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Editorial

Journal of International Nursing Research forges ahead!

Naohiro Hohashi, PhD, RN, PHN, FAAN^{1,2}

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It is with great pleasure that we present our second issue of *Journal of International Nursing Research (JINR)* while at the same time acknowledging the support of The Japan Society of Nursing Research (JSNR), which oversees publication of *JINR*.

By the end of 2022, *JINR* had received more than 50 original submissions per year from around the world. We would like to express our thanks to the authors who have chosen *JINR* for their submissions, the Editorial Committee and our hardworking reviewers. When the number of papers submitted to *JINR* has increased sufficiently and *JINR* has securely established itself as an international journal, we will give consideration to publishing more than one issue per year.

Like most new publications, *JINR* faces a number of challenges, and we are making strong efforts to confront them. The Editorial Committee is constantly discussing the review process and taking steps to improve it, such as by gradually reducing the turn-around time for conducting reviews. In particular, the Editorial Committee continues to encourage submissions from researchers around the world and has been redoubling its efforts to facilitate recruitment of knowledgeable reviewers.

New from 2022 was our launch of awards to recognize excellence in the work our reviewers have been performing. These "Outstanding Reviewer Awards" accord recognition to the achievements by high-quality reviewers of the submissions to *JINR*, so as to promote the development of new research in the field. *JINR* evaluates the peer reviews submitted during each fiscal year, and from these selects up to five deserving reviewers who have demonstrated exceptional excellence in their work. It is hoped that more individuals will agree to undertake reviews for *JINR* so as to make themselves eligible for Outstanding Reviewer Awards.

Since 2020, we believe that new, cutting-edge nursing research and practice have been conducted in a variety of areas related to the novel coronavirus pandemic that has ravaged humanity. *JINR* welcomes a wide variety of submissions on this and other topics that relate to nursing science, in the form of review articles, original research, practice guidelines, technical reports and brief reports. We deeply desire to have *JINR* contribute to the further development of nursing science, and to this end, encourage you to share your research results with our readers, so as to expand the circle of research and practice. For further information including guidelines for submission, please visit the *JINR* web site at https://www.jinr.jsnr.or.jp/.

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Review Article

End-of-life care in intensive care units: A concept analysis

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Abstract

End-of-life care should be considered a part of the nursing profession, specifically in intensive care units [ICUs]. Although various definitions of end-of-life care have been proposed by nursing academies and associations, a clear definition of end-of-life care in ICUs is yet to be determined. Thus, in this concept analysis, we aim to define end-of-life care in the ICU. In this study, we utilized Walker and Avant's concept analysis method, which is designed to identify the structure and definition of a concept like end-of-life care in ICU. In this concept analysis, two antecedents, four attributes, and three consequences of end-of-life care in ICU were extracted, and its definition was thereafter clarified. These results are highly useful and can support critical care nurses, as they are the ones who provide optimal care for dying patients and their families in the ICU; they also form a basis for further research with regard to end-of-life care in the field of critical care nursing. The prominent features of end-of-life care in ICU are as follows: a high dependency on medical equipment, short-term care, and focus on care for families as most patients are unconscious. These features reflect the definition of end-of-life care in ICU. End-of-life care in ICU were defined as intensive and short-term care for patients who are facing imminent death and their families, to help them live out their lives with dignity.

Keywords

end-of-life care, intensive care units, concept analysis, critical care nursing

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Background

Nursing deals with individuals' health at all developmental stages and all points in the health-illness continuum. Thus, end-of-life care should be considered as part of the profession. As nurses assist people in health and recovery, as well as for dying with dignity (International Council of Nurses, 2002), end-of-life care is a significant subject that must be discussed in the field of nursing. Additionally, because nursing care is provided to people at any level of health, end-of-life care is necessary in the critical care provided in intensive care units [ICUs].

ICUs are staffed by specially trained medical personnel

and equipped for continuous monitoring and life support. Their primary purpose is to ensure the survival of patients in a life-threatening state of health (Kelly et al., 2014). Thus, at the beginning of ICU history, end-of-life care might not be included in the primary purpose of the establishment of ICUs. However, death can occur in ICUs for many reasons. Therefore, the need for end-of-life care in ICUs is deemed understandable.

The concept of end-of-life care—including the terms "terminal care" and "palliative care" for patients with cancer or individuals who are HIV-positive—was first defined in the 1990s (Radbruch, 2020). As population aging has seen a steady increase worldwide, the concept has spread to geron-

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Figure 1. Scope of end-of-life care in this study.

tology care, meaning good death or death with dignity. Several organizations have proposed definitions of end-of-life care. For example, the National Health Service (2018) states that "end of life care is support for people who are in the last months or years of their life." At the National Cancer Institute (2021), end-of-life care is defined as "care given to people who are near the end of life and have stopped treatment to cure or control their disease." Given the primary purpose of ICUs, the end-of-life care in ICUs might include different aspects from general definitions and might be more intensive and provided in a short period of time (shown in Figure 1). Thus, there is a need to clarify the definition of end-of-life care in ICUs.

Objective

In this concept analysis, we aimed to determine the definition of end-of-life care in ICUs. A better understanding of this concept may support critical care nurses in providing optimal care for dying patients, and their families, in ICUs, thus contributing to further research related to end-of-life care.

Methods

Concept Analysis Model

Concept analysis refers to "the process of inquiry that explores concepts for their level of development or maturity as revealed by their internal structure, use, representativeness, and/or relations to other concepts" (Morse et al., 1996). In nursing, the foremost concept analysis models are often derived from Wilsonian methods, which include the methods of Walker and Avant (2019). Walker and Avant's methods are known to focus on examining the structures and functions of a concept and identifying it clearly (Walker &

Avant, 2019).

This analysis adopts Walker and Avant's method as it intends to identify the structure and definition of a concept such as end-of-life care in the ICU and further examine endof-life care in critical care nursing, following their steps of analysis;

- 1. Select a concept.
- 2. Determine the aims or purposes of analysis.
- 3. Identify all uses of the concept that you can discover.
- 4. Determine the defining attributes.
- 5. Identify a model case.
- 6. Identify borderline, related, contrary, invented (not always), and illegitimate cases (not always).
- 7. Identify antecedents and consequences.
- 8. Define empirical referents. (Walker & Avant, 2019).

Although this study discusses the steps in the concept analysis as if they were sequential, they are often iterative (Walker & Avant, 2019). The iterative nature of the process enables accurate and precise analysis of a concept.

Data Collection

A literature review was conducted using several databases across disciplines, and a physical search in printed dictionaries and books was also performed. Some older classical texts and literatures were included in the physical search. Other than that, all searches included studies from the past 10 years, and only full texts were extracted, as per the inclusion criteria.

PubMed was used to find studies with the keywords "endof-life care" NOT "nursing" to avoid selecting nursing literatures and to select only medical literatures. Scopus was also searched to find sociological and psychological studies, as it is known to have a rich literature in sociology and psychology. The keywords "end-of-life care" AND "sociology," and "end-of-life care" AND "psychology" were used. As per the exclusion criteria, non-English literatures, other focus (i.e., unrelated to nursing) were excluded.

A more detailed literature search was conducted for nursing. The term "end-of-life" is often discussed in oncology, gerontology, and critical care (Saga et al., 2018). Pediatric end-of-life care also requires interventions, and research in these fields requires for improved interventions (Weaver et al., 2019).

PubMed was used to search keywords "end-of-life care" AND "pediatrics" *or* "end-of-life care" AND "children," for pediatric nursing. The key phrase "concept analysis" was added to these. For oncology nursing, PubMed was used to search the keywords "end-of-life care" AND "cancer" *or* "end-of-life care" AND "oncology." In gerontology nursing, the keywords searched for were "end-of-life care" AND "elderly" *or* "end-of-life care" AND "dementia." For critical care nursing, the keywords were "end-of-life care" AND "ICU," *or* "end-of-life care" AND "critical care," *or* "end-of-life care" AND "critical care," *or* "end-of-life care" AND "search and be added.

Results

Definitions of the Concept of End-of-life Care

Dictionaries and Academic Associations or Professional Organizations

The general dictionary defines end-of-life care as healthcare for people with terminal conditions or in the last days and hours of their lives. End-of-life care also includes palliative care (Macmillan Dictionary, 2021). Although the World Health Organization (2021) does not define end-of-life care, palliative care is defined as "an approach that improves the quality of life of patients and their families facing problems associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial, and spiritual" (p.25). The National Health Service (2018) in the United Kingdom states that "end of life care is support for people who are in the last months or years of their life." At the National Cancer Institute (2021) in the United States, end-of-life care has been defined as "care given to people who are near the end of life and have stopped treatment to cure or control their disease." End-of-life care may include palliative care, supportive care, and hospice care. In medical dictionary, end-oflife care is defined as "multidimensional and multidisciplinary physical, emotional, and spiritual care of patient with terminal illness, including support for family and caregivers" (Medical Dictionary, 2021).

There are some differences between these definitions, in terms of time and period, ranging between the last months or years and the last days and hours. Many definitions do not describe a length of time at all. Related Disciplines Medicine

In total, we found 11,428 papers in the field of medicine, based on the criteria of our literature review. We sorted these using the keyword "concept analysis," and 132 papers remained. Some of these papers were found to be related to treatment, such as chemotherapy or sedation, at the end-oflife (Muishout et al., 2018; Somashekhar et al., 2018). Endof-life symptom management is also an important concern in medicine (Khosravani et al., 2020; Mohamed et al., 2016). Informed consent plays a key role for physicians; moreover, communication with patients and their families is the primary interest of some physicians and certain studies (Masel et al., 2016; Muramoto, 2016). Several papers describe law and ethics for end-of-life care (Derse et al., 2019), and Mohamed et al. (2016) argue that it is important to take a multidisciplinary approach.

Considering these, in the discipline of medicine, the main themes regarding end-of-life care were treatment and symptom management, communication with patients, law and ethics, and multidisciplinary approach.

Sociology

In total, 14 papers from sociology were selected based on our search criteria. One study describes the professional and organizational logistics for the delivery of end-of-life care and how finance is part of it (Bailey et al., 2020). Another focuses on socially vulnerable populations, such as the poor and the homeless (Stajduhar et al., 2019), highlighting the necessity of providing knowledge for service providers and policymakers to remove socioeconomic barriers for equitable end-of-life care for all populations. Some studies also state the importance of cultural beliefs in end-of-life care (Gysels et al., 2011; Inbadas, 2017).

The extracted works show that the issue of financial and social problems such as poverty and the importance of cultural beliefs are delineated.

Psychology

In addition to the criteria described above, the keyword "concept" was added to psychology, and 31 papers were thereafter selected. Similar to sociology, papers discussing culture were found (Strautmann et al., 2020). There were also articles on people suffering from dementia and their families (Krawczyk & Gallagher, 2016; Kupeli et al., 2019). Research on religion or spiritual care regarding end-of-life is a feature of the field of psychology (Choudry et al., 2018; Okamura et al., 2018). In one study, it was found that care homes and hospitals for older adults should consider obtaining more religious resources as support for staff and patients (Okamura et al., 2018). Spiritual care was found to be a fundamental consideration in addressing the holistic experiences of patients receiving palliative care (Choudry et al., 2018).

Attributes of End-of-life Care in ICUs

Discipline of Nursing

Several nursing academies and associations have discussed and educated nurses in regard to end-of-life care. The Endof-Life Nursing Education Consortium (ELNEC) is one such project (End-of-Life Nursing Education Consortium, 2020). According to Ferrell et al. (2015), ELNEC explains that "palliative care nursing reflects a "whole person" philosophy of care implemented across the life span and across diverse healthcare settings. The patient and family is the unit of care. The goal of palliative nursing is to promote quality of life along the illness trajectory through the relief of suffering, and this includes care of the dying and bereavement follow-up for the family and significant others in the patient's life." Another organization that focuses on end-of-life care, the Royal College of Nursing (2020), states that "endof-life care is not just the practical and technical delivery of care provided to the individual who is dying, but also refers to the support and information available both to them and the people who are important to them, e.g., bereavement support."

In nursing, we conducted a more detailed literature search and selected 43 papers from oncology, 68 papers from gerontology, 20 from pediatric, and 49 from critical care nursing.

In critical care nursing, communication with paramedical staff, patients, and families is deemed important (Ecarnot et al., 2018). Chuang et al. (2017) state that communication with terminally ill patients and their families is also for physicians' assistants. Regarding brain death, Muramoto (2016) discusses the difficulties in obtaining informed consent from families. In the field of pediatric nursing, interviews with mothers show the importance of communication between providers and parents about end-of-life care for their child (Neglia et al., 2013).

In end-of-life care, surrogates' decision-making has been identified to be crucial. Discussing end-of-life care preferences early in the treatment could potentially enhance surrogates' end-of-life decision-making processes (Daneau et al., 2020). Aizawa et al. (2013) address the decision-making process for end-of-life care and withholding or discontinuing life-prolonging treatments. Furthermore, to make ethically sound do-not-resuscitate [DNR] decisions, physicians and nurses need to develop appropriate virtues and improve their knowledge on ethical theories and relevant clinical guidelines (Pettersson et al., 2018). Decision-making, especially surrogate decision-making by families or relatives, is the key to end-of-life care.

According to Muishout et al. (2018), applying palliative sedation is one of the primary issues in end-of-life care in relation to patients' religious and cultural backgrounds. Amblàs-Novellas et al. (2016) list symptoms that should be

Alsuwaigh (2015) states that "personhood is temporally and contextually sensitive, allowing for better appreciation of the evolving goals of care that frequently occur at end-oflife. Most importantly, this study reminds healthcare professionals on the importance of "treating persons," and looking beyond familial interests in maintaining the interests and dignity of the patient." Dignity is essential for the concept of end-of-life care, for older adults and for any person who are nearing their end-of-life.

Considering end-of-life preferences of patients with a migration history (Paal & Bükki, 2017), the suppression of end-of-life discussions was associated with suffering and loss of autonomy among migrants. Muishout et al. (2018) describe Muslim norms concerning palliative sedation. Simha et al. (2013) conducted a research on spiritual concerns among people of the Hindu religion undergoing palliative care. Respect for the cultural background of patients is important in the concept of end-of-life care.

Critical Care Nursing

Good communication, supportive decision-making, symptom management, multidisciplinary approach, dignity, and respect for cultural backgrounds are identified as important attributes to the concept of end-of-life care. These are common in not only critical care nursing, but also in pediatric, oncology, and gerontology nursing.

Discussions on withholding and withdrawal in the context of end-of-life care often occur in ICUs, with patients being provided with advanced medical equipment such as ventilators (Aizawa et al., 2013). Once advanced and intensive interventions have started, the DNR directive is always a dilemma among healthcare providers (Paal & Bükki, 2017). A high dependency on medical equipment is one of the key features of end-of-life care in ICUs. This means that critical care nurses are required to assess competencies for analyzing information from medical equipment.

Another feature of end-of-life care in ICUs is the short time period. Compared to other nursing fields, critical care nursing comprises of short-term care. Lunney et al. (2003) have categorized the differences in the trajectories of dying into showing sudden death, terminal illness, organ failure, and frailty, and critical care nursing is related to all these four trajectories. The one in which death is rapidly imminent in hours to days is probably the most relevant to critical care nursing. Often, both the patient and their family are unprepared to face the rapid deterioration of their condition. This is another feature of end-of-life care in ICUs.

Most patients in the ICU do not have the ability to make decisions, due to being sedated, or, otherwise, unconscious. For example, Muramoto (2016) describes the difficulties related to informed consent before brain death is diagnosed. The debates around the withdrawal of life support and organ donation make it even more complicated. In these cases, families or relatives suffer the distress of surrogate decisionmaking even if patients have living will. Diminished or complete lack of the ability of decision-making in patients themselves and the need to focus on the family and surrogate decision-making are other features of end-of-life care in ICUs.

Symptom management is a common feature of end-of-life care in any nursing field. In critical care nursing, patients often experience various symptoms, such as dyspnea, pain, and distress, and these would require strong sedative medication. Appropriate assessment of the effects of medications and the management of physical symptoms with dignity are deemed important.

Therefore, it can be concluded that surrogate decisionmaking support for families, management of physical symptoms with dignity, intensive and short-term care in a state of unpreparedness, and assessment of information from medical devices the patient is highly dependent on for life support are the attributes of end-of-life care in the ICU.

Antecedents and Consequences of the Concept of End-of-life Care in ICUs

In the ICU, there are often few viable treatments available, after the application of many medical devices and several interventions. Additionally, death is imminent for patients who are in an end-of-life state. These are the antecedents of the concept of end-of-life care in ICUs.

The bereavement experience, adaptation, and continuation of bonds and memories are often consequences of a good death (Broden et al., 2020). Furthermore, meeting the needs of family members has been identified as one of the highest priorities while caring for dying patients. Based on interviews with ICU nurses about end-of-life decision-making, Baliza et al. (2015) have stated the importance of patients working and communicating with their families to deal with end-of-life situations.

These studies suggest that the family's situation is key to its consequences. The family's sense of nurses attending to the patient/family and communication between medical staff and patients/family members can be observed in the ICU. Adaptation and memories that are seen as a long-term normal grief process may not be observed in the ICU, even though these are important. ICU nurses can only ensure that family members feel that their loved one has lived their life to the fullest. The factors of good communication with families and medical staff, the family's sense that nurses are always with them, and their feeling that the patient has lived their life to the fullest are suggested as consequences of the concept of end-of-life care in ICUs.

The antecedents, attributes, and consequences derived from our concept analysis are shown in Figure 2.

Example Cases of End-of-life Care in ICU

Next, we will show a model case, borderline case, related case, and contrary case each, in an attempt to explain the concept of end-of-life care in ICUs.

Model Case

Construction of cases from everyday experiences that best reflect or illustrate the concept.

Ms. A, a 55-year-old female with cardiac pulmonary arrest, was transported to the emergency room. She was still in a deep coma after the return of spontaneous circulation and was medically diagnosed with a subarachnoid hemorrhage. The attending physician informed Ms. A's older sister that she has a life-threatening condition and no treatment was available. She was disturbed and crying. A nurse suggested she should call other family members. An hour later, Ms. A's younger sister arrived at the hospital, also crying. The nurse was with the sisters, to respond any questions they may have. The younger one pleaded with the physician to do everything possible. However, the older sister stated Ms. A's wish for a peaceful death under life-threatening conditions. There is no living will of Ms. A. The nurse then asked if that is what Ms. A always thought. The sisters said how gentle and considerate the nurse was, which reminded them of Ms. A's wish for a gentle and peaceful death. Finally, the sisters decided not to resuscitate her. Ms. A was a high school teacher, and the nurse encouraged her sisters to show her pictures of Ms. A's students, as she loved them dearly. Three days later, Ms. A's heart rate declined gradually, and she passed away. The sisters were still crying, but they thanked the medical staff and left the hospital. After 1 month, they came to the hospital and said, "Thank you for your encouragement at that time. We are still grieving, but we have started a new life and spend every day with Ms. A's memories."

Borderline Case

A case that may possibly be an instance of the concept, but the analyst is unsure; some of the features may be present, but other important features may be missing.

Mr. B, a 42-year-old male, with convulsions arrived at the hospital by ambulance. Administration of anticonvulsants caused his convulsions to diminish. His wife arrived and revealed a history of metastatic brain tumor. Due to the anticonvulsants, Mr. B's condition stabilized, and he was transferred from the ICU to a general ward. Mr. B understood that he had a life expectancy of approximately 1 year. Two weeks after being admitted, the patient was unable to walk and eat. Mr. B and his wife were eager to go home before his life ended. They discussed discharge plans with the physician and nurses and informed them of their wish to go back to their home. One week later, Mr. B passed away at home, surrounded by his family.

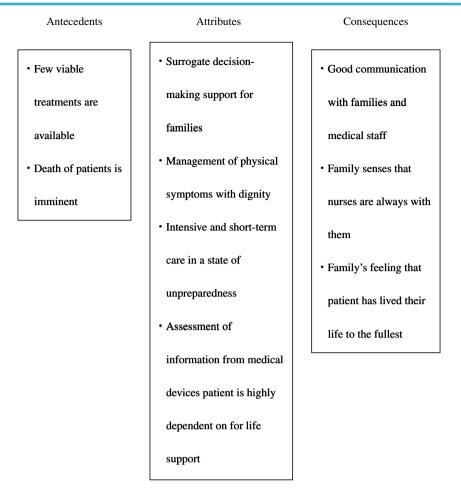


Figure 2. Concept of end-of-life care in ICU.

Related Case

A case illustrating instances related or connected to the concept in an important way.

Mr. C is an 80-year-old male with a history of lung cancer; he was admitted to the hospital with dyspnea and severe back pain. He was diagnosed with lung cancer and a metastatic lumbar tumor. Mr. C required bed rest and position changes; however, when nurses tried to change his position, he complained of back pain. The nurses wanted to alleviate his pain and distress and asked a physician to consult an anesthesiologist with a pain control specialty. Narcotic painkillers were thereafter prescribed to Mr. C whose back pain was alleviated and complaints diminished.

