immunodeficiency, etc.	Case study
22	Hori et al. (1990)	Shi no tenki wo totta kyuseihakketubyoukanji no enjo saigo made toubyouiyoku wo motitudukeruyouni enjo shita jirei wo toushite [Assistance to a child with acute leukemia who had a fatal outcome: A case study of assisting a child to maintain his will to fight the disease until its end]	13 years old	ALL	Case study
23	Hirose et al. (1990)	Kagakuryouhou ni tomonau shintaiteki seisinteki kutuu ni obiyakasareru kyuseihakketubyoukanji no omoi to taiou toubyouiyoku wo iji surutameni [The thoughts and responses of children with acute leukemia threatened by physical and emotional distress associated with chemotherapy for maintaining motivation to fight the disease]	12 and 9 years old	ALL	Case study
24	Shiota et al. (1990)	Kyuseihakketubyou kanji no toubyouiyoku wo sogai suru youin [Factors hindering the motivation of children with acute leukemia to fight the disease]	Unknown	ALL	Review
25	Hashimoto (1990)	Nyuuinkanjin no huan ni taisuru ennjo shisyunki no yogohuryouji heno enjo itami no aru kanji tono kakawari wo toushite [Helping hospitalized children with anxiety: Helping adolescents with poor prognosis by helping children with pain]	15 years old	Malignant paraganglioma	Case study
26	Tahara (1990)	Tyokinyuujin heno enjo kodomo no toubyouiyoku wo dou sasaeruka [Assistance for children hospitalized for long periods: How to support children's will to fight the disease]	Unknown	None	Review
27	Nohara et al. (1986)	Sentensei tahatusei kansetu kousyukusyou ji no hokousyougai ni taisuru enjo toubyouiyoku wo motta kanji kara manandakoto [Assistance for children with congenital multiple joint contractures with gait disorders: Lessons learned from a child with a will to fight the disease]	9 years old	Children with congenital arthrogryposis multiplex	Case study
28	Ootsubo et al. (1985)	Sinjitto wo sirinagara saigomade toubyouiyoku wo motituduketa akuseisyuyoukanji no kea siniyuku kodomo ni ikanisite yasuragi wo ataeruka [Care for a child with a malignant tumor who knew the truth and kept fighting the disease until the end of his life: How can we comfort a dying child?]	11 years old	Rhabdomyosarcoma	Case study

1990). “Cures the disease even if it recurs” was extracted from *factors such as confidence to cure the disease even if it recurs and the strength to face even a recurrence* (Saiki-Craighill et al., 2004). Hospitalized children confronted their own illness when they were first treated and hospitalized or relapsed.

Recognizing the Disease

This category includes two subcategories. “Recognizing the disease”—the children’s willingness to accept hospitalization and treatment—is defined as their attitude of accepting *the disease and coping with the procedures that must be performed* (Tahara, 1990) and *things that they do not want to*

do (Hirose & Yoshino, 1990; Saiki-Craighill et al., 2005; Tahara, 1990). “Recognizing the changes in one’s body” is defined as *accepting the changes in your body caused by the treatment* (Saiki-Craighill et al., 2004). The children’s recognition of their illnesses and treatment was shown as something that was happening to them.

Eagerly Receiving Treatment

This category includes six subcategories. The “willingness to try” was extracted from the phrase *I will do my best to achieve the goals in front of me, I want to go back to school and see everyone soon* (Saiki-Craighill et al., 2004), and *I will work on my tasks even while in hospital* (Mori, 2020).

The “strength to try” refers to *encouragement to treat* (Nagoya & Kaori, 2013) and *motivation to work on their illness* (Yamamura, 2006). “Self-inspiration” was extracted from *I cannot lose myself, and I am sure I will get better* (Saiki-Craighill et al., 2004). The “positive attitude toward treatment” was extracted from the *positive attitude toward myself* (Saiki-Craighill et al., 2004). The “positive self” was extracted from *patients who always had a positive attitude toward their hospital stay* (Youngsook et al., 2006), and the “proactive self” was extracted from *individuals’ proactiveness and initiative in accomplishing tasks themselves* (Matsumi et al., 2016). These attributes indicate that children who are aware of their illness and treatment try their best to cope with the events occurring. This indicates a positive experience of illness and a positive engagement in treatment and hospitalization.

Trying to Focus on Treatment

This category comprised two subcategories: “creating an environment to focus on” and “focusing on the treatment of the disease.” The data were extracted from the following: *I tried to prepare the environment for fighting the disease and facing the treatment*, and *I focused on fighting the disease* (Saiki-Craighill et al., 2004). Respondents indicated that they tried to prepare the disease-fighting environment and concentrate on their treatment.

Endeavoring to Overcome the Disease

This category comprised two subcategories: “driving force to overcome” and “overcoming the disease or treatment.” The data were extracted from the *driving force to overcome the disease* (Tahara, 1990) and *desire to overcome the disease* (Kasai, 2000), which were indicated in hospitalized children.

Trying to Remain Calm and Maintain Composure

This category comprised four subcategories: “keep yourself calm”; “stabilize your mood swings”; “keep running”; and “sustain, keep running, and maintain composure.”

These attributes demonstrated how children stabilize their fluctuating negative and positive feelings as they continue to face illness and treatment. From *keeping maintaining one’s calmness* (Tanaka et al., 2003), *stabilizing fluctuating feelings*, and *continuing to run in a positive direction* (Saiki-Craighill et al., 2004) were extracted.

Keeps Hope Alive

The subcategories of this category were “hopes for the future and what you want to do,” such as *I want to be cured with medicine and injections and return to school soon* (Hirose & Yoshino, 1990) and *I want to be able to sit on my own and eat with my hands* (Matsumi et al., 2016). Children have hope for the future as they face, confront, and work

positively with their illness and treatment.

Determination of Defining Attributes

In this study, we defined the “volition of fighting against illness” among hospitalized children in Japan as follows:

“It is based on one’s own innate ability to understand and cope with the experiences associated with illness and hospitalization, the desire to face the illness and treatment, to accept it with shaken feelings, to actively work hard and maintain treatment, and to hope.”

Model Case

The model case has all the defined attributes.

A second-year junior high school female student received treatment for acute lymphocytic leukemia. Although she was surprised at her sudden hospitalization, when her doctor and parents explained the disease and treatment to her, she accepted her treatment, disease, and hospital stay. Despite experiencing nausea and vomiting because of treatment side effects and being in bed for a long period, she faced her treatment with the mindsets “I will not give in to the disease” and “I will definitely recover from the disease.” In-between treatments, when she was feeling well, she talked about her hopes for the future and showed initiative in her studies so that she did not fall behind in her schoolwork. She also hoped to return to club activities (track and field team) after returning to school life and work hard daily to prevent muscle weakness, such as performing strength training in bed and walking around the ward. By befriending patients in her room, encouraging them, and talking about her favorite things, she found enjoyment in her hospital stay. She also had excellent communication with the medical staff, whom she had asked about her illness and treatment.

This case qualifies as a model case because it has all the defining attributes of “volition of fighting against illness among hospitalized children.”

Borderline Case

Borderline cases include some but not all attributes.

A junior high school male student was being treated for Hodgkin’s lymphoma and informed of his disease and treatment by his doctor and family. He received treatment without refusal but did not ask any questions about the treatment he was receiving. Although he was preparing to take the high school entrance exam, he talked about his inability to study during hospitalization, did very little learning, spent most of his waking hours playing video games, and hardly communicated with other patients or nurses. When he stayed overnight between treatments, his facial expression appeared to soften. After returning from his overnight stay, he talked to the nurses and appeared to be in a good mood.

This case includes “confronting the disease head-on” and “recognizing the disease” but not the other defining attrib-

utes of “volition of fighting against illness among hospitalized children.” Therefore, this is a borderline case.

Contrary Case

Conversely, the contrary case does not satisfy any attributes.

A healthy male sixth grader who goes to school daily works hard to practice for his baseball club after school.

This case does not satisfy a single defining attribute. It is an entirely different case from “volition of fighting against illness among hospitalized children.”

Antecedents

Seven categories were identified as the antecedent requirements for hospitalized children’s “Toubyou-iyoku.”

The Child’s Knowledge and Awareness Regarding the Disease and Treatment

This antecedent comprised four subcategories: “The children are aware of the disease and treatment,” “they receive explanations about their disease and treatment and understand the reasons for receiving treatment,” “they receive explanations about the treatment and side effects from medical personnel,” and “they have a negative image of the disease.”

The Child’s Innate Ability to Handle Difficult Challenges

This antecedent was defined as one’s innate ability to cope with things. The subcategories were “children will distract themselves from anxiety,” “they will think about things in a positive way,” “they will stabilize their emotions,” “they will live a life without awareness of the illness,” “they will be less stressed,” and “they will be more comfortable with their illness,” thus “preventing stress from worsening.”

Mood Swings between Confidence and Anxiety Associated with Treatment and Hospitalization

This antecedent comprised eight subcategories: “hopeful and fulfilled during hospitalization,” “sense of accomplishment,” “finding their place in the world,” “having hope for the future,” “feeling loneliness and fear,” “gaining confidence from the experience,” “feeling insecure from the experience,” and “feelings of uncertainty.”

Painful Experiences Involving Treatment

This antecedent comprised two subcategories: “experiences of distress and pain” and “changes in body image.”

Learning, Playing, and the Living Environment during Hospitalization

This antecedent comprised three subcategories: “hospitalization environment,” “learning environment,” and “availability of a comfortable environment.”

Support from Family Members, Friends, and Healthcare Providers

This antecedent comprised “support from family,” “support from friends,” and “support from surroundings.”

Relationship with Healthcare Providers and Other Children Established during Hospitalization

This antecedent refers to doctors, nurses, and other hospital-

ized children they had met since being hospitalized, and their relationships. The three categories were “relationship with other children,” “trust in doctors,” and “relationship with nurses.”

Consequences

Eight categories were obtained through children’s “Toubyou-iyoku” during hospitalization: “recognizing what matters most” was improved and extracted from the notion that *I now understand the importance of health and life* (Saiki-Craighill et al., 2004). The participants realized that they were “becoming tougher as an individual,” stating, *I don’t feel like losing at anything now that I have defeated my illness* (Saiki-Craighill et al., 2004). This realization led to the following attributes: “acquiring confidence and trust in oneself,” “becoming more capable of taking care of oneself,” and “psychosocial development.” Additionally, they gained “better relationships with others” and a “better physical condition.” It was revealed that the inability to motivate oneself to fight the disease led to “becomes emotionally hesitant.” On the basis of this study’s results, the antecedent requirements, attributes, and consequences are depicted in a conceptual diagram (Figure 2).

Empirical Referents

The final step in conceptual analysis is to define the empirical indicative object, which is an actual phenomenon that exemplifies the occurrence of the concept through its presence (Walker & Avant, 2008). In many cases, the empirical indicative object and the defining attribute coincide, but an empirical indicative object is necessary when the concept under consideration is abstract. In this study, because the defining attribute is abstract, it is necessary to provide a concrete way for “Toubyou-iyoku” to occur in hospitalized children.

Currently, no scale exists to measure “Toubyou-iyoku” in hospitalized children, but its presence can be ascertained by conducting an interview survey with questions such as “how did you feel when facing your illness and treatment?” It may also be possible to use the Optimism and Pessimism Scale (Toyama, 2013) to determine whether their feelings were positive or negative, or the Ego Resiliency Scale (Hata & Onodera, 2013) to measure ego resiliency and assess the ability to flexibly adjust one’s ego to daily internal or external stressors and successfully cope and adapt to situations.

Discussion

This study examines seven antecedent requirements for “the child’s knowledge and awareness regarding the disease and treatment” by extracting the following attributes: “the child’s innate ability to handle difficult challenges”; “mood swings between confidence and anxiety associated with treatment

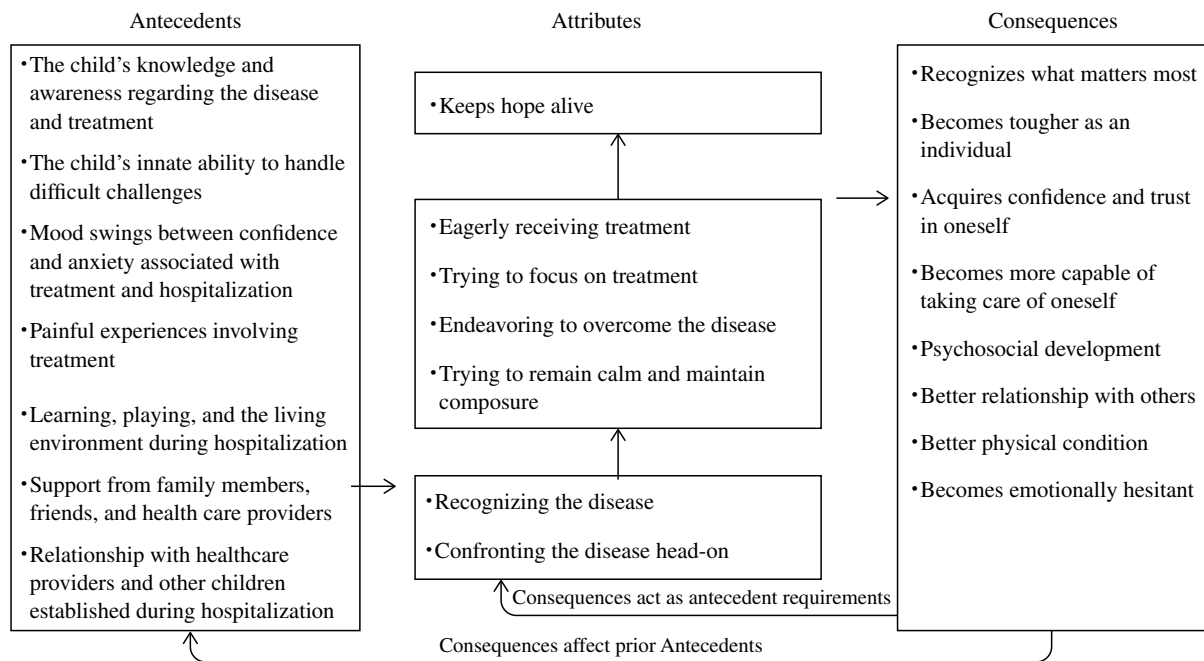


Figure 2. Concept model of “volition to fight against disease in hospitalized children” in Japan.

and hospitalization”; “painful experiences involving treatment”; “learning, playing, and the living environment during hospitalization”; “support from family members, friends, and healthcare providers”; and “relationship with healthcare providers and other children established during hospitalization.” These antecedent requirements were suggested as influential factors for children’s volition of the fight against illness during hospitalization. The two attributes of “confronting the disease head-on” and “recognizing the disease” are foundational because confronting and recognizing are thought to give rise to the next stage of attributes, which are “eagerly receiving treatment,” “trying to focus on treatment,” “endeavoring to overcome the disease,” and “trying to remain calm and maintain composure” during treatment. As these thoughts become stronger or weaker and constantly change, we believe that they will “keeps hope alive” after discharge in the near future. The presence or absence of “Toubyou-iyoku” in hospitalized children was linked to the following seven positive changes: “recognizing what matters most,” “becoming tougher as an individual,” “acquiring confidence and trust in oneself,” “becoming more capable of taking care of oneself,” “psychosocial development,” “better relationship with others,” and “better physical condition,” whereas “becoming emotionally hesitant” was linked to negative changes. The identified antecedent requirements, attributes, and consequences were not unidirectional because, for children in the hospital, having the will to fight the disease itself can help them become more positive about treatment (Mori, 2020), which is a result of having this will. This was connected to the attribute of attempting to approach treatment positively. The consequences of having the

volition to fight against illness served as a driving force for maintaining such volition (Hibi et al., 1992) and sometimes served as an antecedent requirement. Furthermore, the consequences affected the occurrence of the antecedent requirement. Thus, antecedent requirements, attributes, and consequences are believed to circulate in the treatment process from the moment a child encounters an illness.

Definitions and Implications of Nursing

The “Toubyou-iyoku” of hospitalized children in Japan was defined as being “based on one’s own innate ability to understand and cope with the experiences associated with illness and hospitalization, the desire to face the illness and treatment, to accept it with shaken feelings, to actively work hard and maintain treatment, and to hope.” “Toubyou-iyoku” was influenced by the children’s inherent coping ability. In a previous study, children’s perception of illness was linked to their own coping behaviors toward the illness (Suzuki & Tomari, 2020). It has been suggested that hospitalization is a growth experience that is psychologically beneficial for children, but it can also be traumatic because of factors such as coping skills (Shields, 2001). Therefore, supporting children to exercise their coping skills may lead them having “Toubyou-iyoku,” which may also be similar to what psychology defines as the “resilience” to recover from psychological injury or depression brought on by threatening events or the mental processes and outcomes of such recovery. High resilience is associated with fewer mental health problems (Mesman et al., 2020). The field of psychiatric nursing defines resilience as one’s ability to bounce back or recover from adversity (Garcia-Dia et al., 2013). In the field of pedi-

atric nursing, resilience in children is associated with recovery and adaptation, and the attributes of this concept include positive future orientation (Miyazaki, 2009). Concepts of resilience overlap with the attributes “keeps hope alive” and “eagerly receives treatment” in this study, as well as the consequences “better relationship with others” and “acquires confidence and trust in oneself.”

In Japan, “Toubyou-iyoku,” is considered a patient’s positive attitude toward treatment; their innate ability to cope with their illness, treatment, and hospitalization; and their willingness to face these hurdles by accepting their fluctuating feelings and doing their best. Although the expression “Toubyou-iyoku” may be unique to Japan, we believe that the “Toubyou-iyoku” defined in this study exists regardless of the length of hospitalization, environment, or country.

Although the results of this study did not provide a clear measure of hospitalized children’s “Toubyou-iyoku,” it presented its influencing factors, definitions, and effects. Hence, to support “Toubyou-iyoku” among hospitalized children, it is necessary to understand its antecedents, attributes, and consequences.

Nurses should assess the ability of hospitalized children to accept the illness, their motivation in life before hospitalization, and the type of support needed. When the child can cope positively with the illness, treatment, and hospitalization, they should verbalize and talk to the child about what they can do to better demonstrate this ability, provide a positive perspective to a child who appears negative, affirm the child’s condition, and support the child in responding to the illness. Moreover, devising methods and interventions according to the children’s many and varied responses is crucial.

Study Limitations

As a conceptual analysis, this study was limited to Japanese literature and only nursing literature, with 28 references, and was able to define “Toubyou-iyoku” for hospitalized children in Japan. However, further refinement and consideration are required for nursing support. Furthermore, it is necessary to examine literature from other countries while considering cultural contexts and perspectives outside the field of nursing.

Conclusions

The “Toubyou-iyoku” of hospitalized children in Japan is “based on one’s own innate ability to understand and cope with the experiences associated with illness and hospitalization, the desire to face the illness and treatment, to accept it with shaken feelings, to actively work hard and maintain treatment, and to hope.”

The results of this study found that, first, a child’s volition to fight illness during hospitalization is influenced by

their innate ability to cope, as well as other factors. Second, there are positive and negative changes because of the child’s volition to fight illness. Third, the outcome may become the child’s experience and affect their volition to fight the illness, or the change itself may affect this volition.

Author Contributions

Mia Hashimoto was involved in the study concept and design, literature search, data analysis and interpretation, and writing of the manuscript. Wataru Irie, Akiko Sugahara, Yuko Nagoya, and Hitoshi Shiwa were involved in the study concept and design and data analysis and interpretation and critically revised the manuscript’s intellectual content.

Declaration of Conflicting Interests

None.

Ethical Approval

None.

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Original Research

Psychometric properties of the Japanese version of the evidence-based practice beliefs scale among clinical nurses

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Abstract

Objective: This study evaluated the psychometrics of the Japanese version of the evidence-based practice beliefs (EBP-B) scale. **Methods:** The study design was a cross-sectional survey. An online survey was conducted from October 2021 to February 2022. A questionnaire including the 16-item Japanese EBP-B scale was distributed to 2,977 nurses in three university hospitals across Japan. After 14 days, the same questionnaire was distributed to all participants to measure test-retest reliability. The factor structure of the Japanese EBP-B scale was evaluated using principal component analysis, known-group validity, and test-retest reliability. **Results:** Five hundred fifty-one nurses (response rate, 18.5%) completed the first survey, of whom 309 (56.1%) were included in the test-retest analysis. Principal component analysis revealed that the Japanese EBP-B scale tended to be moderately similar to the original version. Regarding known-group validity, the total score of the Japanese EBP-B scale was positively associated with academic background, job title, years of experience, certification of advanced practice nurses, and experience with learning and implementing EBP and conducting nursing research. The weighted kappa coefficients ranged from 0.27 to 0.51 for all scale items. **Conclusions:** Overall, the Japanese version of the EBP-B scale demonstrated psychometrics similar to those of the original version. Test-retest reliability varied among the items.

Keywords

cross-sectional studies, psychometrics, validation study, evidence-based practice, scale development

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Introduction

Positive beliefs regarding evidence-based practice (EBP) are essential for promoting EBP among nurses. Nurses with positive beliefs regarding EBP understand the need for EBP.

Some studies have reported that although several nurses held positive beliefs regarding EBP, their engagement in EBP activities and the knowledge and skills required for EBP were lacking (Clarke et al., 2001; Li et al., 2019; Li et al., 2019; Saunders & Vehviläinen-Julkunen, 2016; Saunders et al.,

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2019). Additionally, beliefs regarding EBP may be positively correlated with individual EBP competencies (Melnik et al., 2018), which may occasionally need to be improved (Melnik & Fineout-Overholt, 2018). However, sometimes, EBP may not be achieved through individual beliefs alone. For instance, organizational culture regarding EBP is also important for its promotion. Additionally, implementing effective approaches or discontinuing ineffective approaches can be complicated sometimes (Damschroder et al., 2022). Thus, belief, implementation, and organizational culture do not always have strong relationships with EBP (Melnik et al., 2018; Yoo et al., 2019). As such, an individual nurse's belief in EBP should be measured independently of other factors associated with EBP.

Previous studies have reported that clinical nurses in Japan exhibit positive attitudes toward EBP; however, evidence indicates a lack of frequency in EBP activities and insufficient knowledge and skills in research (Tomotaki et al., 2020). Moreover, the extent to which nurses recognize and accept EBP remains unknown because of the limited Japanese instruments available for measuring beliefs regarding EBP (Tomotaki et al., 2023). For example, the Japanese version of the Evidence-Based Practice questionnaire (EBPQ-J) (Tomotaki et al., 2018) is a well-known scale to assess practice, attitude, knowledge, and skills of research and practice for EBP; however, it does not adequately reflect beliefs in EBP. Therefore, reliable and valid instruments for measuring beliefs in EBP are warranted (Belita et al., 2020).

The Evidence-Based Practice beliefs (EBP-B) scale was developed in 2008 and is used to evaluate beliefs regarding EBP via self-reports (Melnik et al., 2008). The EBP-B evaluates the degree of nurses' beliefs regarding EBP and its implementation. This scale is available in original and short versions comprising 16 (Melnik et al., 2008) and 3 (Melnik et al., 2021) items, respectively. The EBP-B has already been translated from the original English version into various languages, including Chinese (Wang et al., 2012), Icelandic (Thorsteinsson, 2012), Slovak, Czech (Zeleníková et al., 2016), French (Verloo et al., 2017), German (Kerwien-Jacquier et al., 2020), and Vietnamese (Van Giang et al., 2021). Such translation of the instruments is essential to standardize measurements and enhance EBP research globally, given the numerous EBP-related challenges among nurses that need improvement. Evaluating nurses' perceptions regarding EBP is essential to assess their readiness for EBP and plan an implementation strategy for its dissemination. The Japanese version of EBP-B could help reveal the beliefs regarding EBP among Japanese nurses. This study aimed to evaluate the psychometrics of the Japanese version of EBP-B.

Materials and Methods

Study Design

This cross-sectional study included an online survey to investigate EBP among Japanese nurses. Three university hospitals in Japan were selected for this study via convenience sampling. This study was designed as a part of EBP research in Japan and was reported according to the Strengthening the Reporting of Observational Studies in Epidemiology Statement.

Participants

This study targeted nurses working at three university hospitals in Tokyo and Chiba, Japan. Nursing directors were excluded. The sample size requirement was >112 nurses for the psychometric validation of the Japanese version of the EBP-B scale comprising 16 items based on the criteria of seven times the number of items and ≥ 100 (Mokkink et al., 2019). Additionally, the sample size for the test-retest reliability analysis was estimated to be >100 participants based on the following assumptions: intraclass correlation coefficient (ICC) = 0.7; 95% confidence interval = 0.2. Notably, this study was part of a multipurpose study; therefore, this survey targeted nurses who met the eligibility criteria, with the sample comprising 3,100 nurses from three hospitals.

Measurements

Demographic Data

Participant characteristics included age, sex, academic background, current position, years of clinical experience, years in the current position, certification (e.g., certified nurses, certified nurse specialists, training for nurses on specified medical acts, and certified nurse administrators), experience in conducting nursing research, and experience in learning and practicing EBP. Additionally, we included the EBPQ-J (Tomotaki et al., 2018), which comprises 18 items with four subscales (practice, attitude, knowledge and skills related to research, and knowledge and skills related to practice). Each item is scored on a Likert scale ranging from 1 to 7, with higher scores indicating higher self-reported EBP.

EBP-B Scale

The EBP-B scale is a 16-item self-reported questionnaire scored on a 5-point Likert scale developed by Melnik et al. (2008) to evaluate a person's beliefs regarding the value of EBP and one's ability to implement it. The score for each item can range from 1 (strongly disagree) to 5 (strongly agree), with the total score ranging from 16 to 80. Although a short version of the EBP-B scale with three items is available (Melnik et al., 2021), this study evaluated the long version of the scale comprising 16 items because the EBP-B scale has not yet been translated into Japanese and the long version is required to assess the short version as a gold standard.

The original EBP-B scale was independently translated from English to Japanese by a professional English translator without nursing experience and one of the authors of this study. The five authors of this study reviewed the translated versions of the EBP-B scale and created a draft version. Face validity was assessed by 20 clinical nurses from three hospitals in October 2020. On the basis of the assessment, a description of EBP was added at the beginning of the questionnaire. The revised Japanese EBP-B scale was subsequently back-translated into English and confirmed by the original author.

Data Collection

This study collected data using the online survey tool SurveyMonkey[®]. A leaflet with a QR code and URL to access the survey was distributed to the participants in each hospital. The participants accessed the online survey on their own, answered the questionnaire, and entered their email addresses in the questionnaire (the first survey). After 2 weeks, they received the same questionnaire via email to evaluate the test-retest reliability. The questionnaires for the first and second surveys were linked by their email addresses. If the participants sent questionnaires more than once, responses with the fastest timestamp were adopted for the analysis.

Statistical Analysis

Categorical variables for participants' characteristics and the Japanese EBP-B scale are presented as frequencies and proportions. The Japanese EBP-B scale and EBPQ-J scores were calculated by summing the items' scores. Each subscale of the EBPQ-J was also calculated.

Regarding the psychometrics of the Japanese EBP-B scale, construct validity with a unidimensional construct was evaluated using principal component analysis (PCA) by factor loadings in each item, the same as the statistical method used in the original version (Melnik et al., 2008). Internal consistency was evaluated using Cronbach's alpha. For known-group validity, the differences in the total score of the Japanese EBP-B scale across the following variables were assessed: education level, job title, years of experience, certification of advanced practice, experience in learning and implementing EBP, and conducting nursing research via t-test or F-test (statistical significance level = .05). The effect size for each variable was calculated using Cohen's *d* and η^2 for variables with two and more than two categories, respectively. Additionally, correlation coefficients between the Japanese EBP-B scale and EBPQ-J according to the total scores and those for each subscale were determined to evaluate criterion-related validity.

For the Japanese EBP-B scale's test-retest reliability, the ICC of the total score and weighted kappa coefficients for each item were calculated to assess the degree of agreement between the first and second responses.

Because the online survey did not allow missing values, the imputation of missing values and exclusion of participants with missing values were unnecessary. All statistical analyses were performed using the IBM SPSS[®] software package versions 26 and 27.

Ethical Consideration

This study was approved by the ethics review committee and conducted in accordance with the Ethical Guidelines for Medical and Biological Research Involving Human Subjects and the Act on the Protection of Personal Information in Japan. Before answering the questionnaire, informed consent was obtained from the participants via a web form. As an incentive, each respondent received an online gift card containing 500 Yen (Japan) via email. This study was registered in the University Hospital Medical Information Network Clinical Trials Registry (registration number: UMIN 000045782).

Results

Among the 2,977 nurses included in this study, 551 completed the questionnaires (response rate, 19.0%). Among the participants, 12.2% were managers, 92.6% were women, 44% were <30 years old, 68.4% had graduated from college, 27.8% had learned EBP, and 30% had experience practicing EBP (Table 1).

Construct validity indicated that the first factor had an eigenvalue of 5.6 and accounted for 33.8%. The other factors had eigenvalues of 1.857, 1.249, and 1.03, with variances of 11%, 7.8%, and 6.4%, respectively. Similar to the original EBP-B scale, the Japanese EBP-B scale adopted a single-factor solution; the factor loadings for each item are shown in Table 2. The Cronbach's alpha of the Japanese EBP-B scale was 0.81.

Regarding known-group validity, the following participants showed significantly higher scores: those with higher education, certified nurses and nurse specialists, those with longer clinical experience, those having experience in learning EBP and EBP activities, and those having experience in conducting nursing research ($p < .05$; Table 3). The total score of the Japanese EBP-B was moderately correlated with the total score of the EBPQ-J ($r = 0.51$), and the correlation coefficients for the four subscales, namely, practice, attitude, knowledge and skills related to research, and practice, were 0.387, 0.294, 0.468, and 0.394, respectively. The test-retest reliability analysis revealed that the ICC was 0.756 (95% confidence interval: 0.703-0.800), and the weighted kappa coefficients ranged from 0.27 to 0.50 (Table 4).

Responses to each item revealed that ~90% of the participants agreed that evidence-based guidelines can improve clinical care and that EBP leads to the best clinical care for patients. More than 80% of the participants perceived that

Table 1. Participant characteristics ($N = 551$).

Characteristics		<i>n</i>	%
Job position	Staff nurses	484	87.8
	Nurse manager	67	12.2
Gender	Female	510	92.6
	Male	27	4.9
	Prefer not to answer	14	2.5
Age [year]	<25	121	22.0
	26–30	121	22.0
	31–40	135	24.5
	41–50	107	19.4
	≥51	67	12.2
Years of clinical experience	<1	56	10.2
	2–3	82	14.9
	4–10	161	29.2
	≥11	252	45.7
Years at the current position	<1	81	14.7
	2–3	134	24.3
	4–10	201	36.5
	≥11	135	24.5
Academic background	Vocational school or junior college	117	21.2
	University	377	68.4
	Graduate school	57	10.3
	Master's	54	9.8
	PhD	3	0.5
Certification*	Certified nurses [†]	23	4.2
	Certified nurse specialists [‡]	6	1.1
	Nurses who are attending or have completed a course for training for nurses on specified medical acts [§]	4	0.7
	Certified nurse administrator	49	8.9
Experience with EBP learning	No	194	35.2
	Yes	153	27.8
	Unknown	204	37.0
Experience with EBP activities	No	206	37.4
	Yes	138	25.0
	Unknown	207	37.6
Experience with conducting nursing research	No	152	27.6
	Yes	347	63.0
	Unknown	52	9.4

Note: EBP = evidence-based practice

*The question on certification provided multiple selections.

[†]Certified nurses had advanced practice licenses approved by the Japanese Nursing Association. The CN program has a 6-month course.

[‡]Certified nurse specialists (CNS) had advanced practice licenses approved by the Japanese Nursing Association. CNS courses are available in graduate schools.

[§]Training for nurses on specified medical acts is a program for providing specialized, advanced medical treatment by nurses. Nurses who completed this program were qualified.

the critical examination of rationale is essential in EBP and that its implementation can improve patient care. Conversely, only a few respondents (<10%) stated that they knew how to implement EBP to change current practices and were confident in their ability to implement EBP at their workplace (Table 4).

Discussion

The Japanese EBP-B scale showed eigenvalues and factor loadings similar to those of the original version analyzed using PCA (Melnyk et al., 2008). Although the internal consistency was good, the Cronbach's alpha value of the Japanese EBP-B scale was slightly lower than that of the original and other language versions (Kerwien-Jacquier et al.,

Table 2. Factor loading analyzed using principal component analysis ($N = 551$).

No.	Item	Factor loading
3	I believe that EBP can be implemented.	0.73
2	I clearly understand the steps involved in EBP.	0.72
14	I know how to implement EBP to change current practice.	0.72
10	I understand how to measure clinical care outcomes.	0.70
15	I am confident in my ability to implement EBP where I work.	0.68
7	I believe that I can overcome barriers to implementing EBP.	0.66
8	I believe that EBP can be implemented in an efficient way.	0.65
12	I think I can access the best resources to implement EBP.	0.62
6	I believe that I can search in an efficient way for the best evidence to answer clinical questions.	0.60
9	I believe that the implementation of EBP will lead to improvements in patient care that I provide.	0.51
1	I believe that EBP leads to the best clinical care for patients.	0.48
5	I believe that evidence-based guidelines can improve clinical care.	0.44
4	I think one important step in EBP is to critically examine the rationale.	0.43
16	I think the care that I provide is evidence-based.	0.43
13	I think EBP is difficult.	0.43
11	I think EBP is too time-consuming.	0.20

Note: EBP = evidence-based practice

2020; Melnyk et al., 2008; Thorsteinsson, 2012; Verloo et al., 2017; Wang et al., 2012). Known-group validity was good, with the characteristics of the participants known to have stronger beliefs in EBP tending to be the same as those reported in previous studies.

Among the translated versions, the German and Icelandic EBP-B scales evaluated the construct validity for nurses (excluding students) via PCA, which was also adopted by the original version to identify essential items for measuring the construct (Melnik et al., 2008). The scree plot of the Japanese EBP-B scale was approximately similar to that of the aforementioned translated versions (Kerwien-Jacquier et al., 2020; Thorsteinsson, 2012). However, the factor loadings were not shown under the unidimensional structure. Previous studies have reported that the psychometric properties of the EBP-B scale translated from English into other languages vary across languages. This appeared to have been due to the use of different statistical approaches to test the scale's content validity.

Regarding other psychometrics, findings regarding known-group validity were almost the same as those reported in previous studies, which showed that those with higher education (Thorsteinsson, 2012; Wang et al., 2012), experience with nursing research (Thorsteinsson, 2012), exposure to EBP (Melnik et al., 2008; Perruchoud et al., 2021), and job position (Perruchoud et al., 2021) scored significantly higher compared to those not in any of these categories. Additionally, a survey of nurses in Norway (Stokke et al., 2014) showed that specialist and registered nurses have lower beliefs in EBP than senior nurses, and nurses who learn EBP and participate in EBP activities have higher beliefs in EBP than nurses who do not learn EBP and participate in EBP

activities, by regression analysis adjusting for the participants' demographics. Namely, older and more clinically experienced people are more likely to be in manager positions and have had the opportunity to learn EBP through training in nursing management or graduate school. Clinical nurses with these demographics have the opportunity to reflect on their own practice in addition to learning about EBP and evidence, which may enhance their positive beliefs toward EBP.

Previous studies scarcely reported the test-retest reliability of the EBP-B scale. Hence, items such as "attitude" toward EBP exhibit lower test-retest agreement than items such as "practice" of EBP and "knowledge and skills" required for EBP (Tomotaki et al., 2018). Herein, test-retest reliability analysis also revealed variations among the items. Items that directly ask about individual nurses' perceptions of EBP, such as beliefs and attitudes, may be more likely to vary.

The trend in the responses to each item on the EBP-B scale was similar to that reported by previous studies where many nurses held positive beliefs regarding EBP and its implementation but perceived their ability and knowledge to be low. Estrada (2009) reported that the EBP-B scale had four subscales: knowledge beliefs, value beliefs, resource beliefs, and time and difficulty beliefs, which explains the differences in responses between the domains that comprise beliefs regarding EBPs.

In future research regarding the use of the EBP-B scale, quantitative studies of beliefs in EBP need further development of statistical analysis beyond simple descriptive statistics and relationships between beliefs and participant demographics using only two variables. Reports have shown that several studies regarding the knowledge and skills required

Table 3. Known-group validity.

Characteristics		The score of the Japanese EBP-B		<i>p</i> value*	Effect size [†]
		Mean	<i>SD</i>		
Job position	Staff nurse	51.2	7.1	<.001	0.783
	Nurse manager	56.5	6.4		
Age [year]	<25	50.1	5.5	<.005	0.051
	26–30	51.0	8.0		
	31–40	51.6	7.6		
	41–50	52.7	7.0		
	≥51	55.6	6.7		
Years of clinical experience	<1	49.4	5.2	<.001	0.045
	2–3	51.2	5.5		
	4–10	50.6	8.1		
	≥11	53.4	7.2		
Academic background	Vocational school or junior college	51.4	6.5	<.001	0.068
	University	51.1	7.2		
	Graduate school				
	Master's	57.3	6.9		
Certified nurse [‡]	PhD	59.3	5.9		
Certified nurse [‡]	No	51.7	7.2	.081	0.372
	Yes	54.4	8.0		
Certified nurse specialist [§]	No	51.7	7.2	.002	0.638
	Yes	56.3	6.9		
Experience with EBP learning	Yes	56.5	6.5	<.001	0.162
	No	50.2	6.6		
	Unknown	49.9	6.8		
Experience with EBP activities	Yes	56.7	7.3	<.001	0.150
	No	50.4	6.6		
	Unknown	50.1	6.3		
Experience with conducting nursing research	Yes	52.9	7.3	<.001	0.038
	No	50.4	6.6		
	Unknown	49.0	7.2		

Note: EBP-B scale = evidence-based practice belief scale; *SD* = standard deviation; EBP = evidence-based practice

**p* value was calculated for each variable via the t-test or F-test to determine the difference in Japanese EBP-B scores among categories.

[†]Cohen's *d* and η^2 were calculated for variables with two and more than two categories, respectively.

[‡]Certified nurses had advanced practice licenses approved by the Japanese Nursing Association. The program has a 6-month course.

[§]Certified nurse specialists had advanced practice licenses approved by the Japanese Nursing Association. Certified nurse specialist courses are available in graduate schools.

for EBP use descriptive statistics (Furuki et al., 2022), which may also apply to studies regarding EBP in general. Analyses using statistical models are also required for hypothesis testing through regression analysis, such as adjusting for confounding factors and estimating the effects of variables on each other (Estrada, 2009; Tomotaki et al., 2020). Additionally, statistical analysis that quantitatively considers hierarchies, such as hospitals and units, may be useful for evaluating the influence of organizational culture on individual beliefs in EBP.

Limitations

First, although this study included adequate sample numbers required for statistical evaluation of validity and reliability, the low response rate might not entirely reflect the beliefs in EBP at all three hospitals that participated in this study. Next, the participants were recruited only from the university hospitals located in the urban areas of Japan. These hospitals tend to have a higher proportion of nurses who graduated from universities than other hospitals. Such selection bias may affect the narrow variations in participant re-

Table 4. Item level distribution ($N = 551$) and weighted kappa ($N = 309$) of the evidence-based practice (EBP) beliefs scale.

No.	Item	Item level distribution (n = 551)										Test-retest reliability (n = 309)
		1 = Not at all		2 = I do not think so		3 = I cannot say either way		4 = I think so		5 = I think it is very much so		Weighted Kappa coefficient
		n	%	n	%	n	%	n	%	n	%	
1	I believe that EBP leads to the best clinical care for patients.	2	0.4	3	0.5	54	9.8	316	57.4	176	31.9	0.49
2	I clearly understand the steps involved in EBP.	57	10.3	181	32.8	183	33.2	116	21.1	14	2.5	0.50
3	I believe that EBP can be implemented.	21	3.8	66	12	262	47.5	192	34.8	10	1.8	0.35
4	I think one important step in EBP is to critically examine the rationale.	3	0.5	16	2.9	89	16.2	339	61.5	104	18.9	0.40
5	I believe that evidence-based guidelines can improve clinical care.	2	0.4	2	0.4	44	8	302	54.8	201	36.5	0.40
6	I believe that I can search in an efficient way for the best evidence to answer clinical questions.	14	2.5	117	21.2	212	38.5	186	33.8	22	4	0.32
7	I believe that I can overcome barriers to implementing EBP.	10	1.8	59	10.7	330	59.9	146	26.5	6	1.1	0.31
8	I believe that EBP can be implemented in an efficient way.	11	2	112	20.3	295	53.5	127	23	6	1.1	0.27
9	I believe that the implementation of EBP will lead to improvements in patient care that I provide.	1	0.2	5	0.9	76	13.8	383	69.5	86	15.6	0.36
10	I understand how to measure clinical care outcomes.	47	8.5	168	30.5	212	38.5	118	21.4	6	1.1	0.45
11	I think EBP is too time-consuming.	7	1.3	103	18.7	282	51.2	134	24.3	25	4.5	0.42
12	I think I can access the best resources to implement EBP.	17	3.1	113	20.5	259	47	154	27.9	8	1.5	0.34
13	I think EBP is difficult.	7	1.3	102	18.5	200	36.3	208	37.7	34	6.2	0.42
14	I know how to implement EBP to change current practice.	67	12.2	211	38.3	192	34.8	77	14	4	0.7	0.42
15	I am confident in my ability to implement EBP where I work.	58	10.5	166	30.1	227	41.2	97	17.6	3	0.5	0.42
16	I think the care that I provide is evidence-based.	1	0.2	13	2.4	197	35.8	329	59.7	11	2	0.41

Note: EBP = evidence-based practice

sponses. Second, nurses working at university hospitals in urban areas often have different age and academic background characteristics than those working in rural areas. Hence, further psychometric testing of sample representative of the overall population of nurses in Japan is required.

The construct validity of the EBP-B scale was analyzed using different statistical methods depending on the translated language. Some languages evaluated the validity of the EBP-B scale through exploratory and confirmatory factor analyses, whereas the original version used PCA. Thus, other translated versions had different numbers of items and domains than the original version. The French (in Swiss; Verloo et al., 2017) and Vietnamese (Van Giang et al., 2021) versions of the EBP-B scale excluded some items from the 16 items of the original version and comprised 4 (the French version in Swiss; Verloo et al., 2017) or 3 (the Vietnamese version; Van Giang et al., 2021) subscales. Additionally, the original version has recently been revised into a

three-item version (Melnyk et al., 2021). Further analysis is warranted for the dimensional contraction of the translated version.

Conclusions

This study found that the PCA findings of the Japanese EBP-B scale were similar to those of the original version. The internal consistency was good. The following participants exhibited higher scores: those with a higher academic background, nurse managers, those with extensive experience, certified advanced practice nurses, and those with experience in learning and implementing EBP and conducting nursing research compared to those not in any of these categories. The total score of the Japanese EBP-B scale was positively correlated with that of the EBPQ-J. The test-retest reliability analysis revealed variations among the items.

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Author Contributions

Ai Tomotaki was involved in the design; data acquisition, analysis, and interpretation; writing the initial draft; and manuscript review and editing. Masatoshi Saiki was involved in data acquisition, analysis, and interpretation and manuscript review and editing. Hiroki Fukahori and Takeshi Yamamoto were involved in data acquisition and interpretation and manuscript review and editing. Ikuko Sakai was involved in conceptualization, data acquisition and interpretation, and manuscript review and editing. Masakazu Nishigaki, Chiyo Matsuoka, and Emi Yasuda were involved in the design, data interpretation, and manuscript review and editing. All authors have approved the final version submitted for publication.

Declaration of Conflicting Interests

The authors declare that there are no conflicts of interest.

Ethical Approval

The Ethics Review Committee of the Graduate School of Nursing at Chiba University approved this study (approval number: NR3-25).

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Informed Consent

We obtained informed consent from all the participants involved in this study.

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Original Research

Changes in research activity and obstructive factors among nursing researchers during the first two years of the COVID-19 pandemic: A longitudinal study

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Abstract

Objective: We explored how the effects of obstructive factors changed according to the status of nursing researchers' activities during coronavirus disease 2019 (COVID-19). **Methods:** This study included two online questionnaires in 2020 and 2021 to explore the effect of COVID-19. Participants were 321 nursing researchers from the universities who answered both surveys. The participants were divided into four groups according to the change in research activity status. We compared the results between the four groups in the first survey and the changes between the two surveys in each group. **Results:** The 321 participants comprised 9.0%, 18.4%, 6.9%, and 65.7% in the "Well-maintained," "Improved," "Worsened," and "Difficulty-remained" groups, respectively. As a comparison of the scores of obstructive factors in the first survey between the four groups, the "Well-maintained" group's scores including "information and communication technology (ICT) proficiency needs and support for others" tended to be lower than that of the other groups. Furthermore, the "Improved" group's scores showed a statistically significant improvement in the second survey, particularly in ICT-related factors ($p < .001$). Although the scores for "family role burden and conflicts" tended to improve in the "Well-maintained" and "Improved" groups, the scores in the other two groups remained almost unchanged. **Conclusions:** The prolonged COVID-19 pandemic has had a negative effect on nursing researchers. The results revealed that ICT proficiency, effective use, and managing to balance family roles and work might be key factors in promoting family activities during difficult periods.

Keywords

nursing research, COVID-19, obstructive factor, longitudinal study

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Introduction

The coronavirus disease 2019 (COVID-19) pandemic has posed tremendous challenges to healthcare-related research, both internationally and locally. It revealed major concerns about infection control and gaps in public health policies and processes. Nurses faced challenges related to infection control in various care settings, human care for infected patients and vulnerable populations, and psychosocial support for healthcare professionals (Chen, 2020; Zhang et al., 2020). Measures to address these challenges were based on nursing research, including telehealth services, safe and effective staffing, and support for ethical stress and other dilemmas experienced by healthcare professionals (Lake, 2020). Better nursing practice and nursing research activities are closely associated with each other (Chien, 2019; World Health Organization, 2020); therefore, stagnation in nursing researchers' activities meant that they could not sufficiently be engaged in shaping research agendas and responding to the needs of people, communities, and society during the uncertainty of the COVID-19 pandemic.

Various studies have reported factors that obstruct research activities among nursing researchers, especially in the early stages of the pandemic. Declines in research time were associated with increased time spent in nursing student education due to the shifting from traditional face-to-face education to a new form that includes infection control measures, information and communication technology (ICT), and organizational management roles (Im et al., 2021; Yoshinaga et al., 2021). Limited research fields and settings and difficulties in gaining access to them due to safety and quarantine measures, delays, and modifications in research processes, including limited communication with researchers, and further family role burden of child and elderly care have negatively affected nursing researchers (Im et al., 2021; ResearchGate, 2020; 2021). Nursing researchers in nursing educational institutions also had to deal with increased non-research efforts, such as the demands of clinical activities to maintain the healthcare service delivery system and the alteration of teaching styles due to restrictions in face-to-face teaching facilities (Inoue et al., 2022; Tomietto et al., 2020). In particular, Japanese nursing faculty members have devoted great effort to clinical nursing practice; hence, the effect of the pandemic on changes in clinical practice methods was significant (Im et al., 2021).

Even under difficult situations, not to stagnate nursing research activities leading to better practice, nursing researchers might have tried to change their research designs, processes such as data collection and intervention methods, and communication and collaboration methodologies to conduct research quickly and safely (Cordato et al., 2023; Gralton et al., 2020; Im et al., 2021; Pickler et al., 2020); however, some researchers have still encountered difficulties in con-

ducting their research amidst the prolonged pandemic situation. According to a survey conducted by an academic organization, approximately 2 years after the declaration of the COVID-19 pandemic, the percentage of nursing researchers who felt their activities were obstructed was lower than that in the early stages of the pandemic (Japan Academy of Nursing Science, COVID-19 Nursing Research Countermeasures Committee Member Surveying Team, 2022). Although the circumstances surrounding the activities of nursing researchers should have changed during the COVID-19 pandemic, some nursing researchers have experienced continuous stagnation in research activities (Japan Academy of Nursing Science, COVID-19 Nursing Research Countermeasures Committee Member Surveying Team, 2022). One reason for the different activity status of nursing researchers could be changes in factors that obstruct research activities, but this has not been examined.

Furthermore, previous studies reported that faculty members of health care perceived a decrease in productivity and were concerned about the effect of COVID-19 on their career development (Delaney et al., 2021; Lantsoght et al., 2021), which might have increased COVID-19-related psychological distress among nursing researchers. The unpredictable and negative status of researchers' activities during the pandemic increased their stress and distress during the initial disruption of the pandemic (Jackman et al., 2022; Naumann et al., 2022). The prolonged stagnation of nursing researchers' activities might have caused a mental health crisis. It is important to understand the associations between research activities, characteristics, and mental health.

With the prolonged COVID-19 pandemic, understanding the factors that influenced the research activities of nursing researchers and their mental health during the pandemic will provide a basis for considering their initiatives and support from academic organizations and society; in turn, this can minimize the negative factors that influence their research activities in the face of unexpected events in the future. Therefore, this study aimed to reveal the changes in the factors obstructing these activities of nursing researchers according to the status of research activities for approximately 2 years during the COVID-19 pandemic. Additionally, it explored psychological distress according to the status of research activities. The findings of this study should lead to a deeper understanding of the experiences of nursing researchers during COVID-19.

Materials and Methods

Study Design

This study was conducted as part of a research initiative organized by the Japan Academy of Nursing Science COVID-19 Nursing Research Countermeasures Committee to investigate the effect of COVID-19 on nursing research activities

in Japan. The longitudinal study included two online surveys using self-administered questionnaires (first survey, July–August 2020; second survey, March 2022).

Participants, Recruitment, and Data Collection

The eligibility criteria for participants were that they were members of the Japan Academy of Nursing Science who had registered their email addresses with the academy, agreed to participate in both surveys, belonged to the universities, answered both surveys, and responded to the questionnaire in sufficient detail to explain how their research activities were negatively affected by the COVID-19 pandemic. The Japan Academy of Nursing Science announced the online survey on its website and sent an email invitation with the survey link to members who had registered their email addresses with the academy. The link was accessible to 9,447 and 9,661 members in the first and second surveys, respectively. We linked the respondents of the first survey to those of the second survey using their unique study IDs.

Measures

The COVID-19 Nursing Research Countermeasures Committee Member Surveying Team of the Japan Academy of Nursing Science created the questionnaire based on previous studies and the opinions of nursing research experts. Before implementing the first survey, the JANS board members, who are experts in nursing research, confirmed the survey items. On the basis of their opinions, the face validity, clarity, and interpretability of the survey items were improved (Streiner et al., 2015). Through this process, the first survey questions were finalized and used in the second survey. The participants were asked about their individual and professional attributes in the first survey; their research activities in the previous 3 months; factors obstructing their research activities in the first and second surveys; and psychological distress in the second survey. The full questionnaire can be found on the Japan Academy of Nursing Science's (2021, 2022) website.

Individual and Professional Attributes

The following individual and professional attributes of the participants were collected in the first survey: gender, type of institution in which the participant worked (educational or research institution, or both [e.g., university]), position in organizational hierarchy (professor or associate professor, others), presence of cohabitants, involvement in childcare, and caregiving for older adults and other family members.

Status of Research Activities

The status of the participants' research activities was measured using one item on a 5-point Likert scale. Participants were asked, "How much were your research activities affected by the COVID-19 pandemic? Please select the option that best describes your situation in the past 3 months." Scores ranged from 1 to 5 ("5 = Much more," "4 = More,"

"3 = Neither/About the same," "2 = Less," and "1 = Much less"), with higher total scores indicating a greater negative effect on research activity.

For the purposes of analysis, responses regarding the effect of the COVID-19 pandemic on the status of participants' research activities were categorized into "high impact = More or Much more" and "low impact = Neither/About the same, Less, or Much less." Participants were then divided into four groups according to the changes in their research activity status between the first and second surveys: a group whose research activity remained in good condition (Well-maintained), a group whose research activity status improved (Improved), a group whose research activity status worsened (Worsened), and a group whose research activity status remained negatively affected (Difficulty-remained) (Table 1).

Obstructive Factors in Conducting Research Activities

Factors obstructing the conducting of research activities were categorized into the following seven domains: (1) difficulties in in-person contact and transport, (2) difficulties in communication with researchers and research management, (3) increased time spent on student education, (4) increased time spent on organizational management activities, (5) ICT proficiency needs and support for others, (6) family role burden and conflicts, and (7) changes in social conditions and conflicts related to the COVID-19 pandemic. These seven domains comprised 33 factors that may have affected the research activities of nursing researchers (e.g., "difficulty in in-person contact with study participants"; "difficulty in accessing the equipment, literature, materials, data, computers, and software necessary for research"; "increase in time for research supervision"; and "increased time spent on the health management of students and staff") (Table 2). Each item was rated on a 5-point scale, with the following five response options: "1 = Did not affect (my research activities) at all," "2 = Did not affect (my research activities) much," "3 = Neither," "4 = Affected (my research activities) somewhat," and "5 = Affected (my research activities) significantly." Higher scores indicate a greater effect.

Some obstructive factors are important for continuing research activities; however, they are not applicable depending on the attributes of the participants and the characteristics of their research activity, such as "Increased time spent on childcare owing to COVID-19-related closures of daycares, kindergartens, schools, or restricted attendance of school" and "Difficulty in securing means of transport for overseas travel and business trips." Nonresponse was noted for items that did not apply to participants. Therefore, to allow comparisons between participants even if the sum of scores within a factor differed, missing values were excluded, and the standardized scores of the seven obstructive factors were calculated using the following formula.

Standardized scores for each of the seven categories =

Table 1. Group classification according to changes in research activity during the COVID-19 pandemic.

		Second survey [†]				
		Much less	Less	Neither/About the same	More	Much more
First survey [†]	Much less	Group whose research activity remained in a good condition (Well-maintained group)			Group whose research activity worsened (Worsened group)	
	Less					
	Neither/About the same					
	More	Group whose research activity improved (Improved group)			Group whose research activity remained negatively affected (Difficulty-remained group)	
	Much more					

Note: COVID-19 = coronavirus disease 2019

[†]Participants were asked about the degree to which their research activities were negatively affected in the last 3 months in both surveys.

sum of scores answered by the participant on the response items in each category/number of response items answered by the participant in that category.

For example, “Difficulties in in-person contact and transport” include four items. If a respondent answered only three items, their standardized score was calculated by summarizing the scores of three items/3. This resulted in standardized scores of 1-5.

Psychological Distress (Second Survey Only)

The Japanese version of the six-item Kessler Scale (K6) was used as the psychological distress scale (Furukawa et al., 2008) in the second survey. The K6 was developed by Kessler et al. (2003) to screen for depression, anxiety, and other psychiatric disorders. The questionnaire consists of six items, including the frequency of feeling “nervous” and “hopeless” during the past 30 days.

Responses were provided using a 5-point Likert scale. Scores ranged from 0 to 24, with higher total scores indicating greater psychological distress. The K6 has a sensitivity of 0.36 and a specificity of 0.96 in predicting serious mental illness (Kessler et al., 2003). The cutoff score for assessing psychological stress in the general population is ≥ 5 (Sakurai et al., 2011).

Data Analysis

First, the characteristics of the four groups, divided according to the status of their research activities, were compared using the χ^2 and Kruskal-Wallis tests. Second, differences in the four groups’ standardized scores for obstructive factors in the first survey were also examined using the Kruskal-Wallis test. Thereafter, changes in the standardized scores of obstructive factors in each group were analyzed using the Wilcoxon signed-rank test.

Missing values were not randomly generated, and no missing value completion was performed; for example, those without a childcare or caregiving role often did not respond to the factors related to childcare or caregiving. Participants who did not respond to any of the variables used in the data analysis, except for obstructive factors, were excluded from

the analysis. SPSS software Ver. 27.0 was used for the analysis, and the significance level was set at 5%.

Ethical Considerations

The participants received an email invitation to participate in the study via their email addresses that they had registered with the Japan Academy of Nursing Science, and an overview of the study was shared on the academy’s website. The invitation email and website explained the study’s purpose, content, and privacy protection and that the study was open-ended. The participants first filled out the research participation consent form and then completed the survey. The Japan Academy of Nursing Science collected the data, excluded personally identifiable information, and provided anonymous data to the authors. This study was approved by the University of Miyazaki Ethics Committee (Approval number: O-0733).

Results

An email invitation was sent to 9,447 and 9,661 members of the Japan Academy of Nursing Science in the first and second surveys, respectively. In the first and second surveys, 1,532 of 9,447 members (response rate: 16.2%) and 899 members of 9,661 members (response rate: 9.3%) responded. It was possible to link the responses to the first and second surveys from the 409 participants according to their research IDs. Of the 409 participants, 321 who met the eligibility criteria were included in this study.

Characteristics of the Participants

Table 3 shows the results of the comparison between the individual and professional attributes of the 321 participants in the four groups, classified according to the status of their research activities. The “Well-maintained,” “Improved,” “Worsened,” and “Difficulty-remaining” groups included 29 (9.0%), 59 (18.4%), 22 (6.9%), and 211 (65.7%) participants, respectively. Overall, the almost 2-year pandemic has negatively affected many participants’ research activities.

Table 2. Factors influencing nursing research activities during the COVID-19 pandemic.

The 33 items of the following questions used in this study were classified into seven factors for data analysis.

Description of the questions:

The following items are related to factors that may have affected your research activities during the COVID-19 pandemic. To what extent did these factors affect your research activities? Please select the option that best describes your situation based on the past 3 months (first survey, April to June 2020; second survey, December 2021 to February 2022).

Factors that affected research activities	Items
Difficulties in in-person contact and transport	Difficulty in in-person contact with study participants Difficulty in entering research facilities or institutions Difficulty in securing means of transport for domestic travel and business trips Difficulty in securing means of transport for overseas travel and business trips
Difficulties in communication with researchers and research management	Difficulty in accessing equipment, literature, materials, data, computers, and software necessary for research Difficulty in using research technical assistants Research efficiency lowered by working from home Difficulty in holding meetings with co-researchers inside and outside their affiliated organization Decreased function of departments, organizations, and institutions related to research (administration, ethics review boards, organizations participating in the research project, and partners in outsourcing for surveys and research) Difficulty securing the necessary budget due to changes to the research plan Difficulty of peer support and communication related to research Slowdown in joint research with co-researchers Slowdown in joint research with graduate students
Increased time spent on student education	Increase in time for research supervision Increased time spent for lectures (including preparation and assessment) Increased time spent for seminars (including preparation and assessment) Increased time spent for practicum (including preparation and assessment) Increased time spent for clinical practice
Increased time spent on organizational management activities	Increased time spent on the health management of students and staff (e.g., checking health status) Increased time spent on supporting students and staff showing fear of infection Increased time spent on counseling other students and staff (for employment, mental health, and economic support) Increased time spent on management and administration (meetings, committee activities, open campus, and career workshops)
ICT proficiency needs and support for others	Increased time spent on learning about ICT Increased time spent on ICT-related support for managers, colleagues, subordinates, and the organization (e.g., installation and support for using online meeting systems)
Family role burden and conflicts	Increased time spent on housework related to COVID-19 Increased time spent on infection prevention and health management related to the effects of COVID-19 in the family Internal and interpersonal conflicts in the family related to COVID-19 Increased time spent on childcare due to COVID-19-related closures of daycares, kindergartens, schools, or restricted attendance of school Increased time spent on care of parents or other older adults related to COVID-19 (closures of day services and short stays) Guilt and conflicts in not being able to perform COVID-19 measures adequately in the housework, childcare, or care for older adults and parents (e.g., measures to prevent infection in the home)
Changes in social conditions and conflicts related to the COVID-19 pandemic	Delays in the review and publication processes of submitted manuscripts (Japanese and English) Guilt and conflicts in not being able to contribute to COVID-19 measures professionally Increased time spent on social contributions related to COVID-19 (e.g., academic society committee activities and public lectures)

Note: COVID-19 = coronavirus disease 2019; ICT = information and communication technology; JANS = Japan Academy of Nursing Sciences
Cronbach's α coefficient = .747

A comparison of the four groups' attributes showed no statistically significant differences for any of the items, except for position in the workplace ($p = .043$). In all four groups, women accounted for >80% of the participants. The

most common age group was 46-55 years. In terms of position in the workplace, there were statistically significantly more professors or associate professors in the "Improved" and "Difficulty-remaining" groups ($p = .043$). More than

Table 3. Characteristics of the participants in the first survey ($n = 321$).

Attributes	Well-maintained group ($n = 29$)			Improved group ($n = 59$)			Worsened group ($n = 22$)			Difficulty-remained group ($n = 211$)			p -value
	n	n	(%)	n	n	(%)	n	n	(%)	n	n	(%)	
Gender: n (%)	27			59			22			208			.877 ^a
Women		22	(81.5)		52	(88.1)		19	(86.4)		179	(86.1)	
Men		5	(18.5)		7	(11.9)		3	(13.6)		29	(13.9)	
Age (years): n (%)	29			59			22			211			.107 ^b
25–35		4	(13.8)		3	(5.1)		1	(4.5)		22	(10.4)	
36–45		10	(34.5)		14	(23.7)		7	(31.8)		57	(27.0)	
46–55		11	(37.9)		20	(33.9)		8	(36.4)		71	(33.6)	
56–65		4	(13.8)		20	(33.9)		6	(27.3)		57	(27.0)	
>66		0	(0.0)		2	(3.4)		0	(0.0)		4	(1.9)	
Position in the workplace: n (%)	29			58			21			210			.043 ^a
Professor/Associate Professor		10	(34.5)		35	(60.3)		8	(38.1)		119	(56.7)	
Others		19	(65.5)		23	(39.7)		13	(61.9)		91	(43.3)	
Presence of cohabitant(s): n (%)	27			58			20			204			.938 ^a
Yes		16	(59.3)		32	(55.2)		10	(50.0)		114	(55.9)	
No		11	(40.7)		26	(44.8)		10	(50.0)		90	(44.1)	
Being involved in childcare: n (%)	28			58			20			204			.227 ^a
Yes		7	(25.0)		27	(44.8)		8	(40.0)		67	(32.8)	
No		21	(75.0)		32	(55.2)		12	(60.0)		137	(67.2)	
Caregiving for older adults/ other family members: n (%)	27			58			22			203			.062 ^a
Yes		2	(7.4)		5	(8.6)		0	(0.0)		35	(17.2)	
No		25	(92.6)		53	(91.4)		19	(86.4)		168	(82.8)	

Note: ^a χ^2 test; ^bKruskal–Wallis test

Analyzed after excluding those who did not respond and those who answered, “do not wish to answer.”

50% of all four groups had a cohabitant. The “Improved” group tended to have a higher proportion of participants who raised children, whereas the “Difficulty-remained” group tended to have a higher proportion of participants who cared for older adults and family members.

Table 4 presents a comparison between the scores of the seven obstructive factors in the first survey among the four groups. There were significant differences in “difficulties in in-person contact and transport,” “difficulties in communication with researchers and research management,” “increased time spent on student education,” “increased time spent on organizational management activities,” and “ICT proficiency needs and support for others” ($p < .05$). The “Well-maintained” group tended to score lower than the other groups on the following obstructive factors: “difficulties in in-person contact and transport,” “increased time spent on student education,” and “ICT proficiency needs and support for others.”

Effect of Obstructive Factors on Changes in Research Activity during the COVID-19 Pandemic

After approximately 2 years, there were significant differences in the scores of the obstructive factors between the

four groups, and the “Difficulty-remained” group scored the highest on all factors (Table 5).

Figure 1 shows the changes in the scores of obstructive factors in the four groups classified according to the status of their research activities over approximately 2 years during the pandemic. None of the factors were significantly worse in any of the four groups.

Although scores for “difficulties in in-person contact and transport” decreased (i.e., improved) significantly in the “Improved” and “Difficulty-remained” groups ($p < .01$), the latter group continued to be highly affected in the second survey. For “difficulties in communication with researchers and research management,” the scores of the “Well-maintained,” “Improved,” and “Difficulty-remained” groups decreased significantly ($p < .01$). Regarding “increased time spent on student education,” the “Improved” and “Difficulty-remained” groups, which tended to score higher in the first survey, showed a significant decrease ($p < .01$). For “ICT proficiency needs and support for others,” the “Improved,” “Worsened,” and “Difficulty-remained” groups showed a significant decrease ($p < .05$); however, there was no statistically significant change between the first and second surveys in the “Well-maintained” group ($p = .224$). The “Improved”

Table 4. Comparison of obstructive factor scores among the four groups in the first survey.

Factors	Well-maintained group (n = 29)		Improved group (n = 59)		Worsened group (n = 22)		Difficulty-remained group (n = 211)		p-value [†]
	n	Median (IQR)	n	Median (IQR)	n	Median (IQR)	n	Median (IQR)	
Difficulties in in-person contact and transport	22	3.9 (2.9–4.5)	59	4.5 (4.0–5.0)	19	4.0 (3.0–4.7)	209	4.7 (4.3–5.0)	<.001
Difficulties in communication with researchers and research management	28	3.1 (2.0–3.5)	59	3.4 (3.0–3.8)	21	2.6 (2.1–3.4)	211	3.6 (3.2–4.0)	<.001
Increased time spent on student education	29	3.8 (3.0–4.4)	58	4.3 (3.6–4.7)	21	4.0 (2.8–4.1)	211	4.4 (3.8–4.8)	<.001
Increased time spent on organizational management activities	29	3.5 (3.0–4.3)	58	3.5 (3.0–4.0)	21	3.5 (3.3–4.0)	208	3.8 (3.3–4.3)	.022
ICT proficiency needs and support for others	29	3.0 (3.0–3.8)	59	4.0 (3.0–4.5)	21	3.5 (3.0–4.0)	210	4.0 (3.5–4.5)	<.001
Family role burden and conflicts	28	3.0 (1.8–3.3)	57	3.0 (2.3–3.6)	21	2.6 (1.2–3.1)	206	3.0 (2.0–3.6)	.272
Changes in social conditions and conflicts related to the COVID-19 pandemic	27	3.0 (2.7–3.7)	54	3.0 (2.5–3.5)	21	3.0 (2.0–3.5)	197	3.0 (2.7–3.7)	.098

Note: IQR = interquartile range; ICT = information and communication technology; COVID-19 = coronavirus disease 2019

[†] Comparison of four groups using the Kruskal–Wallis test

Table 5. Comparison of standard scores for obstructive factors among the four groups in the second survey.

Factors	Well-maintained group (n = 29)		Improved group (n = 59)		Worsened group (n = 22)		Difficulty-remained group (n = 211)		p-value [†]
	n	Median (IQR)	n	Median (IQR)	n	Median (IQR)	n	Median (IQR)	
Difficulties in in-person contact and transport	25	3.5 (2.0–4.0)	56	4.0 (3.3–4.5)	22	3.8 (3.0–4.7)	209	4.5 (4.0–5.0)	<.001
Difficulties in communication with researchers and research management	29	2.3 (1.8–2.8)	59	2.8 (2.2–3.1)	21	2.6 (2.0–3.3)	208	3.0 (2.6–3.6)	<.001
Increased time spent on student education	28	3.7 (2.1–4.5)	57	3.6 (3.0–4.0)	22	3.7 (2.8–4.5)	211	4.0 (3.5–4.7)	<.001
Increased time spent on organizational management activities	28	3.4 (2.0–4.0)	58	3.3 (3.0–4.0)	21	3.5 (3.0–4.2)	209	3.8 (3.0–4.3)	.014
ICT proficiency needs and support for others	28	2.8 (2.0–4.0)	58	3.0 (2.0–3.0)	21	3.0 (2.0–4.0)	210	3.5 (2.5–4.0)	.092
Family role burden and conflicts	27	2.0 (1.2–3.0)	56	2.4 (1.7–3.0)	20	2.7 (1.2–3.0)	203	2.7 (1.8–3.4)	.374
Changes in social conditions and conflicts related to the COVID-19 pandemic	28	2.5 (2.0–3.7)	57	3.0 (2.0–3.0)	20	3.0 (2.7–3.0)	206	3.0 (2.3–3.5)	.423

Note: IQR = interquartile range; ICT = information and communication technology; COVID-19 = coronavirus disease 2019

[†] Comparison of four groups using the Kruskal–Wallis test

and “Worsened” groups, which had the highest scores in the first survey, showed more improvement in the former in the second survey. For “family role burden and conflicts,” the scores of the “Improved” and the “Difficulty-remained” groups decreased ($p < .01$). However, even for this factor, the score of the “Difficulty-remained” group was almost unchanged and greater than that of the other groups in the second survey.

Regarding the other two factors, “increased time spent on organizational management activities” and “changes in social conditions and conflicts related to the COVID-19 pan-

dem,” the medians of the scores did not change, although statistically significant differences were observed.

Psychological Distress in the Participants Approximately Two Years after the Initial Wave of COVID-19

Table 6 presents the results of the comparison between the four groups’ K6 scores almost 2 years after the initial spread of COVID-19 infection in Japan. The K6 scores between the four groups and the proportion of those with K6 scores of ≥ 5 within the group were not statistically significant. However, the percentage of participants who scored ≥ 5

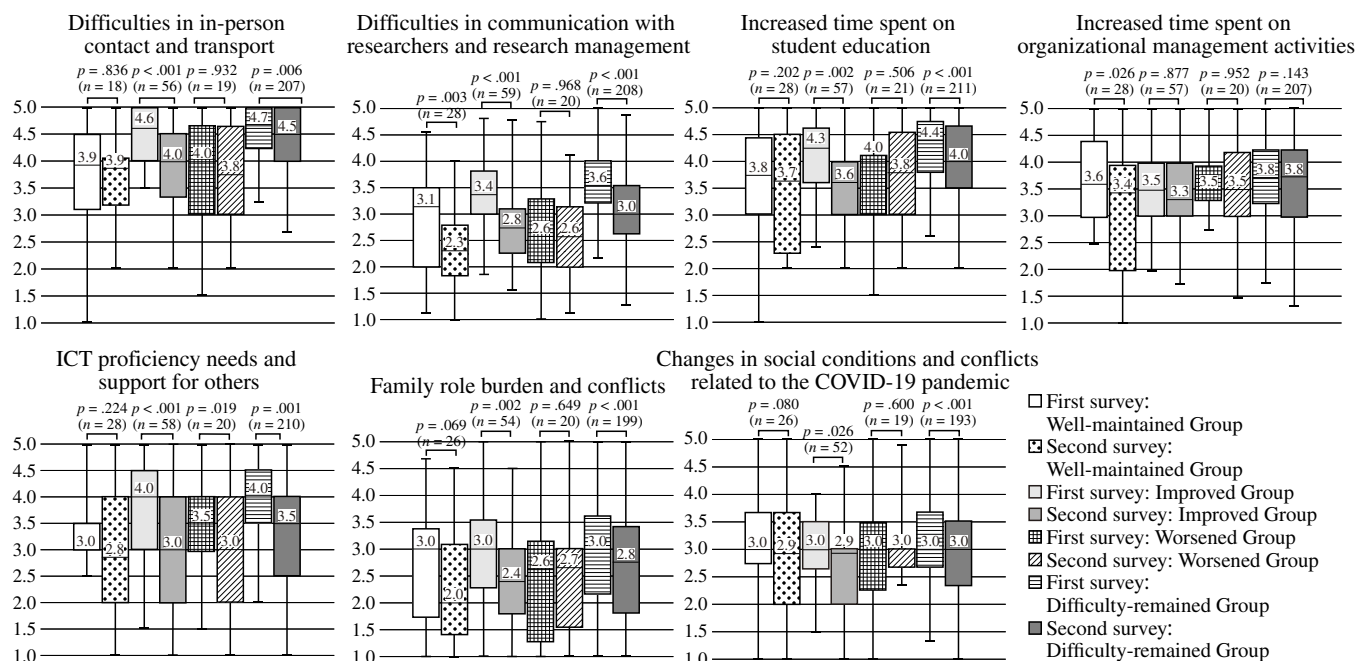


Figure 1. Changes in the scores of obstructive factors in the four groups classified according to the status of research activities.

Note: ICT = information and communication technology; COVID-19 = coronavirus disease 2019

The median values are shown.

Wilcoxon signed-rank test.

Table 6. Comparison of participants' psychological stress levels among the four groups in the second survey.

Attributes	Well-maintained group (n = 29)	Improved group (n = 54)	Worsened group (n = 20)	Difficulty-remained group (n = 192)	p-value [†]
K6 scores: Median (IQR)	3.0 (1.0–8.5)	4.0 (1.0–9.0)	4.0 (2.0–10.8)	5.0 (2.0–11.0)	.599 ^a
Proportion of those with K6 scores of ≥5 within the group: n (%)	13 (44.8)	25 (46.3)	9 (45.0)	111 (57.8)	.259 ^b

Note: K6 = 6-item Kessler Scale; IQR = interquartile range

^aKruskal–Wallis test; ^b χ^2 test

points on the K6 was 57.8% and tended to be higher in the “Difficulty-remained” group than in the other groups.

Discussion

To the best of our knowledge, this is the first report on how obstructive factors of research activities among nursing researchers in educational and research institutions have changed during the approximately 2-year-long COVID-19 pandemic.

This study revealed that most nursing researchers faced difficulties in their research activities during both surveys conducted in 2020 and 2022. A four-group comparison of the effect of obstructive factors on research activities in the early stages of the COVID-19 pandemic was conducted. It was found that in the “Well-maintained” group, the scores

for some obstructive factors in the first survey tended to be lower than those in the other groups. Furthermore, regarding changes in the scores of obstructive factors in the four groups during the 2-year period, no factors were significantly worse, indicating that nursing researchers experienced difficult and long-term challenges during the pandemic.

In this study, only 25.3% of the participants maintained or improved their active research status after the COVID-19 pandemic, which lasted approximately 2 years. The background of these participants' research activities may have implications for priority support for nursing researchers during a prolonged pandemic.

First, the “Well-maintained” group tended to be less affected than the other groups during the first survey in terms of “difficulties in in-person contact and transport,” “increased time spent on student education,” and “ICT profi-

ciency needs and support for others.” The scores of these obstructive factors did not worsen after almost 2 years for the “Well-maintained” group. The “Improved” group also showed a significant improvement in the obstructive factors, except for “increased time spent on organizational management activities.” In particular, this group scored the highest in “ICT proficiency needs and support for others” among the four groups, but it significantly improved later. This group also showed a statistically significant improvement in six obstructive factors, except for organizational management. These results indicate that ICT proficiency and effective use were key factors in streamlining research activities during the COVID-19 pandemic. In nursing research, which often targets vulnerable populations at high risk of contracting COVID-19, many researchers had to transform their research and intervention modalities, combining face-to-face and remote forms as needed (Im et al., 2021; Kazawa et al., 2022a). Therefore, researchers’ ability to become familiar with ICT and use it effectively may have led to a smooth transformation in research modalities. Furthermore, the use of ICT may have contributed to opportunities for researchers to discuss and gain research ideas and new insights by enabling online meetings among researchers, networking and collaboration with new colleagues, and participation in virtual scientific meetings and training (ResearchGate, 2021). Additionally, communication among nursing researchers using ICT could reduce loneliness due to physical distancing (Hossain et al., 2020) and motivate them to conduct their research activities. ICT may also contribute to smooth and sufficient communication among families. It is believed that the improvement of various factors affecting research activities through the use of ICT contributed to a virtuous circle, such as securing time and maintaining motivation for research activities (Lee et al., 2023; Takeuchi et al., 2022). Our findings indicate that ICT proficiency and its effective use can make nursing researchers’ activities more motivated and robust even in the setting of a future pandemic.

This study’s participants were nursing faculty members. During periods of severe COVID-19 infection spread in Japan, citizens were requested to maintain physical distancing, primarily by refraining from going out, except for essential workers, such as healthcare professionals, police, and food providers. Similarly, some nursing educational institutions were temporarily locked down, which called for a switch to a flexible teaching method that combines face-to-face and online teaching, depending on the level of infection spread in February 2020 (Ministry of Education, Culture, Sports, Science and Technology & Ministry of Health, Labour and Welfare, 2020). Many nursing educational institutions have therefore tried innovative initiatives using digital technologies that do not interfere with the students’ learning (An et al., 2022; Kazawa et al., 2022b; Kor et al., 2022; Shorey et al., 2022b); the fact that ICT facilitates such initiatives may

also have helped mitigate the effect on their research activities.

Second, although the scores for “difficulties in communication with researchers and research management” improved significantly in the “Well-maintained,” “Improved,” and “Difficulty-remained” groups ($p < .01$), the latter group continued to be highly affected in the second survey. Because positive and efficient relationships with colleagues contribute to work engagement and productivity (Chiaburu et al., 2008), various communication efforts, including internal and virtual research meetings and scientific networking, might benefit research activities. It has been reported that the pandemic resulted in some researchers adopting a more individualistic working style (Finn et al., 2022; Sarah et al., 2021). Depending on the research field, it might be useful to set up a working environment (e.g., preparing the equipment, literature, materials, data, computers, and software necessary for research) that allows for flexible research activities at home and in the office in the future.

Third, although scores for “family role burden and conflicts” improved in the “Well-maintained” and “Improved” groups, scores in the “Worsened” and “Difficulty-remained” groups remained almost unchanged. The “Improved” group tended to have a higher proportion of participants who raised children, whereas the “Difficulty-remained” group tended to have a higher proportion of participants who cared for older adults and family members. This difference between groups may have had an effect on the results. Globally, school closures and the loss of other forms of childcare have affected how nursing researchers care for children (Im et al., 2021; Lantsoght et al., 2021). However, at the time of this study’s first survey (after the first wave of the pandemic in Japan), schools were closed only temporarily to prevent the spread of the infection. Government and workplace support for people raising children and participants’ own efforts to be flexible and maintain a good work-life balance might have helped mitigate the negative effects of the absence of childcare.

Conversely, many family caregivers of adults with chronic or disabling conditions and older adults have reported experiencing physical and psychosocial care burden during the COVID-19 pandemic (Irani et al., 2021; Zhang et al., 2022). Prolonged public health measures related to COVID-19, including physical distancing, have had unfavorable effects on vulnerable adults, such as reduced social participation and physical activity (Falvo et al., 2021; Gilsbach et al., 2021; Joseph, 2022). A lack of physical and cognitive stimulation may lead to their functional decline (Tosato et al., 2022) and, consequently, increase the burden on family caregivers. Participants’ concerns regarding the risk of infection or changes in the condition of the person they were caring for, as well as the burden of caring for others, might have influenced the results of this study. Establishing instrumental,

emotional, and financial support systems and peer support for researchers caring for older adults and family members, as well as their use of such support, would help them address conflicts between family responsibilities and work.

Furthermore, the degree of influence of “Increased time spent on organizational management activities” did not improve over the 2-year period, except in the “Well-maintained” group. In the other three groups, a higher proportion of participants engaged in organizational management. Managers in clinical and educational settings must make decisions regarding infection control and organizational management in response to repeated infection outbreaks (Sihvola et al., 2022). Nursing educational institutions were also required to respond to nursing students’ concerns about the new learning environment, the acquisition of nursing practice skills, and working and pursuing a career as a nurse (Kobayashi et al., 2022; Rood et al., 2022), along with supporting the mental health of facility members. The burden of following up with both organizational members and nursing students may have significantly affected their research activities. For nursing researchers responsible for organizational management, consulting with external infection control and mental health professionals can assist in organizational management decision-making.

In both surveys, participants responded to free-response items about their new responsibilities during the pandemic and their current or future research. A summary of the free responses is available on the Japan Academy of Nursing Science’s (2022) website. Some participants collaborated with healthcare professionals in clinical settings during the COVID-19 pandemic; for example, one participant surveyed the effects of the pandemic on older adults and provided research-based evidence to help prevent COVID-19 infection among facility-dwelling older people. Furthermore, nursing faculty members were required to educate students about nursing knowledge and skills, and nurses were required to provide care to citizens/patients while preventing infection. This situation promotes the digital transformation of education, remote nursing, and related research, both in Japan and worldwide (Chakeri et al., 2020; Fukushima et al., 2022; Hao et al., 2022; Shorey et al., 2022b).

We also investigated the participants’ distress by conducting research activities. Many respondents in each group had a score of ≥ 5 on the K6. It is possible that one reason for this distress is the change in the obstructive factors. During the pandemic, some nursing researchers were involved in responding to patients with COVID-19 as healthcare professionals, in addition to their research roles (Japan Academy of Nursing Science, 2021), and it has been reported that healthcare professionals working on the frontlines felt psychological stress due to fear of infection and subsequent related discrimination (Stodolska et al., 2023). In terms of research activities, the “Difficulty-remained” group showed the

highest K6 score and the highest scores for the seven obstructive factors among the four groups. COVID-19-related distress might be corroborated by difficulties in addressing these factors.

Future studies should clarify these effects on nursing researchers. Our findings indicate that nursing researchers should flexibly seek appropriate research strategies so that they do not stop or stagnate their research activities during critical social changes such as the COVID-19 pandemic. Simultaneously, the findings indicate that organizations and societies must build a supportive environment for nursing researchers to seek better research activities and address factors that hinder their activities.

Additionally, although restrictions to control COVID-19 infection have been relaxed globally, some infection control measures continue based on local and national infection situations (Chen & Assefa, 2021). For nursing researchers, traveling and face-to-face meetings and exchanges can promote an understanding of each other’s cultures, healthcare systems or policies, and expertise, which can lead to the discussion and implementation of global nursing policies and stimulate the research activities of individual researchers, for example, international collaboration and obtaining mentors (Catton, 2020). To rapidly organize nursing-focused research teams, develop and conduct relevant research, and generate results in response to major social changes such as COVID-19, national and international networking, and collaboration, both face-to-face and virtually, is necessary whenever possible.

This study has some limitations. First, the results may not be transferable because the study only included members of one academy in Japan. Furthermore, the response rate of the members of this academy was not high. Second, the study was based on the subjective evaluation data from nursing researchers only, thereby limiting its objectivity. Third, the participants included only those academy members who responded to both surveys. These participants might have been more affected by the COVID-19 pandemic and, therefore, were more interested in this study. This may have biased the study’s results. Fourth, it has been reported that nursing researchers’ attributes influence their stress and distress, such as the residential area (i.e., country and region; Shorey et al., 2022a). Residential areas possess different influential attributes, including prevalence of and response to COVID-19. However, potential influential attributes for participants’ distress were not fully clarified in our study, except for the obstructive factors that were analyzed. Finally, in consideration of the burden on the participants and the possibilities for responses, we decided to conduct surveys two times.

Thus, in the future, it will be necessary to expand the areas covered by this study’s survey and use objective indicators to assess the status of the nursing researchers’ research activities, such as the time spent on research and research

productivity, including the number of publications or conference presentations.

Conclusions

This study revealed that during the prolonged COVID-19 pandemic, approximately 70% of nursing researchers affiliated with educational and research institutions in Japan faced difficulties in their research activities, or their activity status deteriorated. However, approximately 30% of them maintained or improved their research activities during the pandemic. The association between research activity and obstructive factors may indicate that networking and collaboration among researchers, transforming research designs and processes (e.g., using data collection and intervention methods based on ICT proficiency and effective use), balancing family responsibilities and work, and more effectively managing work effort are key to promoting nursing research during challenging times.

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Author Contributions

All authors contributed to the study conception and design. Kana Kazawa, Naoki Yoshinaga, and Gojiro Nakagami acquired data and performed statistical analysis. Kana Kazawa, Naoki Yoshinaga, Ai Tomotaki, Shinichiroh Yokota, and Gojiro Nakagami drafted the manuscript. Hiroki Fukahori, Yoko Shimpuku, Makiko Tanaka, Mari Ikeda, and Junko Sugama interpreted the data and critically reviewed the manuscript. Junko Sugama supervised the entire study process. All authors have read and approved the final manuscript.

Declaration of Conflicting Interests

The authors declare that there are no conflicts of interest.

Disclaimer

Naoki Yoshinaga is one of the Associate Editors of Journal of International Nursing Research and on the journal's Editorial Committee. He was not involved in the editorial evaluation or decision to accept this article for publication.

Ethical Approval

This study was approved by the University of Miyazaki Ethics Committee (Approval number: O-0733).

Informed Consent

Informed consent was obtained from all participants.

Data Availability

Research data are not shared. The data used for the analysis in this study were part of the original survey data collected by the Japan Academy of Nursing Science, and no consent for secondary use of the data was obtained from the participants.

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Original Research

Sleep quality and depressive symptoms in men during their partner's pregnancy: A cross-sectional observational study using actigraphy

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Abstract

Objective: Changes in sleep are common among parents in the perinatal period. This study aimed to describe objective and subjective sleep quality in men during their partner's pregnancy and its association with depressive symptoms. **Methods:** We used cross-sectional data from a prospective observational study. Men in Japan with primiparous partners after 20 weeks of gestation were recruited. Objective and subjective sleep were measured using actigraphy and the Pittsburgh Sleep Quality Index, respectively, and depressive symptoms were measured using the Edinburgh Postnatal Depression Scale. This study was approved by the ethics committee of the principal investigator's institution. **Results:** A total of 15 men provided valid data for analysis. Actigraphy data showed that, on average, participants slept for 420.3 min per night, took 6.4 min to fall asleep, were awake for 11.3 min per night, and awoke 0.7 times during the night, with 97.4% sleep efficiency. There were no significant associations between sleep parameters and depressive symptoms, except for sleep latency ($r = -0.59$, $p < .05$). **Conclusions:** All participants had good sleep quality and few depressive symptoms, and there were no associations between overall sleep quality and depressive symptoms during pregnancy. This study provides baseline data for assessing changes in sleep after childbirth. Importantly, changes in sleep patterns after childbirth may stress fathers and lead to paternal depression. This illustrates the value of prenatal education, which covers postpartum sleep guidelines and information on infant care to help expectant fathers cope with sleep disruptions and adjust to fatherhood.

Keywords

actigraphy, depression, fathers, perinatal care, sleep

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Introduction

Life changes around childbirth are significant and require psychosocial adjustment for both parents. Alterations in sleep behavior constitute one such life change. According to Maslow's hierarchy, sleep is an essential human need (Ujihara et al., 2004). A lack of sleep can impair human psychological and physical function.

Decreased sleep quality is common in parents after childbirth. However, sleep disturbances also occur during pregnancy. Paavonen et al. (2017) investigated 1,667 mothers and 1,498 fathers in Finland and reported that 11.8% of mothers and 14.9% of fathers suffered from insomnia or short sleep duration (less than 6 h) during pregnancy. This finding is somewhat surprising, because most previous studies of sleep during pregnancy reported sleep disorders in

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women.

As pregnancy progresses, women typically experience physical, hormonal, and psychological changes, which can lead to the deterioration of sleep quality (Smyka et al., 2021). Various pregnancy-related symptoms, such as morning sickness, frequent urination at night, back pain, cramps, abdominal discomfort, breast pain, and heartburn, can cause sleep disturbances (Japanese Society of Sleep Research, 2020). Although men do not experience these physical and hormonal changes during their partner's pregnancy, psychological changes are commonly experienced. Genesoni et al. (2009) reviewed studies of the psychological transition into fatherhood and found that the partner's pregnancy period was experienced as most demanding when men needed to psychologically reorganize the self. Men perceived difficulty in three areas: feelings of unreality about the existence of the unborn child and the desire to develop an emotional bond with the child, disequilibrium in the couple relationship with discrepant needs, and a core identity shift from the role of partner to that of parent. The findings of the review indicated that pregnancy, rather than childbirth, was the most stressful period for some men. The psychological adjustment required for men might partially explain why some men suffer from poor sleep quality during pregnancy.

It has been reported that poorer sleep quality during pregnancy was associated with both maternal and paternal depressive symptoms. Paavonen et al. (2017) measured sleep quality to examine insomnia and insufficient sleep and their relationship to depression during pregnancy (at 32 weeks gestation) in 1,498 fathers and 1,667 mothers in Finland. Both sleep quality and depression were measured by using validated self-report questionnaires. The findings indicated that insomnia was related to depressive symptoms in both fathers and mothers. Among fathers, the likelihood of depressive symptoms was 85% greater in those with insomnia than in those without. A strength of this study is a large sample size; however, the study introduced some inaccuracy of sleep quality as objective measurements were not used.

Paternal depression has a negative impact on families. Depression can impede social skills in expectant fathers, as they feel unable to control their own lives (Holopainen & Hakulinen, 2019). This can lead to reduced support for their partner or deterioration of the marital relationship, which can be a risk factor for depression among women (Liu et al., 2021). Among couples, depression in one partner was reported to be correlated with depression in the other partner, and both men and women simultaneously suffer from depression in some cases (Paulson & Bazemore, 2010). Moreover, if paternal depression persists after childbirth, men's parenting skills may be impaired, potentially leading to child maltreatment (Takehara et al., 2017). In addition, persistent paternal depression can increase the risk of adverse effects on child development (Sweeney & MacBeth,

2016).

Depression before childbirth is a risk factor for postpartum depression (Ansari et al., 2021) and sleep quality is associated with depression (Paavonen et al., 2017). Thus, early interventions targeting paternal sleep during pregnancy are needed. However, there is currently a lack of sleep research in men during pregnancy. Furthermore, sleep is influenced by cultural issues (Owens, 2004). How, where, and with whom people sleep is shaped by their cultural context. For example, Japanese parents and children frequently spend the night in the same room, laying on *futons*, a mattress used on the floor.

During the night, the edges of the *futons* practically meet, making it feasible for the parent to reach the child. This kind of variation suggests the need for sleep research in various countries, including Japan. To our knowledge, no previous studies have investigated men's objective and subjective sleep quality during their partner's pregnancy in Japan. A significant aspect of this study is that it offers baseline data about men's sleep and depressive symptoms during pregnancy, which can be used to assess changes after childbirth. These data may be important for developing sleep interventions for men in the perinatal period.

This study aimed to investigate men's objective and subjective sleep quality and the associations with depressive symptoms during pregnancy.

Materials and Methods

This study used cross-sectional data from a prospective observational study, which examined primiparous paternal sleep and depressive symptoms from pregnancy until 6 months postpartum.

Participants and Recruitment

Study participants were men whose pregnant wives were past 20 weeks gestation. The inclusion criteria were as follows: singleton pregnancy, primiparous wife, and in a marital relationship.

The exclusion criteria were as follows: difficulty communicating in Japanese; serious health problems in either the man, woman, or fetus; and aged 19 years and younger. Potential participants were initially contacted by nurses at a hospital and given a brochure explaining the study. Recruitment was also conducted via Twitter advertisements posted by online medical services. A snowball sampling method was additionally used. All potential participants were given the opportunity to receive a detailed verbal explanation of the study, either face-to-face, online, or via telephone. A written consent form was obtained from each participant. This study was approved by the ethics committee of Chiba University Graduate School of Nursing.

The sample size was calculated using EZR (Saitama

Medical Center, Jichi Medical University, Saitama, Japan) (Kanda, 2013). Since the original study was planned as a prospective observational study, which examined primiparous paternal sleep and depressive symptoms from pregnancy until 6 months postpartum, we calculated the sample size based on a repeated-measures analysis of variance. We assumed five factors (five time points from pregnancy to 6 months postpartum), a medium effect size (0.25), a power of 0.8, and a significance level of 0.05. The calculation indicated that approximately 13 participants were needed. Assuming a dropout rate of 20%-30%, the target number of study participants was set at 20 or more.

Data Collection

We collected data on sleep quality and depressive symptoms after 20 weeks of gestation. Demographic data and clinical characteristics were also collected using a self-report questionnaire. After obtaining a written consent form, a package of data collection materials was sent to the participant's home by mail. Completed questionnaires and other materials were returned in a self-addressed envelope. Following the study procedures, participants were given JPY 3,000 as a gratuity.