Contrary Case

A case or instance that does not reflect the concept.

Ms. D is an 80-year-old female with a history of chronic obstructive pulmonary disease who used home oxygen therapy. She complained of dyspnea and loss of consciousness at home. She decided not to use the ventilator at the outpatient clinic, and her doctor understood and adhered to her wishes. However, Ms. D's daughter became very upset and called the emergency department. The attending physician in the emergency room asked the daughter if she wanted them to intubate and use a ventilator. The daughter, who was still upset, answered affirmatively. After arriving at the emergency room, Ms. D's daughter, who had calmed down, thought that she had perhaps made the wrong choice. She asked the ER physician whether she should use the ventilator. The physician answered, "You wanted to use it. Once a patient has come to the ER, we do our best to save their life." Ms. D was intubated and placed on a ventilator.

Definition

The definition of end-of-life care in ICUs is as follows: Intensive and short-term care for patients who are facing imminent death, and their families, to help them live out their lives with dignity. It is a nursing practice in which nurses focus on being with, and supporting, the patient and their family. Nurses aim to manage painful symptoms and support the surrogate decision-making of families, while accurately assessing the patient's physical functions, to ultimately enable the patient to live their life to the fullest, and the family to feel as such.

Discussion

We extracted four attributes of the concept of end-of-life care in ICUs. Alftberg et al. (2018) describe communication about death and dying with older people in nursing homes as an important consideration in palliative care. This is one of the core attributes, not only for older people in nursing homes, but also for younger people in ICUs. In some cases, ICU patients are in a coma, with their families present. Decision-making issues were shown as another attribute of end-of-life care. Pettersson et al. (2018) state that nurses and physicians need to improve their knowledge of ethical theories and the relevant guidelines regarding DNR decisions in oncology care. This attribute is common to oncology and critical care. Likewise, dignity and symptom management are important in all fields of nursing. In ICUs, the distress related to medical devices, in addition to other physical symptoms such as dyspnea or pain, is noted to be high. Therefore, the management of patients' physical symptoms with dignity is an important attribute of end-of-life care in ICUs.

The prominent features of critical care regarding end-oflife care are discussed next. For one, Aizawa et al. (2013) discuss the withholding and withdrawal of end-of-life treatment. The termination of advanced treatments or interventions such as a ventilator or continuous hemodiafiltration always include an ethical dilemma. A high dependency on medical equipment is a prominent feature of end-of-life care in ICUs. ICU nurses need to assess information from these medical devices, in addition to physically assessing the patient.

Unlike gerontology or oncology nursing, short-term care is another feature of end-of-life care in critical care. In many cases, ICU nurses often start end-of-life care for patients whom they have met for the first time. Additionally, in the ICU, it is not unusual for patients to be unconscious; therefore, end-of-life care tends to focus on families.

The consequences of end-of-life care are good communication with families and medical staff, the sense that nurses are always with them, and the feeling that patients have lived their lives to the fullest. In critical care, consequences are more focused on the families, compared to other fields of nursing. This is because, for some patients, the physical conditions are usually too severe to consider them. The family's feeling that nurses are with them and that the patient has lived their life to the fullest can be observed during the patient's stay in the ICU. Family members' normal grief process is an important consequence of end-of-life care in ICUs; however, it may not be observed in the ICU after the patient's discharge. Suggestions of bereavement care for the family may be helpful. Follow-up care may be needed in the future as a continuing care for families of patients passed away while in ICU.

Conclusion

In this concept analysis of end-of-life care in ICUs, two antecedents are extracted as follows:

- (1) Few viable treatments are available.
- (2) Death of patients is imminent.
- Furthermore, four attributes are indicated as follows:
- (1) Surrogate decision-making support for families
- (2) Management of physical symptoms with dignity
- (3) Intensive and short-term care in a state of unpreparedness
- (4) Assessment of information from patients highly dependent on medical devices for life support

Lastly, the consequences of the concept of end-of-life care in ICUs are as follows:

- (1) Good communication with families and medical staff
- (2) Family's sense that nurses are always with them
- (3) Family's feeling that patient has lived their life to the fullest

These results are highly useful, and may support critical care nurses in providing optimal care for dying patients and their families in the ICU, and contribute to conducting further research related to end-of-life in the field of critical care nursing.

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Author Contributions

Yuri Sakaki was involved in the concept or design of the work, literature search, data analysis and interpretation, drafted the manuscript, and revised it critically for important intellectual content. Misuzu Nakamura was also involved in the concept or design of the work, data analysis and interpretation, and has critically revised the draft for important intellectual content.

Declaration of Conflicting Interests

The authors declare no conflict of interest.

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World Health Organization. (2021). Palliative Care. https://www.who.int/health-topics/palliative-care **Review Article**

Use of comprehensive home care assessment tools for communitydwelling older adults to improve adherence, quality of life, and health outcomes: A systematic review and meta-analysis

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Abstract

Comprehensive homecare assessment has been determined to be essential in the context of care management for community-dwelling older adults. However, the effectiveness of assessment tools for adherence and health outcomes is yet to be fully elucidated. Thus, in this systematic review, we aim to evaluate the effects of comprehensive homecare assessment tools on adherence and other health outcomes among community-dwelling older adults. Database searches were performed using CINAHL Plus with full text, PubMed, EMBASE, CENTRAL, and Ichushi. Randomized controlled trials search were conducted until September 2020. Studies comparing interventions using comprehensive homecare assessment tools were assessed using the Cochrane's risk of bias 2 for quality; in randomized trials, a meta-analysis was performed. Nine articles, including eight studies, were included in this review. All interventions involved comprehensive homecare assessment tools such as CGA, SEISAR, RAI-HC, TARGET combined with interRAI-HC, MDS-HC, and the Omaha system. As per the results of the metaanalysis, no difference was observed with regard to adherence (p = .11), hospital admission (p = .29), nursing home admission (p = .70), and mortality (p = .96) compared with the non-use of the assessment tools. The mental quality of life showed a significant effect in the comprehensive assessment group (standardized mean difference = 0.26; 95% confidence interval = 0.06 to 0.46; p = .01); however, certainty of the evidence (GRADE) was assessed to be moderate. Comprehensive homecare assessment tools may be particularly useful for enhancing the psychological quality of life beyond a comprehensive assessment. This review presents insufficient evidence to support adherence to homecare and the enhancement of other health outcomes for community-dwelling older adults.

Keywords

adherence, homecare assessment tool, meta-analysis, quality of life, systematic review

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Introduction

Homecare demand and the use of health services have seen a recent increase in our super-aged society (Humphries, Thorlby, Holder, Hall, & Charles, 2016; MHLW, 2020). Thus, a standardized homecare assessment in primary care settings has been an urgent requirement to extensively screen and assess people at home (Chi, Chou, Kwan, Lam, & Lam, 2006). A previous study suggested that a proactive, integrated care provision for older adults in the community is needed to address complex care needs, enhance independent living, and improve quality of life (QOL) (Rechel, Grundy, Robine, Cylus, Mackenbach, Knai, & McKee, 2013). A complete in-home assessment of patients as well as informal caregivers has been considered indispensable for identifying specific care needs, coordinating care demands, and appropriate care planning (Fabacher, Josephson, Pietruszka, Linderborn, Morley, & Rubenstein, 1994). Comprehensive multidimensional assessment tools for older adults include the assessment of physical function and psychological state, as well as family caregivers and home environment (Rubenstein, Siu, & Wieland, 1989; Fabacher et al., 1994; Morris et al., 2009; Landi et al., 2000; Japan Visiting Nursing Foundation, 2001; Weatherall, Slow, & Wiltshire, 2004; O'Connor, & Davitt, 2012; Røsstad, Garåsen, Steinsbekk, Sletvold, & Grimsmo, 2013; Røsstad, Salvesen, Steinsbekk, Grimsmo, Sletvold, & Garåsen, 2017; Wagner, Schaffert, Möckli, Zúñiga, & Dratva, 2020). Moreover, it has been suggested that multiple follow-up home visits can be beneficial in preventing nursing home admissions and functional decline in older adults (Stuck, Egger, Hammer, Minder, & Beck, 2002).

The original purpose of homecare assessment was to obtain extensive information regarding a person so that care managers and healthcare providers could provide appropriate care (Wieland & Hirth, 2003). In the late 1980s and the early 2000s, several standardized tools and instruments for homecare assessment have been developed to specifically improve the quality of homecare for older adults. These include the Comprehensive Geriatric Assessment (CGA) (Rubenstein et al., 1989); the Minimum Dataset for Homecare (MDS-HC) (Morris et al., 2009); the Japanese Assessment and Care Plan for Long-Term Care (Jac-LTC) (Japan Visiting Nursing Foundation, 2001), the Outcome and Assessment Information Set (OASIS) (O'Connor, & Davitt, 2012); the Omaha system (Martin, 2005); and the Resident Assessment Instrument for Home Care (RAI-HC) (Wagner et al., 2020). These tools and instruments contain items essential for identifying a patient's community care service needs and quantifying the need for a healthcare reimbursement level (Davitt & Kaye, 2010). Consequently, the National Institute for Health Care Excellence suggested the "social care quality-adjusted life year" (NICE, 2014), which

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has been defined to focus on homecare for older adults, placing more emphasis on QOL rather than physical health.

Assessment Tool Use in Homecare Management and QOL Improvement

Homecare is a type of care delivery characterized by providing interdisciplinary visits to clients at home. In Japan, the number of homecare services has increased fourfold over the past two decades, representing 77.6% of long-term care insurance care deliveries (MHLW, 2020). Under Japan's longterm care insurance system, the first general assessment tool is used to designate the client's care level. Thereafter, care managers perform more comprehensive assessments to make appropriate care plans.

Concerning older adults, age-related frailty and illness are commonly affected by environmental and lifestyle factors (Ye, Gao, & Fu, 2018). Therefore, functional assessments of older adults are required to determine not only their physical care needs but also their psychosocial and lifestyle care needs, as well as their need for OOL. An assessment allows healthcare providers to deliver person-centered care (Wiltjer & Kendall, 2019). Homecare assessment is often performed through professional clinical interviews with the patient and family caregivers with regard to anxiety, depressive symptoms, and observations about activities of daily living, physical function, social relations, and caregiver situation. Recently, several reports suggested that assessment toolbased interventions have the potential to improve health outcomes (Rubenstein et al., 1994; Bruce et al., 2007; Rubenstein, Stuck, Siu, & Wieland., 1991; Suijker, Rijn, Buurman, Ter Riet, Moll van Charante, & Rooij, 2016). Although previous studies have already explored the effectiveness of these tools, adherence and QOL are yet to be adequately discussed.

Thus, in this systematic review and meta-analysis, we aimed to evaluate the effectiveness of a comprehensive assessment tool used to assess intervention adherence and improve health outcomes and QOL of older adults receiving homecare.

Method

In this systematic review, we followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (Moher et al., 2015). The Preferred Reporting Items for Systematic Reviews and Meta-Analyses checklist is presented in Supplementary Table 1. The protocol was registered in the International Prospective Register for Systematic Reviews (PROSPERO) (CRD42021238737) from the National Institute for Health Research.

Published Work Search Strategies and Sources

We performed a comprehensive literature search of the pub-

lished work. The search dates of the databases were not limited. The databases used in this study were the Cumulative Index of Nursing and Allied Health Literature (CINAHL) Plus full text database (including PsycINFO and MEDLINE) through the EBSCOhost interface, PubMed, EMBASE, Cochrane CENTRAL Register of Controlled Trials (CEN-TRAL), and Ichushi-Web, a Japanese literature database. All the databases, keywords, and combinations used in this search are listed in Supplementary Table 2. The search for published work was conducted in September 2020. Published conference proceedings, including abstracts, were also reviewed. Gray literature, such as unpublished articles or articles that were not easily accessible via databases, were excluded. A manual search was not performed.

Study Selection and Data Extraction Process

The suitability of each study was assessed in three steps: First, two of the ten authors and four collaborator dyads independently reviewed the abstracts, screened, and applied selection criteria to identify suitable studies. In this screening process, we used a web app for systematic reviews called Rayyan software (Ouzzani, Hammady, Federowicz, & Elmagarmid, 2016). Second, two author/collaborator dyads independently reviewed the full text of the articles for eligibility. Third, each article was analyzed using the Cochrane Data Extraction and Assessment Template. The suitability of the selected studies for review and meta-analysis was discussed by the entire research team, and any disagreements were resolved via consensus.

The inclusion criteria were as follows: (i) original and peer-reviewed studies written in English or Japanese; (ii) studies using a comprehensive assessment tool for assessing homecare recipients; (iii) studies that reported the development of a care plan by nurses or other healthcare providers, depending on the assessment; and (iv) studies that utilized any type of randomized controlled trial (RCT), such as individual, cluster, quasi, and crossover design RCTs. In this study, an assessment tool was defined as a comprehensive dataset that covered the physical, psychological, and social aspects of homecare recipients.

The exclusion criteria were as follows: (i) qualitative, observational, and quasi-experimental studies; (ii) pre- and post-tests without comparators; (iii) prospective cohort studies; (iv) case studies; (v) studies describing preventive inhome assessments; and (vi) studies with an incomprehensive assessment such as activities of daily living (ADL) and/or instrumental ADL (IADL), which do not provide an organized assessment. If an article did not provide the mean and standard deviation (SD) of the continuous data of the outcomes, we asked the authors via email if they could provide them for the meta-analysis.

Quality Assessment

Two author dyads independently assessed the risk of bias of the included RCTs. The Cochrane's risk of bias 2 (ROB2) for randomized trials (Sterne et al., 2019) was used for the screening. The assessed domains were the randomization process, deviation from interventions, missing outcome data, outcome measurement, and selection of the reported result. Reporting bias was assessed using funnel plots (Higgins & Thomas, 2021). The certainty of the evidence was assessed using GRADEpro software (McMaster University and Evidence Prime Inc., 2021).

Outcomes

We included articles in the meta-analysis if they reported the outcome measures of the following parameters: primary outcome, namely, the number of participants who did not withdraw homecare during the follow-up period (adherence), and secondary outcomes, namely, ADL, QOL, emergency department visits, hospital, and nursing home admission, and mortality.

Statistical Analysis

A meta-analysis was performed using the Review Manager 5.4.3 software (the Nordic Cochrane Center, Copenhagen). Data were thereafter synthesized into forest plots, and a random-effects model was used to analyze the intervention effects across all studies. The risk ratio (RR) was determined for outcome measures of dichotomous variables, whereas the mean difference (MD) or standard mean difference (SMD) was calculated for continuous data. To confirm the reliability of the summary estimates, 95% confidence intervals (CIs) were calculated. The variables in each study were distilled from the data to facilitate intention-to-treat analysis of the original group. We recorded missing data and dropout rates for each RCT and reported the number of participants included in the meta-analysis as the reported number in the study. An estimate of the intracluster correlation coefficient was calculated if the data from a cluster-RCT study were synthesized for meta-analysis and adjusted to correct for the design effect for meta-analysis (Higgins & Thomas, 2021). Sensitivity analyses were performed to assess the stability of the meta-analysis results. Subgroup analysis was performed for groups of studies using the assessment tool. Statistical heterogeneity was analyzed using the I² statistic, and I² \ge 60% was considered to indicate significant heterogeneity. A random-effects model was used in the meta-analysis.

Results

Flow of Study Selection

In total, 2,113 studies were identified during the database

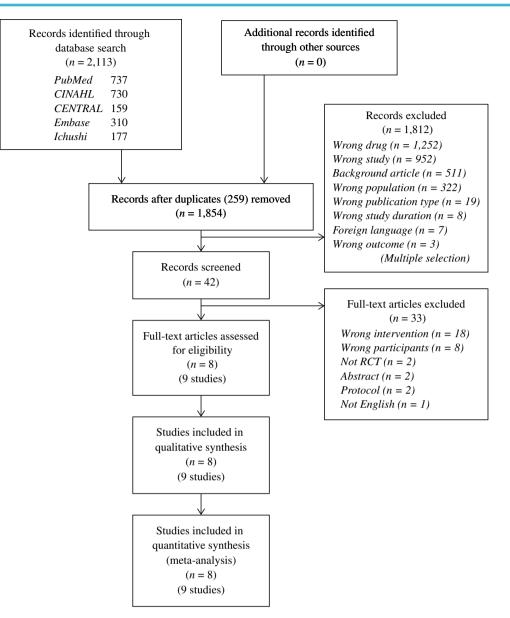


Figure 1. PRISMA flow diagram for article selection.

search. Of these, the full texts of 1,854 studies were screened, and 8 RCTs with 9 studies met the inclusion criteria for this review (Caplan, Williams, Daly, & Abraham, 2004; Jansen et al., 2011; Lampela, Hartikainen, Lavikainen, Sulkava, & Huupponen, 2010; Stolle, Wolter, Roth, & Rothgang, 2012; Parsons, Rouse, Robinson, Sheridan, & Connolly, 2012; Parsons, Sheridan, Rouse, Robinson, & Connolly, 2013; Rosted, Poulsen, Hendriksen, Petersen, & Wagner, 2013; Senior, Parsons, Kerse, Chen, Jacobs, Hoorn, & Anderson, 2014; Wong & Yeung, 2015) (Figure 1). Two studies (Chi et al., 2006; Suijker et al., 2016) were excluded because of incorrect intervention patterns such as preventive interventions for healthy older adults.

Characteristics of the Reviewed Studies

The reviewed studies were published in seven countries: Australia (Caplan et al., 2004), Hong Kong (Wong & Yeung, 2015), Germany (Stolle et al., 2012), the Netherlands (Jansen et al., 2011), Finland (Lampela et al., 2010), New Zealand (Parsons et al., 2012; 2013; Senior et al., 2014), and Denmark (Rosted et al., 2013). All RCTs set up two arms for the intervention and control groups. The duration of the interventions was noted to vary from 2 months (Wong & Yeung, 2015) to 24 months (Senior et al., 2014). The mean age of the participants ranged from 63.6 years (Jansen et al., 2011) to 82.1 years (Caplan et al., 2004). The sample size varied from a minimum of 99 pairs of community-dwelling older adults with dementia symptoms and their caregivers (Jansen et al., 2011) to a maximum of 1,000 older adults (Lampela et al., 2010). One study had a small sample size with fewer than 100 participants (Jansen et al., 2011).

The inclusion criteria of the participants in each study were as follows: community-dwelling older adults, aged 65 vears and older, in new referrals for homecare rehabilitations in New Zealand (Parsons et al., 2012; 2013); older adults, aged 65 or older, who have early symptoms of dementia in the Netherlands (Jansen et al., 2011); frail and at high risk of institutionalization individuals, 65 years or older (≥55 years for one city), in New Zealand (Senior et al., 2014); urban and rural homecare users in Germany (age restriction was not reported) (Stolle et al., 2012); those 70 years and older who were at increased risk of functional decline and readmission and who were discharged home within 3 days of an emergency department admission in the capital region of Denmark (Rosted et al., 2013); those 75 years and older discharged home from an emergency department in Australia (Caplan et al., 2004); older adults in regional hospitals who have the ability to communicate and/or slight to moderate neurological deficit/disability and were discharged home among stroke survivors in Hong Kong (Wong & Yeung, 2015) (age was not restricted); and a home-dwelling subpopulation of the large geriatric multidisciplinary strategy for good care of the elderly study in eastern Finland involving only those aged 75 years and older (Lampela et al., 2010). The comparator received standard emergency care (Caplan et al., 2004; Rosted et al., 2013;), usual community/ nursing home services (Senior et al., 2014; Stolle et al., 2012; Jansen et al., 2011; Lampera et al., 2010; Parsons et al., 2012; 2013), and hospital-based stroke physical training for 3 weeks after hospital discharge (Wong & Yeung, 2015; Lampera et al., 2010) (Table 1).

Settings, Care, and Care Providers

All the reviewed studies compared the comprehensive assessment tool used and simultaneously provided care services such as case-managed restorative care delivered within both residential care facilities and at home (Senior et al., 2014): coordinating functions consisting of assessment, advice, planning coordination, organizing collaboration, and monitoring of care by geriatric specialist nurses (Jansen et al., 2011); team implementation or coordinated care recommendations (Caplan et al., 2004), problem-solving interventions (Rosted et al., 2013); improving or stabilizing functional abilities, cognitive skills, and QOL; reducing institutionalization (Stolle et al., 2012); interdisciplinary primary care such as adjustment of medication and evaluation of the indications for all drugs in use (Lampela et al., 2010); restorative social support and physical function with rehabilitation services (Parsons et al., 2012; 2013); and providing holistic care for stroke survivors (Wong & Yeung, 2015). The targeted participants were older adults who were sent home from the emergency department (Caplan et al., 2004; Rosted et al., 2013). Lampela et al. (2010), Parsons et al. (2012, 2013), Stolle et al. (2012), and Wong and Yeung (2015) explored community-dwelling older adults. Senior et al. (2014) targeted frail older adults at residential care facilities or in homecare for by a multidisciplinary team. In a study by Jansen et al. (2011), primary care practitioners were the first to be visited in case of health problems, and they are considered to play the role of gatekeepers in the Dutch health system, controlling access to specialized care. District nurses specializing in geriatric care acted as case managers. They coordinated various functions including assessment, providing advice and information, planning, coordinating, organizing, collaborating, and monitoring of care. Wong and Yeung (2015) provided nurse-led care coordination and evaluation.