Sleep Quality

Objective sleep was measured using the Micro Sleep Watch Actigraph (Ambulatory Monitoring, Inc., Ardsley, NY, USA), a wrist-worn actigraphy device. An actigraph is a device that automatically senses, records, and stores the amount of activity based on body movements. Actigraphy is based on the assumption that arm movements are reduced during sleep and increased during waking (Israel et al., 2003). It has been widely used in sleep research, such as examining men and women in the perinatal period (Adams et al., 2020). Concordance between actigraphy and polysomnography is 91%-93%, which supports the validity and reliability of actigraphy for measuring sleep-wake activity (Israel et al., 2003). Actigraphy allows naturalistic monitoring of sleep-wake activity unobtrusively in the home because it can be used like a wrist watch. Actigraphy is currently considered the best method for long-term observation of human sleep-wake rhythms (Japanese Society of Sleep Research, 2020). The actigraphic device was worn on the non-dominant wrist of the participant continuously for 7 days except during bathing.

In addition to the actigraph, a sleep diary was used during the data collection period to help with the interpretation of actigraph data. This procedure is important for determining bedtime to calculate sleep latency (Smith et al., 2018). Information elicited in the sleep diary were perceived bedtime, sleepiness each morning, napping events, number of times and duration of awakening during the night, and the time at which the actigraphy device was worn and removed.

Subjective sleep was examined using the Japanese version of the Pittsburgh Sleep Quality Index (PSQI-J) (Doi et al., 2000), a self-report questionnaire that consists of 18 items and yields 7 components: sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbance, use of sleeping medication, and daytime dysfunction. The scores for each component (0-3 points) are added to calculate a total score (0-21 points). Higher scores indicate more disturbed sleep. The cutoff value is set at 5/6 points, with a score of 6 or more indicating the presence of a sleep disorder. In a study of 174 Japanese adults, Cronbach's alpha for a total score of 0.77 was reported, and the PSQI-J was capable of discriminating between psychologically disordered and control subjects, indicating known-groups validity assured (Doi et al., 2000). The sensitivity and specificity of the PSQI-J were 85.7% and 86.6%, respectively, for primary insomnia (Doi et al., 2000). Although the original PSQI was not developed specifically for use in the perinatal period, it has been used in studies with perinatal mothers and fathers (Lolles et al., 2022; Mindell et al., 2013).

Depressive Symptoms

Depressive symptoms were measured using the Japanese version of the Edinburgh Postnatal Depression Scale (EPDS-J) (Okano et al., 1996), a self-report questionnaire designed to quantitatively assess postpartum depressive symptoms. The EPDS-J consists of 10 items and is answered using a four-point Likert scale (from 0 to 3). Possible scores range from 0 to 30, with higher scores indicating more depressive symptoms. Although the original EPDS was developed for mothers (Cox et al., 1987), it can also be used for fathers. In a study of 807 Japanese fathers, Cronbach's alpha of 0.81 was reported (Nishimura et al., 2015), and a cutoff value of eight points or more has been proposed as indicating a high risk of depression for Japanese fathers, with a sensitivity and specificity of 81.8% and 94.1%, respectively (Nishimura & Ohashi, 2010). These indicate that the reliability and criterion validity of the EPDS-J are ensured.

Demographic and Clinical Characteristics

Demographic and clinical characteristics of participants were collected by a self-report questionnaire that included age, occupation, educational level, marital status, well-being, family structure, partner's age, partner's employment status, partner's complications during pregnancy, expected date of childbirth, and infertility treatment. Information about economic status and the marital relationship, as factors related to depressive symptoms (Ansari et al., 2021), was also collected. The marital relationship was assessed by using a single question: How do you feel about the relationship with your wife/partner? The responses were as follows: 1, very satisfied; 2, somewhat satisfied; 3, somewhat dissatisfied; and 4, very dissatisfied.

Statistical Analysis

Descriptive statistics were calculated for demographic and clinical information, actigraph data, the PSQI-J, and the EPDS-J. A paired t-test was used to examine differences between actigraph data and the PSQI-J. Spearman's correlation coefficients were calculated to examine associations between actigraph data, the PSQI-J, and the EPDS-J. A probability of less than 0.05 was considered statistically significant.

Regarding actigraphy, proprietary software (Action-W Version 2, Ambulatory Monitoring Inc., Ardsley, NY, USA) was used to calculate the following actigraph sleep parameters: minutes of sleep (SMIN), total minutes scored as sleep during the nocturnal sleep period; sleep efficiency (SE), percentage of sleep during the nocturnal sleep period; sleep latency (SLAT), total time (minutes) taken to fall asleep followed by ≥ 19 min of sleep; waking after sleep onset (WASO), minutes of wakefulness that occur between sleep onset and waking; and long waking episodes (LWEP), number of episodes of wakefulness ≥ 5 min between sleep onset and waking. In addition, the time of going to bed (bedtime) and waking up (wake-up time) were calculated. Standard levels of activity sampling were used; the actigraph was set to monitor in 1-min epochs, and estimation of sleep or waking was conducted using the Cole-Kripke algorithm in proprietary software (Cole et al., 1992) (Action-W Version 2, Ambulatory Monitoring Inc., Ardsley, NY, USA). Sleeping and waking times were visually estimated as actograms around self-report sleeping and waking times in the sleep diary. Likewise, the period of time that the actigraph was not worn was supplemented and calculated as waking. We considered 168 or more hours (7 days) of actigraph wear time per person as valid. Recordings were taken over 7 days, and we compiled and averaged the results to generate a more typical sleep-wake profile for each individual.

Missing data were handled via pairwise deletion to retain all available data for analysis. All analyses were performed using SPSS version 28 (IBM Corp., Armonk, NY, USA).

Results

Participants' Characteristics

Twenty Japanese men agreed to participate in this study. Four were recruited at a hospital, 14 were recruited via Twitter advertisements, and two were recruited as acquaintances of either enrolled research participants or the researcher. For actigraphy analysis, one participant failed to wear the actigraph before childbirth due to an extended business trip. Four participants worked night shifts. Therefore, the final sample size for analysis was 15. Table 1 shows demographic and clinical characteristics of the 15 participants.

The mean gestation week was 33, ranging from 22 to 39

weeks when the data were collected. Participants' age varied between 27 and 43 years, with a mean age of 33 years. Partners' age varied between 27 and 41 years, with a mean age of 32 years. Educational background included 13 (86.7%) participants who had completed university or graduate school. Regarding occupation, 12 (80.0%) participants were office workers, and 9 (60.0%) did not perceive financial burden. Seven (46.7%) participants had natural conception, and eight (53.3%) participants' partners had some pregnancy complications. All participants were healthy, satisfied with their marital relationship, and lived as a nuclear family.

Objective and Subjective Sleep Quality

Table 2 shows objective and subjective sleep quality measured by actigraphy and the PSQI-J, respectively. Regarding objective sleep quality, each participant provided 189.9 ($SD = 24.8$) h (7.9 days) of actigraph data. On average, participants received 420.27 min of sleep per night, took 6.35 min to fall asleep, spent 11.28 min awake per night, and awoke 0.66 times per night. SE was 97.44%, indicating that men were asleep most of the time they were in bed. The average bedtime was 23:55, and the average wake-up time was 7:22.

Comparison of actigraph data with the PSQI-J revealed differences and similarities. There were significant differences in two parameters: perceived bedtime and wake-up time were 23:32 and 6:49, respectively, with mean differences of -23 min and -33 min, respectively, compared with the actigraph data. Perceived SMIN and SLAT were 416.00 min and 11.20 min, respectively, with 95.49% SE. There were no significant differences in these three sleep parameters between actigraph data and PSQI-J scores. The PSQI-J mean total score was 3.07 ($SD = 1.22$), and no participants scored 6 points or more, indicating that sleep quality was perceived as good for all participants.

Associations between Sleep Quality and Depressive Symptoms

The EPDS-J mean total score was 1.93 ($SD = 1.87$), and no participants scored 8 points or more. There were no significant correlations between the EPDS-J and the PSQI-J total score ($r = 0.36$, $p = .19$) (Table 3). However, SLAT from the actigraph results was significantly correlated with the EPDS-J total score ($r = -0.59$, $p < .05$). SLAT from the PSQI-J had a nonsignificant correlation with the EPDS-J total score ($r = 0.47$, $p = .08$).

Discussion

Paternal Sleep Quality during Pregnancy

Objective and subjective sleep quality assessed by actigraphy and the PSQI-J, respectively, indicated good quality sleep in men during their partner's pregnancy, with nearly 7

Table 1. Demographic and clinical characteristics of participants ($N = 15$).

Variable	Mean (<i>SD</i>)	Range
Age (years)	33 (5.2)	27–43
Partner's age (years)	32 (4.5)	27–41
Gestation (weeks)	33 (4.7)	22–40
Variable	Frequency (<i>N</i>)	Percentage (%)
Education		
High school	1	6.7
Vocational school	1	6.7
University	11	73.3
Graduate school	2	13.3
Occupation		
Office worker	12	80.1
Public servant	1	6.7
Professional	1	6.7
Self-employed	1	6.7
Conception		
Natural	7	46.7
Infertility treatment	2	13.3
ART	6	40.0
Partner's pregnancy complications		
Yes	8	53.3
No	6	40.0
Missing	1	6.7
Family structure		
Nuclear family	15	100.0
Financial burden		
Yes	6	40.0
No	9	60.0
Marital satisfaction		
Very satisfied	13	86.7
A little satisfied	2	13.3

Note: ART = assisted reproductive technology

Table 2. Means, standard deviations, range, and differences between actigraph parameters and PSQI-J ($N = 15$).

Measure	Actigraph			PSQI-J			MD	t*	p
	M	SD	Range	M	SD	Range			
Bedtime (hh:mm)	23:55	1:09	21:14–1:19	23:32	0:57	22:00–1:00	-0:23	-2.63	.02
Wake-up time (hh:mm)	7:22	1:00	5:14–9:19	6:49	0:59	5:00–8:45	-0:33	-3.59	.00
SMIN (minutes)	420.27	32.96	365.00–485.13	416.00	27.46	360.00–450.00	-4.27	-0.46	.65
SE (%)	97.44	1.52	94.13–99.32	95.49	7.03	82.35–107.14	-1.95	-1.06	.31
SLAT (minutes)	6.35	1.07	5.38–8.86	11.20	9.86	1.00–30.00	4.85	1.88	.08
WASO (minutes)	11.28	6.74	2.89–26.71	-	-	-	-	-	-
LWEP (events)	0.66	0.42	0.13–1.50	-	-	-	-	-	-

Note: MD = mean difference; * paired t-test

PSQI-J = Japanese version of the Pittsburgh Sleep Quality Index; SMIN, total minutes scored as sleep during nocturnal sleep period; SE, percentage of sleep during nocturnal sleep period; SLAT, total time taken to fall asleep (minutes) followed by ≥ 19 min of sleep; WASO, minutes of wakefulness that occur between sleep onset and waking; LWEP, number of episodes of wakefulness ≥ 5 min between sleep onset and waking

Table 3. Spearman's correlations for actigraph parameters with the PSQI-J and EPDS-J ($N = 15$).

	Measure	1	2	3	4	5	6	7	8	9	10	11	12	13
Actigraph	1. SMIN (minutes)	-												
	2. SE (%)	0.05	-											
	3. SLAT (minutes)	−0.48	−0.02	-										
	4. WASO (minutes)	0.09	−0.97**	0.02	-									
	5. LWEP (events)	−0.04	−0.80**	0.24	0.76**	-								
PSQI-J	6. Sleep quality	0.41	−0.11	−0.48	0.16	0.01	-							
	7. Sleep latency	−0.09	−0.33	−0.38	0.32	0.03	−0.04	-						
	8. Sleep duration	−0.41	0.10	0.39	−0.09	−0.06	0.15	−0.46	-					
	9. Habitual sleep efficiency	−0.12	−0.37	−0.25	0.31	0.28	0.08	0.33	0.11	-				
	10. Sleep disturbance	−0.10	0.12	−0.10	−0.13	−0.36	−0.17	0.58*	−0.30	0.19	-			
	11. Use of sleeping medication	-	-	-	-	-	-	-	-	-	-	-		
	12. Daytime dysfunction	0.11	−0.26	−0.21	0.31	0.09	−0.14	0.74**	−0.63*	−0.16	0.43	-	-	
	13. PSQI-J total score	−0.14	−0.27	−0.34	0.28	−0.08	0.29	0.80***	−0.04	0.45	0.67**	-	0.51	-
	14. EPDS-J total score	0.12	−0.12	−0.59*	0.02	0.19	0.32	0.47	−0.33	0.38	0.18	-	0.09	0.36

Note: * $p < .05$; ** $p < .01$; *** $p < .001$

PSQI-J = Japanese version of the Pittsburgh Sleep Quality Index; EPDS-J = Japanese version of the Edinburgh Postnatal Depression Scale; SMIN, total minutes scored as sleep during nocturnal sleep period; SE, percentage of sleep during nocturnal sleep period; SLAT, total time taken to fall asleep (minutes) followed by ≥ 19 min of sleep; WASO, minutes of wakefulness that occur between sleep onset and waking; LWEP, number of episodes of wakefulness ≥ 5 min between sleep onset and waking

h of sleep at night and 97.44% of SE. None of the participants scored >6 in the PSQI-J. This finding indicates that participants in this study had sufficient nocturnal sleep with little disturbance. A survey of a general population in Japan reported that 32.7% of men sleep between 6 and 7 h per night, with 37.5% of men sleeping less than 6 h per night (Ministry of Health, Labor and Welfare, 2019). Thus, the men in this study maintained a similar level of sleep quality during pregnancy than that before pregnancy.

The present findings differ from those of a previous study conducted in Finland. Paavonen et al. (2017) evaluated sleep quality in 1,498 men using a questionnaire at 32 weeks gestation and found that approximately 20% of the men suffered from insufficient sleep or insomnia during pregnancy. However, cultural influences should be considered when comparing our data with those of Paavonen et al. In Paavonen et al.'s study, the average duration of sleep at night was 440 min, with an average perceived sleep need of 504 min. This indicates that men in Finland slept longer than men in Japan (440 vs 420 min), yet men in Finland perceived the need for an additional 1 h of sleep. These findings suggest that cultural issues should be considered, which shape how people sleep and the types of sleep problems they experience (Owens, 2004). The average duration of sleep in Japan is the shortest of any country (Japanese Society of Sleep Research, 2020). This may explain why men in this study perceived their sleep as good despite having a shorter sleep duration than that in other places, which might

be considered insufficient by people outside Japan.

The characteristics of the sample in this study could potentially explain why our participants exhibited good sleep quality during pregnancy. All participants in this study were healthy and satisfied with their marital relationships, so would be expected to experience a relatively low level of psychosocial stress. Telecommuting and work during the coronavirus disease 2019 pandemic may have also exerted a positive effect on sleep, by saving large amounts of time each day by working from home and avoiding a commute. Therefore, it is perhaps not surprising that the men in this study slept well during pregnancy.

After childbirth, however, it is common for fathers to exhibit sleep disruption, due to the need to frequently respond to the child's needs (Richter et al., 2019). For example, a large population-based study in Germany reported that sleep duration and satisfaction of 2,118 men and 2,541 women sharply declined after childbirth toward the first 3 months postpartum, with women being more strongly affected (Richter et al., 2019). Neonatal sleep does not have a clear 24-h cycle like adult sleep and typically involves waking every 3-4 h. The circadian rhythm, which is unclear in the neonatal period, emerges before the third month of life and gradually becomes more pronounced with coherent nighttime sleep (Japanese Society of Sleep Research, 2020). Accordingly, frequent childcare is often required during the day and night. For example, the number of feeding times is typically 8-12 per day in the early postpartum period, depending

on the child's needs and the type of feeding (Mori, 2014). Frequent diaper changes and bedtime routines also require a lot of work for fathers. All of these childcare activities potentially disturb paternal sleep after childbirth. Sleep conditions are likely to be perceived differently after childbirth, and this gap between expectations and reality could be stressful for some fathers. A larger perceived gap between expectations and reality is generally associated with greater impact that can greatly vary depending on the context and the individuals involved. In case of expectant fathers, the impacts may encompass stress, anxiety, disappointment, and motivation. This suggests that although sleep quality during pregnancy itself is relatively high for men, a greater gap in sleep expectations could potentially occur after childbirth if they do not anticipate the change.

In addition, the findings of a previous study suggest a further important effect of paternal sleep (Rhee, 2018). Rhee investigated 167 fathers and mothers during the first 6 months postpartum to examine associations between parental sleep and maternal mood and clarified that paternal sleep quality was associated with maternal daily mood (Rhee, 2018). Therefore, anticipatory guidance regarding sleep changes may be helpful for men to prepare and adjust to fatherhood. A previous study reported that a lower level of knowledge about infants, such as infant development and sleep, was associated with depressive symptoms in men, indicating that providing infant knowledge may be effective for increasing men's understanding of infants and preparing them for childcare (Lee et al., 2021). Nurses can talk to men about infant crying, which often disturbs paternal nocturnal sleep and teach them how to deal with it. Information about colic should be provided too, because it often causes difficulty for both parents. Colic is a condition in which a child cries loudly and violently for 3 h or more a day with no apparent cause (Sadeh & Sivan, 2009). This condition typically begins at 2-3 weeks of age and can be exhibited both in the day and at night, often starting in the evening and lasting until midnight. The duration of colic varies from child to child and gradually disappears around 4 months of age. Prenatal education that includes postpartum sleep expectations, preparation for sleep fragmentation and deprivation, and infant knowledge may be effective to help men cope with sleep changes and adjust to fatherhood.

Associations between Paternal Sleep Quality and Depressive Symptoms

Participants in this study not only had good sleep quality but also had few depressive symptoms. The fact that all participants were satisfied with their marital relationships might have influenced the results of depressive symptoms (Ansari et al., 2021). In addition, the EPDS cutoff value set for this study was 7/8, which is lower compared to countries outside Japan. A recent systematic review of validation studies for

the EPDS in fathers found that the cutoff values ranging from 7 to 10 conferred the optimum balance between sensitivity and specificity (Shafian et al., 2022), as in the case of a Japanese study (Nishimura & Ohashi, 2010). One possible reason of the low cutoff value may be due to Japanese cultural values and attitudes toward mental health. In Japan, there may be greater stigma surrounding mental health issues, such as depression. Because Japanese society expects them to be emotionally restrained, Japanese men may be less likely to recognize or report signs of depression. Therefore, it may be possible to identify more mild depressive symptoms in Japanese fathers by using a lower cutoff value.

There were no associations between overall sleep quality and depressive symptoms, except for a significant association between objective SLAT and depressive symptoms. Our findings differ from those of a previous study reporting that poorer sleep quality (insomnia) during pregnancy was associated with paternal depressive symptoms (Paavonen et al., 2017). Another study conducted in 54 fathers at 6 months postpartum also showed that perceived sleep quality was associated with depressive symptoms after controlling for demographic variables (Kalogeropoulos et al., 2021). Moreover, associations between poorer sleep quality and depressive symptoms were reported in women not only during pregnancy but also in the postpartum period (Solomonova et al., 2020). Thus, the linkage between sleep and depressive symptoms has been shown in several studies of both fathers and mothers in the perinatal period. The inconsistency between the present findings and those of previous studies might be partially explained by the characteristics of our study participants. In this study, the relatively good sleep quality and few depressive symptoms of the participants, as well as the small sample size ($N = 15$), might have influenced the findings.

Importantly, changes in sleep following childbirth may cause feelings of unpreparedness and altered expectations when fathers do not anticipate changes in sleep after childbirth (Darwin et al., 2017), which has been reported to be a trigger of paternal depression. Kido et al. (2022) conducted a meta-synthesis about screening and interventions for paternal depression and found that "fear of losing the lifestyle previously enjoyed" can be a trigger of paternal depression. This finding suggests the importance of providing information about life changes around childbirth, particularly changes in sleep. The present findings suggest that better sleep quality during pregnancy may increase the importance of addressing sleep changes after childbirth.

Limitations

The first limitation that should be considered in this study is selection bias. Due to the voluntary nature of the sampling method (particularly the recruitment of participants via a

Twitter advertisement), there may have been a bias toward cooperative men, who may be relatively unlikely to exhibit physical and psychosocial stress. All participants reported that they were healthy and satisfied with their marital relationship. In addition, men with lower levels of education were underrepresented in our sample. These characteristics may have led our participants to exhibit better sleep quality and fewer depressive symptoms compared with the general population.

The second limitation is that actigraphy is prone to overestimating sleep for some people. Because sleep duration is assumed from reduced arm movements, people who are motionless but awake are at risk of being classified incorrectly as being asleep. In this study, there were significant differences between actigraphy and PSQI-J scores in perceived bedtime and wake-up time, with actigraphy indicating a longer time in bed. Therefore, careful consideration should be given to the interpretation and comparison of actigraph data.

The third limitation is that the EPDS-J uses a lower threshold (7/8) in contrast to other countries. It is crucial to acknowledge that the EPDS threshold for detecting paternal depression might fluctuate depending on cultural settings and countries. Therefore, caution is warranted when extending the study's conclusions to populations beyond Japan due to potential limitations in generalizability.

Finally, the small sample size was a limitation in interpreting the current findings. We conducted a post hoc analysis to calculate the power. Using Spearman's correlation coefficient for SLAT with the EPDS-J, a correlation of -0.59 , a sample size of 15, and a significance level of 0.05, the calculation indicated the power of 0.58. This indicates that this study was not adequately powered. In addition, greater diversity in characteristics such as the level of education and well-being would be expected in a larger sample of participants. A larger sample might reveal a wider range of sleep quality and depressive symptoms, potentially increasing the effect size of the associations between these parameters.

To our knowledge, this study is the first to investigate both objective and subjective sleep quality in Japanese men during pregnancy. One strength of this study is that the findings could be used as baseline data regarding sleep and depressive symptoms prior to childbirth. This study allowed us to examine the progression of sleep and depressive symptoms from pregnancy to the postpartum period, which may be beneficial knowledge for developing interventions for fathers.

Conclusions

All participants in this study had good sleep quality and few depressive symptoms, and there were no associations between overall sleep quality and depressive symptoms during

pregnancy. Importantly, changes in sleep following childbirth may cause stress to fathers, which could be a trigger of paternal depression. This suggests the importance of prenatal education, such as postpartum sleep expectations and knowledge about infant care to cope with sleep changes and adjust to fatherhood.

However, perinatal sleep interventions are not readily available for parents in Japan, especially fathers. This is in contrast to the widespread implementation of sleep education for the general public in Japan. An unspoken acceptance that parents who care for infants should expect to be unable to sleep at night may be prevalent in some cultural contexts. The limited timeframe of infant care might also contribute to this view. Although there was no correlation between overall sleep quality and depressive symptoms during pregnancy, additional analysis and discussion of longitudinal postpartum data may provide clues to develop sleep interventions.

Author Contributions

HI, EM, KM, KK, and FT: conceptualization and study design. HI and MS: literature review. HI: statistical analyses. All authors: interpretation of results. HI: drafting the manuscript. All authors: critical revision of manuscript. All authors: final acceptance of manuscript.

Declaration of Conflicting Interests

The authors declare no conflicts of interest.

Ethical Approval

The study was approved by the ethics committee of Chiba University Graduate School of Nursing (NR3-2).

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Original Research

Life experience after robot-assisted radical prostatectomy: A 1-year prospective study

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Abstract

Objective: Although robot-assisted radical prostatectomy (RARP) is widely used for prostate cancer, postoperative deterioration of quality of life (QOL) remains an issue. Many previous QOL studies have used health-related QOL measures after surgery. However, life experiences of patients remain unknown, and QOL measures alone may not be sufficient for understanding multidimensional QOL. This study aimed to clarify the transition in life experiences of patients after RARP. **Methods:** A questionnaire survey that contained 17 independent items was administered to 108 patients at 1, 3, 6, 9, and 12 months after RARP to evaluate life experience. Cochran's Q test was used to evaluate the change over time in life experience. **Results:** A total of 88 men were included in the analysis. Most participants did housework and worked as usual 3 months post-RARP; however, few participants went on trips. Although urinary dysfunction improved over time, participants exhibited long-term support needs, such as pad use. More than half of the participants were anxious about recurrence throughout the postoperative year. **Conclusions:** The transition of 17 life experiences of patients for 1 year after RARP was clarified. Patients presented diverse experiences, both positive and negative. The findings demonstrate a wide range of impacts on life after RARP, thus emphasizing the need for QOL support.

Keywords

prostate cancer, robot-assisted radical prostatectomy, life experience, quality of life

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Introduction

Prostate cancer is one of the most prevalent malignancies in older men. In Japan, prostate cancer has the highest incidence among male cancer patients; the number of cases in 2019 was approximately 95,000 (Cancer Information Service, 2023), with a 5-year relative survival rate of 99.1% (Center for Cancer Control and Information Services, 2020). Localized prostate cancer is treatable, and treatment is expected to lead to long-term survival (Japanese Urological Association, 2016).

Radical prostatectomy is a typical treatment for prostate

cancer. However, patients who undergo surgery experience postoperative urinary incontinence and sexual dysfunction, which reduces their quality of life (QOL) compared to patients who receive other treatments, such as active surveillance, radiation therapy, and hormone therapy (Lane et al., 2022). In particular, postoperative urinary incontinence is an important issue that adversely affects men's social life and life experience (Carrier et al., 2018). In recent years, robot-assisted radical prostatectomy (RARP) has been rapidly established as a new standard procedure in Japan (Japanese Urological Association, 2016). RARP offers more favorable outcomes than conventional procedures, such as a lower

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likelihood of biochemical recurrence and a higher continence rate (Carbonara et al., 2021). However, despite the widespread use of RARP, a decline in postoperative QOL may be an issue among patients (Kawaguchi et al., 2020). Patients who have undergone RARP may be more likely to be regretful or dissatisfied owing to the high expectations raised by the novel treatment (Schroeck et al., 2008). A recent study found higher regret in one-third of patients after RARP, which was associated with a worse QOL (Lindsay et al., 2021). Collaborative and detailed discussion is necessary when counseling patients about RARP (Lindsay et al., 2021; Schroeck et al., 2008). Therefore, it is critical to understand the changes in QOL after RARP.

Studies using QOL measures have shown that QOL declines after surgery and recovers approximately 1 year later, although it may not recover to the preoperative QOL level (Barocas et al., 2017; Hoffman et al., 2020; Kawaguchi et al., 2020; Resnick et al., 2013). In contrast, a systematic review of QOL outcomes following treatment noted that most QOL outcomes are primarily documented using health-related QOL measures (Baker et al., 2016). In addition, reports on life experiences of patients are scarce, and results of QOL measures in several previous studies may be insufficient for understanding multidimensional QOL. A meta-synthesis reported the physical, psychological, and social experiences that impact patients' lives after surgery (Kong et al., 2017). Moreover, we investigated the patients' experiences of improved urinary dysfunction and reported positive changes in their lives and perceptions during the postoperative recovery process (Kawaguchi et al., 2016). However, the interpretation of the findings was limited by the retrospective patient interviews. Although life experiences of patients have been previously reported (Awamlh et al., 2023; Kawaguchi et al., 2016; Vyas et al., 2022), the changes in their experiences over time have not been clarified. Determining life experiences of patients after RARP prospectively is expected to promote a better understanding of multidimensional QOL and, consequently, improve patient support. In particular, there is a need to provide greater lifestyle support to patients undergoing treatment and during survivorship (Prashar et al., 2022).

Therefore, this study aimed to clarify the transition of life experiences of patients after RARP based on qualitative research findings.

Materials and Methods

Study Design and Data Collection

This was a prospective study involving patients with prostate cancer who underwent RARP from May 2016 to October 2017 at Yamagata University Hospital in Japan. The participants provided written informed consent after hospitalization (1-4 days before surgery). Patients were provided self-

administered questionnaires during regular outpatient visits at 1, 3, 6, 9, and 12 months after surgery. Participants who could not answer the questionnaire or scheduled an outpatient visit at another hospital were excluded. The recovery period for QOL was estimated as 1 year (Barocas et al., 2017; Hoffman et al., 2020; Kawaguchi et al., 2020; Resnick et al., 2013). Patients' characteristics and clinical data were obtained from electronic medical records. Questionnaires were distributed and collected directly by researchers to improve the response rate and prevent missing data. In case of missing data, participants were asked to respond again. This study was approved by the Institutional Review Board of Yamagata University Faculty of Medicine (approval no.: 2019-409).

Outcome Measures

Life Experience

Previous qualitative research (Kawaguchi et al., 2016) was used to develop questionnaire items as objective criteria for assessing life experiences of patients. The previous research focused on five postoperative patients with prostate cancer and employed semi-structured interviews related to experiences of patients until postoperative urinary dysfunction improved. Furthermore, it conducted a qualitative descriptive analysis, which involved the extraction of categories, sub-categories, and codes. In this study, two nursing researchers with expertise in prostate cancer and lower urinary tract symptoms thoroughly reviewed the potential questionnaire items of the previous study before the survey was conducted. Based on the previous findings, this study employed specific behaviors and perceptions of postoperative patients, delineated as life experiences, to serve as an objective criterion for evaluating the presence or absence of these in patients' lives. The questionnaire items were designed for "yes" or "no" responses to indicate the presence or absence of experiences. A total of 17 independent questionnaire items, such as "do housework and work as usual" and "feel the improvement of urinary dysfunction," were then delineated (Supplementary Table 1). Urologists and nurses from the urology ward confirmed the validity of the formulated questionnaire items. In this study, the 17 questionnaire items were treated as independent questions, and participants responded with either "yes" or "no" to each question. Since the questions were designed to examine specific behaviors and perceptions of the respondents and treated as independent items rather than a scale, measures of internal consistency were not applicable to this questionnaire.

Characteristics

The age, marital status, employment status, nerve-sparing surgery, D'Amico risk classification, and medical history of patients were investigated.

Data Analysis

We analyzed all participants who responded to the questionnaire at all the five time points. Missing data were excluded from the analysis.

We calculated the participants' median age, as well as the frequency (%) for marital status, employment status, nerve-sparing, D'Amico risk classification, and medical history. For the 17 items of life experience, the respondents (%) who answered "yes" were calculated, and Cochran's Q test was used to evaluate the transition of life experience. We then compared the percentage of "yes" respondents at 1 month and at other times (3, 6, 9, and 12 months) using multiple comparisons employing the Bonferroni method. We found that QOL decline was the worst 1 month after surgery (Barocas et al., 2017; Hoffman et al., 2020; Kawaguchi et al., 2020; Resnick et al., 2013). We then investigated the relationship between life experiences and characteristics. The Mann-Whitney U test was used to determine the relationship between life experiences and age. Chi-square and Fisher's exact tests were used to determine the relationship between life experiences and marital status, employment status, nerve-sparing, D'Amico risk classification, and medical history.

All statistical analyses were performed using the IBM SPSS version 24.0. A two-tailed p -value of $<.05$ was considered statistically significant.

Results

Participants

A total of 108 patients participated in this study, and 92 (85.2%) responded at all the five time points. After excluding four participants with missing data, 88 (81.5%) were analyzed. The median age was 67, and approximately half of the participants were working (Table 1).

Transition of Life Experiences

"Do housework and work as usual" significantly increased after 3 months, reaching 96.9% at 12 months; however, "go on a trip" was 26.1% and 71.6% at 1 month and 12 months, respectively. "Feel the improvement of urinary dysfunction" and "can put up with urination" significantly increased after 3 months, reaching 71.6% and 81.8%, respectively, at 12 months. "Feel relieved by using diapers or pads" remained between 88.6% and 93.2%. "Feel shameful with using diapers or pads" significantly decreased after 6 months, while "freed from diapers or pads" significantly increased after 6 months. "Anxiety about surgery and treatment" significantly changed over time; however, there were no significant differences in the multiple comparisons. "Anxiety about recurrence" was more than 50% at all five time points and did not significantly change. "Perform pelvic floor muscle exer-

Table 1. Patient characteristics.

	$n = 88$	
	n	(%)
Age, years, median (IQR)	67	(52–78)
Spouse		
Yes	82	(93.2)
Employment		
Yes	45	(51.1)
Nerve-sparing surgery		
Yes	17	(19.3)
D'Amico risk classification		
Low	11	(12.5)
Intermediate	35	(39.8)
High	42	(47.7)
Medical history		
Yes	50	(56.8)

Note: IQR = interquartile range.

cises" significantly decreased after 9 months, while "keep urinary diaries" remained between 10.2% and 18.2% (Table 2).

Relationship between Life Experience and Characteristics

"Find out about cancer and treatment" and "exercise" were significantly associated with age. Those finding out about cancer and treatment from the Internet or books were significantly younger at all the five time points than those who did not. Moreover, those who exercised were significantly older at 1, 3, and 9 months than those who did not (Table 3).

"Keep urinary diaries" was significantly associated with employment status. The proportion of workers among those who kept urination records was significantly lower than among those who did not (Table 4).

There was no consistent trend in the relationship between other life experiences and characteristics.

Discussion

To our knowledge, this study is the first to quantitatively evaluate the life experiences of patients with prostate cancer after RARP based on the results of a previous qualitative study (Kawaguchi et al., 2016). The actual conditions of the 17 life experiences during the first year after RARP were categorized into four domains: daily life after surgery, urinary dysfunction, anxiety, and self-care. Participants presented with diverse experiences, both positive and negative.

The proportion of participants who did housework and work as usual was 70% and 90% at 1 month and 3 months, respectively. The result that patients quickly resumed their daily routine during the early postoperative period supported previous findings that RARP results in a faster postoperative

Table 2. Transition of life experiences.

	1 month	3 months	6 months	9 months	12 months	<i>n</i> = 88 <i>p</i> [†]
Do housework and work as usual	70.5	89.8**	92.0**	95.5**	96.9**	<.001
Go on a trip	26.1	48.9**	56.8**	77.3**	71.6**	<.001
Interact with family and others as before	89.8	92.0	97.7*	97.7*	97.7*	.004
Spend time without shame	76.1	84.1	90.9**	85.2	86.4	.009
Feel the improvement of urinary dysfunction	52.3	67.0	75.0**	78.4**	71.6*	<.001
Can put up with urination	54.5	70.5	76.1**	81.8**	81.8**	<.001
Feel relieved by using diapers or pads	90.9	92.0	93.2	92.0	88.6	.778
Feel shameful with using diapers or pads	60.2	53.4	43.2*	39.8**	33.0**	<.001
Freed from diapers or pads	21.6	31.8	48.9**	55.7**	59.1**	<.001
Anxiety about surgery and treatment	39.8	36.4	33.0	23.9	37.5	.049
Anxiety about recurrence	62.5	59.1	52.0	58.0	56.8	.411
Perform pelvic floor muscle exercises	88.6	84.1	75.0	63.6**	59.1**	<.001
Keep urinary diaries	18.2	13.6	11.4	10.2	10.2	.109
Consult a doctor or nurse	69.3	64.8	64.8	60.2	65.9	.657
Talk to other patients with prostate cancer	50.0	53.4	44.3	47.7	50.0	.502
Find out about cancer and treatment from the Internet or books	53.4	56.8	47.7	50.0	51.1	.298
Exercise	50.0	52.3	64.8*	61.4	58.0	.019

Note:

The respondents (%) who answered “yes” at the time of each survey are shown.

†: Cochran’s Q test.

p* < .05, *p* < .01: comparison of the percentage of respondents who answered “yes” at 1 month and at each time point by Bonferroni method.

Table 3. Relationship between life experience and age.

		1 month		3 months		6 months		9 months		12 months	
		Age	<i>p</i>	Age	<i>p</i>	Age	<i>p</i>	Age	<i>p</i>	Age	<i>p</i>
Find out about cancer and treatment from the Internet or books	Yes	66 (52–78)	<.001	66 (52–78)	.004	66 (52–77)	.022	66 (52–78)	.014	66 (52–78)	.017
	No	70 (62–76)		70 (55–76)		69 (55–78)		69 (55–76)		69 (55–75)	
Exercise	Yes	69 (55–77)	.020	69 (52–78)	.048	69 (52–78)	.095	69 (55–78)	.015	69 (52–78)	.065
	No	66 (52–78)		66 (52–78)		66 (55–74)		66 (52–74)		66 (55–74)	

Note:

Median age (minimum–maximum) is shown.

Age comparison using Mann-Whitney U test.

Table 4. Relationship between life experience and employment.

		1 month			3 months			6 months			9 months			12 months		
		Employment			Employment			Employment			Employment			Employment		
		Yes	No	<i>p</i> [†]	Yes	No	<i>p</i> [†]	Yes	No	<i>p</i> [‡]	Yes	No	<i>p</i> [‡]	Yes	No	<i>p</i> [‡]
Keep urinary diaries	Yes	4 (25.0)	12 (75.0)	.021	2 (16.7)	10 (83.3)	.010	2 (20.0)	8 (80.0)	.038	0 (0)	9 (100)	.001	3 (33.3)	6 (66.7)	.220
	No	41 (56.9)	31 (43.1)		43 (56.6)	33 (43.4)		43 (55.1)	35 (44.9)		45 (57.0)	34 (43.0)		42 (53.2)	37 (46.8)	

Note:

The number of respondents (%) is shown.

†: Chi-square test, ‡: Fisher’s exact test.

return to society than open surgery. Patients treated with RARP returned to work after a median of 35 days, whereas the corresponding time for open surgery was 48 days (Plym et al., 2016). A recent systematic review reported that RARP allows patients to return to daily activities earlier than open surgery; however, there is a lack of supporting literature (Veccia et al., 2020). Therefore, returning to work and daily activities after surgery is an important topic for patients and requires further research. On the one hand, previous quantitative studies reported recovery of QOL scores after approximately 6 months to 1 year postoperatively (Barocas et al., 2017; Hoffman et al., 2020; Kawaguchi et al., 2020; Resnick et al., 2013). These conflicting results suggest that regaining daily life does not necessarily imply recovery of QOL. In contrast, the number of participants who went on a trip was 25% and 46% at 1 month and 3 months, respectively, supporting the previous study that urinary incontinence affected travel and going out (Kawaguchi et al., 2016). Postoperative urinary dysfunction resulted in the need to plan previously simple social activities around the accessibility to a toilet (Vyas et al., 2022). Therefore, reducing the impact of urinary incontinence on going out and supporting social activities may improve QOL.

The number of participants who achieved improvement in urinary dysfunction increased over time and reached 70%-80% in 12 months. Our findings were consistent with those of a systematic review, which showed a urinary continence rate of 69%-96% 1 year after RARP (Ficarra et al., 2012). However, this study showed that many participants still used diapers and pads, despite the improvement in urinary dysfunction. In addition, the finding that one in three participants felt shameful when using diapers or pads even at 12 months after surgery suggested that the psychological needs associated with the use of diapers or pads are latent. A previous study showed that some patients experienced lasting urinary incontinence and long-term effects on their lives (Awamlh et al., 2023). Therefore, healthcare professionals should be aware that patients may require long-term incontinence care and associated psychological support. In addition, the finding that participants were reassured by the use of diapers or pads emphasized the importance of cooperating with the patients to develop an effective method of using diapers or pads.

This study showed that more than half of the participants were anxious about recurrence at all the five time points. After the treatment, patients often worried about the uncertainty of whether their future would remain cancer-free (Vyas et al., 2022). Notably, 40% of the participants were anxious about treatment and 60% about recurrence 1 month after the operation. After radical prostatectomy, only postoperative dysfunction was observed, but anxiety may be hidden. In addition, both anxiety and depression were reported to worsen gradually over time (Hu et al., 2021). Therefore,

healthcare professionals should screen patients for anxiety during the early postoperative period and provide information on recurrence and ongoing treatment for the long term to reduce anxiety.

Self-care for urinary incontinence decreased over time. Pelvic floor muscle exercises, which are recommended as treatment for postoperative urinary incontinence (Japanese Urological Association, 2016), were performed at a high rate in the early postoperative period, but the rate significantly decreased after 6 months. Thus, re-guidance after a certain postoperative period may be effective for continuous exercises. In contrast, few participants, such as the workers, kept urination records. Although a bladder diary is a validated and recommended tool to evaluate patients with urinary incontinence, there are concerns regarding the challenges in patients accurately completing a bladder diary (Mehta et al., 2023). Healthcare staff need to provide guidance on maintaining a bladder diary along with performing pelvic floor muscle exercises. For example, a paper bladder diary with instructions that combine completing the diary with an exercise program may be useful. In addition, support that enables patients to balance self-care and work may be effective.

In this study, approximately half of the participants gathered information from various sources. Patients with prostate cancer obtained information from multiple sources, such as healthcare providers and medical websites, which were also perceived as helpful for decision-making (Chhatre et al., 2020). In a previous study of patients with prostate cancer, 38% of the participants collected information after treatment (Darwish-Yassine et al., 2014), and participants of this study also collected information actively. However, this might not be the case for older patients. A large-scale survey of cancer patients in Japan noted that older patients with cancer might have poor information collection (Joint Study Group on the Sociology of Cancer, 2013) and age-related difficulties in understanding the information (Guo et al., 2021). A similar trend was observed in this study. Many patients with prostate cancer are old, suggesting the need to consider personalized information support.

Patients treated with RARP may return to their daily lives postoperatively earlier than those who undergo conventional surgery; however, their postoperative life may still be affected in various ways, such as travel, urination, and anxiety. In particular, although RARP is expected to improve urinary incontinence after treatment (Carbonara et al., 2021), the psychological needs associated with incontinence and pad use were latent both in the postoperative period and over the long term. Postoperative care remains an issue despite the latest robot-assisted surgery, thus emphasizing the importance of QOL support. The findings from this study provide further insight into postoperative life experiences and QOL of patients. The QOL scale alone may not adequately reflect

actual living conditions of patients. We believe that more specific information can be derived from our study and previous studies that used the QOL scale. This information is expected to be effective not only in postoperative care but also in various clinical situations, such as treatment decisions and patient education. Sharing and understanding the life experiences of patients who have received similar treatment resulted in benefits such as gaining knowledge and practical advice about the management of their condition (Prashar et al., 2022). Our findings may guide the development of patient support strategies to improve QOL.

This study has some limitations. First, life experience was evaluated through “yes” or “no” responses, but the frequency and degree were not evaluated. Due to the subjective judgment of the participants, the response criteria might differ among participants. Second, given that no preoperative evaluation was performed, the participants’ original lifestyle may have affected the results. Third, this was a single-center study in Japan. Differences in values across countries and cultures may affect life experiences of patients. For example, in the case of Japan, some patients showed a lower impact of sexual dysfunction and felt a sense of calmness and relief (Hayashi et al., 2022); however, this study included only a few sexuality-related items. Fourth, this study aimed to clarify the transition of life experiences of patients after RARP. To this end, 17 unique questionnaire items related to life experiences were created, and each item was treated as an independent question. In the future, we believe that a scale for evaluating postoperative life experiences and living conditions of patients must be developed based on the questionnaire items used in this study. This instrument could include additional questions and considerations and be assessed using further analyses, such as factor and reliability analyses. Further research in this area is expected to enhance the assessment and understanding of patients’ QOL, leading to more effective support. Specifically, further research using the developed scale to determine the extent of change in life experiences from the time of diagnosis of prostate cancer, taking into account individual values, and comparing RARP with other prostate cancer treatments could enhance the understanding of life experiences of patients. Despite these limitations, this longitudinal study of the actual life experiences of patients receiving RARP may provide a basis for future practice.

In conclusion, this study demonstrated the transition of 17 life experiences of patients for 1 year after RARP. Patients presented with diverse experiences, both positive and negative, after RARP. The results of this study suggest that patients treated with RARP also experience an impact on their lives and require QOL support during the postoperative period. In the future, it will be necessary to develop a scale for evaluating life experiences of patients and support strategies to improve QOL based on this study.

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Author Contributions

Kansuke Kawaguchi: study conception and design, data collection, analysis and interpretation, and writing. Wakako Sato: study conception and design, data collection, analysis and interpretation, and supervision. All authors read and approved the final manuscript.

Declaration of Conflicting Interests

The authors declare no conflicts of interest.

Ethical Approval

This study was approved by the Institutional Review Board of Yamagata University Faculty of Medicine (approval code: 2019-409).

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Original Research

Practical knowledge of healthcare professionals who provided the initial response to victims of the sarin gas attack on the underground in Tokyo

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Abstract

Objective: This study aimed to identify practical knowledge about the initial response at healthcare facilities in the event of a human-induced disaster, based on the narratives of healthcare personnel who experienced the initial response to victims of the sarin gas attack on the Tokyo, Japan, subway system. **Methods:** Six healthcare workers who were engaged in the initial response to the victims of the sarin subway incident were interviewed using semi-structured interviews. **Results:** The narrative was composed of 6 categories, 15 subcategories, and 105 codes. The categories identified were “Complementary clinical judgment,” “Reflection on nursing and healthcare practice,” “Passing on a unique experience,” “Knowledge of biological and chemical weapons,” “Responsibilities as a healthcare professional,” and “Need for medium- to long-term care of victims.” **Conclusions:** It became clear that the acquisition of knowledge and skills to protect oneself first and to minimize secondary disasters, along with the accumulation of daily nursing practice, is necessary. The need for the development of new knowledge and nursing education regarding man-made disasters, including terrorism, was demonstrated.

Keywords

chemical terrorism, practical knowledge, sarin gas attack on underground in Tokyo, nursing education

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Introduction

As shown by the recent conflict between Russia and Ukraine and the pandemic of a new coronavirus infection, the social and international situation is becoming increasingly complex and threatening to people’s health.

Disasters are broadly classified into natural and man-made based on their causes. Man-made disasters are those intentionally caused by human actions, such as large-scale train or airplane crashes, explosions, terrorism using biological or chemical weapons, and wars (Daily, 2010). Although we have prepared for natural disasters such as typhoons, hurricanes, earthquakes, and volcanic eruptions that have occurred globally based on empirical knowledge, the multiplicity

and diversity of disasters have led to a scattering of disaster nursing responses and their teaching content (Littleton & Slepiski, 2008). Ya et al. (2022) focused on radiation, bioterrorism, and warfare as man-made disasters and identified the nursing techniques and skills needed to respond to these disasters.

In conducting research on man-made disasters, including biological and chemical disasters, there was a small number of literatures published in Japan. We wondered if the knowledge we could learn from the chemical disaster and the sarin gas attack on the subway, the largest man-made disasters that ever occurred in Japan, could be widely applied to man-made disaster education.