Types of Assessment Tools and Interventions

The types of assessment tools used in these studies were as follows: Two studies used Comprehensive Geriatric Assessment (CGA) (Caplan et al., 2004; Lampela et al., 2010). The Resident Assessment Instrument (RAI) as the minimum data set for homecare (MDS-HC) (Stolle et al., 2012), RAIhomecare (HC) (Jansen et al., 2011; Senior et al., 2014), and the RAI to achieve realistic goals on the elderly tool (TARGET) (Parsons et al., 2012; 2013) were used to assess adults and older adults. Another study targeted the standard evaluation and intervention for seniors at risk (SEISAR) (Rosted et al., 2013) and the Omaha system (Wong & Yeung, 2015) with a total of 3,447 adults and older participants (Table 1). CGA is known to be a multidimensional, interdisciplinary diagnostic process that focuses on determining the medical, psychosocial, and functional capabilities of older adults to provide a coordinated and integrated plan for treatment and long-term follow-up (Rubenstein et al., 1991). It involves the evaluation of functional status, such as ADL, IADL, cognition, depression, nutrition, falls, social relations, and family caregivers' burden. The RAI-HC (Morris et al., 2009) assesses five key areas of function in older adults, namely, functional performance, sensory performance, mental health, health problems, and service oversight. It assesses an individual's need for care and uses a computerized multidimensional instrument that consists of a minimum dataset (MDS) to assess the general functioning of the patient and client assessment protocols, providing protocols for the management of 30 potential and actual problem areas. Participants and nurses confirmed the problems and thereafter formulated care plans (Landi et al., 2000). The TARGET incorporates cognition, nutrition, functional ability, vision and hearing, continence, and informal care. This tool facilitates the development of a client-generated goal and the steps necessary for attainment (Parsons & Parsons, 2012). In a study by Person et al. (2012; 2013), TARGET, which as-

Table 1. Characteristics of the reviewed articles.	istics of th	e reviewed a	rticles.		
Authors, year of publication, and country of origin	Type of RCT, arm	Duration of inter- vention	Purpose of the study	Type of assessment tool and intervention	Participant characteristics
Caplan, et al., 2004, Australia	RCT, 2 arms	18 months	To study the effects of CGA and multidisci- plinary intervention on elderly patients sent home from the ED.	Patients randomized to the treatment group underwent initial CGA and were followed at home for up to 28 days by a hospital-based multidisciplinary outreach team. The team implemented or coordinated recommendations.	 n = 739 Aged 75 and older discharged home from ED. Intervention group n = 370, Mean age = 82.1 (SD 6.6) yeas old, Female = 60.0% Control group n = 369, Mean age = 82.4 (SD 5.2) years old, Female = 61.0% Go home after randomization with no alteration to the discharge alan formulated by the medical officer in FD (107).
Jansen, et al., 2011, The Netherlands	RCT, 2 arms	12 months	To compare the effects of case management and UC among communi- ty-dwelling older adults with early symptoms of dementia and their pri- mary informal caregiv- ers.	The RAI-HC was assessed by district nurse at the primary care setting for both older adults and informal caregivers for 12 months of case management.	n = 99 Ninety-nine pairs of community-dwelling older adults with dementia symptoms and their primary informal caregivers <i>Intervention group</i> n = 54, mean age = 63.6 (SD 13.8) years old, Female $n = 36Control groupn = 45$, mean age = 61.6 (SD 15.2) years old, Female $n = 33UC in the Netherlands comprehends a diversity of healthcare and welfare services.$
Lampela, et al., 2010, Finland	RCT, 2 arms	12 months	To explore the changes of medication as part of a CGA as well as their ad- herence over 1 year, during which time the patients used the services provided by standard (i.e., non-study) health- care providers.	Patients in the intervention group underwent a CGA con- ducted by the study team, which included two physicians (trainees in geriatrics), two nurses, two physiotherapists (for exercise counselling, strength and balance training in the gym), and a nutritionist.	n = 1,000 <i>Intervention Group</i> $n = 500, 75-79$ years old = 54.4%, 80–84 years old = 29.3%, 85+ years old = 16.3%. <i>Control group</i> $n = 500, 75-79$ years old = 48.6%, 80–84 years old = 31.6%, 85+ years old = 19.8%. They received standard care with the possibility of visiting local health centers, hospitals, or private practitioners when needed.
Parsons, et al., 2012; 2013, New Zealand	Clus- ter- RCT, 2 arms	6 months	To determine the impact of a restorative model of home care on social sup- port and physical func- tion rehabilitation among community-dwelling older people.	The assessor used the tool for an ADL element and goal-setting; TARGET with combination of interRAI assessment: MDS-HC or MDS-contact assessment during the initial assessment process of the participants to establish the aims of the rehabilitation episode. A standardized CGA; the Support Needs Assessment (SNA) tool, including cognition, informal caregiver stress, safety, and nutrition; Nottingham extended activities of daily living scale (NEADL); and the EuroQoL 5D were performed.	n = 205 Intervention group n = 108, Mean age = 79.1 (SD 6.9) years old, Female = 71.3% Control Group n = 97, Mean age = 76.9 (SD 7.6) years old, Female = 60.8% UC as the participants received a standard needs assessment that informed the delivery of home care services

Authors, year of publication, and country of origin	Type of RCT, arm	Duration of inter- vention	Purpose of the study	Type of assessment tool and intervention	Participant characteristics
Rosted, et al., 2013, Denmark	A simple RCT, 2 arms	6 months	To examine the effect of a two-stage nursing as- sessment and interven- tion to address older adults' uncompensated problems and thus intend to prevent readmission and functional decline immediately following discharge from the ED.	The SEISAR tool was used for assessment, which is a standardized nursing assessment with a checklist of 10 medical, social, emotional, and physical items took the form of a conversation during which all 10 items were discussed in an older that suited the participant. The research nurses carried out the problem solving intervention.	n = 271 Intervention group n = 141, Mean age = 81.4 (SD 6.5) years old, Female = 69% <i>Control group</i> n = 130, Mean age = 82.7 (SD 6.7) years old, Female = 64% n = 130, Mean age = 82.7 (SD 6.7) years old, Female = 64% The control group received the standard ED discharge plan- ning that comprised routine notification of the older persons' respective community health centers if patients needed home care services following discharge.
Senior, et al., 2014, New Zealand	RCT, 2 arms	24 months	To evaluate the effec- tiveness of a restorative care service on institu- tion-free survival and health outcomes in frail older people referred for needs assessment in New Zealand.	The program models promoting independence provide case-managed restorative care delivered within both resi- dential care and at home by a multidisciplinary team, based on home treatment teams. Older people who were assessed as being too unstable to return home immediately on hospital discharge or on referral from the community were offered a short-stay needs assessed rehabilitation in residential care with the goal to restore function and return the older person to living in the community. interRAI-HC ver.2.03 was used for assessment.	n = 105 Intervention group n = 52, Mean age = 81.9 (SD 6.8) yeas old, Female = 51.9% Control group n = 53, Mean age = 83.6 (SD 6.9) years old, Female = 56.6% UC that included community services or permanent place- ment in residential care were assessed and service coordinat- ed by a centrally based needs coordinator.
Stolle, et al., 2012, Germany	Cluster RCT, 2 arms	13 months	Assessing RAI can help to improve or stabilize functional abilities and cognitive skills, improve quality of life, and re- duce institutionalization, thereby increasing out- come quality.	The entire home care services team in the treatment group received training in RAI of 6 h over a period of 4 weeks. They were responsible for the implementation of RAI.	 920 clients with 69 home care service providers throughout Germany <i>Intervention group</i> <i>n</i> = 543 from 36 nursing home service providers, mean age = 80.0 years old, female = 64.9%. <i>Control group</i> <i>n</i> = 377 from 33 nursing home service providers, mean age = 77.5 years old, female = 64.4%. Provided UC
Wong & Yeung, 2015, Hong Kong, China	RCT, 2 arms	2 months	To test the effectiveness of a TCP, which was a nurse-led 4-week pro- gram designed based on an assessment-interven- tion evaluation with stroke clients using the Omaha system frame- work.	Used the Omaha system and substantiated it with stroke-specific content to guide the delivery of holistic care in the TCP. To strengthen the interventions to address the specific needs of stroke survivors, the study incorpo- rated six specific domains of care in the scheme: (i) man- agement and prevention of stroke recurrence; (ii) symp- tom assessment and management; (iii) enhancing physical function—self-care abilities and exercise; (iv) healthy be- havior—adherence to medication and diet; (v) building resilience—connections with the self and family, a social life, and a higher being; and (vi) emotion management.	n = 108 Mean age = 69.5 (SD 11.8) years old, Female = 63% <i>Intervention group</i> n = 54, Mean age =67.5 (SD 11.6) years old, Female = 63% <i>Control group</i> n = 54, Mean age =71.5 (SD 11.6) years old, Female = 63% Provide only hospital-based rehabilitation

	Randomization process	Deviation from intended interventions	Missing outcome data	Measurement of the outcome	Selection of the reported result	Overall
Caplan, et al., 2004	High risk	Some concerns	High risk	High risk	Some concerns	High risk
Jansen, et al., 2011	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Lampela, et al., 2010	Low risk	Some concerns	High risk	Low risk	Some concerns	High risk
Parsons, et al., 2012, 2013	Low risk	Low risk	Low risk	Low risk	Some concerns	Some concern
Rosted, et al., 2013	Low risk	Low risk	Low risk	Low risk	Some concerns	Some concern
Senior, et al., 2014	High risk	Low risk	Low risk	Some concerns	Low risk	High risk
Stolle, et al., 2012	Some concerns	Some concerns	High risk	Low risk	Some concerns	High risk
Wong & Yeung, 2015	Low risk	Low risk	Low risk	Low risk	Some concerns	Some concern

 Table 2. Risk of bias assessment in each study.

sesses ADL elements and is a goal-setting tool, was combined with the inter-RAI, MDS-HC, or MDS-CONTACT assessment datasets. The SEISAR is a short, standardized, and comprehensive tool for evaluating active geriatric problems in older adults in the ED. The SEISAR tool is an actionoriented checklist that incorporates recommendations for the most appropriate intervention (McGill University, 2017). The Omaha system is described as an assessment-interventionevaluation framework with a comprehensive assessment framework comprising four domains (Martin, 2005). It was developed in the 1970s, and further research was conducted to establish its reliability, validity, and usability between 1989 and 1993 (Martin, 2005). All interventions involved the physical, psychological, and social aspects of care for older adults.

Risk of Bias in the Included Studies

A summary of the risk of bias in each study is presented in Table 2. All studies reported randomization processes; however, two studies (Caplan et al., 2004; Senior et al., 2014) showed a high risk, whereas one study (Stolle et al., 2012) showed some concerns in the random generation process because of the lack of allocation concealment. Three studies (Caplan et al., 2004; Lampela et al., 2010; Stolle et al., 2012) had some concerns regarding deviations from intended interventions due to the lack of intention-to-treat and the substantial impact of failure. The same three studies were found to have a high risk of blinding of participants and personnel and no information on missing outcome data. One study (Caplan et al., 2004) had a high risk of bias as a consequence of not being blinded to outcome assessors, and one study (Senior et al., 2014) had some concerns with regard to the outcome measurement, as it was not influenced by the knowledge of intervention by use of health service utilization. Six studies (Caplan et al., 2004; Lampela et al., 2010; Parsons et al., 2012; 2013; Rosted et al., 2013; Stolle et al., 2012; Wong & Yeung, 2015) showed some concerns regarding the selection of the reported result because no study protocol was found in five studies (Caplan et al.,

2004; Lampela et al., 2010; Parsons et al., 2012; 2013; Stolle et al., 2012; Wong & Yeung, 2015), and no outcomes were reported in the protocol (Rosted et al., 2013). The overall risk of bias of the selected studies showed either high risk or some concerns, except for one low-risk study.

Synthesis of Results

The primary and secondary outcomes were synthesized (Table 3). Other outcomes (ADL) could not be integrated because they reported different outcome measures or did not provide or calculate the SD results. A meta-analysis was performed to compare the use of assessment tools with that of the control group for each outcome. The results of the sensitivity analysis in adherence and emergency department visits did not identify differences.

Adherence of Intervention

Adherence was evaluated in all studies (Caplan et al., 2004; Jansen et al., 2011; Lampela et al., 2010; Parsons et al., 2012; 2013; Rosted et al., 2013; Senior et al., 2014; Stolle et al., 2012; Wong & Yeung, 2015) and integrated into a meta-analysis. No significant difference was in terms of adherence between the assessment tool use and control groups (RR = 1.04; 95% CI = 0.99-1.08; p = .11) (I² = 12%; Figure 2).

Quality of Life

Two RCTs (Rosted et al., 2013; Wong & Yeung, 2015) were evaluated for health-related QOL using the Medical Outcomes Study 12-item Short-Form Health Survey (SF-12) and 36-item (SF-36) survey and were integrated into the meta-analysis. For physical QOL, statistical heterogeneity was observed between groups ($I^2 = 97\%$). However, a significant difference was noted in mental state QOL between the assessment tool use and control groups (RR = 0.26; 95% CI = 0.06-0.46; p = .01) ($I^2 = 0\%$; Figure 3).

Emergency Department Visit

Two RCTs (Caplan et al., 2004; Wong & Yeung, 2015) were

Clinical outcomes	Number of studies	Total number of participants	Reference
Primary outcome			
Adherence	8	3,447	Caplan, et al., 2006; Jansen, et al., 2011; Lampela, et al., 2010; Parsons, et al., 2012, 2013; Rosted, et al., 2013; Senior, et al., 2014; Stolle, et al., 2012; Wong & Yeung, 2015
Secondary outcomes			
ADL	1	108	Wong & Yeung, 2015
QOL	2	379	Rosted, et al., 2013; Wong & Yeung, 2015
Emergency department visit	2	847	Caplan, et al., 2004; Wong & Yeung, 2015
Number of hospital admissions	3	1,118	Caplan, et al., 2004; Rosted, et al., 2013; Wong & Yeung, 2015
Nursing home admissions	3	1,115	Caplan, et al., 2004; Rosted, et al., 2013; Senior, et al., 2014
Mortality	4	1,320	Caplan, et al., 2004; Parsons, et al., 2012, 2013; Rosted, et al., 2013; Senior, et al., 2014

Table 3. Homecare assessment studies and the reported clinical outcomes.

Notes: ADL, activities of daily living; QOL, quality of life

evaluated for emergency department visits. Statistical heterogeneity was observed between groups (I² = 75%); therefore, we could not synthesize the data. Caplan et al. (2004) reported that the intervention and control groups showed no difference in terms of emergency department visits during the study period (15.7% versus 13.3%, respectively; 95% CI -2.7%-7.5%, p = .349); however, Wong and Yeung (2015) reported that emergency room visits were significantly lower in the intervention group at 8 weeks (1.9% versus 13.0%, respectively, in the intervention and control groups, χ^2 = 4.86, df = 1, p = .027).

Hospital Admission

Three RCTs (Caplan et al., 2004; Rosted et al., 2013; Wong & Yeung, 2015) were evaluated for number of hospital admissions. No significant difference was determined in terms of the admission ratio between the assessment tool use and control groups (RR = 0.88; 95% CI = 0.70-1.11; p = .29) (I² = 0%; Figure 4).

Nursing Home Admission

Three RCTs (Caplan et al., 2004; Rosted et al., 2013; Senior et al., 2014) were evaluated for the ratio of nursing home admissions. No significant difference was found in the admission ratio between the assessment tool use and control groups (RR = 0.94; 95% CI = 0.67-1.31; p = .70) (I² = 0%; Figure 5).

Mortality

Four RCTs (Caplan et al., 2004; Parsons et al., 2012; 2013; Rosted et al., 2013; Senior et al., 2014) were evaluated for mortality. As per our findings, no significant difference was noted in mortality between the assessment tool use and control groups (RR = 0.99; 95% CI = 0.74-1.33; p = .96) (I² = 0%; Figure 6).

Certainty of Evidence

The certainty of the evidence for each outcome is presented in Table 4. Eight studies were synthesized for the metaanalysis of five outcomes. According to the assessment, certainty of the evidence was found to be low in adherence, emergency department visits, hospital admissions, and nursing home admissions and moderate certainty in QOL and mortality. The lower certainty was caused by the nonconcealed allocation, non-blinded outcome measurement, non-reported missing outcome data, imprecision due to the small study participant numbers, inconsistency denoted by high heterogeneity of results, and indirectness of heterogeneity in subjects' diseases.

Discussion

Characteristics and Quality of RCTs

Only eight RCT studies were available within the inclusion criteria; half of the studies were conducted in Europe (n = 4), while the others were conducted in Asia (n = 1) and Oceania (n = 3). The number of eligible participants was 3,447, which is slightly limited. All studies were published between 2004 and 2015. We identified only six outcomes that were statistically integrated because of different measurement tools used, tools were not provided, or SDs could not be calculated. The randomization process and missing outcome data were considered in the studies, and the overall certainty of evidence in this review ranged from very low to moderate.

Summary of Intervention

All the reviewed studies involved the use of a comprehensive assessment tool and provision of care services beyond the usual care based on the assessment. Most homecare service providers highly recommend case management and

Study or Subgroup	Experir Events		Cont Events		Weight	Risk Ratio M-H, Random, 95%	Risk Ratio CI M-H, Random, 95% CI	
1.1.1 CGACaplan et al., 2004Lampela et al., 2010Subtotal (95% CI)Total eventsHeterogeneity: Tau ² = 0.Test for overall effect: Z			282 346 628 If = 1 (p	500 869	46.5%	1.04 [0.96, 1.12] 1.07 [0.99, 1.16] 1.06 [1.00, 1.11]		_
1.1.2 OMAHA Wong & Yeung 2015 Subtotal (95% CI) Total events Heterogeneity: Not appl Test for overall effect: Z		54 54 = .41)	45 45	54 54	7.2% 7.2%	1.07 [0.92, 1.24] 1.07 [0.92, 1.24]	•	
1.1.3 RAI-HC, MDS-HG Jansen et al., 2011 Senior et al., 2014 Stolle et al., 2012 Subtotal (95% CI) Total events Heterogeneity: Tau ² = 0. Test for overall effect: Z	43 8 136 187 .00; Chi ² =		38 5 110 153 1f = 2 (p	45 53 192 290 = .41)		0.94 [0.78, 1.13] 1.63 [0.57, 4.66] 0.86 [0.72, 1.02] 0.90 [0.80, 1.02]		
1.1.4 TARGET+RAI+M Parsons et al., 2012 2013 Subtotal (95% CI) Total events Heterogeneity: Not appl Test for overall effect: Z	IDS-HC 3 65 65 icable	66 66	55 55		24.4% 24.4%	1.06 [0.98, 1.14] 1.06 [0.98, 1.14]	-≣	
1.1.5 SEISAR Rosted et al., 2013 Subtotal (95% CI) Total events Heterogeneity: Not appl Test for overall effect: Z		141 141 = .73)	102 102		10.8% 10.8%	1.02 [0.90, 1.15] 1.02 [0.90, 1.15]	•	
Total (95% CI) Total events Heterogeneity: Tau ² = 0. Test for overall effect: Z Test for subgroup differe	$ = 1.59 \ (p$	= .11)	-	= .34)			0.5 0.7 1 1.5 2 Favours [experimental] Favours [control]	

Figure 2. Forest plot of comparison for primary outcome (adherence of intervention and completion of follow-up): homecare assessment tool use versus usual care for the adherence.

Study or Subgroup	Expe Mean	rimental SD Tot		ontro SD			Std. Mean Difference IV, Random, 95% C	
1.2.1 SF-12 (MCS)		55 10		52	rotui		1,1,11,11,00,000	
Rosted et al., 2013	53.1	9.6 14	41 50.9	11.9	130	71.8%	0.20 [-0.04, 0.44]	+- m
Subtotal (95% CI)		14	41		130	71.8%	0.20 [-0.04, 0.44]	
Heterogeneity: Not	applicabl	e						
Test for overall effe	ct: $Z = 1.0$	57 (p = .)	09)					
1.2.2 SF-36 (MCS) Wong & Yeung, 201 Subtotal (95% CI) Heterogeneity: Not Test for overall effe	15 49.9 applicabl	e	54 49.4 54 04)	1.4		28.2% 28.2%	0.41 [0.03, 0.79] 0.41 [0.03, 0.79]	
Total (95% CI) Heterogeneity: Tau ² Test for overall effe Test for subgroup d	ct: $Z = 2.3$	$Chi^2 = 0.7$ 53 (p = 0	0.01)	a.	37); I ²		0.26 [0.06, 0.46]	-1 -0.5 0 0.5 1 Favours [experimental] Favours [control]

Figure 3. Forest plot of comparison for secondary outcome (mental state of quality of life): homecare assessment tool use versus usual care for the mental state of quality of life.

	Experim		Contr			Risk Ratio	Risk Ratio
Study or Subgroup	Events	Total E	vents	Total	Weight	M-H, Random, 95% Cl	I M-H, Random, 95% CI
1.3.1 CGA							
Caplan et al., 2004	42	370	51	369	37.5%	0.82 [0.56, 1.20]	
Subtotal (95% CI)		370		369	37.5%	0.82 [0.56, 1.20]	-
Total events	42		51				
Heterogeneity: Not ap	plicable						
Test for overall effect:	Z = 1.01	(p = .31)					
1.3.2 OMAHA system	1						
Wong & Yeung, 2015	4	54	8	54	4.2%	0.50 [0.16, 1.56]	
Subtotal (95% CI)		54		54	4.2%	0.50 0.16, 1.56	
Total events	4		8				
Heterogeneity: Not ap	plicable						
Test for overall effect:	1	(p = .23)					
1.3.3 SEISAR							
Rosted et al., 2013	52	141	50	130	58.3%	0.96 [0.71, 1.30]	
Subtotal (95% CI)		141			58.3%	0.96 [0.71, 1.30]	
Total events	52		50				
Heterogeneity: Not ap	plicable						
Test for overall effect:	-	(<i>p</i> = .79)					
Total (95% CI)		565		553	100.0%	0.88 [0.70, 1.11]	
Total events	98	2.55	109	200	100.070	0.00 [0.70, 1.11]	•
Heterogeneity: $Tau^2 =$		$^{2} = 1.40$		(n = 5)	0) $\cdot I^2 = 0$		
Test for overall effect:				φ = .5	0), 1 – 0		0.2 0.5 1 2 5
Test for subgroup diffe		<i>a</i> ,		2(n -	50) I ² -	- 00%	Favours [experimental] Favours [control]
rest for subgroup diffe	cicilites. C	.m = 1.3	7, ui =	$2\psi =$.50), 1 =	- 0 /0	

Figure 4. Forest plot of comparison for secondary outcome (hospital admission): homecare assessment tool use versus usual care for the hospital admission.

Study or Subgroup	Experim Events		Cont Events		Weight	Risk Ratio M-H, Random, 95% CI	Risk Ratio M-H, Random, 95% CI
1.4.1 CGA	Litents	Total	Litents	Iotui	weight	101 11, 10andoni, 95 % CI	
Caplan et al., 2004	32	370	28	369	47.5%	1.14 [0.70, 1.85]	
Subtotal (95% CI)	52	370	20	369		1.14 [0.70, 1.85]	
Total events	32	570	28	507	47.570	1.14 [0.70, 1.05]	
Heterogeneity: Not a			20				
Test for overall effect	11	3(n = 0)	50)				
1.4.2 SEISAR							
Rosted et al., 2013	5	141	6	130	8.3%	0.77 [0.24, 2.46]	
Subtotal (95% CI)		141		130	8.3%	0.77 [0.24, 2.46]	
Total events	5		6				
Heterogeneity: Not a	applicable						
Test for overall effect	et: $Z = 0.44$	(p = .0)	66)				
1.4.3 RAI-HC, MDS	S-HC						
Senior et al., 2014	17	52	22	53	44.2%	0.79 [0.48, 1.30]	
Subtotal (95% CI)		52		53	44.2%	0.79 [0.48, 1.30]	
Total events	17		22				
Heterogeneity: Not a	applicable						
Test for overall effect	11	B(p =)	35)				
Total (95% CI)		563		552	100.0%	0.94 [0.67, 1.31]	
Total events	54	200	56	202			
Heterogeneity: Tau ²		$ni^2 = 1.2$	21. $df = 2$	2(p = .	54): $I^2 =$	0% -	
Test for overall effec				ч.,	- ,,-		0.2 0.5 1 2 5
Test for subgroup di		<i>x</i>	· ·	= 2(p = 2)	$= .55$). I^2	= 0%	Favours [experimental] Favours [control]

Figure 5. Forest plot of comparison for secondary outcome (nursing home admission): homecare assessment tool use versus usual care for the nursing home admission.

	Experim		Cont			Risk Ratio	Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95%	CI M-H, Random, 95% CI
1.5.1 CGA							\perp
Caplan et al., 2004	55	370	53		69.8%	L / J	
Subtotal (95% CI)		370		369	69.8%	1.03 [0.73, 1.47]	•
Total events	55		53				
Heterogeneity: Not appli-							
Test for overall effect: Z	= 0.19 (p =	= .85)					
1.5.2 SEISAR							
Rosted et al., 2013	13	141	9	130	12.7%	1.33 [0.59, 3.01]	
Subtotal (95% CI)		141		130	12.7%	1.33 [0.59, 3.01]	
Total events	13		9				
Heterogeneity: Not appli	cable						
Test for overall effect: Z	= 0.69 (p =	= .49)					
1.5.3 RAI-HC, MDS-HC							
Senior et al., 2014	10	52	14	53	16.6%	0.73 [0.36, 1.49]	
Subtotal (95% CI)		52		53	16.6%	0.73 [0.36, 1.49]	
Total events	10		14				
Heterogeneity: Not appli	cable						
Test for overall effect: Z	= 0.87 (p =	= .38)					
1.5.4 TARGET+RAI+MI	DS-HC						
Parsons et al., 2012 2013	0	66	2	59	0.9%	0.18 [0.01, 3.66]	
Subtotal (95% CI)		66		59	0.9%	L / J	
Total events	0		2				
Heterogeneity: Not appli-	cable						
Test for overall effect: Z		= .26)					
Total (95% CI)		629		611	100.0%	0.99 [0.74, 1.33]	
Total events	78	02)	78	011	100.070	0.77 [0.74, 1.55]	T
Heterogeneity: $Tau^2 = 0.0$		2.51 d		= 47).	$I^2 = 0\%$	1	
Test for overall effect: Z			$n = 5 \ p$),	1 - 070		0.002 0.1 1 10 500
Test for subgroup differe			df = 3	n = 4	7). $I^2 = 0$)%	Favours [experimental] Favours [control]
rest for subgroup unions	liees. em	2.01	, a. – <i>J</i> (4× - • •	, ,, = = 0	.,	

Figure 6. Forest plot of comparison for secondary outcome (mortality): homecare assessment tool use versus usual care for the mortality.

care coordination to appropriately solve problems, improve older adults' functional abilities and cognitive skills, and improve their QOL. Interdisciplinary primary care has been suggested to reduce institutionalization and improve homecare.

Regarding the assessment tools used in the reviewed studies, two studies used CGA, which is well developed for interdisciplinary geriatric care settings. RAI-HC, MDS-HC, and the Omaha system were originally developed to improve the quality of homecare assessment and care plans, whereas the SEISER was developed for standardized nursing assessment. The TARGET was assessed only in terms of the ADL of older adults; therefore, the RAI-HC and MDS datasets were combined for additional assessment. However, we could not compare the effectiveness of these tools in this review because of the limited integration results. All RCTs set two arms for the intervention and control groups, although the comparator exhibited a variety of types such as emergency care, hospital-based rehabilitation, community-based, and nursing home services. The intervention and follow-up duration showed some differences; three studies were less than 6 months, while another study showed 12 to 24 months. Meta-analysis showed no significant subgroup differences. The healthcare providers included nurses, district nurses, research nurses, nurses and physiotherapist teams, physicians, and needs assessment/interdisciplinary outreach and research teams. Based on these results, nurses play a key role in the initial comprehensive assessment and lead the homecare team. The interventions in these reviewed studies have the potential for clinical heterogeneity in the target participants, provided care, and case management details. Consequently, no statistical heterogeneity was noted in terms of adherence, mental QOL, hospital/nursing home admission, and mortality. Compared with the control group, the RAI-HC and MDS-HC subgroups showed excessive participant withdrawal in the intervention group.

Summary of Participants

The youngest among the participants was in the RAI-HC study in the Netherlands (Jansen et al., 2011), whereas the oldest was the CGA study in Australia (Caplan et al., 2004) and RAI-HC study in New Zealand (Senior et al., 2014), in which most participants showed functional and/or cognitive decline. Compared to the two studies by Senior et al. (2014) and Jansen et al. (2011), the oldest intervention group showed 56% loss to follow-up within 12 months, and 85% were lost to follow-up within 24 months (Senior et al., 2014). This indicates that the older participants' prognosis

Homecare assessment tools compared to usual care for older adults	ls compared to us	ual care for older adults				
Patient or population: older adults, Setting: homecare, Intervention:	er adults, Setting:		Homecare assessment tool use, Comparison: usual care	Comparison: usual	care	
	Anticipated	Anticipated absolute effects* (95% CI)	Dolotino offort	Mo of south of	Container, of the	
Outcomes	Risk with usual care	Risk with homecare assess- ment tool use	- Kelalive ellect (95% CI)	no. of partici- pants (studies)	Certainty of ure evidence (GRADE)	Comments
Adherence QOL	692 per 1,000 -	699 per 1,000 (672–727) SMD 0.26 SD (0.06 to 0.46)	RR 1.01 (0.97–1.05) -	3,447 (8 RCTs) 379 (2 RCTs)	$\oplus \oplus \bigcirc \bigcirc Low^{a}$ $\oplus \oplus \oplus \bigcirc Moderate^{b}$	
Emergency department visit	Not pooled	Not pooled	Not pooled	877 (2 RCTs)	⊕ ⊕ ⊖ ⊂ Low [€]	Statistical heterogeneity was observed ($l^2 = 75\%$). Caplan et al. (2004): 15.7% vs 13.3% ($p = .349$) and Wong & Yeung (2015): 1.9% vs 13.0% (interven- tion and control group, respectively) ($p = .027$) visit- ed emergency department during study period.
Hospital admission	197 per 1,000	170 per 1,000 (134–215)	RR 0.86 (0.68–1.09)	1,118 (3 RCTs)	$\oplus \oplus \bigcirc \bigcirc$ Low ^d	
Nursing home admission	101 per 1,000	97 per 1,000 (70–137)	RR 0.96 (0.69–1.35)	1,115 (3 RCTs)	$\oplus \oplus \bigcirc \bigcirc$ Low ^d	
Mortality	123 per 1,000	118 per 1,000 (89–158)	RR 0.96 (0.72–1.28)	1,320 (4 RCTs)	$\oplus \oplus \oplus \bigcirc$ Moderate ^e	
<i>Notes</i> : *The risk in the inter CI: confidence interval; RR	rvention group (at : risk ratio; SMD:	<i>Notes</i> : *The risk in the intervention group (and its 95% confidence interval) is based on the assum CI: confidence interval; RR: risk ratio; SMD: standardized mean difference; QOL: quality of life	is based on the assumed 1 QOL: quality of life	risk in the compari	son group and the relativ	Notes: *The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI). CI: confidence interval; RR: risk ratio; SMD: standardized mean difference; QOL: quality of life
GRADE Working Group grades of evidence	ades of evidence					
High certainty: we are very	confident that the	High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.	he estimate of the effect.			
Moderate certainty: we are Low certainty: our confiden	moderately contic the effect es	Moderate certainty: we are moderately contrident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.	ue effect is likely to be c may be substantially diff	ferent from the est	e of the effect, but there imate of the effect.	Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Very low certainty: we have very little confidence in the effect estimat	e very little confic	estimat	ie: the true effect is likely to be substantially different from the estimate of effect.	substantially differ	cent from the estimate of	effect.
a. Downgraded by two levels: two level for serious risk of bias.b. Downgraded by one level for imprecision denoted by the smi	ls: two level for s l for imprecision d	a. Downgraded by two levels: two level for serious risk of bias.b. Downgraded by one level for imprecision denoted by the small sample size.	e.			
 c. Downgraded by two leve d. Downgraded by two leve 	ls: one level for suls: one level for su	c. Downgraded by two levels: one level for serious risk of bias and one level owing to inconsistency denoted by high heterogeneity of results ($I^2 = 75\%$).	owing to inconsistency c	lenoted by high he	terogeneity of results (I ² the subiects' diseases	= 75%).
e. Downgraded by one level	l for indirectness	e. Downgraded by one level for indirectness by heterogeneity in the subjects' diseases.	diseases.			

Table 4. Summary of findings.

may have been more serious compared to the younger group, with only 20.3% loss at 12 months of follow-up (Jansen et al., 2011). Furthermore, care needs often vary depending on age, functional decline, and frailty; consequently, the characteristics of the participants may impact the results.

Summary of Evidence

This meta-analysis showed that using comprehensive assessment tools, including the nurse-led assessment of older adults' physical functioning, disease, and health state, and social functioning, based on a detailed assessment, nurse's problem-solving intervention, or delivery of holistic care in a transitional care program, was found to be more effective than standardized emergency discharge planning alone or the provision of hospital-based rehabilitation programs only for improving mental OOL. The results may be particularly noteworthy concerning intervention; however, the certainty of the evidence (GRADE) was low for adherence, emergency department visits, and hospital/nursing home admission and moderate for OOL and mortality; therefore, we downgraded the results due to these imprecisions. Moreover, the sensitivity analysis is robust to the decisions made in this review.

In terms of improving people's QOL, as the origin of homecare, evidence is scarce, and more research is needed in this field. We found no intervention effects on any of the primary/secondary outcomes in terms of adherence, ADL, physical QOL, emergency department visits, hospital admission, nursing home admission, or mortality. Moreover, we could not determine an effective intervention period. Studies that represented nurse-led assessments and interventions have been observed to improve mental QOL. Nonetheless, the type of interdisciplinary team and the physical state of older adults could not be clearly discussed in this review, owing to the small number of studies.

This review concludes that the use of nurse-led comprehensive homecare assessment tools has the potential to improve mental QOL for older adults with medical conditions and to improve assistance services from the community if provided with case management. As suggested via selection bias, the results may differ for different target condition groups. The age of the participants with acute and chronic diseases showed a wide range of approximately 20 years. The demand for community services is considered to differ depending on common age-related changes. Moreover, in this meta-analysis, interventions based on the assessment, such as enhancing physical functions, self-care behaviors and medications, older adults' physical functioning, cognitive and mental state, and family caregiver burden, can make the results prone to larger alpha errors, owing to multiple comparisons. Nonetheless, the *p*-value for the outcomes of mental QOL was found to be significant (p = .01).

Implications for Homecare Assessment for Older Adults in Primary Care

In the context of appropriate case management and care planning in primary care, to improve the QOL of older people at home, it is suggested that nurse-led multi-domain observation and interviews should not only assess physical problems and specific care needs but also track their strength and OOL for satisfaction. Therefore, the community care delivery system and multiple community resources have significantly improved mental QOL. Hence, using a comprehensive assessment tool may provide benefits by adding a multi-domain understanding to problem-solving with case management and reinforcing disease management. Moreover, the cost of community service delivery should be considered, specifically for older adults who may require multiple care services for long durations with a financial burden. Training nurses to assess older adults' mental states, such as depression, is also important for developing appropriate referrals and care for depressed patients (Bruce et al., 2007). These opportunities can contribute to improving the quality of homecare.

Owing to the increase in life expectancy, an aging population with diseases has also increased the demand for community care services (WHO, 2011). More than 50% of the participants in this review lived alone. The number and percentage of older people living alone are increasing in most countries (WHO, 2011). Therefore, these services can help lessen social isolation.

Some distinct recommendations emerge from the results: (a) nurse-led homecare assessment for older adults suspected to improve the mental QOL of older adults in the community; (b) incorporating case management, including physical, mental, medical, and functions of daily life, based on an assessment of improved mental QOL; and (c) an interdisciplinary community care team is required for care delivery. However, the results of this review provide relatively low certainty of evidence regarding the effectiveness of using a comprehensive homecare assessment tool to improve outcomes. Thus, future studies may clarify these conclusions. The use of assessment tools provides an opportunity to educate healthcare providers and improve the quality of care delivery in the community.

Limitations

We have only reviewed eight RCT studies, which were split into six major tools; therefore, there was a risk of selection bias. The small number of participants also suggests reporting bias. Owing to the multiple comparisons of tools and clinical interventions, significant pooled effects may emerge as non-significant after statistical adjustment for multiple comparisons. Therefore, the effect may have been overestimated and should be interpreted with caution. We could not determine which type of assessment tool would be appropriate for improving QOL. The certainty of the evidence of assessment tool use for case management was determined to be limited; however, the use of assessment tools was demonstrated to be an indispensable approach to focus on care needs, with no reported harmful results.

Conclusions

In total, 8 RCTs with 3,447 older adults in the community were integrated into a meta-analysis that analyzed the effectiveness of a comprehensive assessment tool used for homecare to improve adherence, QOL, and health outcomes. This meta-analysis showed that the use of an assessment tool was effective in terms of improving the mental QOL during care delivery. However, there is currently insufficient evidence to support which tool would be useful for follow-up because it has not been sufficiently shown to affect health outcomes for homecare in the context of case management.

What Is Already Known about the Topic?

- Homecare demand and the use of health services have recently increased in our super-aged society. Standardized homecare assessment in primary care settings is required to extensively screen and assess older adults at home.
- Several types of comprehensive homecare assessment tools have been used for the management of communitydwelling older adults at home and have been suggested to have the potential to improve the prediction of clinical outcomes.

What This Study Adds

• This meta-analysis has showed that the use of a comprehensive assessment tool with case management has the potential to improve the mental QOL of older adults receiving homecare; however, the certainty of the evidence was found to be moderate. Adherence and other outcomes showed no differences in the use of the assessment tools. Further studies are required to confirm these findings.

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Author Contributions

All authors contributed directly to this study. TK: study concept and design, literature database search, screen, text review and data integration, and drafting the manuscript. SE and AK: database search of the literature with PI, text review, data integration and interpretation, and critical revision of the manuscript. YT, AS, YU, YF, SK, KK, and SS: screen, text review, data extraction, and critical revision of the manuscript. SS supervised the assessment tools. All authors approved the final version of the manuscript.

Declaration of Conflicting Interests

The authors declare they have no economic nor academic conflict of interest for this study. Tomoko Kamei received research fund from Nippon Telegraph and Telephone West; this fund had no relations to this study nor conflict of interest to this study. Yoko Uchida received research fund from joint research fund between Gunma University and Shimoda Industrial Corporation; thus, this fund had no relations to this study.

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Original Research

Physiological and psychological effectiveness of facial massage in women: A randomized crossover trial

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Abstract

Objective: This study aimed to examine the effectiveness of facial massage, as a nursing technique, in alleviating stress in healthy women using physiological and psychological indicators. **Methods:** A crossover design was employed; participants were 22 healthy females between the ages of 20 and 22. Participants were assigned to Sequence 1, wherein they received a 3-minute facial massage in Period I and 3-minute rest in Period II, or Sequence 2, which employed the reverse order. Participants' blood pressure (BP), pulse rate, salivary alpha-amylase (sAA), Profile of Mood States (POMS), "Relaxation level," "Comfort level," and "Wakefulness level," as measured by the Visual Analog Scale (VAS), were assessed before and after the facial massage or resting intervention. **Results:** Between the two groups, changes in systolic BP increased in the facial massage group, but there was no difference in pulse and sAA. While there was no difference between the two groups in the POMS, VAS scores revealed an increase in the "Relaxation level" and "Comfort level" in the facial massage group. Facial massage participants reported feeling "refreshed," whereas the control group reported feeling "sleepy." **Conclusions:** The 3-minute facial massage increased relaxation with respect to psychological measures; however, BP change could not explain stress reduction. (This study was enrolled in the UMIN as an intervention study and as a prospective randomized crossover trial. The trial registration number is UMIN000033939.)

Keywords

crossover study, facial massage, relaxation, Visual Analog Scale, woman

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Introduction

In nursing care, massage therapy has been used as a means to promote comfort and non-verbal communication for patients who present physical and psychological distress (Westman et al., 2016). In recent years, the effects of massage therapy have been investigated in both Japan and overseas, and it has been emphasized as a viable option in complementary and alternative therapies. While many studies have focused on massage therapy for hands, feet, and back, there has been a paucity in research on the massage and care of the face. It has been reported that comfort and relaxation—the psychological effects of a facial massage—are associated with frontal lobe activity (Nakashima et al., 2010). Moreover, studies report that facial care for elderly women can facilitate improvement in their activities of daily living and reduce tension and anxiety (Suga et al., 2015; Machida, et al., 2012). Therefore, we believe that facial massage therapy would be a useful tool in nursing care due to its physical and psychological effects, and we are keen to examine its effectiveness.