The sarin gas attack on the Tokyo subway, Japan’s largest

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ever human-caused disaster, occurred as a terrorist attack using chemical weapons on March 20, 1995. At the time of the incident, the healthcare personnel involved in the initial response to the victims were completely unaware that the attack was terrorism using chemical weapons. Four years after the incident, author Haruki Murakami published *Underground* and *Underground 2: The Promised Land* as a result of interviews with survivors and perpetrators. He interviewed with victims about their experience and discussed the facts of what was going on when the sarin gas attack on the subway occurred. This publication was useful for healthcare personnel to understand the facts from the victim's perspective and the long-term physical and psychological effects of sarin incidents on victims. However, there was no description of the actual response and suffering of the healthcare personnel involved in the initial response to the victims. Moreover, there has been no research on the healthcare personnel who were involved in the initial response to the victims or on the response to terrorism using chemical weapons.

Incidentally, the footage taken at the hospital where the initial response took place has now been used as audiovisual teaching materials of an in-hospital disaster training program in the United States.

Practical knowledge is knowledge that is acquired by day-to-day hands-on experiences (Amanda, 2016). By applying theoretical knowledge in healthcare settings, healthcare personnel gain practical knowledge through doing the various activities and accomplishing tasks they encounter. Moreover, good nursing practice, which would be a part of practical knowledge, is when nurses reflect on past events, critically evaluate their own actions, and take steps toward improvement and new initiatives (Chinn & Kramer, 2004).

Therefore, we conducted an interview survey of these healthcare personnel and this study aimed to reflect on their practices and clarify their practical knowledge from their narratives.

Materials and Methods

Research Design

A qualitative descriptive research design was chosen because the narratives based on the experiences of healthcare workers who were involved in the initial response to the victims of the chemical weapons terrorism outbreak revealed their practical knowledge by reflecting on their practices.

Research Participants

Research participants were healthcare personnel who were involved in the initial response at healthcare institutions in Tokyo at the time of the sarin gas attack on the subway on March 20, 1995, who were able to talk about their past experiences, and who agreed to participate in this study. Selec-

tion of research participants was conducted using the snow-ball sampling method.

Data Collection Method

Data were collected from May 11, 2021, to July 20, 2021, by using the semi-structured interview method.

The one-on-one interviews were conducted online using Zoom and following an interview guide. Interview content included how each participant perceived the sarin gas attack on the subway as chemical terrorism at the time it occurred, what was happening to the victims and what initial responses were made, a review of the nursing and medical activities that were practiced, and what was needed to prepare for the future. The interviews were supervised by a mentor with extensive experience in qualitative research to improve the precision of the interview techniques and data collection.

With the consent of the participants, the interviews were recorded on a digital voice recorder. We also explained to the participants that we would take notes when necessary and obtained consent. There were no changes made to the data collection methods or procedures.

Data Analysis

Data analysis was conducted from May 11, 2021, to September 30, 2021.

The data for this study were verbatim transcripts of the interview content.

Data analysis consisted of the three processes described below.

1. The two content areas extracted were (1) nursing and medical activities practiced during the initial response and (2) the preparedness required of the individual.

2. Conventional content analysis, which intercepts and codes data according to its context, was used (Hsieh & Shannon, 2005).

3. Based on the similarities and differences of the codes, the codes were categorized, and each category was named, returning to the verbatim list as needed.

In the analysis process, the data were cross-checked and verified among multiple researchers with experience in qualitative research to ensure reliability.

Ethical Considerations

Consent was obtained after explaining verbally and in writing to the research participants that their participation was voluntary, which they could withdraw even after giving consent, that the data would not be used for anything other than the research purpose, and that their personal information and privacy would be strictly protected. This study was approved by the Research Ethics Review Committee (Ken02-09) of the university to which the researchers belong.

Table 1. Summary of research participants.

Job title	Years of experience at the time of the incident	Department assigned at that time	Time of interview (min)
Nurse	32	Infection control room	67
Nurse	12	Emergency room	54
Physician	10	Emergency Department	60
Nurse	2	Emergency room	50
Nurse	1	Department of Surgery	65
Nurse	20	Outpatient	60

Table 2. Results of categories and subcategories revealed as practical knowledge.

Category	Subcategory	Number of codes
Complementary clinical judgment	Symptoms of unknown mechanism	5
	Recall of candidate causative agents from experience	5
	Inconsistencies in clinical judgment	4
	Substance name never heard of	9
Reflection on nursing and healthcare practice	Unprotected state	19
	Self-initiated action	5
	Checking and acting on supervisor's instructions	4
	Necessity for decontamination	5
Passing on a unique experience	The importance of daily nursing practice	4
	Past experience as a strength	13
	Knowledge of biological and chemical weapons	5
	Elimination of preconceived notions	2
Responsibilities as a healthcare professional	Reconstructing professionalism as a healthcare professional	4
	Need for psychological follow-up	16
Need for medium- to long-term care of victims	Understanding the existence of medium- and long-term sequelae	5

Results

Descriptions of Participants

At the time of the sarin gas attack on the Tokyo subway, the participants consisted of five nurses and one physician, all of whom worked at a tertiary healthcare institution in Tokyo and were engaged in nursing and medical activities for the victims. The years of clinical experience at the time of the incident ranged from 1 to 32 years (average 12.8 years), and the departments at the time of the incident were the outpatient department, hospital wards, and emergency department. The duration of the interviews ranged from 50 to 67 min (average 59 min) (Table 1).

Analysis Results

Table 2 shows the results of the categories and subcategories identified as practical knowledge as a result of the data analysis; 6 categories, 15 subcategories, and 105 codes were extracted.

The categories were Complementary clinical judgment, Reflection on nursing and healthcare practice, Passing on a unique experience, Knowledge of biological and chemical weapons, Responsibilities as a healthcare professional, and

Need for medium- to long-term care of victims.

Complementary Clinical Judgment

The participants had made clinical judgments based on the information they had obtained, but found symptoms in the victims that shook their clinical judgments, and they were examining whether their judgments were correct. Four subcategories were created, and the category was set to Complementary clinical judgment.

Symptoms of Unknown Mechanism

However, the victims who were transported to the hospital had no external injuries, but had constricted pupils and vomiting, although the cause of the constricted pupils and vomiting was unknown. "With eye pain but no redness, and no abnormal findings in the lung field, we wondered what it meant to have pain in the eyes and difficulty breathing," and it became clear that the victim was showing symptoms that shook our initial clinical judgment. The participants did not understand the mechanism of the victims' symptoms because they "had no knowledge at all and wondered what on earth was going on" and "were in their first year as nurses and did not understand what was going on." Later, the participants recalled that "the first patients affected by the sarin gas attack were three people who came to the emergency

room walking and complained of eye pain,” and they had a better understanding of the unexplained symptoms that appeared among the victims.

Recall of Candidate Causative Agents from Experience

The participants recognized that the victims’ symptoms were constriction of the pupils and increased secretions, because the victims had complained of constriction of the pupils and runny nose that did not stop flowing immediately after the sarin gas attack on the subway. Based on their past experience as healthcare professionals, they were considering the possibility of pesticide poisoning as the symptoms were similar to those of organophosphorus pesticide poisoning. However, when dealing with victims who were transported in cardiopulmonary arrest (CPA), they wondered if tear gas could cause CPA and were not at all sure if tear gas was the cause. It became clear that the participants were repeatedly asking themselves the same question as they responded to the victims.

Inconsistencies in Clinical Judgment

The participants recalled candidate causative agents from their own experience as healthcare professionals, such as tear gas and pesticide poisoning, but “other doctors told me that the patient had constricted pupils,” and “when I examined the patient myself, I saw that his eyes had constricted pupils,” which contradicted the symptoms the victim was presenting and the clinical judgment. The clinical judgment was inconsistent with the symptoms the patient was presenting. While the discrepancy in clinical judgment remained, the participants dealt with the victims and found that “the pupils of patients with CPA were also constricted” and “I wondered why the pupils of patients with CPA should have been dilated.”

Substance Name Never Heard of

The participants received information from healthcare personnel who had responded to victims of the Matsumoto sarin gas attack and from the Self-Defense Forces and were aware that the disaster was caused by a substance they had never heard of, saying “I heard for the first time that sarin was the cause, and I did not understand.” Even when they heard that sarin was the cause, they did not know how to respond because they “did not know the word sarin itself” and “did not know how to protect themselves because they did not know the toxicity of sarin.” Information from outside organizations also provided information on toxic substances, and “when I heard the word acetonitrile, it did not ring a bell at all,” suggesting that the name of the substance, which I had never heard of, was being heard everywhere in the hospital. Upon learning that it was a sarin gas incident, the participants said that they wished they had done a little research on sarin gas. They also recalled that they did not know that pralidoxime iodide injection (Pam) was effective against sarin, that they did not know anything about the effects or indications of the drug when they siphoned off the

Pam, and that they could not handle the situation based on experience alone, since many drugs are encountered for the first time on a daily basis in the first year of nursing. The first-year nurses were unaware of the effects and indications of the drugs.

Reflections on Nursing and Healthcare Practice

Reflections on nursing and healthcare practice were created as a category related to the actual nursing care provided; from the 37 codes, 5 subcategories were included: unprotected state, self-initiated action, checking and acting on supervisor’s instructions, necessity for decontamination, and the importance of daily nursing practice.

Unprotected State

The research participants were inundated with a large number of victims, and they were so occupied with seeing the patients in front of them that they had no time to think due to the desire to act. Thus, they responded without regard for their own selves. In 1995, at the time of the sarin gas attack on the subway system, there were no infection control or defense protocols at all. Thus, they had no knowledge of what was dangerous and had no choice but to take risks. They did not have even the slightest idea that the situation could be a health risk to them. The following facts also reveal that they were not aware of the need for protection: they did not actively use masks or gloves, staff who were securing the route were unprotected without gloves, and they had no knowledge of protective measures at the time of the sarin gas attack on the subway. As future countermeasures, the study participants stated that they felt the need for good protection, as it is important for healthcare professionals to treat and care for patients without being harmed. Furthermore, knowledge of infection control, including protection, is necessary, and thorough standard precautions are needed for personal protection. Knowledge of secondary damage is essential to protect oneself, as well as patients from secondary damage. Protecting oneself first should be a priority.

Self-initiated Action

When responding to disaster victims, it was clear that the study participants took the initiative in acting because “each individual found his or her own place and took action,” “as nurses, we should decide where to move regardless of department,” and “if we wait for instructions, we will not be able to get there in time.” As for what they did on their own initiative, they talked about their actual responses, such as “When the outpatient clinic was closed, I made a decision on the spot to call for emergency support and joined the support personnel” and “I could only secure the route and confirm the name and address.”

Checking and Acting on Supervisor’s Instructions

Alternatively, it was clear that some participants had received clear instructions from their supervisors and responded to them, as they “went to the nursing management

office to ask what I should do,” “some staff members went to the incident site to provide support,” and “responded to patient calls at the direction of the lead nurse.”

Necessity for Decontamination

After reviewing materials on sarin provided by the Self-Defense Forces, the participants recognized the need to remove and decontaminate the victims' clothing, as they “realized that it was not a good idea to leave patients' clothing untouched” and that “sarin left behind in patients' clothing could lead to an increase in the number of ill patients within the hospital.” However, the women were not allowed to use ID cards or other identification. The following issues and measures for decontamination became clear: “Women carry identification cards in their bags, and if they become unconscious, their identities will be lost,” “It is important to manage personal belongings when victims are brought to the hospital,” and “It is important to keep the victim's belongings close to them to prevent them from becoming unidentifiable.” The challenges and countermeasures for decontamination became clear.

The Importance of Daily Nursing Practice

The participants recognized that, unlike in normal times, “it is important for nurses to have the ABCs of Airway Breath Compression (ABC) and basic skills,” but that “knowledge is necessary, but knowledge without knowledge is no protection at all,” and that “it is necessary for people to have at least a minimum knowledge of disasters and still be able to take care of daily nursing care.” It is important to have knowledge as a healthcare professional and to be able to practice nursing on daily basis, and they recognized that disasters are an extension of normal times. The survey also revealed that the challenge for healthcare professionals in times of disaster is “whether or not they can switch their mindset from helping those who can be helped to helping those who can't.”

Passing on a Unique Experience

For the experience of responding to victims of unprecedented terrorism (hereinafter terrorism), a subcategory of past experience as a strength was created from the 13 codes, and the category was defined as Passing on a unique experience.

The participants were aware of the need for a certain level of knowledge about terrorism as healthcare professionals working in the emergency room, although terrorism was unpredictable, because this experience “gave me goosebumps thinking this was sarin,” “I regretted my lack of knowledge as an emergency nurse when I was exposed to terrorism,” and “I felt ashamed as an emergency nurse. However, as a healthcare professional working in the emergency room, I was aware of the need for a certain level of knowledge about terrorism.” “Although there had been an incident in Matsumoto the year before, I had only seen it as a fire on the other side of the river,” and “I realized that what hap-

pened somewhere in the world could happen somewhere close to home.” In addition, they recognized that the one and only experience can raise the ability of healthcare professionals, because “although it was difficult at the time, the past experience became a strength,” “I am proud of my past experience and experiences,” “even if a similar incident occurs, I think we have the manpower and can handle it,” and “we had excellent personnel, including mental follow-ups by liaison nurses.” The unique experience of the project was recognized to be able to raise the level of the healthcare staff's abilities. However, he pointed out that “Japanese people are not good at thinking of the past as over and taking measures for the next time” and that “years have passed and the past has been forgotten by the general public.” He also discussed issues in education regarding the passing on of the past to the next generation, saying “It is important not to let the past fade away and to pass it on to the next generation.”

Knowledge of Biological and Chemical Weapons

After the experience of the sarin gas attack on the subway, knowledge of the necessary preparedness of individuals was raised; from the five codes, a subcategory of Knowledge of biological and chemical weapons was created, and the category was set to Knowledge of biological and chemical weapons.

In addition to the experienced knowledge of healthcare personnel, the participants recognized that general knowledge about biological and chemical weapons was lacking because “it is important to raise the sensitivity to notice something wrong in everyday life,” “knowledge about biological and chemical weapons is necessary,” and “symptoms caused by chemical weapons were not expected, and knowledge was all that was needed.” They recognized that they lacked general knowledge about biological and chemical weapons. They also recognized that “knowledge of disasters such as CBERN disasters and natural disasters is necessary” and “knowledge of how to cooperate when you are the one who discovers a terrorist attack is also necessary.”

Responsibilities as a Healthcare Professional

The participants experienced the sarin gas attack on the subway and felt a sense of responsibility as nationally licensed healthcare professionals. Two subcategories were created from the six codes: Elimination of preconceived notions and Reconstructing of professionalism as a healthcare professional, and the category was set as Responsibilities as a healthcare professional.

Elimination of Preconceived Notions

Before receiving information about sarin, the participants were informed by the Tokyo Fire Department that the results of on-site analysis “information about poison was also initially a substance called acetonitrile.” It was assumed that preconceived notions, such as responding to sarin while considering the possibility of poison, would make it impossible to respond to the victims. The participants recognized that,

as healthcare professionals, “the necessary skill at the time of a disaster is not to have preconceived notions.”

Reconstructing Professionalism as a Healthcare Provider

It is difficult to think of a person who wants to do something about the victims in front of him or her except for a sense of mission and “not only a sense of mission, but also a religious view may be present.” Furthermore, they were aware of the issues that the nursing profession itself lacks, such as “they should envision their own action plan in case of emergency” and “consider how they, as nurses, should respond in case of emergency.”

Need for Medium- and Long-term Care of Victims

The need for mid- to long-term care and the acute period immediately after the incident was discussed. Twenty-one codes were used to create two subcategories: need for psychological follow-up and understanding the existence of medium- and long-term sequelae, and the category was defined as need for of medium- and long-term care of victims.

Need for Psychological Follow-up

The participants expressed that they “needed to make survivors aware of everyday life” after their extraordinary experiences and “expected PTSD symptoms and reactions to emerge after the sarin gas attack on the subway” and “wanted survivors to know about PTSD symptoms and the need to care for them.” Because victims’ “trauma can develop suddenly after years have passed and be overlooked,” she cited issues such as “few people approach PTSD depression as a secondary damage” and “need for victim nursing and victim care in disaster care.” As healthcare professionals, we should be aware of the perspective of victims as a matter of common sense: The victims suffered and regretted because there was little understanding that the sarin gas attack on the subway was terrorism. There is a huge gap between the victims’ feelings and suffering and what the public thinks, and “Physical injuries are recognized as aftereffects, but if there are no injuries and the patient only complains, it is called a mental disorder.” The victims’ feelings and sufferings and what the public thinks are their sufferings are very different. The study also revealed that the victims should be aware that they will be left behind even if society forgets about the terrorist attacks, that the bereaved families are also left behind in natural disasters, that the suffering of the remaining families and victims is still ongoing, and that they are concerned about the incident fading away. The participants also recognized the “need for healthcare professionals to learn and gain knowledge about psychological care” and the “need for support regarding the psychological impact of healthcare personnel involved with the victims” and pointed out that healthcare personnel involved with the victims were also traumatized.

Understanding the Existence of Medium- and Long-term Sequelae

After the sarin gas attack on the subway, the participants un-

derstood the general acute symptoms but did not understand the chronic symptoms caused by sarin and said that it took them nearly 20 years to understand the mid- to long-term effects of sarin. He was aware that in addition to PTSD as an aftereffect, there are medium- and long-term aftereffects of sarin gas. Furthermore, she was concerned about whether the nursing staff was aware of the existence of patients with medium- to long-term posttraumatic stress disorder after the sarin gas attack, and she recognized that it was an issue to understand that a single word from a nurse is very important for patients with medium- to long-term posttraumatic stress disorder.

Discussion

This study aimed to determine whether the practical knowledge that could be learned from the sarin gas attack on the subway, the largest man-made disaster ever to occur in Japan, could be widely applied to man-made disaster education.

Snowball sampling was the recruitment method for research participants. We believe that having access to a specific network from a core of healthcare providers who were initial responders at the time was a great advantage. Six healthcare personnel including one physician participated in this study. The reason for including one physician as a research participant was that emergency medicine is based on a team approach that requires clinical judgment and supervision by physicians and nurses. It is only with precise instructions and advice from the physician that the emergency healthcare team can respond as a team. Taking a bird’s-eye view of what was happening at that time in the physician’s words provides important insight into not only the physician’s preparedness but also the preparation and preparedness of the healthcare personnel including nursing staff who are the initial responders.

Complementary Clinical Judgment

The sarin gas attack on the subway was the C of the CBERN disasters, the chemical weapons disaster.

Upon receiving information that the accident was caused by an explosion in the subway, the participants prepared for the transport of a seriously injured/traumatized patient. The victims who were transported to the hospital had no external injuries, but showed symptoms such as constricted pupils, vomiting, and difficulty breathing. Initially, the participants tried to recall the causative agent and responded to the patient, but there was a discrepancy between the symptoms observed in the patient and their clinical judgment. Chinn and Kramer (2004) stated that empirical knowledge is expressed as scientific competence in practice. This reveals the importance of experiential knowledge as practice knowledge.

Reflection on Nursing and Healthcare Practice

The participants were also acting voluntarily out of a sense of duty as healthcare providers in the chaos of a mass casualty outbreak, and Loke et al. (2021) stated that every time a disaster occurs, nurses, the largest group of healthcare workers, remind the public of the importance of being prepared for disasters. Disasters are not special. Responding to a contingency is just an extension of everyday life. The response to the victims of the sarin subway incident when it occurred was an accumulation of daily nursing practice, and it is important to have the ability to practice nursing on a daily basis.

Need for Medium- to Long-term Care of Victims

Not only physical symptoms immediately after the sarin gas attack on the subway but also “it took nearly 20 years until the mid- to long-term aftereffects caused by sarin were known” and “mid- to long-term aftereffects caused by sarin in addition to PTSD as aftereffects” revealed mid- to long-term symptoms after the sarin gas attack, but an understanding and recognition of these symptoms is lacking. Sugiyama et al.’s (2020) follow-up study of long-term impact factors on survivors 5 to 15 years after the sarin gas attack on the subway reported that a high percentage of symptoms such as eye fatigue (80%), blurred vision (60-70%), difficulty seeing far or near (50%), and difficulty focusing persisted 5 to 14 years after the sarin gas attack. Easy fatigue and headache also remained, and symptoms of numbness in the hands and feet appeared 12 years after the sarin gas attack. This suggests that, as in the case of natural disasters, it is necessary to consider the medium- to long-term symptoms after a terrorist attack from the beginning of the disaster and to be involved with the symptoms in the medium- to long-term period.

Knowledge of Biological and Chemical Weapons

The participants who were forced to respond to the disaster victims were in danger because they did not take care of themselves. Veenema (2003) stated that the preparedness situation against chemical and biological weapons terrorism would require zoning, protection, and decontamination in addition to the normal disaster response. However, Veenema (2003) found that the items mentioned were not in practice at the time of the 1995 disaster. Furthermore, Veenema (2003) stated that the safety of the healthcare workers themselves should be a top priority in any case. We assume that the lack of understanding and knowledge of zoning, protection, and decontamination led to the secondary disaster among the healthcare workers. Therefore, knowledge of zoning, protection, and decontamination is necessary. In addition, the ability to detect and gather information is also required from the codes of “Terrorism is unpredictable, but

when I was attacked, I regretted my lack of knowledge as an emergency nurse” and “I am ashamed as an emergency nurse.” Mondy, Cardenas, and Avila (2003) argue that terrorism preparedness must go beyond the military, police, and emergency healthcare services to include healthcare personnel and public health. Due to the paradigm shift in terrorism preparedness beyond military, police, and emergency medicine to include healthcare personnel and public health, nurses must cover a wide range of topics in preparation for disasters associated with terrorism. To do so, they need to be educated about terrorism, including biological and chemical weapons, and how to respond to them, which is currently lacking in the healthcare workforce.

Passing on a Unique Experience

The response to the victims of the sarin gas attack on the subway was something that had never been experienced before. The research participants considered this experience to be unique and special and also surmised that it was the responsibility of those who had experienced responding to victims to pass on this knowledge. “Japanese people are not good at thinking of the past as something that has already happened and taking measures to deal with the next situation.”

Responsibilities as a Healthcare Professional

This study describes practical knowledge in the initial response to victims of the sarin gas attack on the subway. Based on the results of this study, it is important to accumulate daily practical experience and nursing practice to supplement clinical judgment and reflect on nursing and healthcare practice in the initial response to victims of terrorism. In addition, to prepare for similar man-made disasters that may occur in the future, general knowledge and education about terrorism, zoning, decontamination/protection, biological and chemical weapons, and medium- to long-term care of victims are necessary. In the event of a contingency, practical knowledge can be gained by applying this knowledge. Furthermore, it is the responsibility of healthcare professionals to reconstruct professionalism and consider contingency plans. Healthcare professionals who experienced the initial response to the sarin gas attack on the subway need to consider the place and means of passing on their valuable experience to the next generation. This suggests the need for practical knowledge formation, development of new knowledge, and nursing education on man-made disasters, including terrorism.

Limitations of the Study

The participants of this study were healthcare workers at the same healthcare facility who experienced disaster victim response in Tokyo. It is possible that the situation at other

healthcare facilities and their responses to the victims may have differed. In addition, 29 long years have passed since the sarin gas attack on the subway, so it is possible that there is a bias of fading or ambiguity in memory. The use of snowball sampling undeniably biased the subjects and results. However, some memories remain strong because the terrorist attack was such a memorable disaster. During the interview survey, we asked about the day of the incident over time to facilitate recall and minimize bias.

Conclusions

Interviews with six healthcare personnel who were involved in the initial response to the victims of the sarin gas attack on the Tokyo subway in 1995 revealed that it is necessary to communicate the one and only experience of a terrorist attack using a chemical weapon, sarin, as a preparation for a similar man-made disaster that could occur in the future and to give first priority to protecting oneself. It became clear that the acquisition of knowledge and skills to protect oneself first and to minimize secondary disasters, along with the accumulation of daily nursing practice, is necessary. The need for the development of practical knowledge through the valuable experiences and the nursing education regarding human-made disasters, including terrorism, was demonstrated.

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Author Contributions

Study design: Chizuko Kajiyama, Hanako Misao. Data collection: Chizuko Kajiyama. Data analysis: Chizuko Kajiyama, Hanako Misao. Manuscript writing: Chizuko Kajiyama, Hanako Misao.

Chizuko Kajiyama has contributed all phases of this study. Hanako Misao has contributed data analysis and manuscript writing. All authors critically reviewed the manuscript and confirmed the final manuscript. All authors agree with the content of this manuscript.

Declaration of Conflicting Interests

The authors declare no conflicts of interest.

Ethical Approval

This study was approved by the Institutional Research Ethics Committee of University of Shizuoka School of Nursing (Ken02-09)

Informed Consent

Informed consent was obtained from our healthcare professionals involved in this study.

Disclosure

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Original Research

Engagement in learning activities for newly graduated nurses: Development and psychometric testing of a scale

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Abstract

Objective: This study aimed to develop and assess the psychometric properties of the Engagement in Learning Activities Scale (ELAS) for newly graduated nurses. **Methods:** This cross-sectional study included 58 Japanese medical facilities with >200 beds. A total of 1,405 newly graduated nurses participated in the study, with 299 returning completed questionnaires and 290 providing valid data for analysis. Participants completed a questionnaire that included the ELAS, the Utrecht Work Engagement Scale, the Self-Directed Learning Readiness Scale for Nursing Education, and personal background information. Reliability and validity were assessed through item analysis, exploratory factor analysis, Cronbach's alpha coefficient, correlation with external criteria, and test-retest methods. **Results:** Item and factor analyses yielded 21 items across four factors. Confirmatory factor analysis demonstrated a good fit. Cronbach's alpha of the ELAS subscale ranged from .712 to .839, and test-retest reliability ranged from .45 to .72. The ELAS was correlated with the Utrecht Work Engagement Scale ($r = .454$) and the Self-Directed Learning Readiness Scale for Nursing Education ($r = .393$). **Conclusions:** The study yielded acceptable estimates of the consistency and construct validity of ELAS, thereby allowing for an objective evaluation of newly graduated nurses' learning efforts. However, stability was inadequate, demonstrating the need for further investigation.

Keywords

engagement, learning activities, newly graduated nurses, scale development, cross-sectional study

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Introduction

A gap exists between nursing students' abilities and those required in clinical practice. To address this gap, the Ministry of Health, Labor and Welfare of Japan (2010) highlighted the need to train newly graduated nurses. Furthermore, in recent years, it has been highlighted that newly graduated nurses are experiencing a shortage of practical training in basic education due to the effects of COVID-19. Consequently, the Ministry of Health, Labor and Welfare (2020) implemented additional training for novice nursing staff since 2021, emphasizing the need for strengthened edu-

cational support.

Information on key student experiences (processes) and outcomes is necessary to improve education substantially (Astin, 1984). Furthermore, it is essential to consider how student participation in learning can be enhanced, rather than merely focusing on outcome enhancement (Ewell, 1988). Engagement, based on Deci and Lian's motivational studies (1985), is a concept used to examine the quality of student involvement in learning activities. Increased engagement affects skills and abilities (Skinner & Belmont, 1993). Engagement in learning activities is a psychological state of immersion in a task, expending effort to pay attention to a

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task with interest and enjoyment, and making intentional efforts to work on the task (Reeve, 2002). Thus, to consider effective educational support for fresh nursing graduates, understanding their engagement in learning activities is important to demonstrate the quality of these activities.

Background

The concept of engagement is common in various fields, and the field of education encompasses student engagement (Reeve, 2002; Skinner & Belmont, 1993), school engagement (Fredricks et al., 2004), and academic engagement (Al-rashidi et al., 2016), terms that indicate engagement with learning, such as in school and class. In the workplace, work engagement refers to a positive and fulfilling psychological state for work, and employee engagement is a state in which employees devote themselves to their duties. Additionally, community engagement is an essential motivation for community participation. What the concepts of engagement have in common is that they show the ties and involvement of target people, such as students and employees, with organizations, such as schools, workplaces, and communities. This engagement is enhanced by mutual effort rather than one-sided organizational efforts.

Engagement in learning activities requires measurement of student engagement (Reeve, 2002; Skinner & Belmont, 1993). Skinner et al. (2009) and Reeve and Tseng (2011) developed a method for measuring engagement in learning activities. Reeve and Tseng (2011) developed a measurement instrument that consists of four factors; it requires Skinner's behavioral, emotional, and cognitive engagement, and an agent-based approach.

These studies target students enrolled in educational institutions; however, learning is lifelong, and individuals who are not affiliated with educational institutions but are in the process of acquiring new skills and knowledge can be considered learners. Knowles (1975) argued that learners possess characteristics distinct from students and advocated for the necessity of adult learning. Adult learning is defined as "any sustained changes in thinking, values, or behavior that is brought about by experience" (Cranton, 1992), and rich past experiences serve as resources for learning. In other words, because newly graduated nurses are learners, they primarily learn from practice, leading to a learning environment different from that of students.

Previous research on nursing engagement has used the Utrecht Work Engagement Scale (UWES) (Schaufeli et al., 2002). Work engagement is a "work-related positive and fulfilling psychological state" (Schaufeli et al., 2002, p. 74), and improved work engagement reduces depressive symptoms and contributes to organizational efficiency and quality of care. Work engagement describes the strength of the connection between individuals and their work in the field of industrial psychology. However, engagement in learning ac-

tivities differs in that it shows the quality of the learner's efforts to learn in the field of pedagogy while also demonstrating their immediate short-term state. Focusing on engagement in learning activities makes it possible to extract attitudes and feelings of enthusiasm that appear in the learning scenario rather than considering learning activities in the workplace as part of general work. By measuring engagement according to the learning situation, newly graduated nurses can reflect on their learning experiences, and educators can comprehend learning situations that require support. By developing an engagement measurement scale for the learning activities of newly graduated nurses, it is possible to obtain suggestions to explore more specific support.

Previous research (Reeve, 2002; Skinner & Belmont, 1993; Skinner et al. 2009; Reeve & Tseng, 2011) on engagement in learning activities has focused on students. Moreover, scales are available for measuring student engagement in learning, demonstrating a link with the acquisition of desirable abilities. However, studies targeting nurses is lacking, and no scale currently exists for this population. Therefore, this study aimed to develop and assess the psychometric properties of the Engagement in Learning Activities Scale (ELAS) for newly graduated nurses. Validating this scale is expected to advance research on engagement in learning activities among newly graduated nurses and aid scale development.

On the basis of concept analysis and the literature review, engagement in learning activities in this study was defined as "a psychological state of being deeply engaged in a task, along with the feelings, attitudes, and behaviors brought about by that state" (Katsuyama & Hosoda, 2021). In the qualitative study, data were collected through semistructured interviews with 16 newly graduated nurses. The results indicated that their engagement in learning activities was based on four interrelated concepts: behavioral, emotional, cognitive, and agentic engagement (Katsuyama & Hosoda, 2021). On the basis of these concepts, a draft scale of 84 items rated on a 6-point Likert scale was created to measure engagement. Next, the face and content validity of the ELAS draft was assessed through consultations with experts, and the items were consolidated from 84 to 72 by removing duplicates. Furthermore, an anonymous survey was conducted, and 23 items with an item-level content validity index score of <.78 were excluded, resulting in a final selection of 49 items (Katsuyama & Hosoda, 2020).

Materials and Methods

Design

This study adopted a cross-sectional design.

Development of the Scale

Participants

A total of 208 facilities in Japan were selected through random sampling from medical facilities with over 200 general hospital beds nationwide, and cooperation was obtained from 58 facilities. Survey questionnaires were distributed to 1,405 newly graduated nurses from these facilities. The inclusion criteria were newly graduated nurses with <1 year of experience since joining the facility. The exclusion criteria were nurses with prior work experience and those who had not continued working in the same department since joining the medical facility. All participants who participated in the initial survey were asked to cooperate in the retest. The retest survey questionnaires were distributed to the 153 individuals who agreed to participate.

Data Collection

The survey period was from July to November 2019. A research cooperation request letter and a confirmation postcard regarding cooperation intention were sent to facility managers of randomly selected medical facilities along with the survey questionnaire. For facilities where cooperation intention was confirmed, along with a research cooperation request letter, the first survey questionnaire, a retest cooperation request letter, a resurvey cooperation intention confirmation postcard, a password entry sheet for memoranda, and a reply envelope for the survey questionnaire were sent to facilitate distribution to potential candidates. Responses were collected individually via mail after completion. Retesting targeted newly graduated nurses who agreed to cooperate during the first survey was conducted, and survey questionnaires were sent to specified addresses for individual mail collection. The retest method was performed at 3-week intervals between the first and second surveys. Exploratory factor analysis, a recommended range of 4-10 participants per variable is proposed (Kline, 1993). Rouquette and Falissard (2011) set the sample size for exploratory factor analysis as ≥ 300 , and in this study, a sample size of 300 was set.

Survey Questionnaire

The survey content in this study comprised material from the ELAS, the UWES (Schaufeli et al., 2002; Shimazu et al., 2008), the Self-Directed Learning Readiness Scale for Nursing Education (SDLRSNE) (Fisher & King, 2010; Oyama et al., 2015), and individual characteristics.

The UWES, developed by Schaufeli et al. (2002), was translated into Japanese by Shimazu et al. (2008). This scale measures three subscales (vitality, enthusiasm, and immersion) using 17 items. It has been standardized for use in 23 countries, including the Netherlands, Spain, and Japan. The UWES was validated for reliability (Cronbach's $\alpha = .920$) and construct conceptual validity (Schaufeli et al., 2017; Shimazu et al., 2008). The workplace can be a site for work and learning (Billet, 2004). Individuals acquire and

share new knowledge, skills, and abilities while working. In other words, because work inevitably involves learning (Nakahara, 2010), the concepts of work engagement and engagement in learning activities were considered correlated.

The self-directed learning readiness scale was developed by Guglielmino (1977). Fisher et al. (2001) developed the SDLRSNE as a revised version, which was translated into Japanese by Oyama et al. (2015) and used in this study. This scale has 40 items, and there are three factors related to learners' individual characteristics required for self-determined learning: self-management (13 items), desire for learning (12 items), and self-control (15 items). The SDLRSNE was validated for reliability (Cronbach's $\alpha = .924$) and construct conceptual validity (Fisher et al., 2001; Fujino-Oyama et al., 2016). Knowles (1975, p. 18) defined self-directed learning as "a process in which individuals take the initiative, with or without the help of others, in diagnosing their learning needs, formulating learning goals, identifying human and material resources for learning, choosing, and implementing appropriate learning strategies and evaluating learning outcomes." SDLRSNE, which was used to establish criterion-related validity, is a scale that measures the extent to which an individual possesses the characteristics and attitudes required when engaging in self-directed learning (Oyama et al., 2015). This scale shares commonalities with engagement in learning activities in that it expresses a motivated learning attitude, and the two concepts were considered correlated.

Individual characteristics include gender, age, months of experience as a new nurse, nursing qualifications, highest educational attainment, ward or unit, educational support systems, participation in external training programs, and training content.

Data Analysis

The analysis was conducted following the scale development guidelines outlined in the CONsensus-based Standards for the selection of health Measurement INSTRuments checklist (Prinsen et al., 2016). The statistical analysis was performed using IBM SPSS Statistics Version 22. Data analysis was performed under the supervision of an IBM SPSS expert.

Item Analysis

Item analysis included checking for ceiling and floor effects, assessing kurtosis and skewness, examining corrected item-total correlation (CITC), and conducting interitem correlations. A ceiling effect was defined as the sum of the mean and the standard deviation (SD) exceeding 6, whereas a floor effect was defined as the mean minus the SD being <1. Items with kurtosis or skewness exceeding ± 2.0 were considered for deletion (Kunnan, 1998). For CITC, values of $\leq .30$ were used as the deletion criteria (Polit & Beck, 2017). Subsequently, interitem correlations were examined, and those exceeding .70 were considered for deletion. If interitem

correlations exceeded .70, an item was removed (Polit & Beck, 2017).

Exploratory Factor Analysis

On the basis of qualitative research, face validity, and content validity processes, a four-factor structure was hypothesized. Considering the possibility of other factor structures, an exploratory factor analysis was selected. Additionally, to find the factor structure that best fitted the dataset pattern, the maximum-likelihood method was selected. Given the potential for multiple factors to be correlated, Promax rotation was selected. The Kaiser-Meyer-Olkin measure confirmed the sampling adequacy. Bartlett's sphericity test was performed to test the hypothesis that the correlation matrix is a unit matrix.

Reliability

Internal consistency was verified using Cronbach's alpha for the subscales and the entire scale. Additionally, descriptive statistics and tests for the normality of the scale were conducted. Furthermore, stability was verified using intraclass correlation via a test-retest method.

Criterion-related Validity

Criterion-related validity was tested using Pearson's correlation coefficient to examine the correlation between the scores and subscales of ELAS and UWES and between the scores and subscales of ELAS and SDLRSNE.

Ethical Approval

Ethics approval was obtained from the Research Ethics Committee of the Graduate School of Nursing, Osaka Prefecture University (Application No. 2019-35). Participants were provided with a cover letter outlining the survey, free will, veto of research cooperation, and protection of personal information. Filling out the consent check items and replying to the questionnaire implied provision of informed consent.

Results

Responses were obtained from 299 participants (response rate: 21.2%), and data containing missing values were excluded. Thus, 290 participants (valid response rate: 20.6%) were included in the analysis. Table 1 lists the characteristics of the participants.

Item Analysis

The ceiling effect for all items on the survey ranged from 3.931 to 6.069, and one item with a score >6 was deleted. The floor effect ranged from 1.727 to 4.671, and no items were deleted. Skewness had a range of .221-.765, and no items were deleted. The kurtosis ranged from .565 to 1.632, and five items with a score >1 were deleted. The CITC ranged from .305 to .691, and no item had a correlation coefficient $<.3$.

The interitem correlations ranged from .069 to .750. The item combinations with correlation coefficients of $\geq .700$ were items 1 and 2 ($r = .706$), 1 and 3 ($r = .748$), and 31 and 32 ($r = .750$). Therefore, item 1 (self-learning with interest in the major diseases of their department) was removed. Similarly, item 32 (adjust the learning environment to suit themselves) was removed because it showed high levels of kurtosis. Item analysis revealed that the number of scale items decreased from 49 to 42.

Exploratory Factor Analysis

Exploratory factor analysis was conducted using the 42 items extracted from the item analysis. The Kaiser-Meyer-Olkin measure of sample adequacy was .887, and Bartlett's sphericity test showed a significant difference [$\chi^2 = 5501.160$, degrees of freedom (df) = 861, $p < .001$]. This demonstrates that factor analysis was suitable for the given data. The analysis was conducted on the basis of factor loadings of $\geq .5$, and four factors consisting of 21 items were extracted from the factor analysis. The cumulative contribution ratio was 43.66%, and the interfactor correlations ranged from .479 to .583 (Table 2). The first factor consisted of six items and was named "behavioral engagement" because it involved learning from relationships with senior nurses and doctors. The second factor consisted of seven items and was named "emotional engagement" because the emotions generated through immersion in tasks were collected. The third factor comprised four items and was named "autonomous engagement" because it involved promoting active self-learning. Finally, the fourth factor consisted of four items and was named "cognitive engagement" because intentional behaviors were collected.

Reliability

Cronbach's alphas for the subscales of the ELAS were .809, .839, .712, and .800 for the first, second, third, and fourth factors, respectively. The overall score of the ELAS scale was .883. The ELAS scores for newly graduated nurses ranged from 51 to 118, with a mean of 90.841 ($SD = 10.728$), skewness of $-.138$, and kurtosis of .056. Kolmogorov-Smirnov's (KS) test ($KS = .034$, $df = 290$, $p = .200$) confirmed that the data followed a normal distribution (Table 3).

Overall, 82 respondents responded (response rate: 53.6%), and 74 responses with no missing values (49.0% valid response rate) were included in the analysis. The intraclass correlation coefficient of the ELAS for newly graduated nurses was .652 [95% confidence interval (CI) = .499-.766, $p < .01$] for the overall scale score, .478 (95% CI = .283-.636, $p < .01$), .549 (95% CI = .369-.690, $p < .01$), .716 (95% CI = .584-.811, $p < .01$), and .450 (95% CI = .249-.614, $p < .01$) for factors 1, 2, 3, and 4, respectively.

Table 1. Participant characteristics.

		<i>N</i> = 290	
		<i>n</i>	%
Age		Mean ± SD	
		22.5 ± 1.6	
Gender	Women	276	95.2
	Men	14	4.8
Months of nursing experience		7.1 ± 0.9	
Placement department	Internal medicine ward	70	24.4
	Surgical ward	73	25.1
	Mixed ward	55	18.9
	ICU/CCU	13	4.4
	ECU	7	2.4
	Pediatrics ward	10	3.5
	Obstetrics ward	10	3.5
	NICU	5	1.7
	Psychiatric ward	3	1.0
	Others	44	15.2
Education system	Preceptorship	211	72.8
	Tutorship	24	8.3
	Mentorship	5	1.7
	Team support type	32	11.0
	Mixed	14	4.8
	Others	4	1.4
In-hospital training attendance	Attended with	288	99.3
	Attended without	2	0.7
Out-of-hospital training attendance	Attended with	141	48.6
	Attended without	149	51.4

Note: SD: Standard Deviation, ICU: Intensive Care Unite, CCU: Cardiac Care Unite, ECU: Emergency Care Unite, NICU: Neonatal Intensive Care Unit.

Criterion-related Validity

The UWES scores ranged from 81 to 173, with a mean of 135.11 (SD = 15.34), skewness of $-.078$, and kurtosis of $-.026$. Pearson's correlation coefficient between the overall UWES and ELAS scores of newly graduated nurses was $r = .454$ ($p < .001$). Pearson's correlation coefficient ($r = .181-.453$, $p < .01$) for all subscales implied a weak positive correlation.

The scores of the SDLRSNE ranged from 80 to 178, with a mean of 121.50 (SD = 16.41), skewness of $.145$, and kurtosis of $.384$. Pearson's correlation coefficient between the scores of the entire ELAS and SDLRSNE showed $r = .393$ ($p < .001$). Pearson's correlation coefficient ($r = .128-.453$, $p < .01$) for all subscales implied a weak positive correlation.

Discussion

The ELAS scores of the newly graduated nurses were normally distributed, making the data appropriate for examining the reliability and validity of the ELAS. From the factor analysis, 21 items were extracted across four factors: behav-

ioral, emotional, autonomous, and cognitive engagements. Watkins (2018) emphasized that there is no universally correct method for determining the number of factors and highlighted the importance of including relevant theories and previous research as evidence criteria. Although previous studies (Katsuyama & Hosoda, 2020; Katsuyama & Hosoda, 2021; Skinner et al., 2009; Reeve & Tseng, 2011) indicated a four-factor model for this scale, we considered the possibility of other factor structures. Exploratory factor analysis was conducted. After examining the eigenvalues, scree plots, and three- and five-factor structures, we determined that a four-factor structure was appropriate.

After exploratory factor analysis, the factor termed "agentic engagement," identified in previous research (Katsuyama & Hosoda, 2020), was excluded, and a new factor termed "autonomous engagement" was extracted. The "autonomous engagement" subscale includes self-learning situations in which learners intentionally adjust their learning. Self-regulated learning, a proactive method of learning in which learners independently plan to achieve goals (Schunk, 2001), is a major indicator of cognitive engagement. Newly graduated nurses reported a lack of self-

Table 2. Exploratory factor analysis of the Engagement in Learning Activities Scale.

		Factor loading			
Item		1	2	3	4
Factor1: Behavioral engagement					
9	carefully observing the interactions between senior nurses and patients	0.843	0.009	-0.136	-0.034
8	carefully observing the work of senior nurses	0.825	-0.06	-0.115	0.052
10	carefully observing how senior nurses prioritize their work	0.722	-0.033	-0.032	0.058
11	carefully observing the work of doctors	0.598	0.007	0.099	-0.087
12	taking notes when you gain new knowledge of practice	0.561	-0.017	-0.045	0.036
41	acquiring advice from senior nurses on how to prioritize	0.541	-0.254	0.066	0.081
Factor2: Emotional engagement					
19	viewing training as an opportunity for new learning	-0.068	0.754	0.076	-0.065
15	experiencing satisfaction when there is a response to one's efforts	-0.023	0.663	-0.035	0.067
18	interested in the nursing practices of other units	-0.254	0.649	-0.036	0.138
20	unity participating in training with enthusiasm for practice	0.248	0.644	0.063	-0.151
17	feeling that training is fun	-0.261	0.564	0.067	0.117
21	studying to better understand patients	0.288	0.521	0.126	-0.030
22	studying to facilitate growth as a nurse	0.180	0.509	0.143	0.020
Factor3: Autonomous engagement					
30	setting your own tasks and working systematically on self-learning	-0.067	0.004	0.776	-0.003
4	self-learning forgot about the time	-0.016	0.071	0.62	-0.124
29	deepening your understanding by utilizing external training	-0.169	0.111	0.564	-0.027
26	deepening your understanding by reading various reference books	0.029	0.11	0.564	-0.041
Factor4: Cognitive engagement					
36	reporting in the awareness that it should be transmitted accurately	-0.030	0.009	-0.052	0.767
37	speaking while being aware of the need to build a relationship of trust	0.043	0.124	-0.226	0.718
35	recalling knowledge obtained through studying when practice	-0.038	0.138	0.092	0.575
34	Imaging applying their actions in practice when observing senior nurses	0.191	0.077	-0.003	0.513
Factor correlation matrix					
Factor1		-	0.506	0.521	0.583
Factor2			-	0.479	0.533
Factor3				-	0.480
Factor4					-

Note: Kaiser-Meyer-Olkin sample validity measure 0.887, Bartlett's Spherical Test ($\chi^2=5501.160$, $df=861$, $p<.001$), Factor extraction method: Maximum likelihood method Rotation method: Promax method with Kaiser normalization.

learning during nursing practice (Okuno, 2016), and in previous research (Katsuyama & Hosoda, 2020), they mentioned engaging in extensive self-learning to acquire practical knowledge, unlike when they were students. Therefore, newly graduated nurses recognize the importance of self-learning, which reflects their intentional adjustment of learning practices.