The facial region contains the skin, muscles, nerves, lym-

Correspondence: Y. Ohkawa. Email: yuriko_ookawa@med.miyazaki-u.ac.jp Received: June 10, 2021, Accepted: January 20, 2022, Advance Publication: January 26, 2023, Published: February 17, 2023 Copyright © 2023 The Japan Society of Nursing Research This work is licensed under the Creative Commons Attribution International License (CC BY-NC-SA). phatic glands, and salivary glands, which undergo various physiological changes, such as protection from the external environment (e.g., antimicrobial protection of the skin) and secretion of digestive enzymes (Nguyen and Duong, 2021). Furthermore, the face has sensory organs such as the eyes, nose, and mouth, which not only has important functions in maintaining vital and bodily functions but also serves to reflect negative psychological effects such as chronic dissatisfaction, low self-esteem, and even depression (Kondo et al., 2005). We suppose that massaging the face, which has such diverse facets, can bring about psychological as well as physiological benefits. Hatayama et al. (2008) reported that a facial massage activates the sympathetic nervous system and has a refreshing rather than a relaxing effect. Ejindu (2007) found that the facial massage group induces more drowsiness and lowered blood pressure (BP) than the foot massage group. However, the results of the present study must be interpreted with caution due to problems with its experimental process, such as the small sample size of six participants and the unreported technique of massage.

In studies evaluating the effects of massage therapy, factors related to the stress response of the hypothalamicpituitary-adrenal system and autonomic nervous system have been measured as physiological indicators (Noto, Kitajima, et al., 2010; Noto, Kudo, et al., 2010). These investigations have provided evidence for the positive effects of massage therapy, such as stress relief, relaxation, and immunity enhancement, and, additionally, its effectiveness for female patients with chronic illnesses such as cancer and depression (da Silva et al., 2017; Field, 2016; Ghesquiere et al., 2019; Hernandez-Reif et al., 2004; Lee et al., 2015). In the present study, we measured the effects of facial massage therapy using physiological and psychological indicators of the stress response.

Regarding the method of facial massage, the time and procedure of implementation are varied in various studies. The shortest massage duration was 1 min (Kawaguchiya et al., 2014), and the longest was 45 min (Hatayama et al., 2008). Hatayama et al. (2008) performed a 45-minute facial massage on women in their 20s-40s. It included a steam and ultrasound treatment. Suga et al. (2015) implemented a 3minute \times 3-week face care session, in which elder women applied lotion onto their skin; results indicated increased parasympathetic nerve activity. As the intervention by Suga et al. is similar to massage therapy, in that it involves touching the skin of the face for 3 min, we decided to perform massage for 3 min, as the short duration would not burden the participants or the researchers providing the massage. In this way, the effectiveness of facial massage, performed in various ways for women of various ages, has been investigated. We believe that recruiting healthy female college students as participants would control other confounding variables such as age, body size, life rhythm, and psychological

stress (Bennion et al., 2018; Kubota et al., 2020).

The purpose of our study was to determine the physiological and psychological responses of healthy female college students to a 3-minute facial massage and to examine whether facial massages can be used as a nursing technique for stress relief. With the current study, we want to demonstrate that a 3-minute facial massage is, therefore, safe and effective according to the physiological and psychological indicators and to establish it as a form of care that can be implemented by nurses. We hope that nurses who have mastered this care technique will be assigned to each ward, or that a nurse belonging to the palliative care team, for example, could go to the ward nurses when they request her to do so and systematically engage with patients.

Materials and Methods

Study Design

We wanted to examine the effects of facial massage from both physiological and psychological aspects while controlling for other conditions as far as possible. Therefore, we recruited female students, over 20 years old, enrolled in the nursing department of the author's university. As we planned to recruit female university students, the number of students willing to participate was expected to be lesser than desired due to academic schedules and other factors; moreover, it was unlikely that the number of participants would increase post recruitment; therefore, we adopted a crossover design. Each participant received two interventions in our crossover design-a 3-minute face massage and a 3-minute rest-in different sequences. An advantage of the crossover design is that sufficient statistical power can be attained even with few participants. However, one of its drawbacks is that a carry-over effect can occur. Thus, it is necessary to include a washout period to eliminate the carry-over effect. The length of the washout period depends on the type of treatment; however, 1-2 weeks for single inoculations is suggested (Origasa, 2016). Previous studies on massage and nursing care have also indicated a 1-week washout period (Edwards et al., 2018; Groven et al., 2021; Miyoshi, 2019). The influence of the "carry-over effect" is expected to be eliminated during this period. In the current study, as the facial massage was a one-time intervention and its effects could not be long-term, a 1-week washout period was considered sufficient. As mentioned above, this study is exploratory, as the number of participants was not calculated, and was determined by referring to previous studies, wherein the number of participants ranged from 6 to 12 (Tsubouchi et al., 2010; Ejindu, 2007; Sakai et al., 2012).

The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Institutional Review Board of [name blinded for review] Nursing Science Ethics Committee (approval number D13-06, November 2015). The Clinical Trial Registration number is [Trial registration number deleted to maintain the integrity of the review process].

Participants

During April 2018, when students stayed relatively on campus, we put up posters in classrooms at the University of [name blinded for review] to recruit participants. We selected nursing students who belong to the same university as the researcher for the following two reasons. There are few intervention studies using facial massage, and it was not possible to understand the progress of the subjects after the intervention based on these previous studies. Therefore, in the present study, it was possible that the participants' situation after the facial massage intervention may have required a quick response. We were confident that the physical effects on the subjects in our study would be minimal because the massage intervention was brief and did not involve the use of harmful oils or equipment. However, we invited nursing students from the researcher's university to participate in the study, as we believed that the researcher would be able to respond immediately in the unlikely event that any changes were observed after the intervention. It was also expected that nursing students who agreed with the theme of "stress relief through facial massage" would participate proactively, and that there would be fewer missing responses to the questionnaire and fewer dropouts during the study. Furthermore, it was expected that the nursing students would understand the purpose of the study, which was not directly beneficial to the participants, but would be beneficial to the patients and would improve the quality of nursing care. We valued the participants' time and commitment, and we approached the study with the intention of making their participation meaningful.

During this period, the new university term had just started, and there were few events at the university. Therefore, although the sample size was small, the recruitment was concluded within the planned period, especially considering the impact of changes in the participants' environment if the recruitment were to be extended. The study was conducted from May to June 2018. Participants underwent a sequence of "first intervention-7-day washout-second intervention" during the study period.

The participants were women over 20 years old, who had no underlying or under-treatment illnesses. Participants with skin problems and allergic reactions to jojoba oil and who were smokers were excluded. Similar to previous studies, we did not recruit male participants due to a lack of clarification in the literature on physiological and psychological responses due to sex differences. Additionally, if muscle mass changes were identified due to differences in physique, resulting from sex differences, it may be difficult to unify massage techniques.

Since the participants were university students, it was explained that cooperation or non-cooperation in the research would not affect their academic performance. We explained the participation period, interventions, and exclusion conditions and obtained written consent from the participants who agreed to participate. The intervention allocation order was created by another researcher, who was not involved in the facial massage interventions. The study participants were assigned to two groups: a structured intervention followed by control (Sequence 1) or control followed by the intervention (Sequence 2). A list of all participants was created, and a random number, generated using Excel software, was placed next to each participant's name. These random numbers are generated within the range of 0-1. Participants with numbers higher than or equal to 0.5 were assigned to Sequence 1, and the rest were assigned to Sequence 2. The participants were informed of their group assignment on the day of the experiment. Participants followed that order, and no changes were made. All participants were fully compliant with the research protocol and completed the entire research process. There were no significant changes in the method after the commencement of the study.

Intervention

The massage procedure employed was developed by the Japan Relaxation Care Association (JRC; https://www.npohomepage.go.jp). The purpose of this organization is to contribute to social welfare through the promotion of health and relaxation care. The researchers in the present study were trained in massage procedures by the JRC in 2010, they had received their technical certificate, and their skills were regularly assessed. Jojoba oil—primarily a moisturizing oil with no warnings of toxicity or carcinogenicity—was used for the massage (Habashy et al., 2005). We conducted a patch test to ensure no adverse effects on participants; no skin changes were noted.

The outline of the massage is as follows:

- 1. Apply oil to both cheeks and jaws
- 2. Massage (2 min, 20 s):
 - i. Effleurage of the parotid gland from the jaw
 - ii. Effleurage in front of the ears from the corners of the mouth
 - iii. Effleurage of the temple area from the nose
 - iv. Temple area effleurage,
 - v. Lifting from chin to cheek
 - vi. Lifting from jaw to cheek
- 3. Touch pressure (40 s):
 - i. Margo supraorbitalis (nasal side) and infraorbitalis (median)
 - ii. Under the cheekbones and middle of the jaw.

Experimental Protocol

The day before the experiment, participants were requested

to avoid overeating, consuming too much alcohol and caffeine, staying up late, strenuous exercise, and wearing loosefitting clothes and rinse their mouths before entering the laboratory. When the participants arrived at the laboratory, they sat in chairs, and we asked them to relax. After filling out the questionnaire, they rested on a bed for 10 min.

The participants were asked to respond to the Profile of Mood States (POMS) questionnaire and a Visual Analog Scale (VAS) for relaxation, pleasantness, and arousal before and after the experiment. Next, participants placed themselves in a supine position on the bed, and the cuff of an automatic sphygmomanometer was wrapped around their upper limb to measure BP and pulse. Saliva was collected by placing a stick under the tongue, and salivary alphaamylase (sAA) was measured.

Next, a facial massage, consisting of effleurage and touch pressure, was performed for 3 min, as per the abovementioned procedure. For the control condition, the participants rested on the bed for 3 min. At the end of the experiment, BP, pulse, and sAA levels were measured again. Finally, they were asked to answer questions about their perceptions of the experiment.

Experimental Environment

Data collection was conducted at the [name blinded for review] University School of Medicine, Department of Nursing, from April to June 2018 from 3:00 pm to 5:00 pm. The laboratory environment was $23^{\circ}C \pm 2.2^{\circ}C$, relative humidity $54\% \pm 6.9\%$, and illuminance 323.2 ± 52.5 Lx. The same bed was used for both the experimental and control conditions. Participants laid down on the bed and were covered with a cotton blanket. The same researcher stood beside the participants in the control condition as well.

Outcomes

The primary outcome of the study was BP, as a physiological indicator; pulse and sAA were collected as indicators of the two major stress response systems: the autonomic nervous system and the hypothalamic-pituitary-adrenal system. BP and pulse were measured using an automatic sphygmomanometer (Digital Automatic Sphygmomanometer, HEM-757). Saliva was collected to determine sAA levels, using a dedicated chip and analyzer (Enzyme Analyzer/Saliva Amylase Monitor CM-21; Nakano and Yamaguchi, 2011). The secondary outcome measures were psychological indicators, as measured via the POMS questionnaire and VAS. The POMS was developed by McNair for evaluating mood (Maxwell, 1978) and has also been used in other studies to assess the effects of massages (Chaiyasut et al., 2020; Nadal-Nicolás et al., 2020; Serfaty et al., 2012). It has been translated into Japanese (Yokoyama, 2008) and used in many studies, and its reliability and validity have also been established. An abbreviated version of the Japanese version of POMS (Yokoyama, 2008) was used to assess psychological state. This questionnaire consists of 30 items that are used to measure six moods and emotions (Tension-Anxiety, Depression-Dejection, Anger-Hostility, Vigor-Activity, Fatigue-Inertia, and Confusion-Bewilderment). The test asks participants to describe their current feelings and is scored on a five-point Likert scale ranging from 0 (*Not at all*) to 4 (*Extremely*). For POMS, we explained that although the questionnaire asks the participants to report on their "mood of the past week," for this experiment, the participants were to report their "current mood." We also explained that for both the POMS and the VAS, the participants should answer each question with their current first impression.

"Relaxation," "Comfort," and "Wakefulness" levels were assessed using the VAS. The VAS (Kuhlmann et al., 2017) was introduced as a clinical measurement method for assessing pain. In massage research, the degree of pain, comfort, and drowsiness before and after massages have been measured using the VAS (Buttagat et al., 2020; Cavdar et al., 2020; MacSween et al., 2018). It expresses the amount of sensation through the length of a line segment, and usually, adjectives such as "nothing" and "maximum" are attached to both ends of a 10-centimeter line. The respondents were required to mark their sensations, feelings, and experiences on a line segment before the intervention, post which experience and changes were recorded, based on the participant's subjective understanding.

Statistical Analysis

First, participants were assigned to Sequence 1 and Sequence 2 using a random function, and a two-sample *t*-test was conducted for each of the demographic characteristics. When employing a crossover study, a washout period is necessary to avoid carry-over effects (Origasa, 2016). In the present study, the intervention lasted for 3 min; therefore, the long-term effects on the body were considered to be negligible. Therefore, we can assume that there would be no carry-over effect after providing a 1-week washout period. However, to verify the validity of the study, the amount of change in each variable before and after the intervention was analyzed through repeated-measures analysis of variance (ANOVA). To verify the treatment effect, the change in each item was tested by a two-sample t-test. Statistical significance was set at p < .05. SPSS ver.21 was used for data analysis.

Results

Participant Numbers and Characteristics

Of the 55 potential participants, 23 were enrolled in the trial, but 32 did not register, for example, because they could not participate in the two experiments at the same time zone.

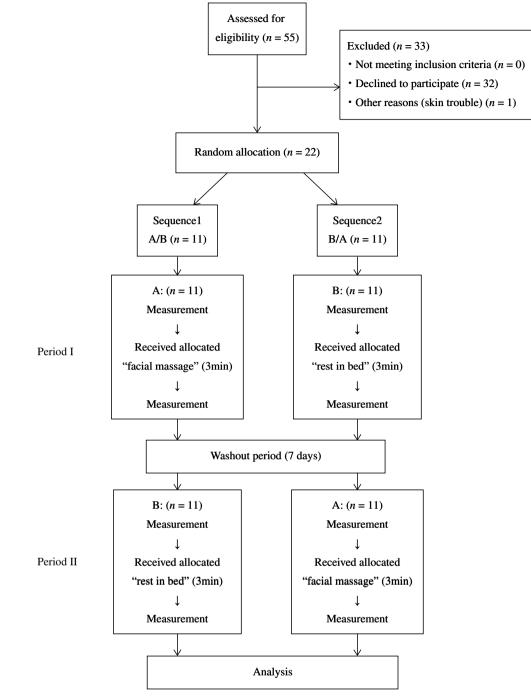


Figure 1. Flow diagram of participants.

In addition, one participant was excluded as we noted acne and redness of the skin. Therefore, 22 individuals eventually participated in the study (Figure 1). The 22 participants were randomly divided into two groups. The difference between the two groups at baseline before the experiment was not statistically significant (Table 1). None of the participants dropped out of the study or complained of changes in their physical condition post participation.

As we analyzed each variable's change before and after the intervention using repeated-measures ANOVA, there was no carry-over effect or period effect due to crossover testing. In the treatment effect, systolic BP was F = 5.132, p = .035; diastolic BP was F = 5.210, p = .034; relax level was F = 23.43, p = .000; and comfort level was F = 13.52, p = .0030. To verify the treatment effect, the amount of change in each item was tested by a two-sample *t*-test. As this is an exploratory study, *p*-values were set without considering multiplicity.

The results of physiological measurements are shown in Table 2. The amount of change in systolic BP was 0.72 (SD

Mariahlar	Mean (SD)			
Variables	Sequence 1 $(n = 11)$	Sequence 2 $(n = 11)$	р	
Age (years)	20.7 (1.1)	20.6 (0.6)	.84	
Body Mass Index	19.5 (1.4)	21.8 (2.9)	.08	
Systolic blood pressure (mmHg)	99.5 (8.7)	107.6 (12.7)	.84	
Diastolic blood pressure (mmHg)	58.0 (5.5)	63.8 (7.2)	.44	
Pulse (bpm)	69.6 (5.4)	74.1 (13.3)	.65	
Salivary α -amylase (kIU/l)	52.4 (24.1)	48.1 (24.5)	.50	

Table 1. Characteristics of participants (n = 22).

Notes: Data are measurements after allocation to Sequence 1 and Sequence 2.

p-values of two-sample *t*-test. **p*<.05.

Table 2. Comparison of the amount of change in physiological measures (n = 22).

Variable	Mean (SI			ES	95% CI		
variable	Facial massage $(n = 22)$	Control $(n = 22)$	l	p	(<i>r</i>)	93% CI	
Systolic BP (mmHg)	0.72 (5.46)	-2.36 (4.49)	2.05	.047*	0.30	[0.05, 6.13]	
Diastolic BP (mmHg)	1.81 (4.61)	-0.77 (4.78)	1.82	.075	0.27	[-0.27, 5.44]	
Pulse rate (bpm)	-4.50 (5.60)	-3.22 (4.47)	-0.83	.410	0.13	[-4.35, 1.81]	
Salivary α -amylase activity (kIU/l)	-11.77 (21.22)	-13.80 (22.57)	0.28	.778	0.05	[-12.43, 16.48]	

Notes: *t*- and *p*-values of two-sample *t*-test. **p*<.05.

Abbreviations: BP, blood pressure; ES, effect size.

5.46) in the facial massage group and -2.36 (SD 4.49) in the control group, with significantly higher change in the facial massage group (t = 2.049, p = .047, r = 0.30). The actual measurements were: pre = 102.4 (SD 9.8) mmHg, post = 103.1 (SD 9.3) mmHg in the facial massage group and pre = 102.7 (SD 12.1) mmHg, post = 101.0 (SD 10.7) mmHg in the control group. The amount of change in diastolic BP was 1.81 (SD 4.61) in the facial massage group and -0.77 (SD 4.78) in the control group, with no significant difference between the two groups (t = 1.82, p = .075, r = 0.27). The amount of change in pulse was -4.50 (SD 5.60) in the facial massage group and -3.22 (SD 4.47) in the control group, with no significant difference between the two (t = -0.83, p = .410, r = 0.13). The change in sAA was -11.77 (SD 21.2) in the facial massage group and -13.80 (SD 22.5) in the control group, with no significant difference between the two (t = 0.28, p = .778, r = 0.05).

The results of psychological measurements are shown in Table 3. In the six domains of POMS, there was no significant difference in the amount of change before and after the intervention in both groups. The amount of change in the "Relaxation level," as measured by VAS, was 2.26 (SD 1.56) in the facial massage group and 0.32 (SD 2.11) in the control group, with significantly higher scores in the facial massage group (t = 3.39, p = .002, r = 0.47). The amount of change in the "Comfort level" was 1.48 (SD 1.4) in the facial massage group and -0.11 (SD 1.75) in the control

group, with significantly higher scores in the facial massage group (t = 3.21, p = .003, r = 0.45). The amount of change in the "Wakefulness level" was -1.12 (SD 3.2) in the facial massage group and -2.10 (SD 2.01) in the control group, and there was no significant difference between the two (t = 1.19, p = .241, r = 0.19).

Participant's Feedback

In the facial massage group, statements such as "I felt wakeful after the facial massage," "I thought it might be beautiful," and "I felt refreshed" were more frequently reported. In the control group, comments such as "I became sleepy," "I was bored," and "Nothing in particular" were reported. In the facial massage group, mood changes were described, and in the control group, drowsiness during rest was described.

Discussion

This study aimed to determine the physiological and psychological effects of a facial massage on healthy female college students. While BP was the primary outcome, as a measure of stress relief, other physiological and psychological responses were the secondary variables, used to evaluate the effects of a 3-minute face massage compared to the 3minute rest group.

Regarding BP, the primary outcome variable, previous

Variable	Mean (SD)				ES	050 01
variable	Facial massage $(n = 22)$	Control $(n = 22)$	- t	р	(<i>r</i>)	95% CI
POMS						
Tension-Anxiety	-5.31 (7.37)	-2.63 (3.52)	-1.53	.131	0.23	[-6.19, 0.83]
Depression-Dejection	-1.54 (3.40)	-2.09 (4.41)	0.45	.649	0.07	[-1.85, 2.94]
Anger-Hostility	-3.27 (6.71)	-1.77 (3.75)	-0.91	.366	0.14	[-4.80, 1.80]
Vigor	-1.18 (8.02)	-4.13 (4.80)	1.48	.146	0.22	[-1.07, 6.97]
Fatigue	-4.00 (6.73)	-1.72 (5.53)	-1.22	.228	0.19	[-6.02, 1.47]
Confusion	-1.22 (5.37)	-1.50 (4.31)	0.18	.854	0.03	[-2.69, 3.23]
VAS						
Relaxation level	2.26 (1.56)	0.32 (2.11)	3.39	.002*	0.47	[0.78, 3.08]
Comfort level	1.48 (1.48)	-0.11 (1.75)	3.21	.003*	0.45	[0.59, 2.59]
Wakefulness level	-1.12 (3.22)	-2.10 (2.01)	1.19	.241	0.19	[-0.68, 2.64]

Table 3. Comp	arison of the amount	of change in	psychological	measures $(n = 22)$.