The subscale labeled "behavioral engagement" refers to the attitude generated by an enthusiastic psychological state, and items on the scale for students include "listening carefully to the instructor" and "participating in discussions in class" (Skinner et al., 2009). The main source of learning for newly graduated nurses is their practical learning experience. Furthermore, the abilities required of newly graduated nurses include "nursing skills," "communication skills," and

"the ability to perform nursing tasks" (Takaya et al., 2013). Specific actions of newly graduated nurses to acquire such abilities by learning from senior nurses and physicians in clinical situations were extracted. For the "emotional engagement" subscale, specific emotions in enthusiastic psychological states were extracted. For newly graduated nurses, learning includes "learning through practice," "learning through participation in training," and "learning through reflection" (Uemura et al., 2016). In this study, emotions in various learning situations-such as training, nursing practice, and self-learning-were extracted. The emotions experienced by a person have been said to affect everything they do, from working and studying to having fun (Izard, 1991/1996). This is an important concept in terms of engagement, and the largest number of items were extracted because

Table 3. Descriptive statistics of the engagement in learning activities scale for newly graduated nurses.

	Range	Min	Max	Mean	SD	Skewness	Kurtosis
Behavioral engagement (6items)	21	15	36	28.131	3.660	-0.105	0.136
Emotional engagement (7items)	35	7	42	31.069	4.828	-0.519	1.593
Autonomous engagement (4items)	18	4	22	13.655	3.220	-0.193	0.104
Cognitive engagement (4items)	13	11	24	17.986	2.550	0.067	-0.422
Overall Score (21items)	67	51	118	90.841	10.728	-0.138	0.056

N = 290

one's approach to learning changes depend on one's emotions. In the subscale "cognitive engagement", newly graduated nurses acted with the intention to "report accurately" and "build trust in relationships," and situations in nursing practice involving newly graduated nurses intentionally adjusting their learning were extracted. Practical learning in nursing involves the acquisition of knowledge through repeated reflective thinking and the development of deeper insights and thought during practical activities (Mitsuhashi, 2003). Therefore, newly graduated nurses consciously act to achieve deep levels of learning by relating their thinking during practice to what they have self-learned and by imagining what it will be like when they practice themselves. The cumulative variance contribution rate being <60% is attributed to the need for further examination of the representation of scale items. Future studies should ensure language uniformity, avoid including multiple inquiries within items, and take measures to facilitate factor coherence.

In this study, each subscale was extracted from items developed on the basis of previous research and is considered appropriate as an indicator of engagement in the learning activities of newly graduated nurses. In criterion-related validity, there was a weak to moderate correlation observed between ELAS and UWES, as well as between ELAS and SDLRSNE. Therefore, the criterion-related validity (concurrent validity) of ELAS for newly graduated nurses was ensured. Cronbach's alpha was calculated to examine internal consistency. The acceptable value of Cronbach's alpha is said to be .70 (Taber, 2018). For all subscales, Cronbach's alpha was >.70, indicating that this scale is reliable. In this study, given that the acceptable value for a reliable correlation coefficient in test-retest reliability is considered $\geq .7$ (Wheeler, 2014), the results indicated insufficient stability, as the observed intraclass correlation coefficient between the study and retest was below this threshold.

The ELAS consists of 21 items with four subscales and is simple to use. Substantive improvements in education require information about major student experiences (the process) and outcomes (Astin, 1984) and should consider how learners' participation in learning can be improved, rather than how outcomes are improved (Ewell, 1988). Engagement occurs when learners are active participants in learning

(Pace, 1982). Given that newly graduated nurses are often treated as passive subjects, they can improve their approach to learning by objectively understanding whether they are actively participating in learning activities and the status of their involvement. Nurses who are educators can obtain objective data on the quality of their involvement in teaching newly graduated nurses. Sharing information among educators can help identify specific points in the learning environment and teaching methods that require correction. This information will also serve as a resource to support newly graduated nurses.

Limitations and Future Implications of This Study

In this study, the correlation coefficient for the retest was low, indicating insufficient reliability. Furthermore, engagement in learning activities is a situational motivation in individual situations and is influenced by daily experiences. Newly graduated nurses, in the process of adaptation, turn their experiences into positive ones through interactions with preceptors and colleagues (Wildermuth et al., 2020). The perception of their experiences affected their engagement in learning activities, leading to insufficient reliability. Future studies should examine the effects of experiences on engagement and investigate the stability of ELAS among newly graduated nurses after considering the retest period.

Conclusions

Understanding the quality of efforts of newly graduated nurses (i.e., learners) in learning is important when considering their education. The reliability and validity of the ELAS for newly graduated nurses were examined. The scale comprises four subscales-behavioral, emotional, autonomous, and cognitive engagements-and 21 items. Furthermore, the ELAS for newly graduated nurses displayed criterion-related validity and internal consistency. However, further studies are necessary because the reliability of the scale did not meet the required standards. The ELAS for newly graduated nurses will help motivate nurses to engage in learning activities and consider effective ways to support them.

Author Contributions

Ai Katsuyama: Substantial contribution to conception, design, data collection, analysis, and manuscript writing.

Yasuko Hosoda: Critical review of important intellectual content, final approval of the published version, and overall accountability

Declaration of Conflicting Interests

The authors declare that there are no conflicts of interest.

Ethical Approval

The study was approved by the Research Ethics Committee of the Graduate School of Nursing, Osaka Prefecture University.

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Original Research

Impact of the coronavirus disease 2019 (COVID-19) pandemic on children and youth with special needs and their families in Japan and support issues

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Abstract

Objective: To elucidate the impact of the coronavirus disease 2019 (COVID-19) pandemic on children and youth with special needs, their families, and their supporters in Japan. **Methods:** This qualitative descriptive study was carried out via focus groups. Participants were care providers and family caregivers of children and youth with special needs. In the survey, the participants were asked about the changes in physical and mental health, caregiving status, and multidisciplinary collaboration during the COVID-19 pandemic. **Results:** The categories of the impact of the COVID-19 pandemic on children and youth with special needs and their families were [Concentration of burden on primary caregivers], [Mental stress of the primary caregiver], [Mental and physical impact on children and youth with special needs], [Dissatisfaction/anxiety about changes in social interactions], [Sibling/family mental stress], and [Increased risk of abuse due to lack of respite]. The problems encountered by service providers during the pandemic included [Difficulty in utilizing social resources], [Disparities in the use of support services and systems], [Problems due to the changes in the way people go to the hospital], [Difficulties in assuring quality of professional care], [Challenges in organizing a pediatric home care team], and [Need to understand a diverse group of children and youth with special needs]. **Conclusions:** Our data suggest the need for support to replace family caregiving, as the burden is concentrated on the primary caregiver. In the future, a system will be required to promptly respond to the special needs of each child through the collaboration of the government, hospital, and community.

Keywords

COVID-19 pandemic, children and youth with special needs, parents, supporters, inequality

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Introduction

As reported in many studies, the impact of the coronavirus disease 2019 (COVID-19) pandemic on children and youth with special needs and their families is wide-ranging, with some of the impact being serious. Among them, the largest study on children and youth with autism reported the impacts of the COVID-19 pandemic including eating and sleeping problems, stress, worsening of symptoms of autism, appearance of aggression and violence, and the possibility of losing previously learned skills (Stankovic et al., 2022). In terms of intellectual disability, remarkable reductions in gross and fine motor skills among non-active children and youth (Sedaghati et al., 2022), as well as no specific changes (Bailey et al., 2021), have been reported. In a study that involved children and youth with special educational needs, the lockdown resulted in the loss of community interaction, daily routine changes, behavioral disturbances, tantrums, and anxiety/depression (Asbury et al., 2021), but lesser anxiety was reported in children and youth with Down syndrome and their families (Sideropoulos et al., 2022). Approximately 80% of children and youth with audiovisual impairments were unaware of any particular health changes, but approximately half of them experienced sleep disturbances during lockdowns, with those having visual impairment more likely to experience such changes and to have communication difficulties due to wearing masks (Bubbico et al., 2021). Sleep disturbances, increased muscle tone, limited range of motion, and decreased physical activity are noted in patients with cerebral palsy (Bıyık et al., 2021).

Alongside these changes in children and youth with special needs, families had a difficult time managing their children's symptoms during the COVID-19 pandemic (Gillespie-Smith et al., 2021); they were isolated (García-Azorín et al., 2021; Goswami et al., 2021; Jeste et al., 2020; White et al., 2021; Zhang et al., 2022) due to a lack of resources, and interactions with other people were limited (Gallegos et al., 2022); and they experienced increased anxiety, depression, and parenting stress, which led to decreased physical health, quality of life, and sense of well-being (Suarez-Balcazar et al., 2021). This has led to increased alcohol use and suicidal ideation among young people and men (Thomson et al., 2021). In Zambia (Hearst et al., 2021) and Serbia (Stankovic et al., 2022), a scarcity of food, shelter, and transportation; lower income; and increased risk of neglect were evident.

The impact of the COVID-19 pandemic was observed not only on children and youth with special needs and their families but also on the management of health services. In previous studies, 74%-100% of parents reported that the COVID-19 pandemic resulted in poor access to medical institutions (Goswami et al., 2021; Jeste et al., 2020; White et al., 2021; Zhang et al., 2022). In terms of rehabilitation,

63%-87% of the participants did not receive such services (Stankovic et al., 2022; Bubbico et al., 2021; Bıyık et al., 2021; Faccioli et al., 2021), 47% stopped receiving respite care in Canada (Fortin-Bédard et al., 2023), and 60% of the parents in India felt that access to emergency care was difficult (Tetali et al., 2022). The impact of these changes on the ability of children and youth with special needs and their families to access hospital services must also be clarified.

Likewise, in Japan, the COVID-19 pandemic caused great disruption in medical services, but no study has elucidated how it affected children and youth with special needs and their families. Therefore, this study, conducted via focus groups (FGs), aimed to clarify the impact of the COVID-19 pandemic on children and youth with special needs, their families, and their supporters in Japan and their responses to the pandemic. The impact in this study was defined as a psychosocial change due to a rapid and sustained change caused by the COVID-19 pandemic.

Materials and Methods

This qualitative descriptive study was conducted via FGs from January 2021 to February 2022. This research method was considered the best for various professionals and families to reflect on their experiences of being involved in a coronavirus disaster.

The participants were nurses, consultation support specialists, and primary family caregivers of children and youth with special needs. In this study, a special need is defined as the need for any kind of care or medical care for physical or mental disabilities. The consultation support specialist works in the consultation support office and is primarily responsible for developing care plans for children and youth with physical and mental disabilities and providing them access to various social services and support teams. Their role will also include leadership of the care team. The criteria for selecting the family members were as follows: They were not afraid to speak in front of professionals, as speaking in front of medical professionals or other experts could be a psychological burden, and they had professional credentials. The researchers performed the recruitment of study participants. Individuals with at least 5 years of clinical experience in handling children and youth who required medical care and the families of these children and youth were selected as supporters.

The research description was sent to the participants who gave informal consent via telephone, and the schedule was adjusted so that there would be two or more participants in one FG as much as possible. Multiple FGs were conducted online to ensure that as many as two or more participants possible were in one study. The FGs were carried out in a way that professionals and family members could participate together. As basic information, professionals were asked

about their job title, years of experience, and the institution they belong to, whereas the families were asked about the age of their children and youth with special needs, main diseases and disabilities, family structure, and so forth. The main questions were the same for both groups, and concerning the impact of the COVID-19 pandemic, the groups were asked about their physical and mental conditions, infection preventive behaviors, caregiving situation, and multiagency and multiprofessional collaborations. The FGs were recorded using IC recorders, and verbatim transcripts were made. To ensure anonymity, proper nouns that could identify the individuals were avoided. The method of analysis involved coding the parts of the FGs that described the impact observed on children and youth with special needs and their families and the challenges encountered by service providers via semantic cohesion and categorizing the codes by comparing and contrasting their similarities and differences. Without any particular distinction, the family and professional narratives were analyzed. The methodology is based on qualitative inductive methods regarding content analysis methods (Funashima & Sugimori, 1997). Multiple researchers carried out and thoughtfully considered the analysis, and an agreement on the content of the analysis was met. The categories are indicated by [], subcategories by “ ”, and codes by < >.

Ethical Considerations

The ethics committee of the authors' institution approved the present study (ID number 2020F10).

Results

COVID-19 Pandemic Status and Study Participants

Among the pandemic waves of COVID-19 in Japan, the first FG was organized on the third wave (January 2021), and the second and third FGs were organized on the sixth wave (February 2022) when the Omicron strain was rampant.

The present study had seven participants, with three in the first FG, two in the second, and two in the third. The participants comprised five nurses, one consultation support specialist, and two mothers of children and youth with special needs (multiple responses). The average age of the children and youth with special needs taken care of by the mothers was 21.5 years. All of the professionals had at least 5 years of clinical experience.

Impact of the COVID-19 Pandemic

To determine the impact of the COVID-19 pandemic on children and youth with special needs and their families, 6 categories, 15 subcategories, and 30 codes were extracted (Table 1).

Concentration of Burden on Primary Caregivers

Children and youth with special needs and their family's “Livelihoods are not possible without access to social re-

source.” In this situation, “Critical care can only be provided by the primary caregiver,” in which “Limited support is available from sub-caregivers.” “If something happens to the primary caregiver, there is no one to provide medical care for the child”; consequently, the “Primary caregiver is very restrained in attending to the children and youth with disability.”

Mental Stress of the Primary Caregiver

The subcategory “increased emotional stress for primary caregivers due to restricted outings” was identified. Moreover, codes including <parents feel stressed out when home care nurses visit wearing personal protective equipment, as if they are treated like an infected person> led to the identification of the subcategory “mental stress of primary caregivers regarding continuation of care during the COVID-19 pandemic.”

Mental and Physical Impact on Children and Youth with Special Needs

The following two subcategories were extracted: “decreased opportunities for exercise due to restricted outings” and “mental stress due to restrictions on overnight stays for children and youth with special needs in residential care.” In the latter subcategory, the code <children and youth with special needs in residential facilities used to be able to stay overnight with their parents, but now they are only allowed to see their parents through the window, which is mentally difficult for them> was determined.

Dissatisfaction and Anxiety about the Changes in Social Interactions

The first changes in social interactions were the “changes in schooling and working patterns and anxiety during the COVID-19 pandemic,” with the main codes being <not being able to return to work because daycare centers for children and youth with special needs were not available when the state of emergency was declared>. In the second subcategory, “changes and dissatisfaction with how they communicate with the mothers,” we identified the code <It is not that we cannot communicate and talk via Zoom or LINE, but we cannot contact each other easily>.

Siblings and Family Mental Stress

The subcategories were “siblings' mental stress due to restricted outings” and “sibling and family mental stress due to lack of respite.” The codes for the category were <The number of days of short-term stay for children and youth with severe mental and physical disabilities has decreased even before the COVID-19 pandemic, which has led to sibling resentment>.

Increased Risk of Abuse due to Lack of Respite

One subcategory was “emergence of physical abuse due to stress of lack of respite,” with codes such as <during the COVID-19 pandemic, children and youth with special needs were often discharged home from short-term care due to fever and so on, and siblings beat and kicked them>. Another

Table 1. Impact of the COVID-19 pandemic on children and youth with disabilities and their families.

Category	Subcategory	Cords
Concentration of burden on primary caregivers	Critical care can only be provided by the primary caregiver.	Family members cannot leave their seats to change the fixation cord of the tracheal cannula during hair washing, even when visited by the caregiver. Family members bear the burden of caring for their children and youth with special needs when the caregiver is unable to do so. When the main caregiver is a pregnant mother and gives birth, the secondary caregiver requires the support of home nursing.
	Primary caregiver is very restrained in attending to disabled children.	In hospitals that require an escort on admission during the COVID-19 pandemic, the escort is subjected to antibody and PCR testing, cannot be replaced by other family members, and is forced to live a very restricted and burdensome life.
	If something happens to the primary caregiver, there is no one to provide medical care for the child.	When the main and secondary caregivers were infected, the children could not be left at the hospital as they would also be considered as close contacts, and home nursing care was only provided when necessary, which placed a very heavy burden on the family. Simulating who would look after the child was difficult, as it was challenging to envisage what would happen if the main caregiver contracted the coronavirus infection. If something happens to the main caregiver, i.e., the mother, the father alone cannot take care of the child, but it is difficult to avail of the new services during a pandemic, and home nursing compensates. If the main caregiver is the mother who has to give birth, the children have to be looked after by a family member with little caregiving experience.
	Limited support available from sub-caregivers	The carer's siblings do not provide any assistance with medical care. If the maternal grandmother was originally a medical professional, she can assist with suctioning and infusion.
	Livelihoods are not possible without access to social resources	It was believed that social resources would provide care services for children and youth with special needs as well as employment and care for other family members, but in reality, this was not possible. When children and youth with special needs are discharged from the hospital, the burden of care for the mother is high without home nursing. Pregnant mothers have to leave their children in short-term care or other facilities, when necessary, even during a pandemic.
Mental stress of primary caregiver	Increased emotional stress for primary caregivers due to restricted outings	Parents themselves also experience stress from being restricted from going out. Two weeks of restraining themselves from going out due to intense contact is both physically and mentally taxing.
	Mental stress of primary caregivers regarding the continuation of care under COVID-19	Parents are stressed out because they feel like they are treated like infected people when they are visited by professionals wearing protective clothing during home care. At the beginning of the spread of coronavirus infections, parents also endured a lot of stress, and when they sought professional help online, they were tearful and wanted someone to listen to them.
Mental and physical impact on children and youth with disabilities	Decreased opportunities for exercise due to restricted outings	Children and youth with reduced physical function have fewer opportunities for physical activity due to pandemic restrictions in terms of going out.
	Mental stress due to restrictions on overnight stays for children and persons with disabilities in residential care	Children in residential care cannot visit their parents. Children and youth in residential facilities used to be able to stay overnight with their parents, but now, they are only allowed to see their parents through the window, which is mentally difficult for them.
Dissatisfaction/anxiety about changes in social interactions	Changes in school and work patterns and anxiety under the COVID-19 pandemic	Not being able to return to work because daycare centers for children and youth with medical care were not available when the state of emergency was declared. The children attended school without any change in their daily routine despite the coronary disaster, but school events have also been cancelled, and they felt that this was not good enough. In residential care facilities adjacent to schools, children in residential care are no longer allowed to attend school because of infection control measures.
	Dissatisfaction with the way they interact with their mothers' friends	It is not that we cannot communicate and talk via Zoom or LINE, but we cannot contact each other easily. Parents feel that texting their friends as a form of interaction is insufficient.

Table 1. Impact of the COVID-19 pandemic on children and youth with disabilities and their families (continued).

Category	Subcategory	Cords
Sibling/family mental stress	Siblings' mental stress due to restricted outings	Parents were concerned about the mental health of their siblings who lived alone in other prefectures, as they had not been able to see them for 2 years due to voluntary restrictions on going out.
	Sibling and family mental stress due to lack of respite	The number of days of short-term stay for children and youth with severe mental and physical disabilities has decreased when compared with that before the COVID-19 pandemic, which has led to resentment from siblings. The whole family is stressed out because of the long periods of staying at home due to the suspension of the daily operations of treatment and education facilities because of the rapid increase in the number of infected patients.
Increased risk of abuse due to lack of respite	Emergence of physical abuse due to stress of lack of respite	During the COVID-19 pandemic, children and youth were often returned from short-term care due to fever and so on, and siblings beat and kicked children and youth in medical care.
	Emergence of neglect due to exhaustion of lack of respite	Caregivers were exhausted because of the unavailability of short-term care and residential care during the COVID-19 pandemic, increasing the risk of neglect and other forms of abuse.

subcategory was “emergence of neglect due to exhaustion from lack of respite,” with codes such as the <caregivers were exhausted due to the unavailability of short-term and residential care during the COVID-19 pandemic, increasing the risk of neglect and other forms of abuse>.

Problems Encountered by Service Providers during the COVID-19 Pandemic

Table 2-4 show the categories and subcategories of the problems encountered by service providers during the COVID-19 pandemic. Six categories, 25 subcategories, and 71 codes were extracted.

Difficulty in Utilizing Social Resources

The subcategory “unable to receive the home-visit care they used to receive” was identified. The other subcategories were “unable to use the respite service with transportation that they have been receiving previously,” “unable to use the in-home or outpatient rehabilitation services that they have been receiving previously,” and “unable to use home-visit nursing services that they have been receiving previously.” It was also revealed that due to the “high financial burden of home nursing costs,” it was impossible for them to use home-visit nursing.

Disparities in the Use of Support Services and Systems

In this category, the following four subcategories were found: “differences in care and services depending on the available financial resources and discretion of city and town officials,” “disparities in social resources based on regional characteristics,” “difference in response by the staff-in-charge,” and “differences in services used by parents depending on the information that they have.”

Problems due to the Changes in the Way People Go to the Hospital

In the subcategory “unable to connect to a medical facility or delays in connecting to a medical facility due to restrictions on hospital visits,” the code <when children and youth

with special needs have a fever, they are required to have a PCR test at another hospital before being seen, and it takes several days before they can be seen by their family doctor> was extracted. The subcategories “discharged from the hospital unprepared and uncoordinated due to concerns about developing an infection during hospitalization,” “incomplete discharge coordination with the home care team,” and “discharged from the hospital without parental connections” were extracted. During the COVID-19 pandemic, we also identified “anxiety related to uncertainty of hospitalization in the event of an infection.”

Difficulties in Assuring the Quality of Professional Care

The subcategories “difficulties in training professionals involved in pediatric home care” and “the increasing advancement of care required in pediatrics” were extracted. Conversely, in the subcategory, “little evidence on quality of care,” the code <some rumors, including the virus eliminating effect of the artificial noses used by children, have circulated, but there is little reliable information> was identified. In the category “difficulty in balancing the implementation of infection control measures and assurance of quality of care,” the following codes were extracted: <there is a method to limit the duration of home-visit nursing care to ≤15 min to prevent the spread of infection, but in the case of children and youth with special needs, it is difficult to limit the time of care because of the child’s need for assistance in expectoration, toileting, and hygiene most of the time>.

Challenges in Organizing a Pediatric Home Care Team

The subcategories of “limited human resources to support pediatric home care” and “limited compensation for personnel supporting pediatric home care providers” were extracted. The present study also revealed the problem of “lack of networking among multidisciplinary professionals in the pediatric home care setting” and “premature networking among multidisciplinary professionals involved in pediatric

Table 2. Impact of the COVID-19 pandemic on healthcare service and health professionals.

Category	Subcategory	Cords
Difficulty in utilizing social resources	High financial burden of home nursing costs	Parents want to use home visit nursing but cannot because it is too expensive. Parents find it challenging to use home visit nursing because it is too expensive if they do not have access to the medical aid scheme.
	Unable to use home nursing as before	Parents attempt to reduce the risk of infection by reducing the number of home nursing visits. They used to ask nursing care professionals to accompany them to the hospital, but they are no longer able to use this service due to the prevention of COVID-19 infection.
	Unable to receive the home-visit care they used to receive	Normally, family members could accompany the patient to hospital, but during the coronary disaster, this was limited to the parents. The hospital escort was provided by a care worker, but due to infection preventive measures, this was no longer available, and the relative had to care for the patient alone.
	Unable to use the respite service with transportation that they have been receiving	Short-term residential facilities were closed due to the corona disaster. Treatment and education facilities had to be suspended due to a sharp increase in the number of infected people. The city issued a request to suspend day services. Many short-stay and day-service establishments stopped accepting patients. Short-term accommodation was not available due to the coronary disaster. Even when this could be used, the duration had to be shortened because of the need to take a PCR test the day before admission and because they were located far away. To avail of the short-stay service, a hospital visit is required, but because of the absence of a corresponding doctor, the patient is unable to use the service. The parents had to take the child to and from the residential and day care services as car transport services were no longer available. If a previous short-term residential facility was suspended, the child had to use another short-term residential facility from a distant location, which was an hour drive away. The child had been attending several rehabilitation facilities, but owing to the coronary disaster, these facilities were reduced to one.
	Unable to use the in-home or out-patient rehabilitation services they have been receiving	Rehabilitation was not available due to restrictions placed on rehabilitation by the treatment and education facilities. In-home rehabilitation is not available due to infection control measures, which results in increased cases of contractures. Before the coronary disaster, training was carried out simultaneously for residents and day carers, but after the coronary disaster, the number of training sessions was reduced from twice to once a week in order to limit the number of close contacts. Parents are unable to perform the activities at the rehabilitation center at home, so children have less time to move.
Disparities in the use of support services and systems	Differences in care and services caused by the financial resources and discretion of cities and towns	Under the Long-Term Care Insurance Act, the support is the same throughout the country, but under the Comprehensive Support for Persons with Disabilities Act, the support varies from city to city. Children necessitate sputum suctioning when being driven to day care or residential facilities, but some prefectures do not permit the use of home visit nursing during transport. Furthermore, even if it is recognized by the prefecture, nursing care during transport may not be recognized by the city or town. Depending on the local government's finances, the accessibility and disaster response are not different between regions.
	Disparities in social resources based on regional characteristics	Regional disparities in social resources exist. There are regional disparities in terms of the response of hospitals and health centers, even within the prefecture, depending on the size of the population, such as difficulties in contacting health centers in more populated areas.
	Difference in response by staff in charge	There is a difference in the response depending on the official in charge.
	Differences in services used by parents based on the amount of information they have	There are parents who can obtain information on social resources on their own, notice regional disparities, and negotiate with the municipality themselves, but there are those who cannot.

Table 3. Impact of the COVID-19 pandemic on healthcare service and health professionals.

Category	Subcategory	Cords
Problems due to the changes in the way people go to the hospital	Unable to connect to a medical facility or delayed in connecting to a medical facility due to restrictions on hospital visits	When children and youth with special needs have a fever, they are required to have a PCR test at another hospital before being seen by a doctor, which could take several days. Due to the coronary disaster, medical institutions restricted the admission of new patients or hospital visits of patients. Parents alone cared for their children and youth with day and night respirators because they were unable to avail of new health services due to relocation or other reasons. At the beginning of the corona pandemic, parents were reluctant to see their children because they did not want them to be infected, but this was less common after the sixth wave.
	Discharged from the hospital unprepared and uncoordinated due to concerns about infection during hospitalization	An increase in the number of parents of hospitalized children and youth who were concerned about the spread of infection and wished to be discharged early without any preparation. Parents of hospitalized children and youth perceived that they could be discharged once they know how to perform suctioning, tube feeding, and respiratory care, and there was an increase in the desire to be discharged without staying overnight in the hospital. In the wards, there was an increase in the number of people who were discharged receiving appropriate care, although they also wanted to proceed with respite services and emergency suctioning after discharge and in anticipation of long-term fatigue. For families, if there is only so much they can do in the wards, they hope that the patients go home early, considering the risk of infection.
	Incomplete discharge coordination is passed on to the home care team	Children and youth with underlying medical conditions have difficulty in understanding the symptom changes. Difficulty in understanding the situation after being discharged from hospital. Unable to fully adjust before discharge due to the lack of test performed during overnight stays at the hospital.
	Discharged from the hospital without being able to make parental connections	Before the COVID-19 pandemic, hospital nurses used to introduce families with the same medical care, such as those with children and youth requiring tracheostomy or ventilator, to each other, creating a support group among them, but this is not possible now. After the COVID-19 pandemic, hospital nurses referred parents to parent associations.
	Anxiety related to uncertainty of hospitalization in the event of infection	Whether a family member can be admitted to a hospital if the beds are full when he or she develops a disease is uncertain. After the COVID-19 pandemic, even for children and youth on ventilators, it was not possible to decide in advance where the caregiver would be admitted in case of an infection. Because the child is on a ventilator, it was not possible to predict whether he would be cared for at home or hospitalized if he develops a COVID-10 infection.
Difficulties in assuring quality of professional care	Little evidence for quality assurance of care	Some rumors circulated that the artificial noses used by children and youth may have a virus-eliminating effect, but there is little reliable information about this. There is little information on the actual situation, as no pediatric respirator user has actually been infected with COVID-19.
	Difficulty in balancing the implementation of infection control measures and assurance of quality of care	There is a method to limit the duration of home-visit nursing care to ≤15 min to prevent spread of infection, but in the case of children and youth, it is difficult to limit the time of care because of the child's need for assistance in expectoration, toileting, and hygiene most of the time. Using a face shield while providing care was a concern as the child's head and face could be touched, and they might injure themselves.
	Difficulties in training professionals involved in pediatric home care	Motivation and professionalism are also important for the nurses. As the methods of medical care differ between home visit nurses, it is necessary to unify the techniques. It is desirable for consultation support specialists to have a medical background as an aptitude. Training for coordinators of children and youth in medical care is provided based on a curriculum, but if the training becomes a mere formality and only carried out to obtain additional fees, it does not contribute to improving the quality of the profession.
	The increasing advancement of care required in pediatrics	Although there has certainly been an increase in the interventions that can be done at home, there is a reckless desire to do home care interventions that are beyond the family's skill level and that can only be done in the hospital.

Table 4. Impact of the COVID-19 pandemic on healthcare service and health professionals.

Category	Subcategory	Cords
Challenges in organizing a pediatric home care team	Limited human resources to support pediatric home care	As there are few speech-language pathologists available for children and youth in the home healthcare team, arrangements are made for visits to be less frequent and with a wider range of visits. In both before and after the COVID-19 pandemic, the consultant support specialist is not able to work with the hospital due to a lack of personnel. Among those qualified to become a “coordinator for medical devices,” only a few are actually carrying out the coordination.
	Limited compensation for personnel who support pediatric home care providers	Training courses for coordinators for children and youth with medical devices have been established, but remuneration is not in place. Additional payments to establishments for the treatment of consultation support specialists are not sufficient.
	Premature networking among multidisciplinary professionals in pediatric home care	Hospital nurses do not receive timely information on model projects and prefectural trends related to pediatric home care; hence, they are unable to utilize this information in family care. The ward nurses are unable to obtain all required information, so they ask the coordinators. Although we hear about people who have received training as coordinators for children and youth in medical care, there are no people with this qualification involved in discharge support at hospitals, and we have not met qualified individuals in the field and do not know how we can find them.
	Lack of common understanding of procedures among facilities, hospitals, and government	When one parent was told that her child needed a PCR-negative certificate for her to avail of day services, she went to the hospital where the test was done and was told that the certificate could not be issued because the PCR test was not done based on the instructions of the health centre. The procedures were not consistent at the respective establishments.
Need to understand a diverse group of children and youth with special needs	Care needed for children and youth with disabilities varies widely by disability	Many children have medical care needs, from very mild to very severely ill. Children and youth with severe disability cannot move on their own; hence, care providers were more likely to keep their distance, so facilities were able to care for them as regular cases. In the case of children and youth with severe mental disability who were able to move, infection prevention was very difficult to perform and facilities strictly require that these measures be performed
	Large differences in family attitudes about the care needed for children and youth with disabilities	Family’s attitudes toward infection control varied widely; in some cases, hand washing and disinfection were sufficient, whereas in others, use of protective clothing and gloves and preventive measures were required. In some cases, families who would even refuse visiting services to prevent infection were taken seriously.
	Lack of variation in measures tailored to disability characteristics	When society as a whole is affected by the coronary disaster, individual disabilities are not understood or considered. The existence of children and youth with disabilities who cannot wear masks, as an infection control measure, is not known. Generally, there are many children and youth with disabilities who cannot easily adapt to changes in their environment, such as going to places that they do not know, even as a preventive measure against the spread of infection. A nurse, unaware that a child with a fever had a disability, responded to an outpatient call at a general hospital in the same way she would normally respond to a child with a fever and was sent around. The child and parents could not go anywhere because the children could not wear masks because of their disability and they could not stay in one place.

home care.” Moreover, the issue of “lack of common understanding of procedures among facilities, hospitals, and government institutions” was determined.

Need to Understand a Diverse Group of Children and Youth with Special Needs

The survey revealed the subcategory “care needed for children and youth with special needs varies widely according

to their disability,” which included the code <the existence of children and youth with disabilities who cannot wear masks, which is an infection control measure, is not known>. In the subcategory “large differences in family’s attitudes about the care needed by children and youth with special needs,” the code <there is a wide range in the families’ approach to infection control, with some families just

washing and disinfecting their hands, while others require the use of protective clothing, hats, and gloves as well> was found. Additionally, in the subcategory “lack of variation in measures tailored to the disability’s characteristics,” the code <a nurse, unaware that a child with a fever had a disability, responded to an outpatient call at a general hospital in the same way she would normally respond to a child with a fever and was sent around>.

Discussion

Effects on Children and Youth with Special Needs and Their Families

In the present study, FGs involving children and youth with special needs, their families, and their supporters were conducted to clarify the impact of the COVID-19 pandemic on children and youth with special needs and their families in Japan, as well as the measures taken to address these issues. In Japan, the burden of caregiving was concentrated on the primary caregiver, usually the mother, and as with the spread of COVID-19 infection, the physical and mental stress of the primary caregiver increased, and the mental health of siblings was also affected. Therefore, mental health care for the primary caregivers was considered important. It was suggested that home-based caregiving quickly disintegrates when the primary caregiver becomes unable to care for the child and youth with special needs due to the spread of infectious diseases.

To ensure family care is continued, mental health care interventions that can be done at home during lockdown must be promoted (Abdat et al., 2023; Isik et al., 2023; Lillie et al., 2021). Several previous studies have reported the need for such support. The measures to enhance self-help capabilities include virtual training on stress management for parents of children and youth with special needs (Abdat et al., 2023) and mask-wearing training for children and youth with autism, which have been reported to have some success (Lillie et al., 2021). For some families, focusing on the idea that “these days will end someday” by engaging in self-activities (such as journaling and exercise) to maintain a stable sense of normalcy, attending free online access to museums and zoos, and active use of telemedicine is effective for some individuals (Isik et al., 2023).

Regarding the prevalence of COVID-19 in Japan, when our study began, most of the patients with COVID-19 infections were aged >70 years. In the first survey, the child-rearing generation was not familiar yet with COVID-19, and it was difficult for them to have a concrete image of what it would be like to be infected. Nevertheless, vaccination began during the fourth wave, and the number of individuals with infections aged >70 years decreased. During the sixth wave, the number of infected persons aged <10 years, and those in their teens increased remarkably. In the second and

subsequent waves of interviews, as cases of pediatric COVID-19 infections have been reported, there was an increase in the codes about mental stress. There was also an increased risk of physical abuse and neglect due to prolonged lack of respite, rehabilitation, and other services. For children and youth with severe mental and physical disabilities and medical care and their families, there was a lack of information about the disease; hence, although they have an imminent risk of developing the infection, they were unable to decide on what to do in case an infection develops in the family.

Hence, correct information must be promptly provided to children and youth with special needs and their families. Telemedicine is believed to offer significant advantages to children and youth with special needs who experience difficulties with mobility and their families. Previous studies examining telemedicine for children and youth with mental impairment (Selick et al., 2023) and autism (Burke et al., 2022) have reported that >80% of parents of children and youth with neurodevelopmental disabilities were highly satisfied with telerehabilitation (Frigerio et al., 2022). Nevertheless, some populations have difficulty accessing telemedicine, with single-parent families, those with low educational levels (high school), those with a low income, and those with older children; part-time workers; and men reportedly less likely to receive services (Gonzalez et al., 2022). Although this study also noted disparities in the services between regions, the abovementioned disparities related to telemedicine should be noted.

In terms of education, appropriate information has been provided by the government through its website. Nevertheless, the dissemination of information to children and youth with special needs who have various characteristics can probably be improved. For example, codes including “In infection control measures, understanding of the individual characteristics of children and youth with disabilities that they cannot wear masks should be given” were extracted, even if masks are required to be worn in schools. The information on the website lacked information on the level of consideration that could be given, and information on individual consultation services was considered important.

Impact on Medical Institutions and Services and Countermeasures

This study also found that the COVID-19 pandemic also caused difficulties in accessing medical facilities and utilizing social resources for welfare. Moreover, the COVID-19 pandemic has changed the way people go to the hospital. Increasingly, children and youth with special needs are discharged from the hospital without any coordination, which makes it more challenging to maintain the quality of pediatric care and to build home care teams. Considering that pediatric home care in Japan varies per municipality, a disparity between municipalities that were able to move flexibly to

address these issues and those that were not was observed.

Previous studies have reported the impact of the unavailability of respite services on siblings. A previous qualitative study that involved siblings (Bichard et al., 2022) reported that they were also burdened with helping their siblings with special needs at home when school was canceled, which affected their ability to work on their school activities. It has also been reported that 75% of children and youth with special educational needs have been bullied or hurt by their siblings, which is more common among children and youth with mild disabilities than among those with severe disabilities (Toseeb, 2022). One in three siblings bullies a child with a disability almost daily, and siblings who are younger than the child with a disability have better language skills and do not have an Education, Health and Care Plan and are more likely to engage in bullying (Toseeb, 2022). In Japan, due to the shortage of consultation support specialists, care planning has been widely used among all families. Based on the results of the previous studies mentioned above, an approach on how to expand the care management services that target the entire family must be established.

Lack of staff was due to the unavailability of medical facilities, considering that many medical staff became concentrated contacts of COVID-19 and many retired. In the United States, the rapid turnover of professionals who directly support children (persons) with disabilities during the COVID-19 pandemic has led to an investigation of factors that increase staff resilience during these stressful and difficult times (Desroches & Tyo, 2023). To ensure that family physicians of children and youth with disabilities can continue to provide care in preparation for further pandemics, measures to prevent turnovers in such emergencies should also be taken.

The limitations of the present study included the small sample size and the fact that the study was conducted at two time points. Despite these limitations, we believe that our study is a valuable resource because it describes how the COVID-19 pandemic affected children and youth with special needs and their families in Japan. The daily care of children and youth with special needs is highly dependent on their primary caregivers. Therefore, the social resource systems must be expanded, and mental health measures that families can utilize themselves in case public services are temporarily unavailable due to a pandemic should be promoted. The government must make efforts to correct disparities between municipalities from normal times in preparation for emergencies, such as the spread of COVID-19 infection. Furthermore, a system that enables smooth cooperation between the government, hospitals, and communities and ensures that information reaches children and youth with special needs and various characteristics must be developed.

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Author Contributions

KO contributed to the conception and design of the study, data collection, data analysis and interpretation, drafting of the Introduction and Discussion sections, and critical revision of the manuscript. CH contributed to the study conception, data collection, data analysis, and drafting of the Results section. KF contributed to the data collection, data analysis and interpretation process, and drafting of the Methods section. JH and TY contributed to the study conception, data collection, and data analysis and interpretation process.

Declaration of Conflicting Interests

None.

Ethical Approval

Approval for this study was given by the Institutional Review Board College of Nursing Art and Science, University of Hyogo, and Research Institute of Nursing Care for People and Community (ID number 2020F10).

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Original Research

Factors related to subjective well-being among nurses working in hospitals in Japan

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Abstract

Objective: Given nurses' workload and demanding professional life, this study explored subjective well-being and associated factors among nurses employed in hospitals in Japan. **Methods:** An anonymous self-administered questionnaire survey was given to 1,359 nurses working in two university hospitals in Japan. Subjective well-being (mental health and fatigue) was assessed using the Japanese version of the Subjective Health Perception Scale. The relationships between work environment, lifestyle, and occupational stress were examined using multiple regression analysis. **Results:** Data from 589 female nurses (response rate: 43%) were analyzed. The proportion of participants in the low mental fatigue group was 49.4%. Factors associated with mental fatigue included items related to occupational stress, such as interpersonal stress at work, irritability, anxiety, depression, physical complaints, support from family and friends, and satisfaction with work and life ($p < .05$). **Conclusions:** Approximately half of the nurses working at university hospitals had high levels of mental fatigue. This study revealed associations between stress reactions and greater support from family and friends. Additionally, satisfaction with work and life is related to occupational stress, highlighting the importance of considering whether nurses perceive stress reactions and assessing the need for support based on support from family and friends.

Keywords

nurse, subjective well-being, work environment, lifestyle, occupational stress

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Introduction

The global population is aging rapidly, with Japan having the most significant aging population worldwide (Cabinet Office, 2024). Hence, medical needs and the demand for nurses will likely increase. However, nurses have traditionally faced physical problems such as musculoskeletal disorders (e.g., stiff shoulders), gastrointestinal disorders, and psychological issues such as burnout (Geiger-Brown & Lipscomb, 2010; Nakagawa & Hagino, 2023). The continuation

of these issues may lead to an increase in health concerns among nurses. Recent research reveals that work-related stress adversely affects nurses' quality of life and health, affecting patient care quality (Babapour et al., 2022). Therefore, interventions to support nurses' health are necessary to ensure quality nursing care.

Maddox and Douglass (1973) mention the significant difficulties of using objective indicators such as physician diagnosis and laboratory data to evaluate medical health conditions. Therefore, this study focuses on subjective well-being.

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Studies using the Japanese version of the Subjective Well-being Inventory (SUBI) have reported that approximately one-third of nurses exhibit low scores on mental well-being (Kitahara & Bogaki, 2012). However, the scale item of mental fatigue has rarely been studied. Research on nurses' subjective well-being in other countries has reported that nurses' subjective well-being is not ideal, with approximately 40% of nurses reporting low subjective well-being (Insaf et al., 2014; Miao et al., 2024). Additionally, putting off actions on health issues, such as exercise and diet, reportedly decreases subjective well-being (Basirimoghadam et al., 2020). The research question for this study was whether Japanese nurses have low subjective well-being.

Previous research on subjective well-being has reported that work environment, home-work balance, personal factors, and coping behaviors affect workers' subjective well-being (Elliott & Fry, 2020; Hirokawa et al., 2020). Nurses working night and rotating shifts and those engaged in these shifts reportedly have diverse subjective symptoms of fatigue (Nagata & Ikezaki, 2024). In addition, a study of occupational stress among nurses reported that about half of nurses felt work-related stress (Tsegaw et al., 2022), which led us to consider as a research question the possibility that "Are nurses' lifestyle, work environment, and occupational stress with subjective well-being?" Research on nurses' subjective well-being and its factors could help support their future health. In this study, we hypothesized that nurses' subjective well-being is low and that lifestyle, work environment, and occupational stress are related to the low subjective well-being.

Materials and Methods

Study Design and Participants

This cross-sectional study used an anonymous, self-administered questionnaire survey conducted in March 2022. This study targeted nurses working night shifts and in multiple clinical departments at two major university hospitals in Japan. The study excluded individuals within their probationary period (less than one year of employment), and part-time staff with fewer scheduled working days. The study required 274 participants; the sample size was calculated using G*Power 3.1.9.7, considering an effect size (f^2) of .15, a significance level (p) of 5% two-sided, a statistical power ($1 - \beta$) of 95%, and 34 explanatory variables, determined by multiple regression analysis. We distributed the questionnaire to 1,500 people to account for potential dropouts and missing data, aiming for a 20% recovery rate.

Variables

Framework of the Study

According to Ware (1986), subjective well-being is a comprehensive health indicator that can be conveniently assessed

and reflects objective physical and mental health. The SUBI, developed by Sell (1994), includes 11 subscales: satisfaction, achievement, confidence, and social support. Previous research on general workers reported associations between the work environment, lifestyle, occupational stress, and subjective well-being. As assessed using the Simplified Occupational Stress Survey developed by Shimomitsu and Odagiri (2004), occupational stress consists of four subscales (job stressors, psychological stress reactions, physical stress reactions, and modifying factors). Therefore, this study constructed a conceptual framework with lifestyle, work environment, and occupational stress as independent variables and subjective well-being as the dependent variable, as illustrated in Figure 1.

Subjective Well-being

The Japanese version of the SUBI, translated by Fujinami et al. (1995) from the original SUBI developed by Sell (1994), was used to assess subjective well-being in this study. This scale measures healthy individuals' physical, mental, and social well-being. It includes items related to physical aspects such as pain, palpitations, dizziness, mental health, and mental fatigue. It has 11 subscales: 1) satisfaction, 2) achievement, 3) confidence, 4) bliss, 5) support from close relatives, 6) social support, 7) family relationships, 8) mental control, 9) physical discomfort, 10) lack of social connections, and 11) a sense of disappointment in life, as in the original scale (Table 1). Items 1-7 are subscales of mental health, while items 8-11 are subscales of mental fatigue. The translator granted permission to use this scale. The questionnaire consists of 40 items, each rated on a three-point scale ("do not think so much," "somewhat think so," "strongly think so"). Higher scores indicate better mental health and lower mental fatigue. Items 14, 27, and 29 were excluded in this study as they pertained to questions about spouses and children. Scores were calculated according to the World Health Organization (WHO) SUBI Manual 2nd Edition (2010) by dividing the subscale scores by the number of items; individuals with high mental health scores (total scores of 42 or more) are considered to have stable relationships with others, receive necessary assistance when needed, are satisfied with daily life, and live confidently. Conversely, those with low scores (total score of less than 31) are perceived as not experiencing these feelings. Individuals with low mental fatigue scores (total score of less than 48) may be considered physically and mentally tired, especially those under 43, requiring careful attention. The scale's reliability coefficient (α coefficient) averages .73, indicating good reliability, and validity has also been ensured (Fujinami, 1995). As SUBI adds scores separately for mental health and mental fatigue, this study analyzed mental health and mental fatigue separately as subjective health indices.

Characteristics

Information on age, gender, marital status, body mass index

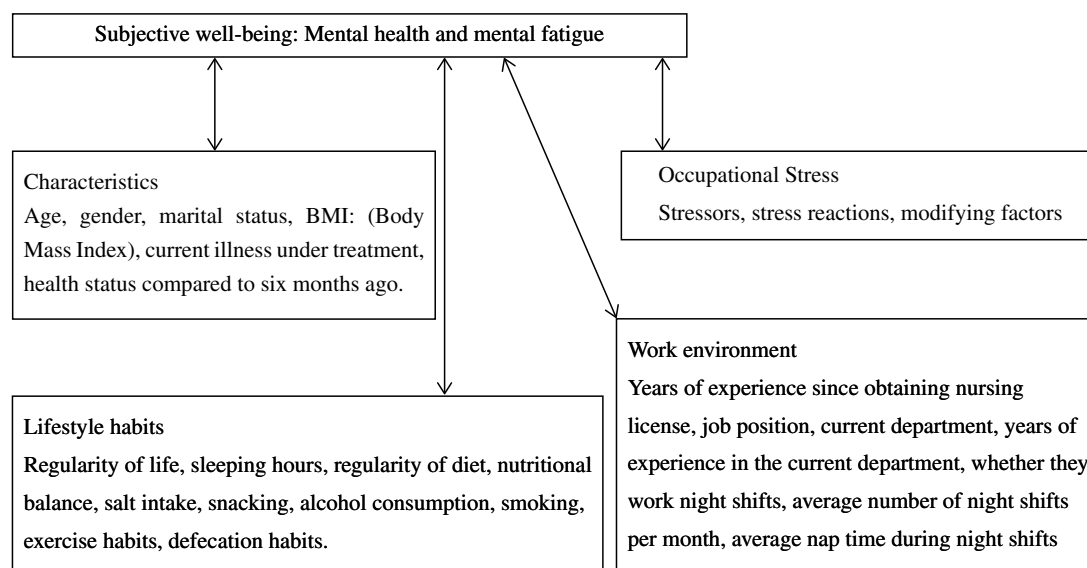


Figure 1. Conceptual framework.

Note: BMI=Body Mass Index

Table 1. Subscales and question contents of subjective well-being and occupational stress.

Scale	Subscale	Items
Subjective well-being		
Mental health	1) Satisfaction (3 items)	Current happiness compared to the past
	2) Sense of accomplishment (3 items)	Living standards and social status as expected
	3) Confidence (3 items)	Handling crisis situations
	4) Bliss (3 items)	Sense of belonging with others
	5) Support of close relatives (3 items)	Family assistance
	6) Social support (3 items)	Support from friends and relatives
Mental fatigue	8) Sense of mental control (7 items)	Immediate reactions to situations
	9) Physical ill-health (6 items)	Physical symptoms and health-related anxiety
	10) Lack of social connections (3 items)	Relationships with others
	11) Disappointment with life (3 items)	Anxiety regarding the future
Occupational stress	Stressors	Psychological job burden and job control
	Stress reactions	Feelings of irritation and depression
	Modifying factors	Support from family, friends, and supervisors

(BMI), current illness under treatment, and health status compared to six months ago were sought and analyzed.

Work Environment

The following variables were analyzed under the work environment: years of experience since obtaining a nursing license, job position, current department, years of experience in the current department, whether they worked night shifts, average number of night shifts per month, and average nap time during night shifts.

Lifestyle Habits

The lifestyle items were developed based on Breslow's health habits (Breslow & Enstrom, 1980). The 10 items used in this study were as follows: 1) regularity of life, 2) sleeping hours, 3) regularity of diet, 4) nutritional balance, 5) salt

intake, 6) snacking, 7) alcohol consumption, 8) smoking, 9) exercise habits, and 10) defecation habits.

Occupational Stress

Occupational stress was assessed using the Simplified Occupational Stress Survey (Shimomitsu & Odagiri, 2004). The developer granted permission to use this scale. The scale consists of three components: job stressors (17 items), stress reactions (29 items), and modifying factors (11 items) (Table 1). Based on the conversion table, these factors can be classified into nine stressors, six stress reactions, and four modifying factors. The response method used a 4-point Likert scale, making it a user-friendly tool that could be completed in approximately 10 min. The reliability coefficients of the subscales ranged from .77 to .92, indicating high reliability.

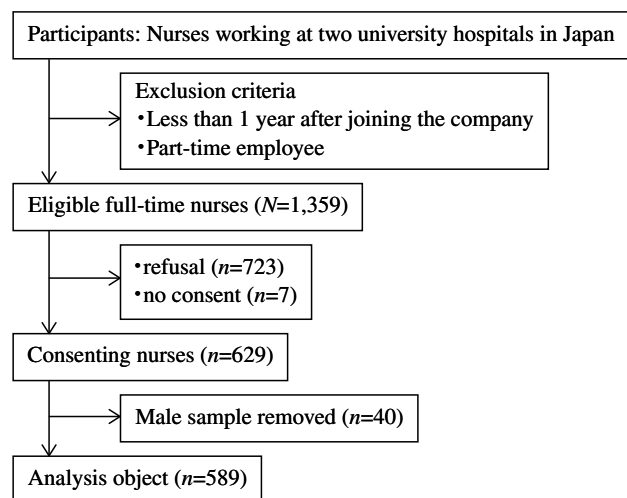


Figure 2. Participant flow diagram.

ability. Its strong correlations with the National Institute for Occupational Safety and Health and the Job Content Questionnaire exhibit high validity. Calculations were performed using a conversion table (females). In this study, the terms “low/somewhat low” were categorized as the “low group,” and “high/somewhat high” were categorized as the “high group.” The data were divided into three groups for analyses: low, intermediate, and high.

Statistical Methods

Descriptive statistics were calculated for SUBI, demographics, work environment, lifestyle, and occupational stress. If subjective well-being was low, to test for association, Mann-Whitney’s U test was used for comparisons of two independent groups with no correspondence, and Kruskal-Wallis’s test was used for comparisons of three or more independent groups. A multiple regression analysis using the forced entry method was performed with SUBI (mental health and mental fatigue) as the dependent variable and work environment, lifestyle, and occupational stress as independent variables to examine the factors related to low subjective well-being. Age, marital status, presence of ongoing illnesses, BMI, and self-perceived health compared to six months ago were included as adjusting variables. IBM SPSS Statistics 22 was used for the statistical analysis, with a significance level set at 5%.

Ethical Considerations and Participant Consent

The Ethics Review Committee affiliated with the researchers approved this study. The survey was designed to ensure anonymity, and only data from participants who provided consent were used. A secure environment was created online using a username and password known only to the authors. The USB device containing the data was stored in a locked locker. Throughout the paper, care was taken to respect

Table 2. Participant characteristics ($n = 589$).

		<i>n</i> (%)
Age		
By age group (years)	20s	310 (52.6)
	30s	127 (21.5)
	40s	101 (17.1)
	50s	51 (8.7)
Marital status	married	216 (36.8)
	unmarried	373 (63.3)
If treatment is being sought for any disease	Yes	121 (2.5)
	No	468 (79.5)
BMI	<18.5	77 (13.1)
	$18.5 \leq <25$	446 (75.7)
	$25 \leq$	66 (11.2)
My health status compared to 6 months ago	Better	51 (8.7)
	No change	403 (68.4)
	Worse	135 (22.9)

Note: BMI=Body Mass Index

Table 3. Subjective well-being inventory ($n = 589$).

		Mean $\pm$ SD	<i>n</i> (%)
Mental health	Low (0–30 paints)		106 (18.0)
	Middle (31–41 paints)		408 (69.3)
	High (42–57 paints)		75 (12.7)
		37.5 $\pm$ 5.7	
Mental fatigue	Low (0–42 paints)		291 (49.4)
	Middle (43–47 paints)		203 (34.5)
	High (48–63 paints)		95 (16.1)
		45.7 $\pm$ 6.6	

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Results

Participant Characteristics

Of 1,359 distributed survey forms, 636 individuals responded (46.8%). Seven respondents who did not consent to participate in the study were excluded, leaving 629 individuals (effective response rate: 46.3%). Given the limited number of men among participants (40) and the availability of gender-specific mean values in the Japanese version of SUBI for comparison, the analysis focused on 589 female participants (Figure 2). As shown in Table 2, the average age of the participants was 32.7 ± 9.9 , with the majority in their 20s ($n = 310$; 52.6%).

Subjective Well-being Inventory (SUBI)

The average mental health and mental fatigue scores were 37.5 ± 5.7 and 45.7 ± 6.6 , respectively (Table 3). The pro-

Table 4. Work environment ($n = 589$).

		<i>n</i> (%)	Median (IQR)
Years of nursing experience since becoming licensed to practice nursing			
Years			2.0 (1–5)
	1–3 years	206 (35.0)	
	4–6 years	98 (16.6)	
	6–9 years	48 (8.1)	
	10–14 years	63 (1.7)	
	>15 years	174 (29.5)	
Position (average age)	Staff (29.74)	469 (79.6)	
	Administrators (46.17)	52 (8.8)	
	Deputy Chief (39.69)	68 (11.5)	
Department	Surgical	171 (29.0)	
	Internal medicine	105 (17.8)	
	Outpatient	83 (14.1)	
	Operating room	17 (2.9)	
	Emergency center/Intensive care unit	89 (15.1)	
	Mixed medical and surgical	23 (3.9)	
	Psychiatry	3 (.5)	
	Rehabilitation	5 (.8)	
	Women's (Gynecology, Breast Surgery)	8 (1.4)	
	Perinatal	28 (4.8)	
	Pediatric	16 (2.7)	
	Others	41 (7.0)	
Department years of experience By rank			2.0 (2–5)
	1–3 years	380 (64.5)	
	4–6 years	113 (19.2)	
	7–9 years	36 (6.1)	
	>10 years	60 (1.2)	
Night shift	Yes	446 (75.7)	
	No	143 (24.3)	
Average number of night shifts per month	0 times	147 (25.0)	
	1–3 times	129 (21.9)	
	4–6 times	254 (43.1)	
	>7 times	59 (1.0)	
Average naps per night shift	0–30 min	140 (23.8)	
	31–60 min	69 (11.7)	
	61–90 min	135 (22.9)	
	91–120 min	162 (27.5)	
	>120 min	83 (14.1)	

*Note: IQR=interquartile range

portions of participants with low mental health and mental fatigue were 18.0% and 49.4%, respectively. The reliability coefficients (α coefficients) were .862 for mental health and .860 for mental fatigue. As many participants had high levels of mental fatigue, the results with mental fatigue as the dependent variable are discussed.

Work Environment

The median (IQR) years of experience after obtaining a nursing license was 2.0 (1–5) years, with the majority having

1–3 years of experience ($n = 206$; 35.0%) (Table 4). The predominant position was “the staff,” with 469 individuals (79.6%). The median (IQR) years of experience in the current department was 2.0 (2–5) years, and the majority had 1–3 years of experience ($n = 380$; 64.5%). Regarding night shifts, 446 individuals (75.7%) reported working night shifts, with the most common response for the average number of night shifts per month being four to six shifts, indicated by 254 individuals (43.1%). The average nap time during night shifts was most frequently reported to be 91–

Table 5. Lifestyle habit ($n = 589$).

n (%)			n (%)		
Regularity of life	Very regular	26 (4.4)	Do you avoid salt intake?	I refrain from doing so	87 (14.8)
	Regular	191 (32.4)		Not very much	328 (55.7)
	Not very regular	210 (35.7)		I don't abstain	174 (29.5)
	Irregular	162 (27.5)	Frequency of snacking	I don't eat	13 (2.2)
Average hours of sleep	>8 h	15 (2.5)		Almost never	59 (10)
	7 to <8 h	133 (22.6)		Occasionally eat	329 (55.9)
	6 to <7 h	264 (44.8)	Drinking alcohol	Frequently eat	188 (31.9)
	<6 h	177 (3.1)		Do not drink at all	189 (32.1)
Frequency of regular exercise	>3 times a week	28 (4.8)		Hardly drink	154 (26.1)
	Twice a week	52 (8.8)	Smoking	Drink occasionally	192 (32.6)
	Once a week	94 (16)		Drink every day	54 (9.2)
	I don't exercise	415 (7.5)		I don't smoke	526 (89.3)
Regularity of meals	Regular	234 (39.7)		I used to smoke	46 (7.8)
	Irregular	355 (6.3)		I still smoke	17 (2.9)
Are you conscious of nutritional balance?	Very conscious	28 (4.8)			
	Fairly conscious	284 (48.2)			
	Not very conscious of it	212 (36)			
	Not conscious of it	65 (11)			

Table 6. Occupational stress ($n = 589$).

n (%)				n (%)			
Stressors	Psychological workload (quantity)	Low	28 (4.8)	Stress reaction	Vitality	Low	170 (28.9)
		Middle	178 (3.2)		Middle	257 (43.6)	
		High	383 (65)		High	162 (27.5)	
	Psychological workload (quality)	Low	9 (1.5)		Irritability	Low	124 (21.1)
		Middle	48 (8.1)		Middle	301 (51.1)	
		High	532 (9.3)		High	164 (27.8)	
	Perceived degree of physical workload	Low	6 (1)		Fatigue	Low	76 (12.9)
		Middle	45 (7.6)		Middle	230 (39)	
		High	538 (91.3)		High	283 (48)	
	Interpersonal stress at work	Low	142 (24.1)		Anxiety	Low	126 (21.4)
		Middle	307 (52.1)		Middle	271 (46)	
		High	140 (23.8)		High	192 (32.6)	
	Work environment stress	Low	93 (15.8)		Depression	Low	159 (27)
		Middle	280 (47.5)		Middle	203 (34.5)	
		High	216 (36.7)		High	227 (38.5)	
	Work control	Low	112 (19)		Somatic complaints	Low	187 (31.7)
		Middle	313 (53.1)		Middle	195 (33.1)	
		High	164 (27.8)		High	207 (35.1)	
	Utilization of skills	Low	190 (32.3)		Supervisor support	Low	66 (11.2)
		Middle	310 (52.6)		Middle	266 (45.2)	
		High	89 (15.1)		High	257 (43.6)	
	Job aptitude	Low	188 (31.9)		Support from colleagues	Low	201 (34.1)
		Middle	352 (59.8)		Middle	237 (40.2)	
		High	49 (8.3)		High	151 (25.6)	
Being worth doing	Low	135 (22.9)	Modifying factors	Support from family and friends	Low	102 (17.3)	
	Middle	351 (59.6)		Middle	129 (21.9)		
	High	103 (17.5)		High	358 (60.8)		
		Satisfaction with work and life		Low	119 (20.2)		
		Middle		368 (62.5)			
		High		102 (17.3)			

Table 7. The subjective well-being inventory (mental fatigue) and work environment.

	<i>n</i> = 589		
	<i>n</i>	Mean ± SD	<i>p</i> -value
Position			
Staff	469	45.5 ± 6.6	.324
Administrators	68	46.3 ± 6.3	
Deputy chief	52	46.8 ± 6.4	
Night shift			
Yes	446	45.6 ± 6.7	.811
No	143	45.8 ± 6.1	
Average number of night shifts per month			
0 times	147	45.6 ± 6.1	.892
1–3 times	129	45.9 ± 6.9	
4–6 times	254	45.5 ± 6.6	
>7 times	59	45.2 ± 6.9	
Average naps per night shift			
0–30 min	140	45.1 ± 6.6	.034*
31–60 min	69	44.6 ± 6.3	
61–90 min	135	45.0 ± 6.6	
91–120 min	162	46.7 ± 6.5	
>121 min	83	46.6 ± 6.4	
Years of nursing experience since licensed to practice nursing			
1–3 years	206	44.9 ± 6.7	.022*
4–6 years	98	46.4 ± 5.9	
6–9 years	48	44.3 ± 7.0	
10–14 years	63	45.0 ± 6.8	
>15 years	174	46.8 ± 6.4	
Department years of experience			
1–3 years	380	45.6 ± 6.4	.503
4–6 years	113	46.2 ± 6.7	
7–9 years	36	44.6 ± 7.3	
>10 years	60	45.8 ± 7.0	

Note: $p < .05^*$, $p < .01^{**}$, $p < .001^{***}$

120 minutes, as reported by 162 individuals (27.5%).

Lifestyle

The average sleep duration was 6–7 hours for 264 individuals (44.8%) (Table 5). The majority, 415 individuals (70.5%), reported not engaging in regular exercise. Regarding meal habits, 355 participants (60.3%) reported irregular eating patterns. 284 (48.2%) participants reported nutritional balance awareness. Salt consumption was not significantly reduced by 328 participants (55.7%). Snacking habits varied, with 329 participants (55.9%) reporting occasional snacking. Drinking habits indicated that 192 individuals (32.6%) occasionally consumed alcohol, whereas smoking was reported by only 89.3% who did not smoke.

Occupational Stress

When categorizing occupational stress into the three groups, the most frequently reported high-stress items were psychological job burden (quantity), psychological job burden

(quality), self-perceived physical burden, fatigue, feelings of depression, physical complaints, and support from family and friends (Table 6). The items most frequently reported in the intermediate stress group were interpersonal relationship stress in the workplace, stress due to the work environment, control over one's job, utilization of skills, perceived suitability, job satisfaction, vitality, feelings of irritation, feelings of anxiety, support from superiors, support from colleagues, and satisfaction with work and life. No specific items were significantly more prevalent in the low-stress group.

Association between Mental Fatigue and Work Environment, Lifestyle, and Occupational Stress

Univariate analyses were conducted for mental fatigue and each factor of work environment, lifestyle, and occupational stress. The average nap time during night shifts and the number of years of postlicensure experience as a nurse exhibited significant associations ($p < .05$) in the work envi-

Table 8. The subjective well-being inventory (mental fatigue) and lifestyle habit.

<i>n</i> = 589							
	<i>n</i>	Mean ± SD	<i>p</i> -value		<i>n</i>	Mean ± SD	<i>p</i> -value
Regularity of life				Do you avoid salt intake?			
Very regular	26	47.5 ± 5.9	.013*	I refrain from doing so	87	46.2 ± 6.8	.650
Regular	191	46.6 ± 6.1		Not very much	328	45.7 ± 6.2	
Not very regular	210	45.6 ± 6.7		I don't abstain	174	45.3 ± 7.2	
Irregular	162	44.4 ± 6.8		Frequency of snacking			
Average hours of sleep				I don't eat	13	44.6 ± 7.0	.481
>8 h	15	46.0 ± 6.8	.000***	Almost never	59	46.4 ± 6.7	
7 to <8 h	133	47.8 ± 6.2		Occasionally eat	329	45.9 ± 6.6	
6 to <7 h	264	45.7 ± 6.0		Frequently eat	188	45.2 ± 6.4	
<6 hours	177	44.1 ± 7.2		Drinking alcohol			
Frequency of regular exercise				Do not drink at all	189	45.4 ± 6.7	.816
>3 times a week	28	42.9 ± 7.4	.140	Hardly drink	154	45.5 ± 6.3	
Twice a week	52	45.4 ± 7.0		Drink occasionally	192	45.9 ± 6.8	
Once a week	94	46.3 ± 6.2		Drink every day	54	46.4 ± 5.9	
I don't exercise	415	45.8 ± 6.5		Smoking			
Regularity of meals				I don't smoke	526	45.8 ± 6.5	.677
Regular	234	46.6 ± 6.9	.005**	I used to smoke	46	44.7 ± 7.2	
Irregular	355	45.1 ± 6.3		I still smoke	17	45.1 ± 5.8	
Are you conscious of nutritional balance?							
Very conscious	28	45.0 ± 7.8	.118				
Fairly conscious	284	46.4 ± 6.2					
Not very conscious of it	212	45.3 ± 6.4					
Not conscious of it	65	44.1 ± 7.7					

Note: $p < .05^*$, $p < .01^{**}$, $p < .001^{***}$

ronment factor (Table 7). As for lifestyle, regularity of life, average hours of sleep, and regularity of meals demonstrated significant associations ($p < .05$) (Table 8). In occupational stress, psychological workload (quantity), psychological workload (quality), interpersonal stress at work, stress due to work environment, degree of control over work, degree of aptitude you feel, job satisfaction, vitality, irritability, fatigue, anxiety, depression, physical complaints, support from supervisor, support from colleagues, support from family and friends, and job and life satisfaction exhibited significant associations ($p < .05$) (Table 9).

When considering mental fatigue as the dependent variable and work environment, lifestyle, and occupational stress as the independent variables, the results revealed no significant associations between mental fatigue and lifestyle or work environment. However, occupational stress was significantly associated with feelings of interpersonal stress at work, irritation, anxiety, depression, physical complaints, support from family and friends, and work and life satisfaction (Table 10). The adjusted R-squared was .493.

Discussion

Current State of Nurses' Subjective Well-being

In this study, nurses' mental well-being scores were higher

than the national average for adult women aged 20 and above (34.7). The percentage of nurses with low mental well-being scores was 18.0%, including 106 females in this category. Previous research using the Japanese version of the SUBI reported that less than 30% of the nurses had low mental well-being scores, indicating a need for assistance (Kitahara & Bogaki, 2012). The results of the present study showed a lower percentage.

In contrast, the mental fatigue scores were generally lower than the national average (51.2). According to the WHO SUBI manual, individuals in the low category are at risk of experiencing both mental and physical fatigue (Ohno & Yoshimura, 2010). In this survey, a significant proportion of female nurses reported high mental fatigue, indicating that approximately half required attention. Although it is impossible to generalize the survey results since it was conducted at only two hospitals, it highlights the need for providing support and paying attention to the level of mental fatigue among nurses.

Relationship between Subjective Well-being (Mental Fatigue) and Other Factors

The results showed no significant associations between mental fatigue and factors such as work environment or lifestyle. Occupational stress, irritability, anxiety, depression, and

Table 9. The subjective well-being inventory (mental fatigue) and occupational stress.*n* = 589

	<i>n</i>	Mean ± SD	<i>p</i> -value		<i>n</i>	Mean ± SD	<i>p</i> -value
Psychological workload (quantity)				Irritability			
Low	28	49.2 ± 6.9	.000***	Low	124	49.5 ± 5.8	.000***
Middle	178	47.6 ± 5.9		Middle	301	46.1 ± 5.7	
High	383	44.5 ± 6.6		High	164	41.9 ± 6.7	
Psychological workload (quality)				Fatigue			
Low	9	51.3 ± 7.1	.001**	Low	76	51.7 ± 4.4	.000***
Middle	48	47.9 ± 6.2		Middle	230	47.3 ± 5.5	
High	532	45.4 ± 6.5		High	283	42.7 ± 6.3	
Perceived degree of physical workload				Anxiety			
Low	6	46.6 ± 6.2	.801	Low	126	51.4 ± 4.9	.000***
Middle	45	46.4 ± 5.9		Middle	271	46.3 ± 5.1	
High	538	45.6 ± 6.6		High	192	41.1 ± 6.2	
Interpersonal stress at work				Depression			
Low	142	47.6 ± 5.9	.000***	Low	159	51.1 ± 4.6	.000***
Middle	307	46.0 ± 6.4		Middle	203	46.2 ± 5.1	
High	140	42.9 ± 6.8		High	227	41.4 ± 5.9	
Work environment stress				Somatic complaints			
Low	93	46.9 ± 6.3	.002**	Low	187	39.6 ± 5.7	.000***
Middle	280	46.3 ± 6.2		Middle	195	37.2 ± 5.1	
High	216	44.4 ± 6.9		High	207	35.9 ± 5.5	
Work control				Supervisor support			
Low	112	43.3 ± 7.0	.000***	Low	66	42.4 ± 8.1	.000***
Middle	313	46.0 ± 6.2		Middle	266	44.9 ± 6.4	
High	164	46.7 ± 6.6		High	257	47.4 ± 5.8	
Utilization of skills				Support from colleagues			
Low	190	44.8 ± 7.2	.072	Low	201	44.2 ± 7.1	.000***
Middle	310	45.9 ± 6.3		Middle	237	45.9 ± 6.1	
High	89	46.8 ± 5.9		High	151	47.4 ± 6.0	
Job aptitude				Support from family and friends			
Low	188	42.8 ± 6.6	.000***	Low	102	43.0 ± 7.3	.000***
Middle	352	46.8 ± 6.1		Middle	129	44.1 ± 6.5	
High	49	48.6 ± 6.2		High	358	47.0 ± 6.0	
being worth doing				Satisfaction with work and life			
Low	135	42.7 ± 6.9	.000***	Low	119	41.2 ± 6.8	.000***
Middle	351	45.9 ± 6.3		Middle	368	46.1 ± 5.9	
High	103	48.8 ± 5.5		High	102	49.3 ± 5.6	
vitality							
Low	170	42.7 ± 7.1	.000***				
Middle	257	45.9 ± 5.9					
High	162	48.5 ± 5.7					

Note: *p* < .05*, *p* < .01**, *p* < .001***

physical complaints were significantly associated with mental fatigue. Individuals who were aware of symptoms, such as irritability, depression, and physical complaints, tended to have lower mental fatigue scores, suggesting that mental fatigue could improve through effective coping behaviors for fatigue recovery and stress. However, as this was a cross-sectional study, future longitudinal research is essential to determine whether these factors influence mental fatigue.

Regarding the moderating factors of occupational stress,

there was a significant association between higher mental fatigue scores, greater support from family or friends, and higher job and life satisfaction. There were significant associations between less interpersonal stress at work among stressors and lower levels of mental fatigue. Previous studies have reported that even with a high psychological workload (quantity), people were able to control their work, and with support from their supervisors and colleagues, they were less likely to fall into exhaustion and had lower overall

Table 10. Multiple regression analysis with SUBI (mental fatigue) as the dependent variable.

Note: **p* < .05, ***p* < .01, ****p* < .001

*R*²: coefficient of determination, VIF = Variance inflation factor

Age, marital status, presence of illness under treatment, BMI, and own health status compared to six months ago were analyzed as adjustment variables.

health risks (Fukuoka et al., 2007; Sakata, 2016). In this survey, those with higher support from family and friends than supervisors and coworkers had higher scores for mental fatigue. These results indicate that individuals with less support outside the workplace may experience higher levels of mental fatigue. As nurses' quality of life can affect the quality of patient care (Babapour et al., 2022), addressing the impact of mental fatigue on nurses' quality of life is crucial. Therefore, it was hypothesized that venting stress outside the workplace may have affected mental fatigue. Many nurses suffer from work-related stress and fatigue (Nagata & Ikezaki, 2024; Tsegaw et al., 2022), and interpersonal relationships at work are more stressful than patients and their families (Jinguji, 2020). This finding suggests that coping with fatigue and stress outside of the workplace can enhance

subjective health.

By focusing on the subjective well-being of nurses and elucidating the related factors, this study contributes to supporting nurses' health and preventing a decline in the quality of nursing care. This study suggests that assessing stress responses and providing support from family or friends can be valuable for identifying the need for assistance. However, the specific factors influencing support from family or friends and job and life satisfaction remain unclear. Future studies, particularly qualitative analyses, are necessary to uncover these causes and develop more specific support strategies.

Limitations of this Study

This study had certain limitations that warrant caution when

interpreting the results. This study was conducted in only two hospitals, limiting the findings' generalizability. Additionally, many previous studies were conducted before the onset of the COVID-19 pandemic, whereas this study was conducted during the pandemic. Therefore, there is a possibility that the ongoing pandemic might have influenced the results. Further, as this was a cross-sectional study, causation could not be definitively established. Future research, particularly prospective or intervention studies, must delve deeper into the causal relationships.

Conclusion

This study revealed that mental fatigue was higher than the national average among adult women in Japan, among the indicators of nurses' subjective well-being. There were significant associations between lower mental fatigue and lower levels of interpersonal stress at work, irritability, anxiety, depression, and physical complaints related to occupational stress, greater support from family or friends, and higher job and life satisfaction levels. Therefore, assessing stress responses and support from family or friends could be crucial for addressing mental fatigue among nurses and potentially lowering their mental fatigue levels.

Author Contributions

Seita Katsurakawa and Professor Sayuri Nakamura contributed to the conceptualization, design, data collection, analysis, interpretation, and manuscript preparation. Yumiko Miyoshi, Junko Sugama, and Kimie Takehara revised the manuscript. All authors have reviewed and approved the final manuscript.

Declaration of Conflicting Interests

The Conflict-of-Interest Committee affiliated with the researchers approved this study. No external research funds, materials, or human support was used in this study.

Ethical Approval

The Fujita Health University Medical Research Ethics Committee approved this study. The approval code is HM21-418. The survey was designed to ensure anonymity, and only data from participants who provided consent were used. A secure environment was created online, using a username and password known only to the authors. The USB device containing the data was stored in a locked locker. Throughout the paper, care was taken to respect copyright, including proper citations of authors and works when referencing.

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Original Research

Development of a scale to assess psychological adjustment in survivors of women's cancers: Reliability and validity

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Abstract

Objective: The present study aims to develop the psychological adjustment in survivors of women's cancers (PASWC) scale and examine its validity and reliability. **Methods:** A draft scale comprising 32 items was prepared based on a pilot study. The participants for analysis were 304 survivors of women's cancers. A PASWC model was created, and the goodness of fit was evaluated based on the covariance structure for a confirmatory factor analysis. **Results:** Five subscales comprising 20 items were extracted as a result of the factor analysis. The statistical model fit the actual data: goodness of fit index, 0.903; adjusted goodness of fit index, 0.872; comparative fit index, 0.920; and root mean square error of approximation, 0.060. The subscales were as follows: "connecting with others," "being a charming me," "being myself," "overcoming pessimism," and "living more independently as a woman." The scale reliability was confirmed based on Cronbach's α for an internal consistency of 0.87 for the 20 items. The criterion-related validity was almost satisfactory for all areas. **Conclusions:** We confirmed this scale's reliability and validity; hence, it can become a useful tool for measuring the psychological adjustment of female cancer survivors in clinical settings.

Keywords

women's cancers, cancer survivors, psychological adaptation, scale

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Introduction

Cancer patients are survivors starting on the day of diagnosis (Marzorati, et al., 2017). Therefore, we refer to women who live with breast, uterine, or ovarian cancer as women's cancer survivors. Overall, as of 2020, breast cancer is the most common type of cancer among female patients in Japan. Uterine and ovarian cancer are the third and sixth most

common cancer types, respectively (Ministry of Health, Labour and Welfare, 2024). Treatment based on recent guidelines has markedly prolonged the survival of patients with breast cancer and cancers of the female reproductive organs, including uterine and ovarian cancer. Thus, these patients require long-term medical follow-up, even after completing aggressive treatment. This study focuses on the psychological adjustment in survivors of women's cancer because they

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share some common psychological stresses, regardless of the cancer type.

Fertility loss associated with cancer treatment is a common issue faced by survivors of women's cancers. Breast, uterine, and ovarian cancer often require a resection of the affected female reproductive organs. Even if these organs are preserved, patients usually require chemotherapy, radiotherapy, or hormone therapy that temporarily or permanently affects fertility. The psychological stress associated with such a loss was reported to be serious in the survivors of both breast (Kirkman et al., 2014) and gynecologic cancer (Lawrenz et al., 2016). Survivors of women's cancers often suffer from sexual dysfunction (Boquiren et al., 2016; Ciani et al., 2023) and changes in their relationships with their partners (Arring et al., 2023; Miaja et al., 2017). Women who undergo lymphadenectomy may experience appearance alteration caused by complications, such as lymphedema (Dessources et al., 2020; Fu et al., 2023). Although returning to work is important for cancer survivors to return to their normal lives, treatment and physical symptoms may make it difficult (Bijker et al., 2018; Sun et al., 2021). Moreover, the advancement of genomic medicine in recent years has led to stress associated with treatment choices, such as risk-reducing mastectomy for hereditary breast and ovarian cancer syndrome (Imai et al., 2024). The survivors of breast (Khajoei et al., 2023) and cervical cancer (Maguire et al., 2015) desire support to cope with the psychological stresses associated with problems related to reproduction and relationships with others, including their partners. For survivors of women's cancers, successfully coping with these psychological stresses is important in maintaining their identities as women (Ciria-Suarez et al., 2012) and for their self-esteem (Pinar, et al., 2012) because they are at a higher risk of depression and anxiety (Bae & Park, 2016; Tsaras, et al., 2015). Suzuki et al. (2015) indicated the importance of nursing, focusing on female-specific problems from the femininity perspective. Therefore, an important role of nursing practice is to help survivors of women's cancers efficiently cope with high stress levels and find the strength to live with cancer.

Research on support for cancer survivors has entered the era of psychosocial intervention studies, and a number of scales are used to measure the effectiveness of such interventions. For example, the Japanese version of the Mental Adjustment to Cancer (MAC) Scale (Watson et al., 1988; Akechi et al., 1997) is a scale for measuring intervention outcomes. However, this scale was developed to assess coping by patients with cancer (Akechi et al., 1997). The Psychological Adjustment of Cancer Survivors (PACS) Scale (Ueta & Onishi, 2016) was developed to focus on psychological adjustment through cognitive reappraisal (Lazarus & Folkman, 1984). The development of the PACS scale enabled the measurement of psychological adjustment among

survivors, which could not be captured by the Health-related Quality of Life Scale or the psychiatric diagnostic scales for anxiety or depression. However, gender was not incorporated in the PACS scale because it was developed as a versatile scale that can be used in all cancer survivors; thus, it cannot be used to evaluate reproduction-related issues or issues associated with the loss of sense of identity as a woman mentioned above among survivors of women's cancers. Parsons (1956) pointed out that women are more expressive than men, and that they play the role of coordinating and maintaining interactions and emotional support among family members. Moriya (1997) suggested that women, more frequently than men, deal with negative feelings in daily life by adjusting themselves to other people or circumstances instead of changing other people or the circumstances. Therefore, the psychological adjustment by survivors of women's cancers is speculated to differ from that of male survivors. Nevertheless, there is no dedicated scale for measuring the psychological adjustment among women. Hence, the development of such a scale is desired. This study aims to develop a scale for measuring the psychological adjustment in survivors of women's cancers and to examine the scale validity and reliability.

Materials and Methods

Definition of Terms

The psychological adjustment in survivors of women's cancers refers to the state of living with cancer that survivors of women's cancers achieve through coping strategies at the time of diagnosis and treatment. During this state, patients have overcome pessimism, feel connected with others, and have not only returned to how they were, but are also charming as women, have expanded their way of living as women, and are independent.

Process of Scale Development to Measure Psychological Adjustment in Survivors of Women's Cancers

Extraction of Constructs and Preparation of Questions

To identify the constructs of psychological adjustment in survivors of women's cancers, we performed a qualitative study, in which we interviewed 29 survivors of women's cancers. We started the interviews by asking the participants for their self-rated scores of psychological adjustment at the time of cancer diagnosis and at the time of the interview on a 100-point scale. Next, we asked about their ideas of the psychologically adjusted state of cancer survivors as women. As a result, "being myself," "being a charming me," "living independently as a woman," "expanding my life as a woman," "connecting with others," and "overcoming pessimism" were identified as the constructs of psychological adjustment in survivors of women's cancers (Ueta et al., 2020). The sub-concepts of these constructs were generated

from an analysis of the participants' narratives independent of cancer site. "Being myself" represents living a normal life, even with cancer, such as having good times with friends as usual. "Being a charming me" represents being charming as a woman despite being a cancer survivor, for example, dressing up despite the loss of breasts and getting a manicure on nails that turned black due to treatment side effects. "Living independently as a woman" includes making decisions independently, for example, even if family members want the patient to give priority to treatment contrary to her desire to preserve her fertility. "Expanding my life as a woman" includes being able to think that childbearing does not determine a woman's value, and that the experience of cancer has widened their lifestyle choices as a woman beyond the confines of conventional values. "Connecting with others" represents being able to feel connected with others, including one's partner, colleagues, people in the same situation, and friends. "Overcoming pessimism" represents being able to feel having overcome the sadness of experiencing cancer, such as getting one's smile back when accepting reality and being able to tell someone else about cancer. We developed 6-7 questions in simple language for each of the six constructs (40 questions in total), including some inverse scale questions.

Evaluation of Content Validity by Cancer Experts

To examine the face and content validities of questions regarding the psychological adjustment in survivors of women's cancers, we conducted a questionnaire survey of 10 certified nurse specialists in cancer nursing and cancer nursing researchers and obtained their advice from the specialist point of view. The experts were asked to rate each question on a 4-point scale from "1. not appropriate" to "4. very appropriate." The questions rated as 3 or 4 by at least 83% of the experts were considered appropriate (Lynn, 1986). As a result, 38 questions were deemed appropriate and collectively formed the draft of psychological adjustment in survivors of women's cancers (PASWC)-38.

Correction of the Draft Based on a Preliminary Survey

We conducted a survey of the survivors of women's cancers using the PASWC-38 draft in July 2018. Face validity was confirmed based on 30 valid responses (response rate, 75.0%). We kept 32 questions based on the item analysis, which formed the corrected PASWC-32.

Main Survey

Study Participants and Survey Period

The study participants were patients diagnosed with women's cancer and being continuously treated on an outpatient basis, regardless of the cancer stage, treatment, and age. Patients who received an explanation of their diagnosis and were not mentally confused to an abnormal extent were selected. Patients who were diagnosed or told about recurrence within the past 6 weeks and those with terminal dis-

ease or severe physical or psychological pain were excluded. The survey was conducted from August 2018 to March 2019 at a designated cancer care hospital and two breast cancer clinics in the Chugoku and Shikoku regions.

Questionnaires and Methods for Distribution and Collection
We asked the study participants to complete the corrected PASWC-32 by choosing one response from the four response choices for each question: "1. not at all," "2. somewhat true," "3. mostly true," and "4. definitely." The MAC scale (Watson et al., 1988; Akechi et al., 1997), Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983; Kitamura, 1993), and PACS scale (Ueta & Onishi, 2016) were used for external verification. We also asked about their age, time elapsed since cancer diagnosis, cancer type, stage, surgery they underwent, current treatment and symptoms, performance status (PS), whether they had any child with their spouse or partner, and employment status.

We asked the director of the hospital or the nursing department to refer patients who meet the study criteria, requested participation in the survey, and handed the questionnaires to those who gave consent. The questionnaires were collected by mail. The survey was conducted as an anonymous self-administered questionnaire survey.

MAC Scale

The MAC scale is a 40-item, four-level scale for the measurement of coping with cancer. Its reliability and validity are verified, and it consists of the following five subscales: "fighting spirit (FS)," "helplessness/hopelessness (H/H)," "anxious preoccupation (AP)," "fatalism (F)," and "avoidance (A)." The MAC scale was used because FS represented psychologically beneficial coping, and H/H represented psychologically harmful coping (Akechi et al., 2001). These subscales were considered to be related to psychological adjustment, which was the topic of interest in this study.

HADS

HADS is the most extensively validated scale to screen for emotional distress in Japanese patients with cancer. HADS is a 14-item, four-level scale to screen for anxiety and depression in patients with physical diseases. Its reliability and validity were verified (Kugaya et al., 1998). When major depressive disorder based on the Diagnostic and Statistical Manual of Mental Disorders, third edition, revised (DSM-IIIIR) was used as an external criterion, sensitivity was 82.4%, and specificity was 96.3%. HADS is commonly used to screen for anxiety and depression in cancer patients in Japan (Minowa et al., 2019; Takeuchi et al., 2016). HADS was selected herein because the HADS score was expected to be negatively correlated with the PASWC score from the psychiatric perspective.

PACS Scale

The PACS scale is an 18-item, four-level scale for measuring the psychological adjustment in all cancer survivors, regardless of sex and cancer type. Its reliability and validity

were verified (Ueta et al., 2016), and it comprised the following subscales: “accepting myself as a patient living with cancer,” “feeling personal psychological growth,” “regaining myself,” and “experiencing a lack of well-being.” The PACS scale was selected because the PACS score was expected to be positively correlated with the PASWC score.

Analytic Method

We performed an item analysis by examining the floor and ceiling effects, item-total correlation, and item-rest coefficient. We also performed a good-poor (G-P) analysis. The PASWC model was created after an exploratory factor analysis. The goodness of fit was evaluated using the covariance structure analysis as a confirmatory factor analysis. The goodness of fit was evaluated using the goodness of fit index (GFI), adjusted goodness of fit index (AGFI), comparative fit index (CFI), and root mean square error of approximation (RMSEA). The internal consistency was confirmed based on Cronbach’s α of each factor and the entire scale. The structure of the constructs at the time of scale preparation and that of the subscales after scale preparation were confirmed to verify the validity. The Pearson correlation coefficients between the PASWC and MAC, HADS, or PACS scales were calculated, as well. Multidimensional scaling was used to graphically confirm the similarity (dissimilarity) of these factors. Moreover, all data were randomly divided into two groups to confirm cross-validity. Models 1 and 2 were prepared based on the final PASWC model. The factorial invariance was evaluated based on the difference in the goodness of fit according to simultaneous factor analyses. For statistical analyses, SPSS Statistics 24.0 J and Amos 19.0 J were used.

Ethical Considerations

This study was conducted after approval was obtained from the clinical research ethics committees of the institutions to which the researchers belonged to (approval number, 3240) and after the ethics review at the institutions where the study was conducted. In requesting cooperation with the study, the researchers explained the study content and carefully observed the reactions of the prospective study participant to evaluate any anticipated problems with conducting the survey. Using relevant documents, the researchers also explained that study participation was voluntary that the study participants were free to discontinue (withdraw from) participation that protection of personal information and anonymity were guaranteed, how data will be stored and disposed that medical or nursing care was not associated with the study participation, and that study results will be published. The study participants were considered to have agreed to participate in the study by returning the survey questionnaire. The permission of the parties that created the PACS and MAC scales was obtained for their use in this

work.

Results

Of the 470 patients asked to participate in the survey, only 313 patients responded (response rate, 66.6%). A total of 304 valid responses were obtained, which excluded responses with missing data (valid response rate, 64.7%).

Participant Characteristics

The study participant characteristics are shown in Table 1. The mean age was 56.1 ± 11.4 years. The cancer type distribution was as follows: breast cancer, 74.3%; endometrial cancer, 10.2%; and cervical cancer, 9.5%. The mean time elapsed since being informed of the cancer diagnosis was 81.2 ± 66.0 months. Hormone therapy was the most common current treatment (45.7%). Approximately 20%-30% of the study participants showed symptoms, such as fatigue and peripheral nerve symptoms. PS was 0 in 75.7% of the study participants.

Item Analysis

The following five items were removed from the nine items showing ceiling effects: “value as a woman does not depend on giving birth to a child,” “I make the final decision on treatment,” “I constantly feel like my core is shaken (inverse scale item),” “I feel like I’m not a woman anymore after treatment (inverse scale item),” and “I’m being my usual self.” Four items with skewness coefficient <1.0 were tentatively retained because the deviation from the normal distribution was negligible (Nakayama, 2018), and the scale contents were valid. The item-rest coefficient was 0.3 or lower for two items, of which one item had already been removed because of the ceiling effect. Correspondingly, the item “I do not want to mention cancer (inverse scale item)” was removed to ensure the scale’s internal consistency. The item-total correlation coefficients ranged from 0.36 to 0.75; no items were removed. As part of the G-P analysis, the study participants were divided into high- and low-score groups based on the mean total score of the scale, 81.2. A t test was also performed. The mean score of the high-score group was 91.3 ± 6.6 , which was significantly higher than 70.7 ± 7.6 in the low-score group ($p < .001$), confirming an appropriate correspondence between the item scores and the total score. Thus, 26 items were maintained in consideration of the overlap among the removed items (Table 2).

Exploratory Factor Analysis

An exploratory factor analysis of these 26 items was performed using the unweighted least squares-promax rotation method (Table 3). The scree plot showed a steep slope between factors 4 and 5. To ensure a fixed value ≥ 1 , four or five factors were considered possible. With a standard partial

Table 1. Participant characteristics ($N = 304$).

Demographics		<i>n</i>	(%)
Age	Mean 56.1 ± 11.4 years (range 26–85)		
Time since cancer diagnosis	Mean 81.2 ± 66.0 months (range 2–426)		
Cancer type	Breast	226	(74.3)
	Cervical	29	(9.5)
	Endometrial	31	(10.2)
	Ovarian	16	(5.3)
Stage	0	17	(5.6)
	I	125	(41.1)
	II	90	(29.6)
	III	40	(13.2)
	IV	23	(7.6)
Surgery	Partial mastectomy	59	(19.4)
	Partial mastectomy + SLNB	62	(20.4)
	Partial mastectomy + ALND	46	(15.1)
	Total mastectomy	47	(15.5)
	Total mastectomy + reconstruction	9	(3.0)
	Conization	6	(2.0)
	RH/STH	30	(9.9)
	RH/STH + BA + PEN ± PAN ± OM	25	(8.2)
	LSO/RSO	9	(3.0)
Therapy	No surgery	11	(3.6)
	Chemotherapy	25	(8.2)
	Molecularly targeted agent	9	(3.0)
	Radiotherapy	14	(4.6)
Symptoms	Hormone therapy	139	(45.7)
	Pain	71	(23.4)
	Fatigue	82	(27.0)
	Peripheral nerve symptoms	101	(33.2)
	Hot flash	94	(30.9)
	Lymphedema	28	(9.2)
Performance status	Sex pain	15	(4.9)
	0	230	(75.7)
	1	68	(22.4)
	2	2	(0.7)
Married/partner	3	2	(0.7)
	Married/partner	221	(72.7)
	Mother with children	233	(76.6)
	Employment type		
	Full-time	97	(31.9)
	Part-time	75	(24.7)
Employment type	On leave	8	(2.6)
	Quit job	24	(7.9)
	Not working	100	(32.9)

Note: excludes unknown/blank, surgical; SLNB = sentinel lymph-node biopsy; ALND = axillary lymph-node dissection; STH = simple total hysterectomy; RH = radical hysterectomy; BA = bilateral adnexectomy; LSO/RSO = left/right salpingo-oophorectomy; PEN = pelvic lymph nodes; PAN = para-aortic lymph nodes; OM = omentectomy

regression coefficient $\geq .50$, items with factor loading $\geq .50$ were removed to ensure a simple structure without the influence of multiple common factors. Consequently, a five-factor structure with 20 items was employed.

Each of the factors consisted of four items. The items of the first factor included “I’m not alone” and “I have someone who understands me,” which were questions created in the phase of the question development for the “connecting with others” subscale. The items of the second factor included “I enjoy fashion” and “I won’t hide my womanhood; I won’t wither,” which were questions for the “being a charming me” subscale. The items of the third factor included “I have time for myself that I can enjoy” and “I’m not good if I try to do my best too much,” which were questions for the “being myself” subscale. The items of the fourth factor included “I still feel down (inverse scale item)” and “I’m still not being true to my feelings (inverse scale item),” which were questions for the “overcoming pessimism” subscale. The items of the fifth factor included “My cancer survivor experience is expanding my life as a woman” and “I have the right to choose,” which were questions for the “living independently as a woman” and “expanding my life as a woman” subscales. To reflect both of these subscales, this factor was referred to as “living more independently as a woman.” The six sub-concepts originally established were consolidated into five factors through the factor analysis, but no swapping of items was done between the sub-concepts.