Notes: t- and p-values of two-sample t-test. *p<.05.

Abbreviations: POMS, Profile of Mood Scale; VAS, Visual Analog Scale; ES, Effect Size.

Table 4. Participant's feedback.

Facial massage	Control
• I got sleepy during the massage. Afterwards, when I opened my eyes, I felt like I was awake.	Just from resting, I got a bit slow and gradually became sleepy.I fell asleep during the experiment.
 I got sleepy, but after the facial massage, I felt refreshed. I expected that receiving a facial massage would result in beauty enhancement. I would like to receive a facial massage as an aesthetic agent. I thought it might be beautiful. It was good! The massage was relaxing. I closed my eyes during the facial massage, then my hands felt warm and I felt calmer. The facial massage provided a sense of ease. The massage ended quickly. I hope it's a little longer. 	 I got sleepy gradually when I was daydreaming for a few minutes I felt a bit lonely. I was bored. Nothing in particular.

studies have reported a decrease in BP post massage (Liao et al., 2016; Givi et al., 2018; Moraska et al., 2008). In the current study, systolic BP increased in the facial massage group, but the amount of change in both groups was small and not a clinically significant value. Thus, there was almost no change in BP in both groups compared to previous reports, possibly due to participant characteristics and the time and frequency of facial massage. This study targeted healthy female college students; however, many previous studies have targeted individuals with hypertension or hypertension reserves, or individuals with anxiety or pain, and slightly high baseline BP (Liao et al., 2016; Givi et al., 2018; Moraska et al., 2008). These participants were given multiple stress-relieving massages over a medium to long term. Liao et al. (2016) gave eight women with hypertension (or reserves) a weekly, 1-hour, full-body Swedish massage for 4

weeks, leading to a sustained reduction in systolic BP until 4 weeks later. In a study by Givi et al. (2018), 25 women with prehypertension were massaged for 15 min, three times a week for 10 sessions; their BP, as measured 72 h after the massage, was significantly lower than that of the control group. Two weeks after the end of the massage, the decrease in BP was no longer observed. This clarifies the period after which the effect of massage dissipates and indicates the necessity of repeating massages at appropriate intervals, for maintaining the decrease in BP due to massage. Thus, while previous studies report a decrease in BP after continuous massage, a similar decrease was unlikely to occur with only one massage conducted in this study. Moreover, the massage time of 3 min employed in the current study can be considered a factor affecting the lack of decrease in BP. According to a study by Sato et al. (2007), a massage-like stimulus administered to the abdomen of rats for 5 min reduced BP by up to 20 mmHg; however, this decrease was dampened in a 2-minute stimulus, which soon reached the original levels. Other studies have reported that the decrease in BP is further sustained by the secretion of oxytocin when the skin is stimulated by massage for 5 min or longer (Araki et al., 1984; Sato et al., 2007). Therefore, it is possible that the 3minute face massage employed in the present study did not have a physiological effect and, thus, did not reduce BP.

It was also considered that participants' stress level was related to the change in BP. In the present study, the baseline value of α -amylase in saliva, which is an index of stress, indicated mild stress; however, there was almost no change post intervention. Sripongngam et al. (2015) performed Thai Traditional Massage after introducing a 10minute mental arithmetic test to participants whose stress levels were mild as assessed by the Suanprung Stress Test-20, before the intervention. Participants' stress level decreased, as indicated by a decrease in sAA and an increase in the high frequency component of heart rate variability (HRV). Thus, application of massage during a certain amount of mental stress can predominate parasympathetic nerve activity and induce a stress-relieving response. Moreover, although participants in the present study are thought to have stress peculiar to university students (Kubota et al., 2020), but due to the low levels of stress, no autonomic nervous system changes occurred after 3 min of stimulation with facial massage. Therefore, the facial massage did not trigger a nervous system response, and thus, the BP did not show a decrease.

We also wondered if the psychological response of massaging the face affected changes in BP, possibly due to the peculiarity of facial massage. Generally, the face is a body part rarely touched by others. Therefore, we believe that such an experience of someone touching one's face might have induced tension in some participants. Participants also reported different expectations from the massage, such as "I expected a beauty effect by receiving a facial massage" and "I thought it might be beautiful." Thus, such psychological tension could have affected the lack of pulse rate change noted in this study. Hatayama et al. (2008) found that HRV significantly increases sympathetic nervous system activity after a facial massage, although no such changes were observed in pulse rate. The authors asserted that facial massage has a refreshing effect and activates sympathetic nerve activity (Hatayama et al., 2008). Furthermore, in this study, participants reported experiences such as feeling "refreshed" and "feeling awake"; thus, we suppose that the enhanced mood acted on the sympathetic nerves and it did not reduce the BP or pulse (Meier et al., 2020). In other words, we speculate that the emotional response of massage was regulated by the limbic system, which is closely related to the autonomic nervous system, and affected sympathetic nerve activity (Aourell et al., 2005). Although a study of makeup behavior rather than facial massage, Watanabe (2013) compared emotional responses in the makeup behavior group and the control group by VAS and found that the scores are significantly higher after the make-up action, especially for the items "feel comfortable," "gets energized," "vibrant," "enchanted," and "enjoyed." Therefore, stimulating the face may bring about a feeling of tension or mood upliftment, engaging in predominantly sympathetic nerve activity, which may slightly increase BP rather than decrease it. Therefore, we suppose that massaging only the face, as in this study, activates the sympathetic nervous system rather than the parasympathetic nervous system.

As a secondary outcome, we also measured "mood change" using the POMS questionnaire and "Relaxation," "Comfort," and "Wakefulness" levels using the VAS. Results indicated that POMS score was not different between the two groups, but "Relaxation" and "Comfort" levels measured by the VAS were significantly increased in the facial massage group. In previous studies, "mood and emotional changes" indicated through POMS and VAS have often shown similar trends. As there were few studies on face massage, we examined studies that have tried to relieve stress by massaging the head. Shimada et al. (2013) measured stress relief by scalp massage using POMS and VAS. Before and after scalp massages, POMS scores were lesser for negative emotional items, and VAS scores indicated reduced physical fatigue. An increase in the degree of relaxation was observed, and scores of both POMS and VAS agreed. In addition, salivary cortisol concentration, which indicates the degree of stress, decreased, and secretory immunoglobulin A concentration significantly increased, thus suggesting that psychological and physiological changes were consistent. Murota et al. (2016) performed head massage using an Ayurveda-based technique to reduce diastolic BP and increase the high-frequency component of HRV and "Liveliness," as measured by VAS. Results revealed a decrease in "depression" and scores of the State-Trait Anxiety Inventory.

Thus, previous studies have reported agreement in physiological and psychological changes caused by massage. Moreover, to the best of our knowledge, no study reported different tendencies for the two psychological indicators, as observed in this study. The research design could be one of the factors that might have influenced this finding in our study. In the current study, we limited the participants to healthy female college students, so that their age, gender, daily living environment, etc. could be controlled; therefore, we recruited participants and conducted the study at the university to which the researchers belong. Consequently, the participants and researchers were acquainted with each other, and we suspect that some psychological bias, possibly the Hawthorne effect, occurred for the participants. The Hawthorne effect explains participants' psychological factors

that influence the outcome of nursing research interventions (Tagaya, 2014). The Hawthorne effect may occur on the part of the participants, wherein they may be "over-adapted" (Tasaki and Shin, 2017) to meet the expectations of the evaluator/observer and give a better response than their actual experience. VAS scores are indicated on a 10-centimeter horizontal line, and there is a possibility that a value close to the positive end (10 cm) will be indicated (Tasaki and Shin, 2017). On the other hand, in the case of POMS, 30 questions are answered intuitively in 5 steps; thus, there is a possibility of taking an "acquiescence response style" that agrees without thoroughly examining the content (Tasaki and Shin, 2017). In this way, when examining the effects of person-to-person intervention, as in the current study, results may be affected by psychological factors depending on the relationship between the participant and the researcher. Careful selection of study designs and methods, such as the adoption of randomized controlled trials and the adoption of appropriate physiological and psychological indicators, is required to mitigate this effect. The abovementioned research on head massage by Murota et al. (2016) was also conducted with female university students; however, the massage was performed by a therapist rather than the researcher to avoid the Hawthorne effect. Resultantly, the changes in physiological and psychological indicators agreed, and thus, the reliability of the data increased. In our future research, we shall endeavor to eliminate such feelings of pressure for participants.

In sum, this study did not indicate a decrease in BP or stress relief due to a 3-minute facial massage in healthy female college students. However, it is possible to induce positive emotions by massaging the face, and psychological changes can lead to physiological responses (Meier et al., 2020). Furthermore, to apply it as a nursing technique, it is necessary to consider the stress level of the subject, their feelings toward facial massage, the time and frequency of massage, and the implementation period.

In this study, participants were healthy female university students. Thus, the results obtained in this study could be used as the basis to explore these variables with diverse participant populations further and to conduct large-scale confirmation studies. Moreover, we recommended collecting data independently in the intervention and control groups. Furthermore, there may be differences in interest in facial massage between men and women. For example, in a previous study of facial massage (Ejindu, 2007), when recruiting participants, only one man offered to participate in the study. Thus, future studies should investigate the physical and psychological reactions of men during facial massage. Further, in the present study, as the facial massage was performed only once and for short period, it is likely that the effect was not fully exerted. Therefore, we would like to further investigate the stress-relieving effects of facial massage and techniques that caregivers can easily and continuously employ at nursing facilities and hospitals.

Conclusion

BP increased slightly after the facial massage, but the amount of change was similar to that of the control group. The amount of change in pulse and sAA was also the same as in the control group. With respect to psychological measures, POMS did not differ between the two groups; however, "Relaxation" and "Comfort" levels as measured by VAS increased significantly with facial massage. Facial massage had a positive effect on some psychological indices, but changes in physiological indices, such as BP, could not explain the stress relief.

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Author Contributions

All authors have approved the final article and acknowledge that all those entitled to authorship are listed as authors. All authors met the criteria of authorship, substantial contributions to (1) conception and design, acquisition of data, or analysis and interpretation of data; (2) drafting the article or revising it critically for important intellectual content; and (3) approval of the final manuscript. Yuriko Ohkawa (YO), Hiroki Tanoue (HT), and Kiyoko Fukai (KF) especially contributed to the study design, coordinated the study, interpreted the data, and drafted and reviewed the manuscript. YO especially contributed to the collection of data and the performance of statistical analyses. YO and HT especially contributed to program development and the supervision of program implementation.

Declaration of Conflicting Interests

The authors declare that they have no conflict of interest.

Disclaimer

KF is an Editorial Adviser of Journal of International Nursing Research and on the journal's Editorial Committee. She was not involved in the editorial evaluation or decision to accept this article for publication at all.

Ethical Approval

The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Institutional Review Board of the Okayama University Graduate School Nursing Science Ethics Committee (approval number: D13-06, November 2015).

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Proficiency evaluation of simulation education on the entire tracheal suctioning process using a motion capture system and a catheter control sensing device

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Abstract

Objective: We developed a suctioning catheter control sensing device given the increasing demand for skilled home-based healthcare techniques, such as tracheal suctioning. This study evaluated the proficiency of the entire tracheal suctioning process between expert and novice groups via the suctioning catheter control sensing device and a motion capture system. Our hypothesis is that motion capture can measure the proficiency of tracheal suctioning despite the biological reactions of the simulator and the characteristics of participants. **Methods:** Nine expert nurses, each with more than three years of clinical experience in tracheal suctioning, and 13 nursing students from an urban university nursing department participated. The performance time, pelvic forward bending angle, travel distance, posing time, posing frequency of bilateral dorsum manus, and suctioning catheter control between the two groups with/without simulated biological reactions were analyzed. **Results:** The two-way analysis of variance demonstrated that the biological reactions (or lack thereof) and the proficiency level did not interact. The main effect of performance time, posing time, and posing frequency was statistically significant; experts performed tracheal suctioning more expeditiously and skillfully. The sensing device could detect hesitance or rough catheter control. **Conclusions:** Our results indicated that performance time, posing time, and posing frequency levels of tracheal suctioning.

Keywords

projection mapping, biological reactions, skill evaluation, nursing education, VR/AR/MR/XR

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Introduction

The number of children (0-19 years old) requiring technology-dependent, specific home-based healthcare techniques, such as tracheal suctioning, tracheostomy, and percutaneous endoscopic gastrostomy, has doubled from 8,438 in

2007 to 19,712 in 2017 in Japan despite vast improvements in the survival rates of premature infants (Ministry of Health, Labour and Welfare, 2020). An analogous trend was also observed internationally (Breneol et al., 2019; Choi et al., 2020). The demand for registered community nurses is increasing to provide technical advice to family caregivers in

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addition to the employment of hygienic, accurate, and comfortable healthcare techniques (Nageswaran et al., 2017; Sobotka et al., 2019; Choi et al., 2020; Colley et al., 2020a; Whalen et al., 2020).

Tracheal suctioning is an invasive nursing technique that requires adequate knowledge, appropriate clinical judgment skills (Kim et al., 2016), and adequate mastery to prevent unexpected adverse events, such as hypoxia, alveolar collapse, cardiac arrhythmia, blood pressure changes, raised intracranial pressure, and ventilator-associated pneumonia (Schults, 2021). Subject to these biologically invasive characteristics, objective skill evaluation criteria that can be used as indices to quantify the level of mastery are necessary (Nishiyama, 2016; Garner et al., 2020). There are two mainstreams in conventional pedagogical evaluation in nursing: technical observation by instructors and/or judgment of selfefficacy among students (Garner et al., 2020). However, these evaluation methods cannot entirely exclude the subjective influences of instructors and/or learners. Zughoul et al. surveyed existing studies on pedagogical evaluation among various academic domains, including nursing education. They reported that assessment criteria are necessary to quantify student capability, learning outcome, performance, knowledge, and skills (Zughoul et al., 2018).

Recently, motion capture has been used extensively as a nursing research methodology to facilitate visualization of the joint motion of dominant and nondominant upper limbs for operations, such as opening ampoules (Hirano et al., 2019), transfer of patients with occupational lower-back pain from a bed to a wheelchair (Nakagawa et al., 2017; Lin, 2018; Zhou et al., 2021), and ultrasound-guided peripheral intravenous catheter placement (Good et al., 2018). Quantitative parameters, such as performance time, path length, velocity, and acceleration, have been gradually adopted as rigid evaluation criteria for these clinical skills (Zago et al., 2020). Further, several studies have attempted to determine the relationship between suctioning catheter control and tracheal secretion viscosity and concluded that greater sidehole diameter, nonparallel positioning, and the duration of suctioning affect the effectiveness (Shah et al., 2005; Colley et al., 2020b). However, there has been no consensus regarding standardized parameters to assess skill acquisition in the case of tracheal suctioning. There also exists limited evidence on the quantification of proficiency during the entire process of tracheal suctioning.

Therefore, in this study, we aim to compare the skill proficiency over the entire process of tracheal suctioning between expert and novice groups via a motion capture system and a catheter control sensing device developed by us. Our hypothesis is that motion capture can measure the proficiency of tracheal suctioning despite the biological reactions of the simulator and the participants' characteristics.

Materials and Methods

Tracheal Suctioning Simulator

Tracheal suctioning is an airway management technique used to maintain the natural or artificial airway patency by removing sputum with a thin suctioning tube. This is achieved by applying negative pressure, which requires hygienic handling by the dominant hand, gentle manipulation of the suctioning catheter, and shorter application of negative pressure in the airway (Pasrija & Hall, 2021). Researchers have developed a tracheal suctioning simulator called the endotracheal suctioning training environment simulator (ESTE-SIM). It comprises an artificial trachea membrane model with load sensors (Colley et al., 2016; Ninomiya et al., 2017; Hayashi et al., 2018; Ninomiya et al., 2018; Ninomiya et al., 2019), a patient upper body manikin, a projector for facial expression generation (Fauzi et al., 2019a; Fauzi et al., 2019b), an android tablet for simulated pulse-oximeter readings (Colley et al., 2018; Komizunai et al., 2018), and a control personal computer (PC). The artificial trachea membrane model with load sensors, namely the ESTE sensing device (ESTE-SD), can measure the contact force and insertion depth of the suctioning catheter tip inserted in the tracheal tube with the use of the load sensors attached to the artificial trachea membrane model. The data from the ESTE-SD are sent to the control PC, which generates the facial expression on the patient upper body manikin via projection mapping (Komizunai et al., 2019).

In this study, a cough sound function generates sounds 10 s later after removing an airway filter. The simulated pulseoximeter values, from pulse oximetry data during tracheal suctioning in our previous study (Komizunai et al., 2019), were implemented in addition to facial expression changes, as shown in Figure 1. Herein, the term, biological reactions (BRs), is used for these reactions as an umbrella term.

ESTE-SD

Figure 2 shows the schematic of the ESTE-SD depicting the force along the superior-inferior direction (Fx), momentum force along the left-right direction (My), and the force along the head-tail direction (z-axis). The three functions of ESTE-SD include the estimation of the inserted length of a suctioning catheter using the measured forces Fx and My, the sensing force on the artificial tracheal membrane, and weighing of the suctioned artificial phlegm.

Participants

The required sample size was calculated using the software G*Power (Version 3.1.9.2, Institute for Digital Research & Education, California, Los Angeles, USA) a priori. We recruited 10 participants per group, which led to a power of 95% with an effect size of 0.25 for detection between groups ($\alpha = 0.05$). A total of nine expert nurses, each with

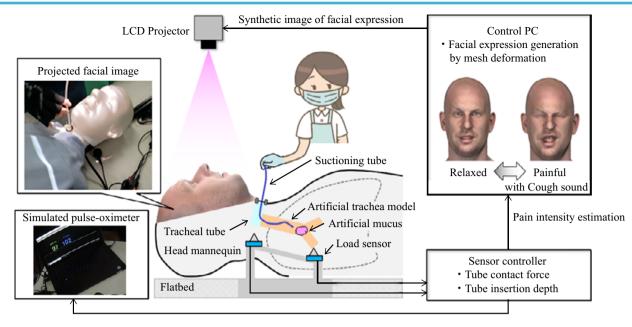


Figure 1. Endotracheal suctioning training environment simulator (ESTE-SIM).

more than three years of clinical experience in tracheal suctioning, and 13 nursing students from the Department of Nursing in an urban university participated in the study. The recruitment of registered nurses was conducted through the internet. The registered nurses were from five institutions and had frequent opportunities to perform tracheal suctioning. The nursing students were in the third year of their bachelor's courses, and they had completed lectures on tracheal suctioning as part of the regular course before the experiment was conducted. None of them had any prior clinical experience. These students were recruited via poster announcements and convenient recruitment within the university. Exclusion criteria included left-handed participants because they may introduce differentiation along the travel distance, and five novice participants were excluded comparing immature hygiene manipulation or different order of procedure. There is no significant difference in the average height of novice groups before and after exclusion (159.38±3.92, p > .05).

Before beginning the experiment, institutional review board approval was obtained from the institution's ethical committee. In addition, all participants provided written consent forms (17-81-2). To ensure anonymity, numbers N1-N9 were used to represent the registered nurses, and numbers S1-S13 were used to represent the nursing students. Table 1 lists the participants' characteristics.

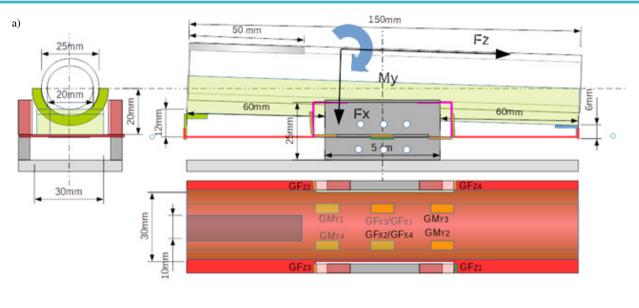
Motion Capture System

An inertial magnetic motion capture system (Perception Neuron, Noitom, China) was selected to measure the motion of the study participants. This system comprises a series of inertial measurement unit nodes referred to as "neurons" that are integrated with a 3-axis gyroscope, 3-axis accelerometer, and 3-axis magnetometer to record body movements digitally, with a sampling rate of 60 Hz. A total of 18 neurons were placed on the participants' heads, bilateral shoulders, upper backs, bilateral lower backs, bilateral upper arms, bilateral lower arms, bilateral dorsum manus (BDM), bilateral upper thighs, bilateral lower thighs, and bilateral dorsum pedis.