Confirmatory Factor Analysis

For the confirmatory factor analysis, a model was established based on the constructs assuming that subscales influence its corresponding items, and there was covariance among all the factors; the model had a satisfactory goodness of fit. As a result of removing items with small standardized coefficients, the final model had 20 items and five factors (Figure 1). The indices for the goodness of fit of the model were as follows: GFI, 0.903; AGFI, 0.872; CFI, 0.920; and RMSEA, 0.060. These findings showed that the model was statistically acceptable and supported the exploratory factor analysis. The result of the Kolmogorov-Smirnov test for the overall score was $p = .073$. The null hypothesis was not rejected, and a final model with 20 items, which was normally distributed, was confirmed.

Reliability

Cronbach’s α coefficient was 0.87 for the whole scale. Cronbach’s α ranged from 0.85 to 0.63 for each subscale.

Validity

The structure of the constructs and the subscales of the scale was confirmed. Among the six original constructs, the factors “living independently as a woman” and “expanding my

Table 2. Item analysis (corrected PASWC-32).

Sub-concept	Item	N	Min.	Max.	M	(SD)	Ceiling effect	Floor effect	Item-rest coefficient	Item-total correlation coefficient
Being myself	† 15. I'm not good if I try to do my best too much.	304	1	4	2.97	(0.90)	3.87	2.07	0.37	0.425**
	† 18. I have time for myself that I can enjoy.	304	1	4	3.18	(0.82)	4.00	2.36	0.52	0.566**
	† 19. I won't stick to the values I've had so far.	304	1	4	3.08	(0.85)	3.94	2.23	0.45	0.501**
	24. I have things to support me. ^b	304	1	4	3.13	(0.80)	3.93	2.34	0.54	0.578**
	27. I'm being my usual self.	304	1	4	3.29	(0.75)	4.04 ^a	2.54	0.56	0.596**
	29. I think it's okay to have weaknesses. ^b	304	1	4	2.98	(0.90)	3.88	2.08	0.37	0.425**
	† 32. I can be lazy when I want to be lazy.	304	1	4	3.07	(0.94)	4.00	2.13	0.37	0.431**
Being a charming me	† 8. I enjoy fashion.	304	1	4	2.82	(0.92)	3.73	1.90	0.55	0.591**
	† 9. I won't hide my womanhood; I won't wither.	304	1	4	2.93	(0.89)	3.83	2.04	0.63	0.665**
	† 10. I'm pretty cool now.	304	1	4	2.36	(0.89)	3.25	1.46	0.59	0.635**
	† 28. I have kindness in my heart.	304	1	4	3.01	(0.85)	3.86	2.16	0.67	0.706**
	31. I will continue to be myself as a woman. ^b	304	1	4	2.81	(0.95)	3.76	1.85	0.45	0.507**
Living independently as a woman	† 5. I have the right to choose.	304	1	4	3.10	(0.90)	3.99	2.20	0.40	0.452**
	6. I make the final decision on treatment.	304	1	4	3.44	(0.78)	4.21 ^a	2.66	0.31	0.363**
	† 11. I don't regret my decision.	304	1	4	3.17	(0.82)	3.99	2.35	0.45	0.496**
	14. I constantly feel like my core is shaken (inverse scale item).	304	1	4	3.44	(0.83)	4.27 ^a	2.61	0.40	0.447**
	† 25. I am myself.	304	1	4	3.08	(0.81)	3.90	2.27	0.72	0.751**
Expanding my life as a woman	13. I feel like I'm not a woman anymore after treatment (inverse scale item).	304	1	4	3.25	(0.91)	4.16 ^a	2.34	0.33	0.385**
	16. I'm not losing hope. ^b	304	1	4	3.28	(0.78)	4.06	2.50	0.56	0.600**
	21. I want to make use of my cancer experience for others. ^b	304	1	4	2.88	(0.90)	3.79	1.98	0.30	0.360**
	† 22. My cancer survivor experience is expanding my life as a woman.	304	1	4	2.37	(1.01)	3.37	1.36	0.38	0.438**
	30. I think my value as a woman does not depend on giving birth.	304	1	4	3.32	(0.92)	4.23 ^a	2.40	0.26 ^a	0.321**
Connecting with others	† 3. I have someone who understands me.	304	1	4	3.12	(0.83)	3.96	2.29	0.57	0.614**
	† 4. I'm not alone.	304	1	4	3.37	(0.81)	4.18	2.55	0.53	0.569**
	† 7. I feel that I have strengthened my ties with my husband or partner.	304	1	4	2.87	(0.98)	3.84	1.89	0.38	0.442**
	† 17. I have someone who listens to me.	304	1	4	3.24	(0.89)	4.13	2.35	0.60	0.637**
	26. I do not want to mention cancer (inverse scale item).	304	1	4	2.94	(1.03)	3.97	1.91	0.15 ^a	0.218**
Overcoming pessimism	1. I'm smiling. ^b	304	1	4	3.15	(0.77)	3.92	2.38	0.56	0.596**
	† 2. It's hard to think; I feel hazy (inverse scale item).	304	1	4	2.79	(0.94)	3.73	1.85	0.39	0.449**
	† 12. I still feel down (inverse scale item).	304	1	4	3.07	(0.94)	4.02	2.13	0.36	0.421**
	† 20. I'm still not being true to my feelings (inverse scale item).	304	1	4	3.05	(0.91)	3.95	2.14	0.33	0.386**
	† 23. I can't stand it when people around me are worrying about me (inverse scale item).	304	1	4	3.04	(0.88)	3.92	2.16	0.31	0.366**

Note: ** $p < .001$

†: adopted as PAWCS-20; ^aremoved during the item analysis; ^bremoved during the confirmatory factor analysis

life as a woman” were combined into “living more independently as a woman.” The other four constructs were kept as four separate factors. None of the items was associated with a different factor beyond the framework of each corresponding construct.

Table 4 shows the correlations between the scale factors. The five factors of the PASWC scale were significantly and

positively correlated with the FS of the MAC scale and the three factors of the PACS scale and were significantly and negatively correlated with H/H of the MAC scale and depression and anxiety of HADS ($p < .05$).

Figure 2 shows the multidimensional scaling output. The five factors of the PASWC scale were located in the positive area of Dimension 1, while the three factors of the PACS

Table 3. Exploratory factor analysis.

Factor/scale	Standard partial regression coefficient				
	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5
Factor 1. Connecting with others ($\alpha = .85$)					
4. I'm not alone.	0.867	-0.045	-0.057	0.067	0.061
3. I have someone who understands me.	0.854	-0.068	0.075	0.109	-0.132
17. I have someone who listens to me.	0.702	-0.009	0.128	-0.060	0.099
7. I feel that I have strengthened my ties with my husband or partner.	0.676	0.122	-0.124	-0.171	0.046
Factor 2. Being a charming me ($\alpha = .86$)					
8. I enjoy fashion.	-0.029	0.883	-0.052	-0.039	-0.019
9. I won't hide my womanhood; I won't wither.	0.031	0.842	0.018	0.002	-0.057
10. I'm pretty cool now.	-0.024	0.729	-0.083	0.107	0.111
28. I have kindness in my heart.	0.070	0.444	0.292	0.055	0.045
Factor 3. Being myself ($\alpha = .70$)					
18. I have time for myself that I can enjoy.	0.008	0.067	0.835	-0.001	-0.167
15. I'm not good if I try to do my best too much.	0.060	-0.059	0.637	0.009	-0.128
32. I can be lazy when I want to be lazy.	-0.091	-0.117	0.552	-0.107	0.365
19. I won't stick to the values I've had so far.	-0.047	-0.014	0.512	-0.003	0.055
Factor 4. Overcoming pessimism ($\alpha = .70$)					
12. I still feel down (inverse scale item).	-0.069	-0.012	0.054	0.681	-0.044
20. I'm still not being true to my feelings (inverse scale item).	-0.010	0.097	-0.006	0.601	-0.107
23. I can't stand it when people around me are worrying about me (inverse scale item).	0.017	-0.097	-0.016	0.595	0.106
2. It's hard to think; I feel hazy (inverse scale item).	0.021	0.095	-0.103	0.530	0.104
Factor 5. Living more independently as a woman ($\alpha = .63$)					
22. My cancer survivor experience is expanding my life as a woman.	0.012	-0.094	-0.099	0.204	0.641
5. I have the right to choose.	0.030	0.140	0.213	0.082	0.525
25. I am myself.	0.049	0.169	-0.095	-0.224	0.518
11. I don't regret my decision.	-0.014	0.071	0.172	0.062	0.510
(Correlation between factors)					
Factor 2	0.441				
Factor 3	0.543	0.468			
Factor 4	0.282	0.404	0.345		
Factor 5	0.449	0.625	0.518	0.338	

Note: Unweighted least squares–promax rotation

Standard partial regression coefficients were set to .50 or higher; if more than one factor was .50 or higher for one item, it was removed.

scale, which were positively correlated with the PASWC scale, were located in the negative area. All PASWC factors, except for “living more independently as a woman,” were located in a different area or far from the FS of the MAC scale. Therefore, our interpretation is that these factors should be distinct. Kruskal's stress ranged from 0.23 to 0.11. The correlation square, which indicated variance, was always 0.83 or higher, indicating validity and an explanatory power of 83% or higher.

The goodness of fit resulted in the simultaneous factor analysis of models 1 and 2 based on the final PASWC model created by randomly dividing all data into two groups. For Model 1, the GFI was 0.834; the AGFI was 0.787; the CFI was 0.873; and the RMSEA was 0.078. For Model 2, the GFI was 0.874; the AGFI was 0.834; the CFI

was 0.934; and the RMSEA was 0.055.

Discussion

Examination of the Reliability and Validity of the PASWC Scale

For reliability, Cronbach's α was 0.87 for the whole scale and ranged from 0.85 to 0.63 for each subfactor, confirming internal consistency. The PASWC scale validity for measuring the psychological adjustment status was examined using the method described by Messick (1989). First, evidence for the validity associated with the content and the essential aspects of the scale was obtained from the following: 1) objective assessment of the content validity in the scale's questions by cancer nursing experts using a 4-point scale during

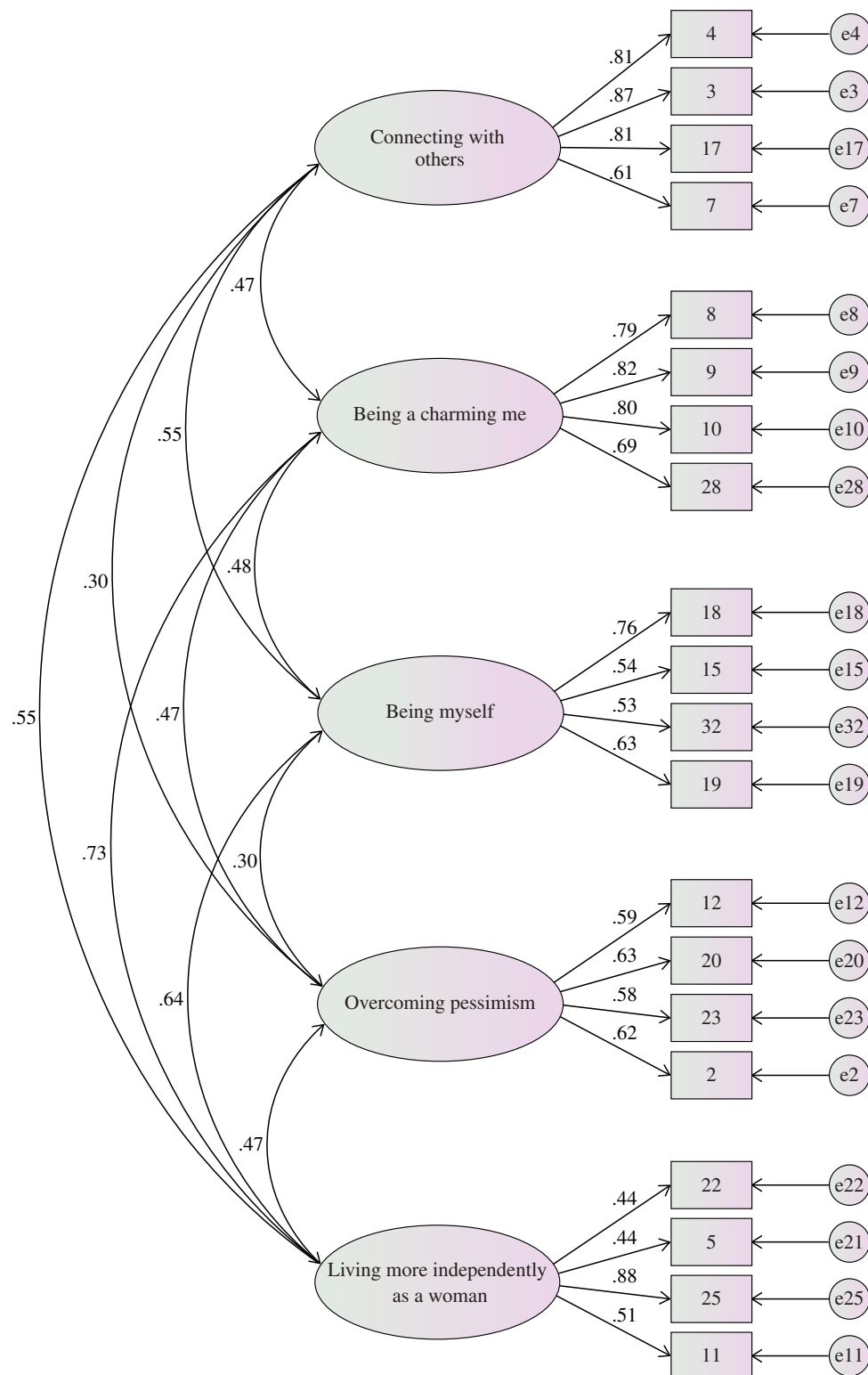


Figure 1. Final PASWC model.

Goodness of fit of the model: goodness of fit index, 0.903; adjusted goodness of fit index, 0.872; comparative fit index, 0.920; and root mean square error of approximation, 0.060.

the draft scale preparation; 2) confirmation of the consistency between the constructs representing the psychological adjustment of survivors of women's cancers identified before

the preparation of the scale and the subscales of the prepared scale; 3) analysis of the correlation between items; and 4) G-P and other analyses. Second, as evidence for ex-

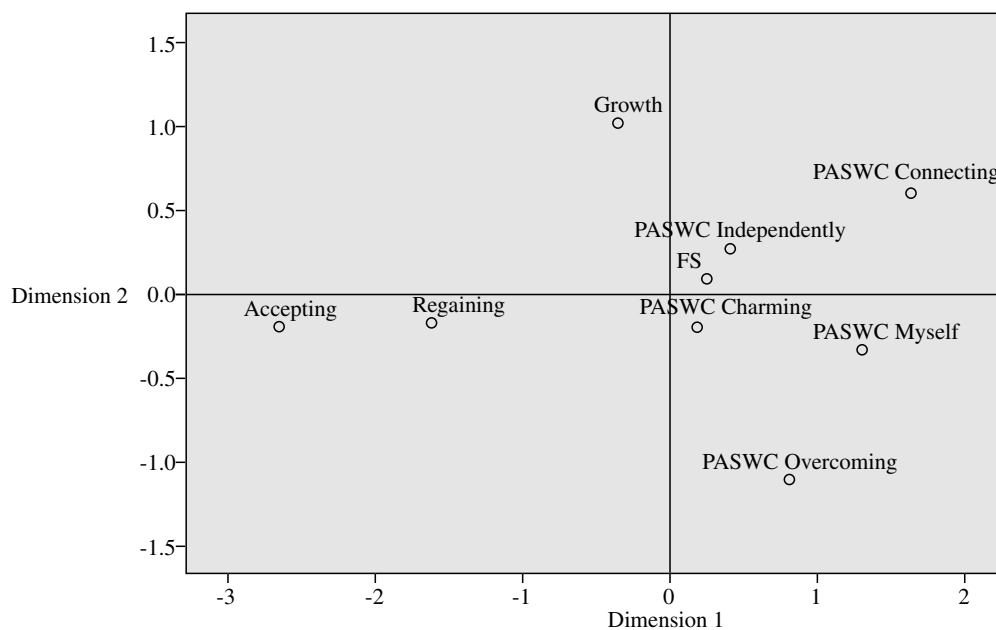
Table 4. Correlations between PASWC MAC HADS and PACS.

		PASWC					
		Connecting with someone	Being a charming me	Being myself	Overcoming pessimism	Living more independently as a woman	
PASWC	Being a charming me	0.422 **					
	Being myself	0.412 **	0.385 **				
	Overcoming pessimism	0.201 **	0.367 **	0.208 **			
	Living more independently as a woman	0.414 **	0.582 **	0.413 **	0.288 **		
MAC	Fighting spirit	0.462 **	0.487 **	0.382 **	0.141 *	0.574 **	
	Helpless/hopeless	-0.181 *	-0.381 **	-0.179 *	-0.404 **	-0.307 **	
	Anxious preoccupation	0.060	-0.141 *	0.023	-0.481 **	-0.050	
	Fatalism	0.089	-0.052	0.105	-0.153 *	0.089	
	Avoidance	0.132 *	0.147 *	0.100	-0.001	0.110	
HADS	Anxiety	-0.304 **	-0.355 **	-0.331 **	-0.587 **	-0.295 **	
	Depression	-0.349 **	-0.548 **	-0.330 **	-0.558 **	-0.374 **	
PACS	Accepting myself as a cancer patient	0.385 **	0.438 **	0.362 **	0.367 **	0.542 **	
	Feeling personal psychological growth	0.432 **	0.465 **	0.265 **	0.201 **	0.604 **	
	Regaining myself	0.335 **	0.421 **	0.219 **	0.361 **	0.416 **	
	Experiencing a lack of well-being	-0.330 **	-0.448 **	-0.286 **	-0.593 **	-0.372 **	

Note: Pearson's correlation coefficient. $N = 304$

PASWC, Psychological Adjustment in Survivors of Women's Cancers; MAC, Mental Adjustment to Cancer; HADS, Hospital Anxiety and Depression Scale; PACS, Psychological Adjustment of Cancer Survivors

* $p < .05$, ** $p < .001$

**Figure 2.** Output of multidimensional scaling.

Abbreviations: Subscales of psychological adjustment in survivors of women's cancers: PASWC Connecting, connecting with someone; PASWC Charming, being a charming me; PASWC Myself, being myself; PASWC Overcoming, overcoming pessimism; and PASWC Independently, living more independently as a woman. Subscales of Mental Adjustment to Cancer: FS, fighting spirit. Subscales of Psychological Adjustment of Cancer Survivors: Accepting, accepting myself as a patient living with cancer; Growth, feeling personal psychological growth; and Regaining, regaining myself.

ternal validity, the five subscales of the PASWC scale were shown to be positively correlated with the FS of the MAC scale, indicating independent recuperation of cancer survivors. The PASWC scale was also positively correlated with three factors of the PACS scale, indicating a favorable psychological adjustment status. The PASWC scale was negatively correlated with anxiety and depression of HADS. The evidence for generalizability was obtained from the cross-validity analysis. The goodness of fit for models 1 and 2 based on the final PASWC model was largely consistent; factors and factor loading were shown to be stable. As evidence for the scale's structural aspect, the model's goodness of fit was shown to be favorable in the confirmatory factor analysis. Thus, the PASWC scale was confirmed to have sufficient statistical explanatory power, and its validity was verified in terms of its content, essential, external, and structural validity and generalizability.

Characteristics of the Factors Composing the Scale of PASWC

First, dissimilarity was evaluated based on the results of multidimensional scaling, specifically the distance and the positioning of the concepts in the PASWC subscales and other scales. In multidimensional scaling, similar subscales are located close to each other, while less similar subscales are located farther from each other. Four PASWC subscales were located in an area different from FS of the MAC scale. The three factors of the PACS scale were also far away from the four PASWC subscales. This positioning suggests that these factors were related, but had characteristics that were distinct from each other. The five factors of the PASWC scale showed some characteristics related to femininity. The first factor, i.e., "connecting with others," consisted of items, such as "I have someone who understands me," and can be attributed to a common characteristic of women, which is to value connection with others. Women have been shown to be more emotionally expressive and more likely to seek support from others than men (Seale et al., 2006; Tifferet, 2020). The second factor is "being a charming me." In a recent study, cancer patients had high levels of interest in appearance and high need for information on appearance as they try to compensate for the changes in their appearance caused by cancer treatment (Nozawa & Fujima, 2020). Even if they have cancer, women can recover from a depressed mood and regain motivation to take action by dressing up and taking care of their appearance. This means that they can continue to express themselves as a woman.

The third to fifth factors reflect the strength and the flexibility of the survivors of women's cancers. The third factor, i.e., "being myself," represents the identity of the survivor who is coming to terms with cancer (Carter, 1993) and getting back to normal (Amir et al., 2008). We do not think that the third factor represents a confrontation of cancer, but

rather reflects the flexibility of women as they adjust themselves to the status of having cancer and recover their identity. Regarding the fourth factor, "overcoming pessimism," the original expression before converting it into an inverse scale item, "I still feel down," was "I no longer feel down." This item represented women's strength, i.e., resilience (Manne et al., 2015), despite the loss of reproductive function or femininity, as well as uncertainty about the future. The fifth factor, "living more independently as a woman," represents a challenge concerning self-involvement (i.e., self-identity of a woman as an independent entity). Survivors of women's cancers achieve psychological adjustment with an attitude of agency, i.e., an attempt to make choices. For example, survivors of women's cancers may make decisions about fertility by discontinuing life-saving cancer treatments to prioritize pregnancy or birth and not being markedly affected by the opinions of people around them, medical perspectives, or feelings in general. Cancer survivors are said to experience personal growth through their cancer experience (Greenwald & McCorkle, 2007; Kolokotroni et al., 2014). The factor "living more independently as a woman" in our study indicated their growth, including departure from a feminine identity, expansion of the way of life, and transformation of values through the treatment experience.

The factors "living independently as a woman" and "expanding my life as a woman" were combined because several items, including "I make the final decision on treatment," "value as a woman does not depend on giving birth to a child," and "I feel like I'm not a woman anymore after treatment (inverse scale item)," were deleted because of the ceiling effects. Many survivors of women's cancers selected the response "4. definitely" for these items probably because many survivors of women's cancers become aware of their departure from gender norms through their cancer experience and realize that women should make the final decisions as regards treatment by themselves.

Significance of Scale for the PASWC

The factor "connecting with others," which indicates a common characteristic of women, namely, living in relationships with others, the factor "being a charming me," which means enjoying being a woman, even while being treated for cancer, and the factors "being myself," "overcoming pessimism," and "living more independently as a woman," which reflect the strength and flexibility of women, capture the psychological adjustment of survivors of women's cancers in terms of femininity, regardless of the cancer site. Furthermore, these factors had distinct characteristics compared with the MAC and PACS scales. The PASWC scale is a unique scale dedicated to the psychological adjustment of survivors of women's cancers, which could not be measured by existing scales. We expect that further exploratory studies using PASWC as the dependent variable and participants'

characteristics, such as disease stage and age, as independent variables will provide insights into the new nursing interventions for survivors of women's cancers. The use of the PASWC scale to assess the outcome of nursing interventions makes it possible to support female survivors in living with cancer.

Study Limitations and Future Tasks

This study was conducted in patients whose disease condition was relatively stable, regardless of age. The participants' characteristics, including cancer stage, were not considered. Therefore, we plan to verify the utility of this scale, keeping in mind that we developed it as a measurement tool for survivors of women's cancers, and not for those who are in the terminal stage or those who had just been notified of having the disease.

Conclusions

In this study, we developed the PASWC scale, a 20-item scale with five subscales for measuring the psychological adjustment in survivors of women's cancers. The subscales were as follows: "connecting with others," "being a charming me," "being myself," "overcoming pessimism," and "living more independently as a woman." We confirmed certain reliability and validity levels; thus, this scale can become a useful tool for measuring the psychological adjustment of female cancer survivors in clinical settings.

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Author Contributions

Isako Ueta: conceptualization, methodology, investigation, data curation, formal analysis, writing—original draft, project administration, and funding acquisition. Hiroko Ota, Miho Ono, & Chiemi Onishi: supervision, funding acquisition, data curation, and writing—review and editing. Sanae Asano, Masato Nishimura, & Akiko Abe: data curation and writing—review and editing. All authors read and approved the final manuscript.

Declaration of Conflicting Interests

We have no conflict of interest to disclose.

Ethical Approval

Ethics Committee of Tokushima University Hospital, Approval No. 3240

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Informed Consent

Informed consent was obtained from all participants involved in this study.

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Brief Report

The survival process of newly graduated Japanese nurses in their first year of clinical practice: A qualitative study using modified grounded theory approach

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Abstract

Turnover of newly graduated nurses is an international problem. Although there are many studies on the learning process of newly graduated nurses, there is little research on why they were able to stay and survive. Therefore, this study aimed to clarify the survival processes of newly graduated nurses in clinical practice. Interviews were held with 12 nurses who had graduated from a 4-year nursing college, had 3-4 years of clinical experience in a general hospital ward, and were currently in a preceptor or similar educational role. Modified grounded theory was used for data collection and analysis. Consequently, we identified 1 core category, 1 category, 7 subcategories, and 31 concepts. The category "It's Sink or Swim" was a major turning point in the survival process of newly graduated nurses in the clinical field, after which the daily intention of the core category "Keeping my Commitment" continued with new realizations and repetitions of actions. The repetition of this routine also meant that the breadth of the newly graduated nurse's experience was broadened, and the burden of the core category "Keeping my Commitment" gradually reduced. In this way, new nurses survived in clinical settings. These findings showed that for newly graduated nurses to survive in a clinical setting, the core category of "Keeping my Commitment" while building relationships with their seniors was important. Therefore, it may be important for nursing education to strengthen not only supportive interpersonal relationships with patients but also foundational skills for interpersonal relationships with senior nurses.

Keywords

newly graduated nurses, role transition, survival process, turnover, realistic job preview

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Introduction

Many newly graduated nurses who start working at medical institutions encounter such difficulties in the clinical field that they choose to leave their employment and change jobs. Of the approximately 5.3 million newly graduated nurses in Japan each year (Ministry of Health, Labor and Welfare, 2016), 9% quit within 1 year of graduation, and in Tokyo,

12% will quit and change jobs (Japan Nursing Association, 2021). In addition, the turnover rate of newly graduated nurses within 1 year is 30% in the USA (Nursing Solutions Inc., 2022), which indicates that the early turnover of newly graduated nurses is a major international problem. Early turnover makes it difficult for newly graduated nurses to accumulate experience in clinical practice and develop their professional careers. A systematic review suggested that

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early turnover might have a significant impact on individuals, organizations, and society (Zhang et al., 2016), considering that the first year experience of newly graduated nurses has a significant effect on their future career development (Parker et al., 2014).

For newly graduated nurses, it has been shown that the transition from student to nurse is complex, challenging, and stressful (Parker et al., 2014). In describing the transition from schooling to the work, Zheng (2022) found that newly graduated nurses experience “phases of reality shock” such as overwork and significant responsibility. In addition, the transition from student to newly graduated nurse was said to be the most vulnerable period for them to commit to their profession and organization (Zheng et al., 2022). Hence, this 1-year period for newly graduated nurses could be understood as a process of surviving the year rather than growing from various difficulties in their new environment.

Various educational programs have been developed and implemented to compensate for difficulties and turnover factors experienced by newly graduated nurses. Simulation education and multiple-task training (Okada et al., 2017) have been designed to improve nursing skills and to help students learn about the gaps between their own abilities and clinical demands. However, the aforementioned educational interventions focused on promoting the adaptation of newly graduated nurses and educating them to improve their nursing practice skills. In other words, they do not focus on the skills that form the foundation for newly graduated nurses’ professional growth in clinical settings.

Historically, in the field of psychology, Wang (1995) identified the process for continuous employment of new employees in a company as “Survive.” In the field of education, Maistre and Pare (2010) also described the coping process of new teachers during the transition from college to the workplace as “Survive.” While several studies have examined why registered nurses have been able to keep their jobs (Ahlstedt et al., 2019), few have exclusively focused on newly graduated nurses to determine what keeps them in the workplace and how they survive even in challenging situations. Nevertheless, this information is crucial for nurses’ career development and growth.

Therefore, this study aimed to clarify the survival process of newly graduated nurses in their first year of clinical practice.

Materials and Methods

Design

This qualitative study used a modified grounded theory approach (M-GTA; Kinoshita, 2020), developed by adopting the theoretical properties of the grounded theory approach (Glaser & Strauss, 1967).

The M-GTA was considered appropriate for this study be-

cause it was designed to develop explanatory models for specific analytical themes, has limited generalizability, and can be adjusted and optimized by newly graduated nurses in their practice. (For a full description, refer to the Supplementary Methods)

Participants

Twelve female nurses working in preceptor roles or similar educational roles in private and public urban hospitals participated in this study and were recruited through seed-based snowball sampling.

Data Collection and Analysis

The interviews were conducted by the first author. The interviews were conducted one-on-one online with security features, field notes were taken, and the interviews were recorded using a digital recorder with the consent of the participants. During the interviews, participants were asked to discuss the most difficult experiences in their first year as a nurse related to nursing practice and work culture (Table 1).

Data Analysis

We focused on clusters of meanings related to the analysis theme “the process of newly graduated nurses’ survival in clinical practice” and the focused persons “nurses with experience in educational roles,” extracted specific examples, and described them on an analysis worksheet. The results of the semantic content interpretation were used as definitions. In addition, a concise expression of the semantic content of the definition was named a concept. The generated concepts, definitions, and concrete examples were then checked against those of other interviewees and conducting a continuous comparative analysis.

After generating the concepts, we performed a reversal check based on the analysis worksheet to confirm the “small theoretical saturation” as the second step, which judges the completeness of the concept generation from the researchers. The relationships among the created concepts were then examined and categories were generated.

The relationships among the categories were examined to confirm whether there was a core category for the analyzed theme. Finally, the results of the analysis were represented as a result diagram and a summary was written as a storyline. (For a full description, refer to the Supplementary Methods)

Ethical Considerations

This study was approved by the Institutional Review Board of St. Luke’s International University (21-A-019).

Table 1. Interview guide.

Personal background
· Is your current clinical experience in your third or fourth year?
· What department did you belong to in your first year?
Experience
What was the most difficult thing about your first year as a newcomer or a difficult experience that made it difficult for you to continue working? (Not only those related to nursing practice but also those related to human relations, work environment, etc.)
· What was the experience like?
· When did this happen (after you started working) ?
· How did you react, act, or think about the difficulties?
· Looking back, why do you think you got into this situation?
Looking back, how have your experiences in the first year shaped who you are today?
· Have your feelings changed in response to the difficulties you have experienced (including changes in your own feelings and values) ?
· Please tell us what you think has changed and why.
· What triggered the change?

Table 2. Characteristics of participants.

Identification code	Age group	Years of clinical experience	Department	Number of nurses	Number of hospital beds	Work schedules
A	22–25	3	Palliative care	25	23	2 shift-work
B	22–25	3	Neurosurgery	30	30	2 shift-work
C	22–25	4	Respiratory surgery, medicine, and digestive surgery	30	40	3 shift-work
D	22–25	3	Respiratory surgery, medicine ophthalmology	30	45	3 shift-work
E	26–30	4	Respiratory surgery, medicine	30	30	3 shift-work
F	22–25	3	Neurosurgery	25	33	2 shift-work
G	22–25	3	Cardiology, cardiovascular surgery	30	23	2 shift-work
H	22–25	3	Respiratory surgery, medicine	30	42	2 shift-work
I	22–25	3	Neurosurgery	30	30	2 shift-work
J	26–30	4	Neurosurgery	25	35	2 shift-work
K	22–25	4	Pediatrics	30	32	2 shift-work
L	22–25	4	Pediatrics	30	30	2 shift-work

Results

Participants' Characteristics

The participants were 12 nurses with 3-4 years of clinical experience who were currently in a preceptor role or a similar educational role in a general ward. Table 2 shows that the interviews were conducted with each participant.

Categories and Concepts

The results yielded 31 concepts, from which 7 subcategories, 1 category, and 1 core category emerged (Table 3). These relationships are shown in Figure 1. The storylines are presented first, followed by the subcategories.

Storylines

As newly graduated nurses began working in hospitals, three factors became apparent. They were the subcategory "Nervous Just Going to Work," and they encountered the subcategory

"Many Frustrations" and they felt at the mercy of the subcategory "Intentions of Immeasurable Senior Nurses." Yet, throughout this period, they also began to note that they had colleagues and others providing the subcategory "Clarity and Nurturing from the Others," and thus they felt supported. However, when their daily routine was shaken due to the subcategory "Intentions of Immeasurable Senior Nurses," the newly graduated nurses reached a turning point with the awareness of the category "It's Sink or Swim."

This turning point brought new nurses to the subcategory "Knowing the True Intention of Senior Nurses" and to the subcategory "Acting After Organizing," but even so, the days of the subcategory "It's Still Not Easy" continued day after day. The repetition of this cycle broadened the experience of newly graduated nurses in the clinical setting. This expansion also brought new nurses joy and positive discoveries that they had never experienced before, such as *worthwhile involvement* and *awareness of improvement*. The bur-

Table 3. A core category, categories, subcategories, and concepts of the survival process of newly graduated nurses.

Core category	Category	Subcategory	Concept
Keeping My Commitment	Nervous Just Going to Work		Being nervous for inexperienced Trying things out Heavy responsibility
			Being unable to take control Who should I approach and what should I ask Choose the wrong action Have a difficult handoff Sacrificing patient's comfort No confidence Standing in amazement Being amazed and disheartened by failure
			Concerning about unnecessary nuisance Saving face Intimidated by their presence Seeking the proper attitude
	Intentions of Immeasurable Senior Nurses		Senior nurses were one step ahead Not intimidated by their presence Support from colleagues
			True significance of relying on others Paying the price for not caring about patient's comfort
	It's Sink or Swim		Careful reflection Relationship among senior nurses Positive feedback
			Approaching proactively senior nurses Importance of proactive approach Realizing patient's comfort Imitating senior nurse's attitude
	Knowing the True Intention of Senior Nurses		It's Still Not Easy Proactively approaching senior nurses Awareness of improvement Worthwhile involvement Role model

den on newly graduated nurses of the core category “Keeping My Commitment” gradually decreased during this cycle. The newly graduated nurse survived by continuing her intention of the core category “Keeping My Commitment,” and clinical days became a natural part of the new routine, after which the burden of the core category “Keeping My Commitment” gradually reduced for new nurses. In this way, the newly graduated nurses survived in the clinical field.

Nervous Just Going to Work

The subcategory “Nervous Just Going to Work” concerns what makes newly graduated nurses nervous just to go to work every day. (A detailed explanation is provided in the Supplementary Results)

Many Frustrations

As the days passed, newly graduated nurses encountered the subcategory “Many Frustrations.” This begins with frustration of *being unable to take control*. (A detailed explanation is provided in the Supplementary Results)

Intentions of Immeasurable Senior Nurses

The subcategory “Intentions of Immeasurable Senior Nurses” refers to newly graduated nurses working in situations where they do not fully understand the intention of the senior's words, actions, and behavior. It is an entity that interacts with newly graduated nurses' subcategory “Many Frustrations.” (A detailed explanation is provided in the Supplementary Results)

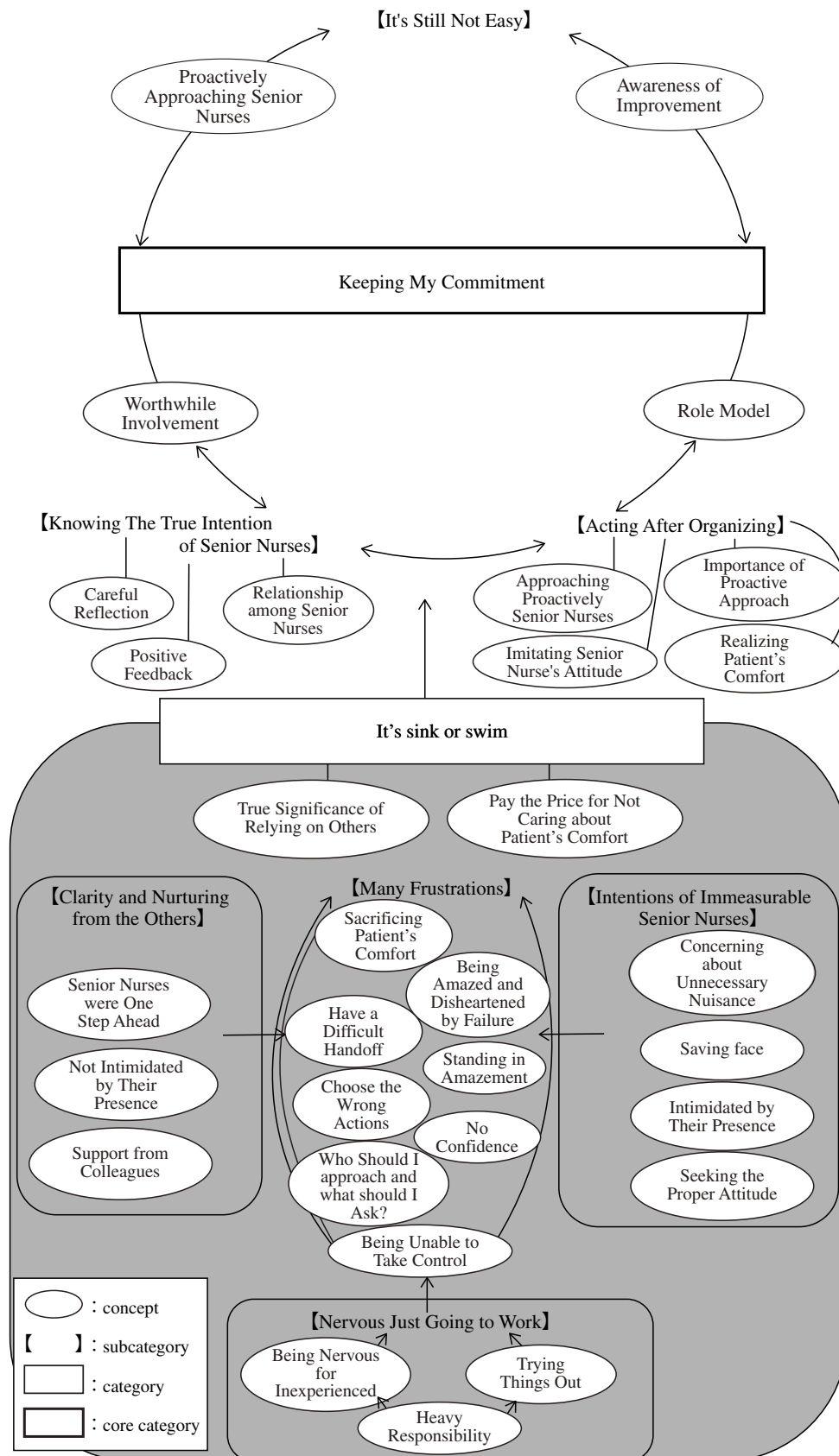


Figure 1. The survival process of newly graduated nurses.

Clarity and Nurturing from the Others

Although “Intentions of Immeasurable Senior Nurses” accelerates the days of “Many Frustrations,” “Clarity and Nurturing from the Others” means the newly graduated nurses feel that situation has improved through the help of those around them. The arrows from “Clarity and Nurturing from the Others” and “Intentions of Immeasurable Senior Nurses” indicate the impact on the days of “Many Frustrations,” and the presence of “Clarity and Nurturing from the Others” barely keeps the daily life of “Many Frustrations.” (A detailed explanation is provided in the Supplementary Results)

“It’s Sink or Swim”

Newly graduated nurses spent their days with the subcategory “Many Frustrations” with the support of the subcategory “Clarity and Nurturing from Others,” while being tossed about by the subcategory “Intentions of Immeasurable Senior Nurses,” but when the experiences with this subcategory greatly exceeded the presence of those who *provided clarity and nurturing*, their subcategory “Many Frustrations” would intensify and they would become discom-bobulated. Being so confused or unsettled, the newly graduated nurse entered the category “It’s Sink or Swim,” meaning that the new nurse began to emerge from the darkness. This dynamic demonstrated the transition from believing that they had to do everything themselves to not only feeling the need to rely on the help of others to improve patient care but also seeing the wisdom in it. Whether newly graduated nurses reached this turning point seemed to be the key to their survival during their first year. (A detailed explanation is provided in the Supplementary Results)

“Keeping My Commitment”

The core category, “Keeping My Commitment,” was exemplified by new nurses feeling the positive aspects of their subcategory “Many Frustrations” and not wanting to quit their jobs. This core category was present in all stages of the survival process and included the three subcategories: “Knowing the True Intention of Senior Nurses,” “Acting after Organizing,” and “It’s Still Not Easy.”

Knowing the True Intentions of Senior Nurses

This subcategory pertained to new nurses realizing that their image of seniors differed from what they had imagined. For example, the careful reflection of new nurses by their seniors was not always positive; however, the new nurses felt that they were taking time to instruct them carefully. (A detailed explanation is provided in the Supplementary Results)

“Acting After Organizing”

The subcategory “Acting after Organizing” is where the new nurses become aware of the importance of considering the

situation before acting. This is not an easy task for new nurses and is an action that new nurses can take because they have organized their thinking in the process so far. (A detailed explanation is provided in the Supplementary Results)

“It’s Still Not Easy”

This refers to the frustration that new nurses feel when they try to put into practice the actions and awareness that they have organized, but the results are not as expected.

As newly graduated nurses moved back and forth among these three subcategories, “Knowing the True Intention of Senior Nurses,” “Acting After Organizing,” and “It’s Still Not Easy,” their burden of the core category “Keeping My Commitment” gradually decreased. Newly graduated nurses gradually acquired the ability to survive in the clinical field by continually reverting to the core category “Keeping My Commitment.” (A detailed explanation is provided in the Supplementary Results)

Discussion

Importance of Relationships with Senior Nurses

The results of this study show that the presence of seniority, represented by the subcategory “Intentions of Immeasurable Senior Nurses,” is what accelerates the subcategory “Many Frustrations” of new nurses. Previous studies have identified a negative workplace culture for new nurses related to communication skills (Liang et al., 2018). New nurses also experience difficulties in their relationships with multiple entities, such as physicians, colleagues, and patients (Lee et al., 2019). These results show that the presence of senior colleagues was discussed in terms of “surviving.” In contrast to previous reports that new nurses experienced the greatest difficulties in their relationships with physicians (See et al., 2022), the new nurses in this study reported difficulties in working out their relationships with their colleagues, especially senior nurses. Ease of interaction with senior nurses and how problems are solved influence the survival process of new nurses.

Effects of “Keeping My Commitment”

The core category “Keeping My Commitment” was relevant to all phases of this process, and its meaning and weight differed for each phase. The beginning of the change in the meaning and weight of the core category “Keeping My Commitment” is in the breadth of new nurses’ everyday experience that occurs when they are the subcategory “Knowing the True Intention of Senior Nurses,” “Acting After Organizing,” and “It’s Still Not Easy,” after they face the qualitative turning point of realizing the core category “It’s Sink or Swim.” Previous studies of the growth process of new nurses have shown that the first year of a new nurse’s career

is challenging; however, positive changes occur after the second year (Zheng et al., 2022). However, in this study, we believe that “Keeping my Commitment” was the core category and the identification of the gradual reduction in this burden over the course of a year is a unique result.

Applications to Practice in the Process of Survival of Newly Graduated Nurses in Clinical Practice

The survival process of new graduate nurses identified in this analysis is the process of role transition from nursing students while performing their roles. The performing role included feeling unprepared, discouraging realities and unsupportive cultures, and lack of confidence/feeling insecure (Hallaran et al., 2022), and the survival process for new nurses in this study was similar. To facilitate these transitions, healthcare organizations have implemented practice transition programs such as orientation, preceptorship, and residency (Hampton et al., 2021). However, some of the difficulties arise in the post-role process from nursing students independently in the field (See et al., 2022). Care institutions and education have the ability to prepare and provide new nurses with tools to successfully transition into nursing practice. Moreover, it has been suggested that the role transition from student to freshman is promoted by a Realistic Job Preview (RJP), an evidence-based human resource management that focuses on the facts rather than the good aspects of the organization and job that the new employee will be a part of in the future (Gilmartin et al., 2013). We believe that the introduction of RJP into nursing education will help successfully transition the role of nursing students to that of new graduate nurses.

In university nursing education, simulation education and multiple-task training (Okada et al., 2017) have been conducted to enhance educational content and compensate for difficulties and turnover factors. These seem to be examples of education that promotes role transitions. However, the perspective of “surviving” the clinical setting in this study indicates that smooth interaction with senior colleagues is significant.

Many nursing colleges conduct communicative practices and exercises (Sowko et al., 2019) to facilitate assistive communication. However, the results of this study suggest that promoting assistive communication with patients is insufficient to promote the role transition of new nurses. Therefore, the students’ basic interpersonal skills with supervisors, such as senior nurses, should be improved in basic nursing education.

In addition, providing nursing students with the experience process described in the research results may lead to the development of more realistic work expectations, similar to RJP, and should enhance their readiness to work in clinical settings and promote transition (Sternier et al., 2021).

Author Contributions

Haruna Aiyoshi and Yumi Sakyo conceived the idea of the study and significantly analyzed and interpreted the data. Haruna Aiyoshi substantially drafted the manuscript. Both authors critically reviewed and revised the manuscript draft and approved the final version for submission.

Declaration of Conflicting Interests

The authors declare no conflicts of interest.

Ethical Approval

This study was approved by the Institutional Review Board of the St. Luke’s International University [No: 21-A-019].

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Informed Consent

Informed consent was obtained from all participants in this study.