Motion parameters, such as performance time, pelvic forward bending angle, travel distance of the BDM, and posing time and posing frequency of the BDM, were calculated (Osanai et al., 2019; Colley et al., 2020c). Their parameters were determined from observing nursing students' tracheal suctioning procedures. As the performance time, the posing time, and the posing frequency increase, the waiting time of patients increases. The pelvic forward bending angle was measured as higher values are considered to constitute a high risk of droplet infection. Considering that removing the suctioning catheter from the trachea is associated with the slowest motion, the posing time was defined as 1 cm/s (Osanai et al., 2019; Colley et al., 2020c). The obtained data were analyzed using the Axis Neuron (Noitom, China) software.

Procedures

The participants were requested to perform the entire process of tracheal suctioning twice with the BRs and twice without them. The entire process of tracheal suctioning is as follows: disposable glove placement, the connection of the suctioning catheter, wiping the catheter with alcohol wipes, turning the suctioning machine on, vacuuming rinse water, checking the negative pressure, removing the airway filter,



b)

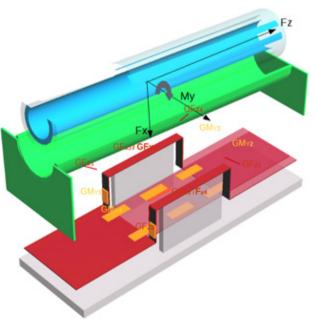


Figure 2. Three-dimensional (3D) schematic of the apparatus of ESTE-SD: a) drawing and b) 3D view.

Table 1. Background	information for	study's participants.
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	Dominant hand (Left:Right)	Gender (Male:Female)	Height Mean ± S.D. (cm)	Clinical experience Mean ± S.D. (years)
Experts	1:8	0:9	157.11 ± 6.78	12.89 ± 6.72
Novices	0:13	1:12	159.62 ± 5.68	0

inserting the suctioning catheter, applying negative pressure for 10 s, removing the suctioning catheter, putting the airway filter back, wiping the catheter by alcohol wipes, vacuuming rinse water, disconnecting the suctioning catheter, turning the suctioning machine off, and disposing of the gloves. Before the experiment, the three BRs of ESTE-SIM- which lead to changes in simulated pulse-oximeter readings, cough sounds, and changes in facial expressions-were explained to each participant. A standing position that allowed for the participants to lower and relax both their arms on both sides of the trunk was set as the base posture. Following the signal from the researcher, the participants per-

Table 2. Summary of results.

		Experts Mean ± S.D.	Novices Mean ± S.D.	Interaction <i>p</i> -value	Main effect <i>p</i> -value	F-value	η2
Performance time [sec.]	Without BRs	67.05 ± 14.06	102.31 ± 24.54	.62	.00	24.90	0.02
	With BRs	69.08 ± 14.47	97.97 ± 11.48				
Pelvic forward bending	Without BRs	9.44 ± 5.44	13.39 ± 8.56	.98	.14	2.23	-
angle [deg.]	With BRs	10.72 ± 4.25	14.55 ± 8.32				
Travel distance of left	Without BRs	14.48 ± 2.77	15.69 ± 3.33	.48	.77	0.08	-
BDM [m]	With BRs	14.58 ± 4.39	14.07 ± 1.61				
Travel distance of right	Without BRs	18.55 ± 3.32	19.38 ± 4.47	.44	.64	0.21	-
BDM [m]	With BRs	18.97 ± 3.49	17.71 ± 3.13				
Posing time of left BDM	Without BRs	20.01 ± 11.47	46.39 ± 20.04	.96	.00	20.46	0.03
[sec.]	With BRs	21.21 ± 13.46	47.08 ± 14.81				
Posing time of right	Without BRs	11.76 ± 6.27	32.39 ± 10.46	.75	.00	35.88	0.02
BDM [sec.]	With BRs	11.10 ± 7.19	33.86 ± 12.85				
Posing frequency of left	Without BRs	8.63 ± 3.24	15.25 ± 6.38	.70	.01	11.63	0.06
BDM [times]	With BRs	7.88 ± 3.37	13.13 ± 4.73				
Posing frequency of right	Without BRs	5.63 ± 2.39	14.63 ± 4.50	.66	.00	43.44	0.02
BDM [times]	With BRs	4.75 ± 2.54	12.63 ± 3.67				

formed the entire process of tracheal suctioning, from the first step, which involved glove placement, to the final step, which involved glove removal. The movement measurement started once the base posture was assumed and stopped when the participants reverted to the base posture at the end. The height of the bed and the positions of the equipment were kept constant.

Statistical Analysis

Variables were tested for normality based on the assessment of the data distribution on a histogram. Motion parameter data were tested with a two-way mixed analysis of variance (ANOVA) for the evaluation of the main effects of the two different proficiency groups with/without BRs and their interaction. The significance level was p < .05. Sidak's post hoc tests were used for effect analysis. Microsoft Excel 2016 and MATLAB 2014a were used for analyzing data.

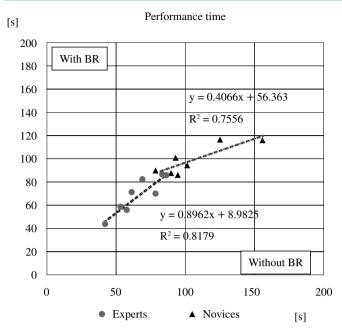
Results

Valid datasets for eight nurses and eight students were carefully selected from the two sets of trials. The performance time, pelvic forward bending angle, travel distance of the BDM, posing time and posing frequency of the BDM from the perception neuron, and information on suctioning catheter control from the ESTE-SD were analyzed with/without the simulated BRs.

Body Motion Detected by Motion Capture System

Table 2 summarizes the results of the two-way mixed ANOVA. No statistically significant interactions appeared between the two proficiency groups and the presence/absence of BRs. There were no main effects of the presence/ absence of BRs in performance time, pelvic forward bending angle, travel distance of the left BDM, travel distance of right BDM, posing time of left BDM, posing time of right BDM, posing frequency of left BDM, and posing frequency of right BDM (p = .86, .62, .53, .87, .42, .27, .87, and .90, respectively). However, the main effect of the performance time [s] yielded F(1, 28) = 24.895, p < .01, $\eta^2 = 0.024$; a posing time of the left BDM [s], F(1, 28) = 5457.513, p $< .01, \eta^2 = 0.030$; a posing time of the right BDM [s], F(1, 28) = 3747.615, p < .01, $\eta^2 = 0.020$; a posing frequency of the left BDM [count], F(1, 28) = 11.628, p < .01, η^2 = 0.062; and a posing frequency of the right BDM [count], F $(1, 28) = 43.437, p < .01, \eta^2 = 0.017$ between the two groups. This indicates the existence of significant differences with small effect sizes in the performance time, a posing time of the left and right BDM, and a posing frequency of the right BDM between the expert and novice groups. A middle effect size appeared in the posing frequency of the left BDM ($\eta^2 > 0.06$), which implies that the proficiency difference in the posing frequency of the left BDM is larger than that of the right BDM. The pelvic forward bending angle and travel distance of the BDM did not contribute significantly to proficiency.

Figure 3 shows the scatterplot of the performance time for the two groups with/without BRs. By comparing the results of the two groups, we found that the expert group required a performance time that was approximately 34.5% smaller than that of the novice group despite the presence of simulated BRs. We estimated that the novice group would require a longer performance time in the trials without the BRs, yet there were no main effects between the BRs and



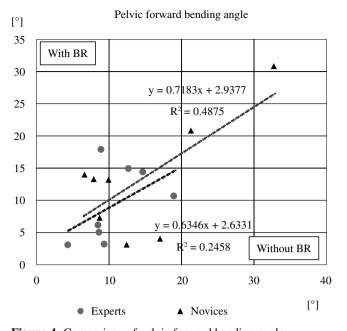


Figure 3. Comparison of performance time.

Figure 4. Comparison of pelvic forward bending angle.

the no-BRs of the student group.

The comparison of the pelvic forward bending angle is shown in Figure 4. Although several individuals tended to tilt their upper body forward during tracheal suctioning, no main effects were apparent based on the result of the twoway ANOVA. However, such a tilting posture on the tracheal tube can increase the risks of droplet infection, and proper instruction will be required for these individuals.

Three typical patterns of the travel distance of BDM are presented in Figure 5, namely, right predominance, equal pattern, and left predominance. There were no interactions and primary effects between the different proficiency groups and the presence of BR from the results of the two-way ANOVA; however, these three patterns indicate that it is possible to detect inefficient movements of the dominant hand. Considering that all participants were right-handed, the travel distance of the BDM divided by the performance time could be applied to evaluate proficiency.

Figure 6 compares the performance time and posing time of the BDM with/without BRs. In the case in which no BRs occurred, the posing time percentages within the performance time in the experts' left and right BDM were 29.8% and 17.5%, respectively. In the case in which BRs occurred, the percentages of posing time within the performance time in the experts' left BDM and right BDM were 30.7% and 14.9%, respectively. For the novice group, the percentages of posing time within the performance time increased in both the BDM with/without BRs. The left and right BDM of the novice group without BRs were 46.6% and 29.7%, respectively; they slightly increased to 50.0% and 31.1% with BRs. Table 2 indicates that the development in the skill proficiency between experts and novices is 34-44% smaller

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than that in the posing time in the expert group.

The posing frequency of the BDM is shown in Figure 7. The two-way ANOVA results indicate that there is no statistical significance with/without BRs, and there is entrainment of the posing frequency in the left and right BDM. However, the main effect is detected between the expert and novice groups. Thus, experts performed tracheal suctioning with a statistically lower posing frequency despite the presence of the BRs, which could be considered a criterion for proficiency evaluation.

Catheter Movement Detected by ESTE-SD

The typical result from the ESTE-SD is shown in Figure 8. The numbers in brackets indicate the amount of phlegm suctioned. The suctioning catheter movements of N4, S3, and S6 differentiate the load on the surface of the artificial membrane [gf], the length of catheter insertion [cm], and shearing force [gf]. N4 performed effective suctioning of increased amounts of phlegm with smaller loads and shearing force. The duration for which the catheter tip touches the phlegm may influence the amount of the suctioned phlegm. S3 in Figure 8 performed suctioning hesitantly. While S6 demonstrated rough suctioning skills, the risk of tracheal membrane damage was high even though a relatively large amount of phlegm was suctioned.

Discussion

This study aimed to compare the skill proficiency of the entire tracheal suctioning process between expert and novice groups via a motion capture system and a catheter control sensing device developed by us. The two-way ANOVA dem-

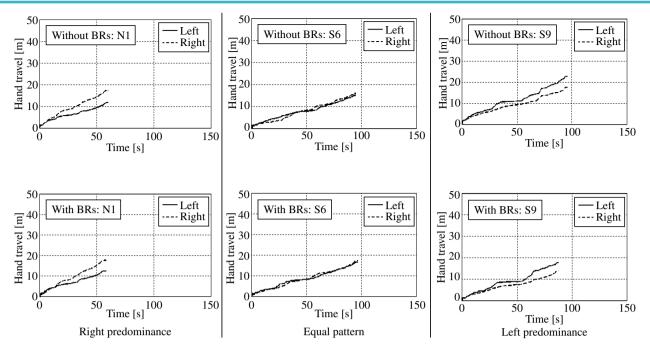


Figure 5. Three patterns of bilateral dorsum manus (BDM) travel distances.

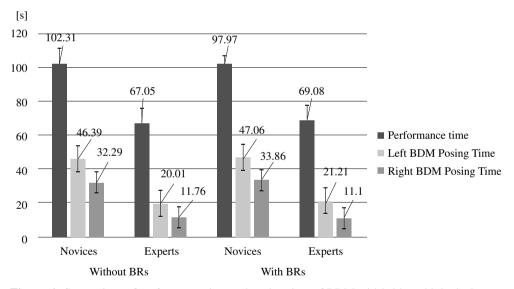
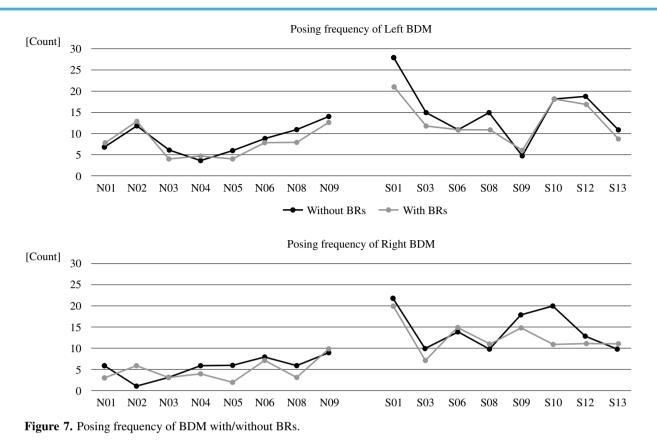


Figure 6. Comparison of performance time and posing time of BDM with/without biological reactions (BRs).

onstrated that there is no interrelation between the BRs and the levels of proficiency. The main effect of performance time, posing time, and posing frequency was statistically significant; irrespective of the presence of BRs, the experts performed tracheal suctioning more expeditiously and efficiently. The average performance time of the nursing students was longer without BRs than with BRs. This finding implies that the presence of BRs may make them to act hastily. The sensing device could clearly detect hesitance or rough catheter control. There were variations of catheter control in the load on the surface of the artificial membrane, the length of catheter insertion, shearing force, and the amount of phlegm suctioned.

The parameters used to assess skill acquisition of tracheal suctioning was not standardized (Osanai et al., 2019); however, these results indicated that the load on the surface of the artificial membrane, the length of catheter insertion, shearing force, and the amount of phlegm suctioned as well as performance time, posing time, and posing frequency could be educational criteria for tracheal suctioning with/ without BRs.

Majima et al. (2012) conducted research that evaluated



nursing students' skill proficiency for performing intravenous injections by using motion sensors on students' fingers and reported enhanced learning effectiveness with prompt feedback. Depending on which nursing skill was evaluated, the appropriate location and numbers of motion sensors may differ. In addition, Otto (2020) pointed out the importance of the development of evidence on skills competency when nursing educators introduce virtual reality simulators as the students' cognition was influenced by the representation of reality. Thus, several parameters were discovered in this research to assess the tracheal suctioning technique. However, additional research on the standardization of quantitative and qualitative proficiency evaluation methods and the constant development of the virtual/augmented reality simulator to improve the tracheal suctioning technique needs to be maintained.

Limitations

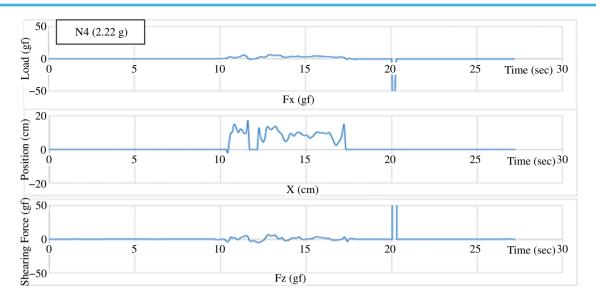
The artificial trachea used in this research was a single size. Experts in real settings may perform tracheal suctioning according to a variety of the tree topology, i.e., airway caliber, branch orientation, and branching angle (Muthu et al., 2019). Despite the patient ages and tracheas' tree topology, the identification of hygienic and safe catheter handling is required. This research methodology did not involve measuring hand-eye coordination.

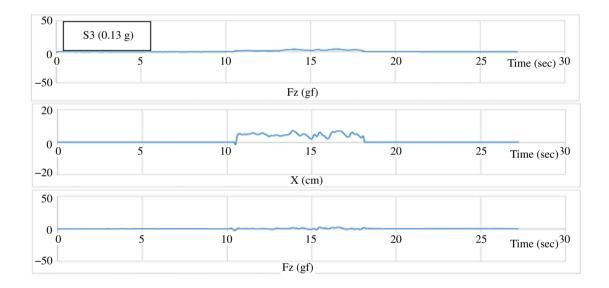
Conclusions

Herein, we explored the performance time, pelvic forward bending angle, travel distance of the BDM, posing time and posing frequency of the BDM, and the suctioning catheter control information between two different proficiency groups (novice and experts) with/without simulator BRs. The results of two-way ANOVA showed that these proficiency criteria were not affected irrespective of whether BRs were used or the levels of proficiency. The main effect of performance time, posing time, and posing frequency was statistically significant; the experts performed tracheal suctioning more expeditiously and efficiently. The ESTE-SD clearly detected hesitant or rough catheter controls; There were catheter control variations. Additional studies on the statistical analysis of the data obtained from the ESTE-SD as well as cognitive functioning related to the decisionmaking of the need for tracheal suctioning, the assessment of the quantity and quality of suctioned phlegm, and the accuracy of hygienic manipulation and safe catheter control, may be required to develop proficiency evaluation schemes.

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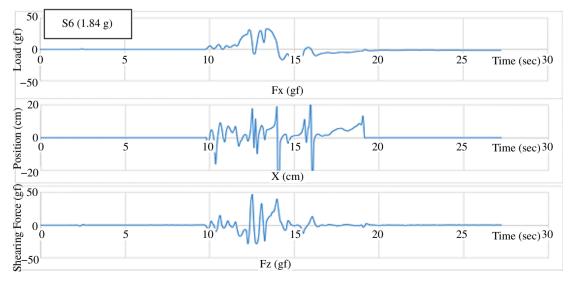


Figure 8. Suctioning catheter movement obtained from ESTE-SD.

Author Contributions

Substantial contributions to the conception of the work; NC, the data acquisition; NC, SK, KS, KA, SI, interpretation of data for the work; NC, SN, SK, drafting the work NC, or revising it critically for important intellectual content; SK, AK, SK, SI, MN, SN, final approval of the version to be published; NC, SK, AK, SK, SI, MN, SN.

Declaration of Conflicting Interests

No potential competing interest was reported by the authors.

Ethical Approval

Approval code: 17-81-2

Name of the institution that granted the approval: Hokkaido University

Data Availability Statement

All data generated or analyzed during this study are included in this published article.

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Original Research

Effects of footbaths on prefrontal cortex activity and autonomic nervous function: A randomized controlled crossover trial

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Abstract

Objective: Footbaths are employed in nursing practice in East Asian countries. Assessing the effects of footbaths based on the findings of multiple physiological responses is relevant to ensuring evidence-based nursing practice. This study aimed to investigate the effects of thermal stimulation by a footbath on prefrontal cortex activity and autonomic nervous function. **Methods:** This study was a randomized controlled crossover trial conducted on healthy participants from a college student population. Each participant underwent a footbath in warm water and a control condition for 10 min on two different days. The order of the two treatments was randomized. The oxygenated hemoglobin concentration in the prefrontal cortex, laterality scores of the oxygenated hemoglobin concentration concentration. A footbath in warm water significantly reduced both the prefrontal cortex and sympathetic nerve activities 7 min after the start of the footbath compared with the control condition. Moreover, a footbath in warm water tended to activate the left prefrontal cortex rather than the right prefrontal cortex. **Conclusions:** The changes in the prefrontal cortex activity and autonomic nervous function were associated with the relaxing effect of the thermal stimulation by the footbath. Furthermore, this effect was highest at 7 min after the start of the footbath. This study has the potential to contribute to the evidence-based use of footbaths. **Trial Registration:** UMIN-CTR Clinical Trial: UMIN 000033735

Keywords

footbath, prefrontal cortex activity, autonomic nervous function, near-infrared spectroscopy

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Introduction

Footbath is a frequently performed nursing practice in East Asian countries, particularly in Japan (Choi & Song, 2017). This nursing practice helps maintain the foot's skin integrity or function. In addition, it influences human physiology and mental function. For example, a study assessing the effects of footbaths on autonomic activity using heart rate variability (HRV) demonstrated that at 40°C, it increases parasympathetic nerve activity associated with physical relaxation (Saeki, 2000). Furthermore, a footbath in warm water suppresses arteriosclerosis (Kobayashi et al., 2019), promotes sleep (Kim et al., 2016), and improves muscle tone (Matsumoto et al., 2014). Therefore, it is clear that warm stimulation of the feet has multiple effects on the human body.

It is generally believed that thermal stimulation by a footbath provides subjective pleasantness. Pleasant/unpleasant emotions are associated with prefrontal cortex activity within the central nervous system (Hoshi et al., 2011). A functional magnetic resonance imaging (fMRI) study demonstrated that pleasantness from thermal stimulation was associated with the caudate nucleus and frontal regions (Ai-

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zawa et al., 2019). Although a footbath in warm water may be related to prefrontal cortex activity, thus far, only a few studies have investigated the effects of a footbath on the prefrontal cortex (Xu & Uebaba, 2003). Some studies have demonstrated that assessment of the left-right superiority of prefrontal cortex activity can be used to objectively evaluate stress (Tanida et al., 2008) and determine if the participants feel pleasure or discomfort (Tanida et al., 2017). In addition, it is reported that the prefrontal cortex is not only involved in cognitive function and emotion but also plays a significant role in the control of autonomic nervous function in stress response (Buijs & van Eden, 2000). Therefore, to scientifically elucidate the effects of footbath in warm water, it is important to measure not only the effect of the footbath on prefrontal cortex activity but also the differences in the activity of the left-right hemispheres of the prefrontal cortex and the effect on the autonomic nervous function. Assessing the effects of footbath in warm water, based on the findings of multiple physiological responses, may contribute to the provision of evidence-based nursing practices.