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Brief Report

Practice for cancer pharmacotherapy among nurses, physicians, and pharmacists in Japan: A descriptive cross-sectional study

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Abstract

Objective: This study describes and compares the practices of the nurses, pharmacists, and physicians from a Japanese university hospital on cancer patient support during pharmacotherapy and gather suggestions for enhancing the effectiveness of the pharmacotherapy delivery system for patients with cancer. **Methods:** This descriptive cross-sectional study involved 430 nurses, 76 physicians, and 22 pharmacists from a university hospital in Japan and was conducted from February to April 2022. A uniform questionnaire was distributed to all three groups of professionals. The practices of indication judgments for pharmacotherapy (e.g., confirming that it is an established standard or equivalent treatment for the cancer type concerned) were asked using six items on a four-point scale. Their perceptions of patient support issues were asked using five items. The data were analyzed using the Mann-Whitney *U* test and Fisher's exact test. The Ethics Review Committee of the Graduate School of Nursing of Chiba University approved the present study. **Results:** The analysis included a final number of 184 nurses, 35 physicians, and 12 pharmacists after applying the eligibility criteria. Statistically significant differences were observed in four items, including "Confirm that the treatment has been established as standard treatment or equivalent treatment for the cancer type in question." Variances regarding what are checked to judge pharmacotherapy indications were noted among the three groups of professionals. The common situation and practice identified across these professions included information exchange through electronic charts, sharing knowledge on managing new pharmacotherapies, and ensuring adequate time for patient self-care support. **Conclusion:** This study uncovered variations in the perceptions of nurses, physicians, and pharmacists on cancer pharmacotherapy. The key to fostering an effective collaboration is the implementation of a systematic approach for sharing patient information and pharmacotherapy knowledge while ensuring a clear understanding of the role of each profession.

Keywords

cross-sectional survey, interprofessional care, interprofessional collaboration, pharmacotherapy

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Introduction

Approximately 18 million people are diagnosed with cancer globally, and its incidence rate is projected to increase by

75% in 2030, with 22 million new cases, primarily because of the increasing number of aging individuals and reproductive, dietary, smoking, and hormonal risk factors (Dyba et al., 2021; Japan, 2022; Organization, 2020). Cancer has

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been the number one cause of death in Japan since 1981. The 4th Basic Plan for Promotion of Cancer Control was formulated in March 2023 (Ministry of Health, 2023). This plan was based on the overall goal of “promoting cancer countermeasures that leave no one behind and aiming to overcome cancer with all citizens.” While maintaining the structure of the three pillars of improvement of cancer care and coexistence with cancer, the measures for addressing the current situation and issues in each field must be determined. In the field of cancer medical care, in particular, improving the system for receiving appropriate medical care will improve the cancer survival rates, reduce the cancer mortality rates, and improve the quality of life of all cancer patients receiving treatment, as well as that of their families (Ministry of Health, 2023). It is important to promote team medical care, including equalizing and centralizing the system for receiving appropriate medical care. Although various cancer countermeasures are currently being promoted, such as improving the medical care delivery systems, discrepancies in progress are still present among medical institutions. Hence, further promotion of information provision and awareness regarding cancer is necessary.

Cancer pharmacotherapy requires interprofessional collaboration because of the high-volume, high-risk clinical interventions, and despite significant effort and intention, errors in the course of chemotherapy reported personal knowledge of medication errors (Neuss et al., 2017). The Oncology Nursing Society and the American Society of Clinical Oncology have aspired to provide standards for minimizing the risk of errors in chemotherapy ordering, preparation, and administration, including oral and parenteral therapies, in the outpatient and inpatient settings (Neuss et al., 2017). In Japan, multiple academic societies have jointly announced guidelines on extravasation associated with cancer drug therapy. Accordingly, seminars are being held under the initiative of academic societies (Japanese Society of Cancer Nursing, 2023). Additionally, oncology specialists and teams should discuss potential issues before treatment. Patients should also fully understand the potential of developing exacerbations of the condition. In many cases, the benefit of receiving therapy for cancer outweighs the risks of possibly worsening an autoimmune condition (Seery, 2017). Previous studies reported that a standardized approach to chemotherapy educational processes by an interprofessional clinical team can improve patient satisfaction, increase knowledge of the side effects related to chemotherapy, and increase the efficacy of healthcare providers in terms of time and quality of care provided to the patients (Aebersold et al., 2021; Gallegos et al., 2019; Yamamoto, 2021). With the advent of new drugs, the roles required of each specialist in pharmacotherapy for patients with cancer have become more sophisticated (Michaeli et al., 2023).

In fact, issues, such as poor communication during cancer

pharmacotherapy and misunderstandings about cancer pharmacotherapy and the professional’s role in interprofessional collaboration (IPC), still exist. The actual situation leading to the construction and resolution of systems that include not only physicians and pharmacists, but also nurses, at Japanese university hospitals has not yet been clarified; thus, it is necessary to clarify how each profession practices cancer pharmacotherapy. Therefore, in this study, we aimed to investigate the degree of practice and manual use of pharmacotherapy through a cross-sectional survey. This study aimed to describe pharmacotherapy practice for patients with cancer and the situation of manual use encountered during cancer pharmacotherapy by the nurses, physicians, and pharmacists from a Japanese university hospital.

Materials and Methods

Design

This descriptive cross-sectional study utilized web- and paper-based surveys and followed the STROBE guideline.

Setting and Participants

The study sample was conveniently recruited from a university hospital in Kanto Region, Japan (Hospital A). Hospital A is a regional cancer treatment cooperation base hospital involved in medical treatment, education, and research related to cancer control. This general hospital provides cancer chemotherapy in multiple departments. This study enrolled nurses, physicians, and pharmacists working in the hospital wards and outpatient departments, where pharmacotherapy regimens are being registered. The nurses, physicians, and pharmacists working in unit-based departments (e.g., intensive care unit, orthopedic wards, cardiology, psychiatric ward, coronavirus disease 2019 managed ward, and operating rooms) were excluded from the analysis. The present survey was conducted from March to April 2023.

Measurements

The participants were asked to provide their demographic data, including age, sex, educational background, years of healthcare practice, and years of experience working in cancer care. The survey items were created specifically to ask about the general content required for pharmacotherapy, regardless of the patients’ cancer type. We created draft survey items based on the cancer drug therapy or biological therapy manual (revised in June 2022) used at Hospital A. This manual was designed to be accessible to all professionals involved in cancer pharmacotherapy in Hospital A, regardless of their professional field. It covered basic information on cancer pharmacotherapy, such as the role and practice of physicians, nurses, and pharmacists, treatment decision making, and regimen ordering system. This manual also described the types of drugs used in pharmacotherapy, their

administration process, observation points during their administration, ways of dealing with extravascular leakage and drug hypersensitivity reactions, and use of observation and recording sheets. The manual was created based on clinical guidelines and annually reviewed for revision. Appendix 1 shows the manual index. To determine whether cancer patients were suitable to receive cancer pharmacotherapy, we asked the participants about their practices when handling patients receiving pharmacotherapy and the degree of their practice, including the performance status (PS) of confirmation and ensuring that the patient's general condition is maintained, and the major organ function is preserved. The survey has six items rated as follows: 0 = not applicable; 1 = never; 2 = rarely; 3 = occasionally; and 4 = always. To determine whether the participants faced challenges during cancer pharmacotherapy, the survey was conducted using six items, which included their understanding of manual and providing self-care support to patients with cancer and their families. The participants responded to each item with either "yes" or "no."

The nurses certified in cancer chemotherapy at Hospital A, the nurse manager of the outpatient pharmacotherapy, and a university faculty member familiar with cancer nursing created an item proposal. The research members examined its face validity.

Data Collection

The paper-based questionnaire sheets and the electronic survey link were distributed by the manager of each professional in Hospital A. The participants could choose to respond either via the web or on paper depending on their preferences. For paper responses, the data were gathered from the collection boxes located in each department.

Statistical Analysis

Descriptive statistics were utilized for the participant characteristics. The practices of the three groups of professionals were compared by initially performing the Kruskal-Wallis test after excluding the responses marked as "not applicable (0)" from the dataset. Post-hoc analyses were performed using the Mann-Whitney *U* test with Bonferroni correction for multiple comparisons for items that differed significantly. Fisher's exact test was used to assess the differences in the perceived challenges for supporting patients on cancer pharmacotherapy across professionals. The null hypothesis was that practice and manual usage were not professional-dependent. The RStudio software (version 2023.06.1+524, Free Software Foundation, Inc.) for Windows was used for the analysis. The statistical significance threshold was set at 5%.

Ethical Consideration

The ethical approval for this study was obtained from the

Ethics Review Committee, Graduate School of Nursing, Chiba University. The participants provided written informed consent prior to study participation. The consent form provided information regarding the aim, procedures, and potential risks and benefits of the study.

The present research was part of an IPC study aimed to support patients undergoing pharmacotherapy, which was conducted by a graduate school of nursing in collaboration with a university hospital.

Results

Demographic Data

A total of 184 nurses, 35 physicians, and 12 pharmacists were analyzed. Although half of the nurses were in their 20s, more than half of the physicians were in their 30s-40s, and the pharmacists were in their 40s (Table 1). Altogether, 60%-80% of the enrolled physicians and pharmacists had over 10 years of clinical experience. More than half of the nurses had <10 years of clinical experience. Regarding the clinical experience in cancer care, approximately 60% of the physicians and pharmacists had over 10 years over of experience, and approximately 5% of nurses had over 10 years of experience.

Degree of Practice on the Care of Patients Receiving Pharmacotherapy

Table 2 shows the effect of the degree of practice on the care of patients with cancer receiving pharmacotherapy. All six items differed significantly among the three professional groups (i.e., physicians, nurses, and pharmacists) in the Kruskal-Wallis test. Physicians had significantly higher scores than nurses and pharmacists in confirming that the treatment was established as a standard or equivalent treatment for the cancer type in question and in assessing PS to ensure that the patient's general condition is maintained. Additionally, physicians had significantly higher scores than nurses in confirming that the major organ function is preserved. Pharmacists had significantly lower scores than the other professionals in confirming about obtaining informed consent from patients, support for the patients from their families or caregivers, and financial problems. Particularly, all professionals had lower scores in the financial problem item compared to the other items. Pharmacists had lower scores in four items than the other professionals.

Understanding and Using the Manual in Pharmacotherapy

Table 3 shows the perceived challenges in pharmacotherapy among all professionals. Only the item "Lack of time to provide self-care support to patients and their families" differed significantly among the professionals ($p = .011$), in which most of the pharmacists answered "No."

Less than 50% of the participants in all groups answered

Table 1. Demographic data.

	Nurses <i>n</i> = 184		Physicians <i>n</i> = 35		Pharmacists <i>n</i> = 12	
	<i>n</i>	(%)	<i>n</i>	(%)	<i>n</i>	(%)
Age						
<25	41	(22.3)	0	(0.0)	0	(0.0)
25–29	51	(27.7)	2	(5.7)	4	(33.3)
30–34	30	(16.3)	3	(8.6)	0	(0.0)
35–39	17	(9.2)	8	(22.9)	1	(8.3)
40–44	17	(9.2)	9	(25.7)	5	(41.7)
45–49	14	(7.6)	6	(17.1)	1	(8.3)
50–54	7	(3.8)	4	(11.4)	1	(8.3)
≥55	7	(3.8)	3	(8.6)	0	(0.0)
Education						
University	130	(70.7)	8	(22.9)	4	(33.3)
Graduate school	2	(1.1)	27	(77.1)	8	(66.7)
Vocational school	36	(19.6)	–	–	–	–
Junior college	14	(7.6)	–	–	–	–
Other	2	(1.1)	–	–	–	–
Clinical experience (years)						
<1	18	(9.8)	1	(2.9)	0	(0.0)
1–3	42	(22.8)	0	(0.0)	2	(16.7)
4–5	17	(9.2)	2	(5.7)	2	(16.7)
6–9	43	(23.4)	3	(8.6)	0	(0.0)
10–14	20	(10.9)	8	(22.9)	2	(16.7)
15–19	16	(8.7)	9	(25.7)	4	(33.3)
≥20	28	(15.2)	12	(34.3)	2	(16.7)
Experience in cancer care (years)						
<1	36	(19.6)	1	(2.9)	2	(16.7)
1–3	80	(43.5)	4	(11.4)	1	(8.3)
4–5	30	(16.3)	3	(8.6)	2	(16.7)
6–9	29	(15.8)	3	(8.6)	0	(0.0)
10–14	4	(2.2)	12	(34.3)	1	(8.3)
15–19	1	(0.5)	6	(17.1)	5	(41.7)
≥20	4	(2.2)	6	(17.1)	1	(8.3)

“Yes” to not understanding the manuals. More than 50% of the physicians and pharmacists and approximately 50% of the nurses responded not being able to share their manuals within their group of professionals. More than 60% of the participants in the three groups responded not being able to share information with multiple professionals using electronic medical records. Moreover, 70% of the physicians and pharmacists responded not being able to share methods of managing adverse events of new drug therapies.

Discussion

The present study uncovered variations in practices and usage of manuals on cancer pharmacotherapy among nurses,

physicians, and pharmacists. Altogether, 70.7% of nurses had university degrees, and 77.1% and 66.7% of the physicians and pharmacists, respectively, had master’s degrees, indicating that a high level of educational background is a characteristic of a university hospital in Japan. More than 90% of the physicians had >6 years of clinical experience, and >65% of the pharmacists had >10 years of clinical experience. Regarding the years of experience in cancer care, 90% of the nurses had <10 years of experience, and >50% of the physicians and pharmacists had >10 years of experience. This difference was thought to be caused by the career development characteristics in Japan, wherein nurses rotate between departments, and physicians and pharmacists specialize in their field (Association, 2023; Japan Medical Labor Federation, 2023; Masayoshi & Nakamura, 2013).

In the two practices, that is, confirming that the treatment has been established as a standard or equivalent treatment for the cancer type in question and confirming that the major organ function is preserved, significant differences were observed among the three groups, with the physicians obtaining higher scores than the nurses and the pharmacists. However, while the physicians confirm treatment regimens, the other professionals required understanding the standard treatment as they also participate as interprofessional teams in patient care, including administering and dispensing drugs. Previous studies demonstrated the role of nurses in oncology care and emphasized that nurses are a key part of the team addressing the supportive care needs and management of cancer patients. They also stated that ongoing communication between the patient and the oncology nurses regarding the development of adverse events is a critical component for maximizing the treatment outcomes and the patients’ quality of life (Meenaghan et al., 2023; Parreira et al., 2024; Sánchez-Lorenzo et al., 2024). In cancer pharmacotherapy, nurses have an important role in providing direct care, and they play a central role in understanding the patients’ condition and treatment response, as well as sharing information with the interprofessional team. In this study, more than 70% of the nurses responded that they understood the manual. More than 50% of the physicians and pharmacists gave the same response. When cancer pharmacotherapy is implemented by a multidisciplinary team, it is important to understand the treatment guidelines and manuals before exercising each profession’s expertise. Our study results suggest the necessity to examine more detailed understanding and knowledge of cancer treatment and provide appropriate education for these professionals.

The pharmacists in this study confirmed and ensured less frequently than nurses and physicians in three items. In addition, the majority of them could not share information about treatment and adverse events with interprofessionals. Furthermore, they were also less likely to confirm whether the patients had understood their treatment and provided

Table 2. Degree of practice for patients receiving pharmacotherapy.

	Nurses (A)		Physicians (B)		Pharmacists (C)		Multiple comparisons
	Mean (SD)	Median	Mean (SD)	Median	Mean (SD)	Median	
Confirm that the treatment has been established as standard treatment or equivalent treatment for the cancer type in question	2.78 (.81)	3	3.74 (.51)	4	3.25 (.62)	3	A<B ($p < .001$) B>C ($p = .021$)
Performance status to ensure that patient's general condition is maintained	3.32 (.68)	3	3.60 (.65)	4	3.17 (.58)	3	B>C ($p = .049$)
Confirm that the major organ function is preserved	2.99 (.69)	3	3.59 (.56)	4	3.25 (.87)	3	A<B ($p < .001$)
Confirm that patient's understanding and consent were obtained	3.55 (.61)	4	3.65 (.49)	4	2.58 (1.16)	3	A>C ($p < .001$) B>C ($p = .021$)
Confirm that patient has support from families or caregivers	3.09 (.65)	3	3.09 (.62)	3	2.08 (.79)	2	A>C ($p < .001$) B>C ($p = .002$)
Confirm if there are any financial problems	2.69 (.77)	3	2.63 (.88)	3	1.73 (.79)	2	A>C ($p < .001$) B>C ($p = .007$)

Note: "Not applicable" were excluded. Multiple comparisons were conducted with the Mann–Whitney U test for each pair.

Table 3. Understanding and using of manual in pharmacotherapy.

		Nurses $n = 184$		Physicians $n = 35$		Pharmacists $n = 12$		p^*
		n	%	n	%	n	%	
A lack of understanding of manuals in Hospital A	Yes	49	(26.6)	16	(45.7)	5	(41.7)	.055
	No	135	(73.4)	19	(54.3)	7	(58.3)	
Unable to share this manual among the team in own occupation	Yes	87	(47.3)	23	(65.7)	7	(58.3)	.111
	No	97	(52.7)	12	(34.3)	5	(41.7)	
Unable to share this manual with interprofessionals	Yes	87	(47.3)	20	(57.1)	7	(58.3)	.475
	No	97	(52.7)	15	(42.9)	5	(41.7)	
Unable to share information with interprofessionals using electronic medical records	Yes	127	(69.0)	27	(77.1)	10	(83.3)	.473
	No	57	(31.0)	8	(22.9)	2	(16.7)	
Unable to share methods for managing adverse events when new drugs are introduced	Yes	109	(59.2)	26	(74.3)	9	(75.0)	.169
	No	75	(40.8)	9	(25.7)	3	(25.0)	
Lack of time to provide self-care support to patients and their families	Yes	106	(57.6)	16	(45.7)	2	(16.7)	.011
	No	78	(42.4)	19	(54.3)	10	(83.3)	

Note: Fisher's exact test was conducted.

consent, as compared to nurses and physicians. The timely management of cancer pharmacotherapy is critical for achieving positive patient outcomes, and there are many opportunities for IPC in the diagnosis and detection of adverse events (Seery, 2017). Regarding the role of pharmacists in the interprofessional care team, they can assist in managing cases with chronic disease conditions by providing drug information to patients and other healthcare providers and by acting as consultants for treatment-related issues (Rahayu et al., 2021). Furthermore, pharmacist-managed pharmacotherapy reportedly shortens the time to take for the oncologists

to manage the treatment and contribute to increasing physician satisfaction (Le et al., 2021). Although some bodies of literature described the role of pharmacists in IPC, the pharmacists in Hospital A may have fewer opportunities to interact directly with cancer patients. Therefore, it cannot be generalized because professional practice might differ slightly from one institution to another; thus, these results highlight the features of the hospital in this study.

No significant difference was observed regarding information sharing of the manual among professionals, and the three professions reported similar trends that they could not

do so; hence, there is a need to build a unified information-sharing system among professionals. Previous studies concluded that there was no sufficient evidence on the effects of IPC; nevertheless, cancer patients assumed IPC positively and it had an impact on their well-being (Kurniasih et al., 2023; Reeves et al., 2017). Furthermore, implementing IPC in the clinical setting is complex because it includes various types of interventions, including team action planning, inter-professional rounds, interprofessional checklists, and inter-professional meetings (Didier et al., 2020; Kurniasih et al., 2023).

Limitation

This study has several limitations. First, this study was conducted at one university hospital only, which presents challenges in generalizing the study findings. However, the demographics of the study participants were similar to those reported in previous studies conducted at other university hospitals. Second, the reliability and the validity of the scales used in the present study were not fully verified. In this study, the scale for measuring practices commonly implemented in wards and outpatient clinics, regardless of the department, was developed based on a manual used in Hospital A. Although the content validity was ensured by the research team members, and the reliability was evaluated with Cronbach's alpha coefficient, some items were interpreted as having a double meaning; therefore, caution should be exercised when interpreting our study results. Further studies could consider modifying the scale items and assess practices using the existing validated scale.

Conclusions

Our study demonstrated variations in the practice of nurses, physicians, and pharmacists on cancer pharmacotherapy. The key to fostering an effective collaboration is the implementation of a systematic approach for sharing patient information and pharmacotherapy knowledge while ensuring a clear understanding of the role of each profession.

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Author Contributions

All authors have significantly contributed to this work by engaging in the conception, design, and acquisition of data, as well as conducting analysis and interpreting results. They collectively participated in drafting, revising, and critically reviewing the article. The final approval for publication was given by all authors, who also unanimously agreed on the choice of journal for submission. Each author acknowledges

personal accountability for all facets of the research.

Declaration of Conflicting Interests

We have no conflict of interest to disclose.

Ethical Approval

This study was approved by the Institutional Ethics Review Board of the Chiba University Graduate School of Nursing (No. NR4-105).

Data Sharing

The participants of this study did not give written consent for their data to be shared publicly. Therefore, due to the sensitive nature of the research, supporting data are not available. The data supporting the findings of this study are available from the corresponding author, Tomoko Majima, upon reasonable request.

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Brief Report

Development of a decision support tool for patients with Crohn's disease considering biologic treatment

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Abstract

The study aimed to develop a decision support tool for patients with Crohn's disease considering biologic treatment and evaluate its usability, validity, and acceptability. A prototype was systematically developed based on the Ottawa Decision Support Framework. The prototype met all the qualifying criteria of the International Patient Decision Aid Standards instrument. A questionnaire survey was designed to assess the prototype, with 22 patients and six clinicians recruited. We calculated the descriptive statistics for the survey data and analyzed the free responses using a qualitative content analysis and the prototype features requiring refinement extraction. The survey was completed by 18 patients and six clinicians. The prototype was assessed as "very useful" by 66.7% of the patients and clinicians and "quite useful" by 33.3%. The information that patients must know was considered to be "well represented" by the prototype, as expressed by 72.2% of the patients and 66.7% of the clinicians, and as "somewhat represented," as expressed by 27.8 and 33.3%, respectively. Most respondents reported that the content was "easy to understand" (patients: 83.3%; clinicians: 100%); the format was "easy to use" (patients: 77.8%; clinicians: 100%); and the information presentation was "well-balanced" (patients: 83.3%; clinicians: 100%). The patients suggested improvements, such as using figures to make the text concise and revising the checklist format and content to facilitate decision making. We created an evidence-based decision support tool after modifying the prototype according to the survey results. Further investigation of the tool effectiveness for Crohn's disease patients considering biologic treatment is needed.

Keywords

Crohn's disease, decision support tool, decision making

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Introduction

Crohn's disease (CD) is defined as a chronic inflammatory bowel disease characterized by periods of activity and remission. Most patients are diagnosed during their 20s-40s and require lifelong medical treatment. The estimated number of Japanese CD patients increased by approximately 100% from 2009 to 44,245 in 2019 (Japan Intractable Diseases Information Center, 2021).

CD is typically treated with aminosalicylates and nutrition therapy, with the use of steroids for disease relapse. Biologic infliximab was approved for CD use in Japan in 2002. Since then, the conceptual understanding and treatment targets of CD have substantially changed. In addition to symptom reduction, treatment goals now include the prevention of intestinal tract complications, mucosal healing, and increasing patient participation in life events (e.g., work). However, biologic use is associated with side effects and response loss

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(Qiu et al., 2017). Five biologics (i.e., infliximab, adalimumab, ustekinumab, vedolizumab, and risankizumab) are now approved in Japan. With the increase of the biologic availability, patients and clinicians may have difficulty deciding on optimal treatments.

In shared decision making (SDM), clinicians and patients share the best available evidence, and patients are supported to consider their options and make informed decisions (Stacey et al., 2017). Many decision aids (DAs) are available to guide decision making. These tools support patients by helping explicate their decisions, offering information about treatment options and associated benefits/harms, and clarifying the connection between decisions and the patient's personal values (Stacey et al., 2017).

A previous study showed that patients who received biologic treatment for CD considered SDM more important than those who did not (Morishige et al., 2017). We asked gastroenterologists who treated patients with CD as regards the types of treatment decisions appropriate for SDM (Nunotani & Ishibashi, 2021). Of the respondents, 94% thought that the selection of treatments that may have substantial risks and benefits (e.g., biologics) is the most appropriate type of decision for SDM. Approximately half of the respondents felt that the lack of decision support tools was the key barrier to SDM. Therefore, tools that CD patients and clinicians can use in SDM must be urgently developed.

Almario et al. (2018) developed an online DA that facilitates biologic treatment-related decisions for patients with inflammatory bowel disease; however, this DA is not tailored for CD patients. Approved biologics in the United States differ from those in Japan; hence, the treatment choices in the two countries differ. In this work, we developed a novel decision support tool for patients with CD considering biologic treatment in Japan and evaluated its usability, validity, and acceptability.

Materials and Methods

Study Design

We follow Coulter et al.'s (2013) DA development guidelines and report herein the decision support tool development process.

Scoping

The target users were CD patients considering biologic treatment options in Japan. Patients who were prior biologic users and needed to switch to another biologic (e.g., because of side effects) were also included.

Steering Committee

The steering committee comprised the following content and process experts: one gastroenterologist and two nurses who routinely cared for CD patients and a researcher experienced

in developing patient decision support tools. Patient advocates and patients previously treated with ≥ 1 biologics also provided input about the content and the format.

Prototype Development

We developed a prototype by referring to a previous study on patients' views on decisional needs (Nunotani & Suzuki, 2016) (design 1) and a previous study on gastroenterologists' views on SDM (Nunotani & Ishibashi, 2021) (design 2). We also referred to online patient DAs on the biologic selection for inflammatory bowel disease (Almario et al., 2018) and on the selection for ulcerative colitis surgery (Ottawa Hospital Research Institute, 2021) (design 3). Additionally, we reviewed and synthesized evidence using CD medical guidelines (Development Committee of Evidence-Based Clinical Practice Guidelines for Inflammatory Bowel Disease, 2020; Matsuoka, 2021) and systematic reviews of the effects and safety profile of CD biologics (Močko et al., 2016; Singh et al., 2018). A prototype was created using the Ottawa Decision Support Framework to reflect the following decision-making process: Step 1: Know how to make a decision with conviction; Step 2: Understand the option characteristics; Step 3: Clarify what is important to you; Step 4: Confirm whether or not you are ready to make a decision; and Step 5: Make the treatment decision with healthcare professionals. Each step included (with their permission) narratives of CD patients who experienced biologic treatment decision making. Images and diagrams were included in the prototype to improve patient understanding. Each step included a memo column that patients could write in and use during counseling with clinicians.

Quality Evaluation of the Prototype

The International Patient Decision Aid Standards instrument (IPDASi) is a quality criterion framework for patient DAs (Elwyn et al., 2006). We evaluated the prototype development process and the SDM design components using the Japanese version of the IPDASi (version 4.0) (Osaka et al., 2017). The quality criteria comprised 44 items: qualifying criteria (six items), certification criteria (10 items), and quality criteria (28 items). Each item was rated as present/absent. A prototype must meet all six qualifying criteria to be considered a DA. DAs that failed to meet the certification criteria were considered to have a high risk of harmful bias. The certification criteria were rated from 1 (strongly disagree) to 4 (strongly agree), reflecting the extent to which the DA meets each criterion. Only items rated as ≥ 3 met the criteria. DAs meeting the quality criteria were superior, but failure to meet these criteria did not indicate a high risk of harmful bias. The quality criteria were rated on the same four-point scale. After excluding four certification criteria items and five quality criteria items about the clinical screening examination, we used 35 items for the prototype

evaluation. After examination by the steering committee, the prototype met all six qualifying criteria of the Japanese IPDASi. Five of the six certification criteria items (C1, 2, 3, 4, and 6) were rated as 4, while C5 was rated as 3. Eleven of the 23 quality criteria items (QU2, 3, 9, 10, 11, 12, 13, 14, 15, 16, and 17) were rated as 4; six (QU4, 5, 18, 19, 20, and 21) were rated as 3; three (QU6, 7, and 8) were rated as 2; and three (QU1, 22, and 23) were rated as 1 (Table 1).

Alpha Testing

Alpha testing is a standard step in DA development, which provides stakeholder feedback on comprehensibility and usability. We selected a sample size of 22 following previous studies that used alpha testing (McAlpine et al., 2019; Shishido et al., 2020). The participants involved in the first alpha testing (alpha testing 1) were 22 CD patients from a specialized clinic in Kansai, Japan. Currently, over 100 patients are being treated for CD at this clinic. The alpha testing 2 participants were two gastroenterologists and four nurses with more than 3 years of experience in treating or nursing CD patients and who were not steering committee members. We asked the participants to review the prototype and provide feedback on its usability, validity, and acceptability using an anonymous questionnaire. We tested usability by assessing whether the overall prototype and each step were helpful for the CD patients considering biologic treatment using a four-point Likert scale: “very useful,” “quite useful,” “not very useful,” and “quite useless.” We tested validity by assessing whether the overall prototype and each step included information based on the patients’ needs. We used a four-point Likert scale to assess whether the information was “well represented,” “somewhat represented,” “partly represented,” or “not represented at all.” We tested acceptability by assessing the following general features of the prototype: length, font size, amount of information, balance of information, clarity of content, and ease of use. The questionnaire also included an open-response item to enable the participants to freely express their opinions of the prototype. The feedback was reviewed by the steering committee and incorporated into the final product by consensus.

Data Analysis

We calculated the descriptive statistics for the alpha testing data using SPSS version 29.0 (IBM SPSS Statistics for Windows, Armonk, NY, USA). The free responses were analyzed using a qualitative content analysis, and the prototype features requiring refinement were extracted based on the content similarity.

Ethical Considerations

The study was approved by the ethics committee of Mukogawa Women’s University (No. 20-39) and the ethics committee of the institution that performed alpha testing

(Aoyama Medical Clinic; No. 2020-1). All the participants were informed of the study’s purpose and methods. All of them also provided written consent for participation and for publication of the study.

Results

Characteristics of the Participants Involved in the Alpha Testing

Alpha testing 1 was completed by 18 patients. The mean age was 38.3 (range 23-64) years; 61.1% were men; and the mean CD onset age was 26.1 (range 14-62) years. Alpha testing 2 was completed by two gastroenterologists and four nurses. The mean clinical practice years was 18.8 (range 15-27), and the mean clinical practice years treating/nursing CD patients was 10.5 (range 3-21). All respondents completed the questionnaire.

Prototype Evaluation

Table 2 shows the results of the prototype usability and validity assessment by the 18 patients. Table 3 presents the results of the same assessment by the six clinicians. The overall prototype was assessed as “very useful” by 66.7% of the patients and 66.7% of the clinicians and as “quite useful” by 33.3% of the patients and 33.3% of the clinicians. Additionally, 72.2% of the patients and 66.7% of the clinicians considered the information to be “well represented” and 27.8% and 33.3% considered it “somewhat represented.”

More patients than clinicians rated the contents of Steps 1 (ability to make a decision with conviction), 3 (clarifying what is important), 4 (readiness to make a decision), and 5 (making the treatment decision) as “very useful.” More clinicians than patients rated Step 2 (understanding the options) as “very useful.”

More patients than clinicians considered the Steps 3 and 4 information to be “well represented.” However, more clinicians than patients considered the Step 2 information as “well represented.”

The prototype length was considered “appropriate” by 83.3 and 50.0% and “long” by 16.7 and 50.0% of patients and clinicians, respectively. The amount of information was considered “appropriate” by 77.8 and 66.7% and “too much” by 16.7 and 33.3% of patients and clinicians, respectively. All participants felt the font size was “appropriate.” Most participants felt the content was “easy to understand” (patients: 83.3%; clinicians: 100%); the format was “easy to use” (patients: 77.8%; clinicians: 100%); and the information presentation was “well-balanced” (patients 83.3%; clinicians: 100%).

Table 4 shows the free responses. The patients gave positive responses about the prototype construction and the treatment option table. The patients and clinicians responded positively to the narratives of the experienced patients. The

Table 1. Evaluation of decision support tool using IPDASi (2017)-Japanese version criteria.

Item dimension	Qualifying criteria	Certification criteria	Quality criteria
Information	Q1. Describes the health condition or problem for which a decision is required Q2. Explicitly states a decision that must be considered Q3. Describes the available options for the index decision Q4. Describes the positive features of each option Q5. Describes the negative features of each option	C1. Shows the negative and positive features of options with equal detail	QU1. Describes the natural course of the health condition or problem if no action is taken QU2. Facilitates a comparison of the positive and negative features of the available options
Probability			QU3. Provides information about the outcome probabilities associated with the options QU4. Specifies the defined group of patients for whom the outcome probabilities apply QU5. Specifies the event rates for the outcome probabilities QU6. Allows the users to compare the outcome probabilities across options for the same time period QU7. Allows the users to compare the outcome probabilities across the same denominator QU8. Provides more than one way of viewing the probabilities (e.g., words, numbers, and diagrams)
Values	Q6. Describes what it is like to experience the consequences of the options		QU9. Asks patients to think about which positive and negative features of options matter most to them
Guidance			QU10. Provides a step-by-step method for decision making QU11. Includes tools like worksheets or lists of questions to use when discussing options with a practitioner
Development			QU12. Development process included a needs assessment with clients or patients QU13. Development process included a needs assessment with health professionals QU14. Development process included a review by clients/patients not involved in producing the decision support intervention QU15. Development process included a review by professionals not involved in producing the decision support intervention QU16. Field tested with patients who were facing the decision QU17. Field tested with practitioners who counsel patients who face the decision
Evidence		C2. Provides citations to the evidence selected C3. Provides a production or publication date C4. Provides information about the update policy C5. Provides information about the uncertainty level about the event or outcome probabilities	QU18. Describes how research evidence was selected or synthesized QU19. Describes the quality of the research evidence used
Disclosure		C6. Provides information about the funding source used for development	QU20. Includes authors'/developers' credentials or qualifications
Plain language			QU21. Reports readability levels
Evaluation			QU22. Evidence improves match between preferences of the informed patient and the option chosen QU23. Evidence in the patient decision aid helps patients to increase their knowledge about options' features

Note: The gray hatching shows the criteria that the developed decision support tool did “not meet” or did “not meet at all.” IPDASi = International Patient Decision Aid Standards instrument.

Table 2. Usability and validity assessment of the decision aid prototype among crohn's disease patients ($N = 18$).

	<i>n</i> (%)				Median	IQR
Usability	Very useful	Quite useful	Not very useful	Quite useless		
Overall	12 (66.7)	6 (33.3)	0 (0.0)	0 (0.0)	4.0	3–4
Step 1	15 (83.3)	3 (16.7)	0 (0.0)	0 (0.0)	4.0	4–4
Step 2	13 (72.2)	5 (27.8)	0 (0.0)	0 (0.0)	4.0	3–4
Step 3	14 (77.8)	3 (16.7)	1 (5.5)	0 (0.0)	4.0	3–4
Step 4	12 (66.7)	4 (22.2)	2 (11.1)	0 (0.0)	4.0	3–4
Step 5	12 (66.7)	6 (33.3)	0 (0.0)	0 (0.0)	4.0	3–4
Validity	Well represented	Somewhat represented	Partly represented	Not represented at all		
Overall	13 (72.2)	5 (27.8)	0 (0.0)	0 (0.0)	4.0	3–4
Step 1	10 (55.6)	8 (44.4)	0 (0.0)	0 (0.0)	4.0	3–4
Step 2	14 (77.8)	4 (22.2)	0 (0.0)	0 (0.0)	4.0	4–4
Step 3	13 (72.2)	5 (27.8)	0 (0.0)	0 (0.0)	4.0	3–4
Step 4	11 (61.1)	6 (33.3)	1 (5.5)	0 (0.0)	4.0	3–4
Step 5	12 (66.7)	6 (33.3)	0 (0.0)	0 (0.0)	4.0	3–4

Note: IQR = interquartile range (25th–75th percentile).

Step 1: Know how to make a decision with conviction; Step 2: Understand the option characteristics; Step 3: Clarify what is important to you; Step 4: Confirm whether you are ready to make a decision; and Step 5: Make the treatment decision with healthcare professionals.

Table 3. Usability and validity assessment of the decision aid prototype among clinicians ($N = 6$).

	<i>n</i> (%)				Median	IQR
Usability	Very useful	Quite useful	Not very useful	Quite useless		
Overall	4 (66.7)	2 (33.3)	0 (0.0)	0 (0.0)	4.0	3–4
Step 1	4 (66.7)	2 (33.3)	0 (0.0)	0 (0.0)	4.0	3–4
Step 2	5 (83.3)	1 (16.7)	0 (0.0)	0 (0.0)	4.0	3–4
Step 3	4 (66.7)	2 (33.3)	0 (0.0)	0 (0.0)	4.0	3–4
Step 4	3 (50.0)	3 (50.0)	0 (0.0)	0 (0.0)	3.5	3–4
Step 5	3 (50.0)	3 (50.0)	0 (0.0)	0 (0.0)	3.5	3–4
Validity	Well represented	Somewhat represented	Partly represented	Not represented at all		
Overall	4 (66.7)	2 (33.3)	0 (0.0)	0 (0.0)	4.0	3–4
Step 1	4 (66.7)	2 (33.3)	0 (0.0)	0 (0.0)	4.0	3–4
Step 2	6 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	4.0	4–4
Step 3	4 (66.7)	2 (33.3)	0 (0.0)	0 (0.0)	4.0	3–4
Step 4	3 (50.0)	3 (50.0)	0 (0.0)	0 (0.0)	3.5	3–4
Step 5	4 (66.7)	2 (33.3)	0 (0.0)	0 (0.0)	4.0	3–4

Note: IQR = interquartile range (25th–75th percentile).

Step 1: Know how to make a decision with conviction; Step 2: Understand the option characteristics; Step 3: Clarify what is important to you; Step 4: Confirm whether you are ready to make a decision; and Step 5: Make the treatment decision with healthcare professionals.

patients' suggestions for improvement included using figures to make the text concise and revising the Step 4 checklist format and text to clarify it and improve ease of use. The alpha testing results were used to modify the DA prototype to create a final version.

Discussion

We report herein the systematic development of an evidence-based decision support tool using the Ottawa Deci-

sion Support Framework. The quality evaluation showed that the prototype met all six qualifying and six certification criteria. However, three quality criteria on the probabilities were not met. One possible reason for this failure is the limitations of the systematic reviews used in design 4. No direct head-to-head trials compared the CD biologics. Additionally, although long-term outcomes for infliximab and adalimumab, which were approved in the early 2000s, were reported, only short-term outcomes were reported for ustekinumab and vedolizumab, which were approved after

Table 4. Free responses from the alpha testing questionnaire.

Positive responses	Responses suggesting improvements
I felt that the construction of the decision aid was good. It enabled me to confirm my decision using the STEP process and compare treatment options. (Patient participant)	I felt that there was a lot of text, and I think that you could use a figure to make the text more concise. (Patient participant)
The treatment option table in STEP 2 was quite clear. (Patient participant)	It was hard to check the items included in Step 4. (Patient participant)
STEP 2 was very useful to me. (Patient participant)	I was worried that patients will not read through the whole decision aid. (Clinician participant)
My anxiety was reduced by learning about the experiences of other patients. (Patient participant)	I wanted explanations about other medications in addition to biologics. (Patient participant)
I think that patients should have such a guide at the time of their disease onset. (Patient participant)	
As my knowledge has increased by having read this guide, I think that I can move forward more easily and talk to healthcare professionals. (Patient participant)	
I was pleased that a variety of opinions from experienced patients were included. I realized that there is no one correct answer during treatment decision making, and that it is important that patients make their own treatment decisions. (Clinician participant)	
I want to use this booklet to practice shared decision making with patients. (Clinician participant)	

2017. Therefore, the prototype did not allow users to compare the outcome probabilities across options for the same time period and denominator. More systematic reviews are needed to further review and synthesize evidence on the effects and safety of CD biologics and update evidence on the probabilities included in the tool. Two evaluation quality criteria were not met because we focused on the tool development process. Beta field testing with patients and clinicians is needed to assess the tool's feasibility and effects.

The alpha testing results were highly favorable. All participants rated the overall tool as very or quite useful, feeling that the necessary information was well or somewhat represented and confirming the tool's usability and validity. More clinicians than patients rated Step 2 positively. This step reflected direct clinician involvement in providing treatment information to patients. Clinicians may have felt that the tool provided necessary information and could be used during SDM with patients, as expressed in a free response from one of the clinician participants.

Conversely, more patients than clinicians rated Steps 3 (clarifying what is important) and 4 (readiness to make a decision) positively. Some patients worried about serious infections, such as sepsis, despite the low incidence of adverse events, while others focused on effects (e.g., remission rate), administration method, or the cost of biologics. The type and the order of priorities in treatment decision making depend on the patients' values and life events and stages, such as employment, pregnancy, and older age (Aoyama & Shimizu, 2021). Patients may find it easier to obtain and understand information about biologic options than determine how important the advantages and disadvantages of those options are for themselves. The memo columns for Steps 3 and 4 enabled patients to record and clarify their values and confirm their readiness for decision making. This helped patients to express their unspoken thoughts and feelings. This may explain the positive responses from the patients.

Regarding the tool's acceptability, the free responses from one patient and one clinician indicated a problem with the

text length and the amount of information. More patients than clinicians felt that the length and the amount of information were appropriate. One patient expressed a desire to receive explanations about other medications in addition to biologics. Conversely, one clinician was worried that patients would not read the whole decision support tool. This indicates that patients may want more information than clinicians think. All participants were adults; hence, their understanding of the tool context was high. However, population aging in Japan has increased the number of older patients with CD; thus, it would be useful to consider whether or not the tool contains too much information and use a figure to keep the text concise.

The alpha testing results indicated that the tool may be useful in supporting decision making for CD patients considering biologic treatment. This tool could be used by nurses in advocating for the CD patients' right to be informed and supporting them in treatment decision making.

In conclusion, we tested a prototype novel decision support tool for CD patients considering biologic treatment and evaluated its usability, validity, and acceptability. The prototype met all six qualifying and six certification criteria, and the patients and clinicians found the tool acceptable and useful. Therefore, the tool addresses a substantial gap in the resources available for CD patients. We revised the prototype to create a final version in response to the participant suggestions. Beta testing with patients and clinicians from other clinics is now needed to assess the tool's feasibility and facilitate its use in SDM for CD management.

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in 2021.

Author Contributions

M.N. participated in the design and coordination of the study, performed data analysis and interpretation, and wrote the manuscript; M.T. performed alpha testing and data interpretation; and N.A. made substantial contributions to the DA prototype development and project supervision.

Declaration of Conflicting Interests

The authors declare that there are no conflicts of interest.

Ethical Approval

This study was approved by the ethics committee of Mukogawa Women's University (No. 20-39) and the ethics committee of Aoyama Medical Clinic (No. 2020-1).

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The individuals named below have been recognized as recipients of Outstanding Reviewer Awards in 2025

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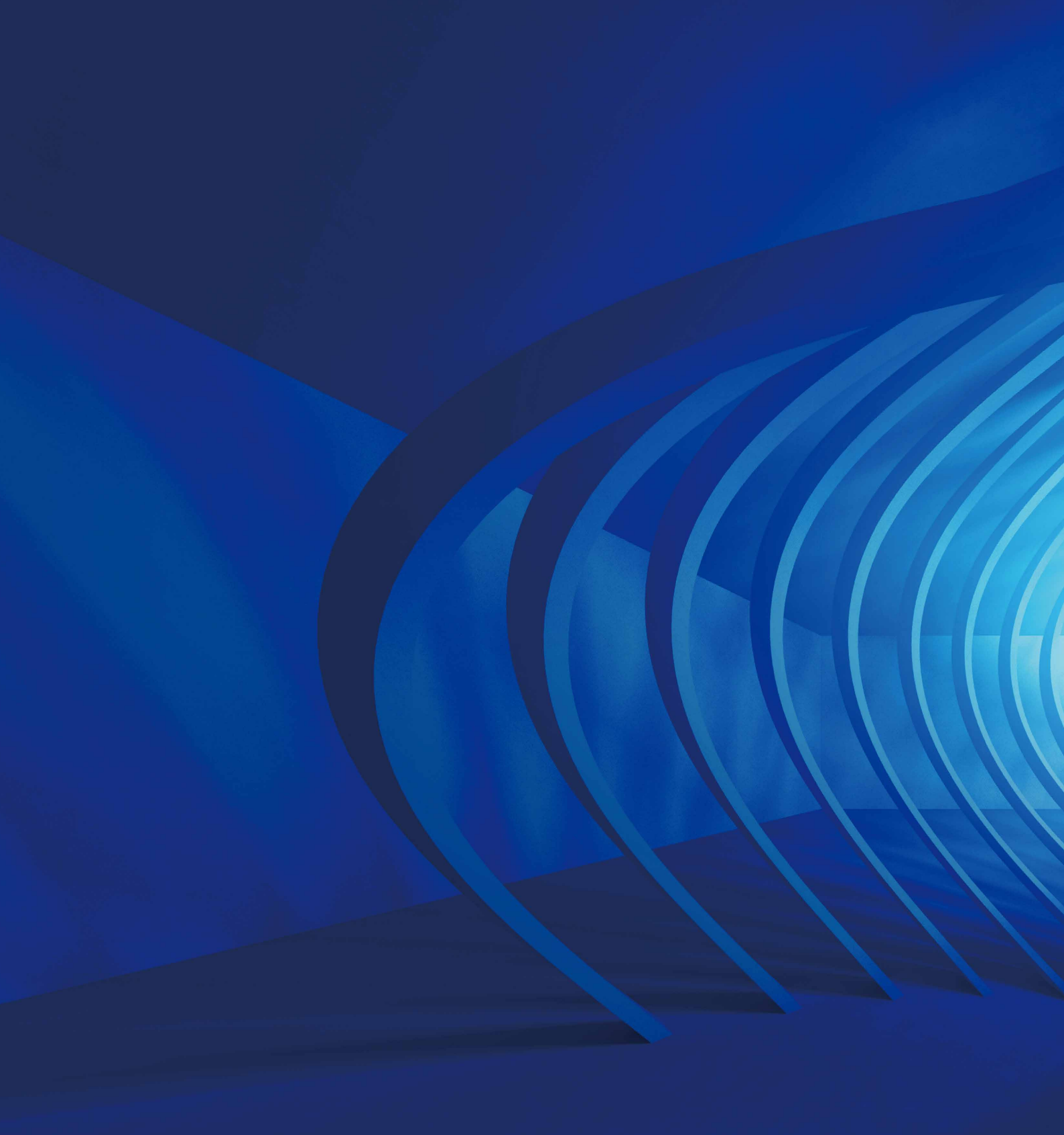
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