Previous studies have compared data obtained before and after a footbath (Saeki, 2000; Saeki et al., 2007; Yamamoto et al., 2008) and reported on the comparisons between conditions with and without footbaths (Choi & Song, 2017; Kobayashi et al., 2019; Matsumoto et al., 2014). However, in this study, to confirm the effects of thermal stimulation by a footbath, we performed the footbath under both the intervention and control conditions. This difference could eliminate the previously overlooked effects of hydrostatic pressure and buoyancy.

This study aimed to investigate the effect of thermal stimulation using a footbath by measuring prefrontal cortex activity and the autonomic nervous function simultaneously. We examined cerebral activity and autonomic nervous function using near-infrared spectroscopy (NIRS) and spectral analysis of HRV, respectively. Laterality scores (Tanida et al., 2004) were used to evaluate the left-right superiority of prefrontal cortex activities. To evaluate the impact of the warm sensation of a footbath, we performed the footbaths at two different temperatures.

Materials and Methods

Participants

Healthy college students were recruited to obtain fundamental knowledge of the effects of footbaths. Only right-handed students were included because brain functions differ depending on the dominant hemisphere. The included participants had no history of circulatory organ disorders or leg skin abnormalities. To eliminate the effects of the sexual cycle, female participants were included in the lowtemperature group based on the measurement of their basal body temperatures. We calculated the sample size using a two-tailed test with moderate effect size (d = 0.6), a significance level of 5% (α = 0.05), and a power of 80% (power = 0.8) and found that 19 participants were required. To account for potential attrition, 22 participants were included. Data were collected between December 2018 and February 2019. The study protocol was explained to the participants verbally and in writing; written informed consent was obtained from them. This research was conducted in accordance with the Declaration of Helsinki, approved by the author's Institutional Ethics Committee (18029), and enrolled as a clinical trial (UMIN-CTR Clinical Trial: UMIN 000033735).

Footbath Method

A randomized controlled crossover trial was employed for all the study participants. All experiments were conducted in a quiet laboratory in which the room temperature was controlled within the range of 23°C-25°C. The participants rested for 300 s prior to starting the footbath (rest period). For the last 30 s during the rest period, they were instructed to place their feet on a platform next to the footbath. Subsequently, they undertook one of the following two protocols in a sitting position: (1) a footbath in which both feet are soaked in warm water at the lower leg skin surface temperature + 10°C (footbath in warm water [WFB]) or (2) a footbath in which both feet are soaked in warm water at the lower leg skin surface temperature (control condition). Thermal sensation of local heat or cold was initially determined by the skin temperature without any influence of core body temperature or environmental condition (Aizawa et al., 2019). When the footbath temperature is set to a certain temperature, the perceptions of temperature sensations, such as hot or lukewarm, differ according to subject-specific characteristics. When nurses perform WFB, they customize the WFB temperature according to the skin temperature of each patient's lower leg and the patient's temperature preference rather than using the fixed temperature described in nursing textbooks. Therefore, to reduce the variability of the participants' temperature sensations, in this study, the WFB temperature was set according to the skin temperature of each patient's lower leg. Based on a report (Xu & Uebaba, 2003) that the appropriate time and temperature for a safe footbath is 600 s at 42°C or 900 s at 40°C, the WFB condition in this study was set to be the lower leg skin surface temperature + 10°C to set a safe water temperature not exceeding 42°C.

The footbaths lasted a total of 10 min (Figure 1). The water was filled to 6 cm higher than the top of each participant's external malleolus as temperature sensations differ depending on the depth at which the feet are soaked. Although footbaths often include simultaneous body scrubbing and massage, such procedures were not performed in this study's protocol, which was limited to only soaking both feet.

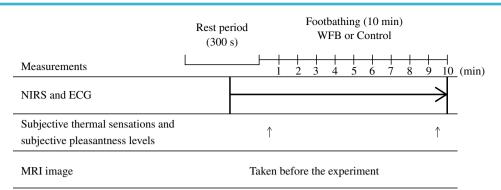


Figure 1. Experimental design. The subjective index survey is conducted following the footbath at both time points.

Arrows and ↑ indicate measurement times; Control, control condition; ECG, electrocardiography; MRI, magnetic resonance imaging; NIRS, near-infrared spectroscopy; WFB, footbath in warm water.

The participants were instructed to close their eyes to eliminate visual information that could affect their cerebral activity and to avoid sleeping during the footbaths. Each of them was randomly allocated to the WFB or control conditions on different days.

Measurements

Prefrontal Cortex Activity (NIRS)

Changes in regional cerebral blood flow induced by sensory stimulation are used as an alternative marker to neural activity changes (Matsuura & Kanno, 2001). When the nerve is active, more oxygen is sent to the site of nerve activity than the brain tissue needs. In other words, when a part of the brain is active, the blood flow to that part of the brain increases. In this study, the cerebral hemodynamics in the prefrontal cortex were measured using the functional NIRS system (LabNIRS, Shimadzu Corp., Japan). This system can measure fluctuations in the concentrations of oxygenated, deoxygenated, and total hemoglobin (oxy-Hb, deoxy-Hb, and total-Bb, respectively). When interpreting the NIRS signals, oxy-Hb is considered to be the parameter that best reflects brain activity as it is associated with regional cerebral blood flow (Hoshi et al., 2001). In addition, in a study where magnetic resonance imaging (MRI) and NIRS measurements were simultaneously performed, the authors reported a correlation between oxy-Hb measured via NIRS and the BOLD signal of MRI (Okamoto et al., 2004). Therefore, in this study, we used fluctuations in the oxy-Hb concentration as an indicator of prefrontal cortex activity.

The oxy-Hb concentration on the forehead was measured with 42 channels (CH) using a forehead fiber holder (Figure 2). The probe for each CH was placed according to the International 10-20 system. The oxy-Hb concentration was continuously assessed during the rest period and the footbath.

Magnetic Resonance Imaging

MRI scans were used to identify the brain regions for each CH of NIRS. A clinical MRI device (Achieva 3.0T, Philips Japan, Ltd., Japan) was used to capture images before the experiment. The entire brain was captured using a T1-weighted three-dimensional gradient echo.

Autonomic Nervous Activity and Heart Rate

The autonomic nervous activity and heart rate were measured *via* electrocardiography (WEB-1000, Nihon Kohden Corp., Japan). Similar to the oxy-Hb concentration, they were continuously examined during the rest period and the footbath.

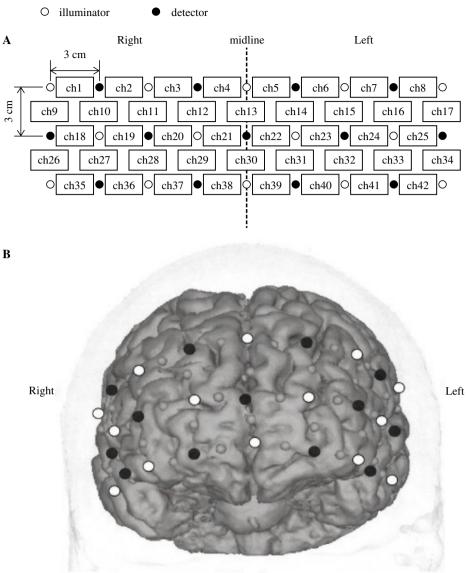
Subjective Thermal Sensations and Pleasantness Levels

To validate the sensation induced by the footbath among the participants, the subjective thermal sensations and pleasantness levels were investigated using a visual analogue scale (VAS). For the former and the latter, the points at 0 and 100 mm were considered cold and hot and unpleasant and pleasant, respectively. We assessed each participant's sensations at two points: immediately after the initiation and at the termination of the footbath.

Analysis Methods

NIRS Data and MRI Images

The NIRS signals were sampled at a rate of 10 Hz. The data were smoothed and provided every 2 s. The oxy-Hb was processed using a band-pass filter. The high-pass filter was set to 0.0056 Hz (Ozawa & Hiraki, 2017) and the low-pass filter to 0.5 Hz (Kirilina et al., 2012). NIRS measurement data have fluctuations of varying degrees in various frequency bands (physiological fluctuations). To reduce the impact of this variation, the primary line connecting the pre-intervention and post-intervention data needs to be treated as the baseline for analysis. A linear baseline correction was made using the mean value of the first 200 s of the rest period and the 30 s immediately after the end of the footbath.



Prefrontal cortex

Figure 2. (A) Positions of the light guides. The oxy-Hb concentration changes are measured in 42 areas (channel, CH) between each pair of illuminators and detectors. (B) Brain area beneath the light guide in a participant. White dots are the illuminators; black dots, detectors; and gray dots, CH. oxy-Hb, oxygenated hemoglobin.

The oxy-Hb concentration data measured *via* NIRS shows the amount of change relative to the starting point, and the data in this state cannot be statistically processed. To conduct statistical analysis, the data of each participant must be standardized into scores. The z-score is one of the standard scoring methods. The z-score was calculated using the formula z-score = (mean data – mean baseline)/the standard deviations (SDs) of baseline, and the average value of the rest period from 200 to 260 s was used as the baseline data (baseline). The NIRS data were hence transformed into zscores ranging from 0 to 1 (Matsuda & Hiraki, 2006). For artifact rejection, all values between the sampling data and their SDs were calculated, and data exceeding ± 8 SDs were excluded from the analysis (Ozawa et al., 2014).

The brain MRI images of each participant were superimposed on the probes and the CHs of the NIRS using MRI image superposition software (Fusion, Shimadzu Corp., Japan). Because the shape and size of the brain differ among the participants, two researchers confirmed the positions of the CHs on MRI images. Based on the Brodmann area, the CHs were located in the frontal pole (Ba10) and the dorsolateral prefrontal cortex (Ba9/46). Although the stimulation method was different from that used in this study, changes in cerebral blood flow in the regions of Ba10 (Minematsu et al., 2018) and Ba9/46 (Billot et al., 2017) have been reported to be related to sensations of pleasantness and un-

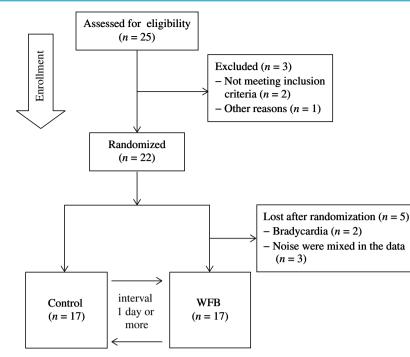


Figure 3. Participant flow chart. Control, control condition; WFB, footbath in warm water.

pleasantness. To examine the effects of footbaths using multiple physiological responses, this study focused on the superstructure (prefrontal cortex) of Ba10 and Ba9/46 rather than analyzing each region in detail. The activity of the left prefrontal cortex was measured by the CH of Ba10 and Ba9/46 in the left prefrontal cortex, whereas the activity of the right prefrontal cortex was measured by the CH of Ba10 and Ba9/46 in the right prefrontal cortex.

To confirm the gradual change during the footbath, we grouped the data in 60-s intervals and analyzed all the data at every 60 s. The z-score for every 2 s was used to calculate the average alteration in the value for each period relative to the baseline. Because the data obtained were non-normally distributed, differences in cerebral blood flow in both the left and right prefrontal cortices between the WFB and control conditions were statistically analyzed using the Wilcoxon signed-rank test.

To evaluate the asymmetry of the oxy-Hb concentration changes in the right and left prefrontal cortices, we calculated the laterality ratio scores for each period. (i.e., [(right - left)/(right + left), changes in z-score]) (Tanida et al., 2004). Positive laterality ratio scores indicated that the increase in the oxy-Hb concentration in the right prefrontal cortex was larger than that in the left, whereas negative scores indicate a reverse relationship.

Autonomic Nervous Activity and Heart Rate

The HRV was calculated from the R-R intervals of the electrocardiogram using the maximum entropy method for spectral analysis (MemCalc/Tarawa, GMS Corp., Japan). The areas of the two components of the spectral analysis were measured by integrating the low-frequency (LF; 0.02-0.15 Hz) and high-frequency (HF; 0.15-0.40 Hz) components; moreover, the LF/HF ratio was calculated. Autonomic nervous system activity was assessed assuming that HF and LF/HF represented parasympathetic and sympathetic nervous system activities, respectively.

The sample period used for analysis lasted a total of 60 s. HF and LF/HF were used to calculate the change in value for each period relative to the baseline. Since the data were non-normally distributed, the Wilcoxon signed-rank tests were employed to analyze HF and LF/HF. The heart rate data were normally distributed and, therefore, analyzed using a paired t-test.

Subjective Thermal Sensations and Pleasantness Levels

Because the subjective thermal sensation and pleasantness level data were non-normally distributed, the Wilcoxon signed-rank test was conducted to identify the differences between the WFB and control conditions at each time point (at the start and end of the footbath).

Results

A flowchart of the experiments is represented in Figure 3. The characteristics at baseline of the 17 healthy participants included in the analysis are presented in Table 1. The mean WFB temperature was $38.5^{\circ}C \pm 1.6^{\circ}C$, and that of the control condition was $27.5^{\circ}C \pm 1.4^{\circ}C$. The temperature and humidity of the experimental room were $23.6^{\circ}C \pm 0.4^{\circ}C$ and

Table 1. Selected	participant	characteristics.
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Age, years (SD)	20.9 (1.2)
Sex, <i>n</i> (%)	
Men	7 (41)
Women	10 (59)
Anthropometric measures	
Height, cm (SD)	163.3 (9.7)
Body weight, kg (SD)	56.4 (7.8)
BMI, kg/m ² (SD)	21.1 (2.1)
Hemodynamic measures	
Heart rate, bpm (SD)	71.9 (7.0)
Systolic BP, mmHg (SD)	108.1 (9.7)
Diastolic BP, mmHg (SD)	68.4 (8.0)
Temperature of the skin surface of the lower limbs, °C (SD)	27.7 (2.5)

Notes. BMI, body mass index; BP, blood pressure; SD, standard deviation.

 $28.4\% \pm 5.1\%$, respectively. All data were analyzed for differences in the order of the experiments and sex; however, no significant effects of these differences were noted.

No differences were observed in heart rates between the WFB and control conditions (Figure 4). The WFB condition was warmer and more pleasant than the control condition, showing significantly higher subjective thermal sensations and subjective pleasantness levels than the control condition at all time points (Table 2).

NIRS Data (Prefrontal Cortex Activity)

Figure 5 presents the cerebral blood flow in the prefrontal cortex. No significant differences were observed at baseline between the WFB and control conditions. At the 1-min time period, the WFB's z-score was significantly higher than that of the control condition (r = -1.96, p < .001); however, at the 7-min time point, it demonstrated a significantly lower

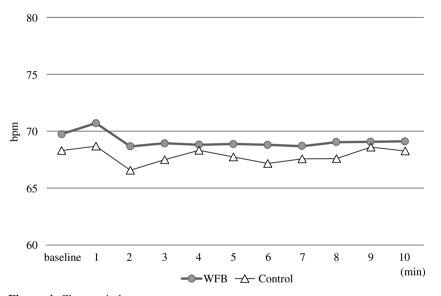


Figure 4. Changes in heart rate.

Paired *t*-tests are conducted for comparison between the groups. bpm, beats per minute; Control, control condition; WFB, footbath in warm water. No statistically significant differences are observed between the groups.

Table 2. Between-group comparisons of the subjective thermal sensations and pleasant levels.

				n = 17
Variable and timing	WFB Median (range)	Control Median (range)	Z value	p value
Subjective thermal sensations				
Immediately after the start of the footbath	77 (57–89)	24 (1-64)	-3.622	<.001*
At the end of the footbath	55 (28–72)	44 (9–53)	-3.518	<.001*
Subjective pleasantness levels				
Immediately after the start of the footbath	90 (68-100)	52 (16-100)	-3.527	<.001*
At the end of the footbath	85 (25–100)	46 (8–72)	-3.622	<.001*

Notes. The Wilcoxon signed-rank test was conducted for comparison between groups.

Control, control condition; WFB, footbath in warm water.

* A significance level of .05 was observed for the median difference.

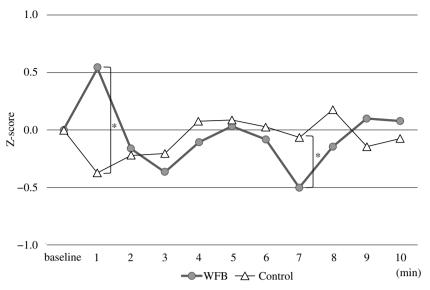


Figure 5. Changes in cerebral blood flow in the prefrontal cortex. The Wilcoxon signed-rank test is conducted for comparison between the groups. Control, control condition; WFB, footbath in warm water.

* A significance level of .05, vs. control condition, is observed for the median difference.

Table 3. The laterality scores of the oxy-Hbconcentration changes.

		<i>n</i> = 17
Time period	WFB	Control
1 min	-0.15	0.37
2 min	-0.09	-0.01
3 min	-0.24	-0.14
4 min	-0.80	0.49
5 min	-0.70	0.31
6 min	-0.93	-0.20
7 min	-0.06	-0.38
8 min	-0.52	-0.90
9 min	-0.39	0.19
10 min	-0.88	0.89

Notes. A statistical significance test was not conducted between the conditions.

Control, control condition; oxy-Hb, oxygenated hemoglobin; WFB, footbath in warm water.

value than the control condition (r = -0.75, p = .002).

The laterality scores of the oxy-Hb concentration changes are presented in Table 3. When either or both data from the two hemispheres showed negative values, the following formula was used to look at the relationship between the left and right hemispheres in z-score: laterality ratio score = (right - left)/(lrightl + lleftl). The laterality score of the WFB was negative at all time points, whereas those of the control condition were a mixture of positive and negative values.

Autonomic Nervous Activity

Figure 6 present the results of HF and LF/HF, respectively. No significant differences were observed in both values at baseline between the WFB and control conditions. Furthermore, there were no significant differences in HF. At the 7-min time point, the WFB's LF/HF was significantly lower than that in the control condition (r = -0.49, p = .04).

Discussion

Our study was able to accurately investigate the effects of WFBs on prefrontal cortex activity. The strength of this study is that it capitalized on the use of NIRS probes based on individual differences in brain shapes captured with MRI. The NIRS has low spatial resolution for accurately identifying the exact measurement sites (Okamoto & Dan, 2007). Using both the NIRS and MRI, we were able to identify the location of the prefrontal cortex, which was ambiguous in the previous studies (Xu & Uebaba, 2003). In addition, in this study, we did not set one temperature of WFB but changed the temperature of WFB according to the skin temperature of each participant's lower leg.

In a previous study that used a fixed 40°C footbath temperature, the VAS score for the post-WFB temperature sensation had an interquartile range of 20 (Maeda & Shuda, 2018). The VAS score of the post-WFB temperature sensation had an interquartile range of 12 in the present study, using the same measurement method as that described by Maeda and Shuda (2018); thus, the method in the present

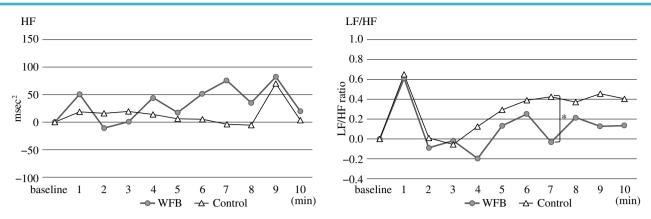


Figure 6. Changes in HF and LF/HF.

The Wilcoxon signed-rank test is conducted for comparison between the groups.

Control, control condition; HF, high-frequency components; LF, low-frequency components; WFB, footbath in warm water.

* A significance level of .05, vs. control condition, is observed for the median difference.

study had less variation than the fixed-temperature method. This suggests that setting the WFB temperature according to the skin temperature of each participant's lower leg is able to better control for individual differences in temperature sensation than using a fixed temperature. In addition, because of the small individual differences, we were able to evaluate the footbaths practiced by nurses, i.e., customizing the temperature according to each patient's lower leg. Therefore, the method used in this study might be able to lead to a new research method that will strengthen the evidence on nursing practice.

As a result of measuring the gradual changes in prefrontal cortex activity and autonomic nervous function during the footbaths, our findings provide evidence that WFBs have a relaxing effect. This conclusion is suggested by the following three considerations:

First, the WFB reduced the prefrontal cortex activity 7 min after initiation. Previous report (Xu & Uebaba, 2003) examining the relationship between WFB and prefrontal cortex blood flow has not investigated the gradual changes during WFB; to the best of our knowledge, this is the first study to examine prefrontal cortex blood flow during WFB. It is known that increases or decreases in the quantity of blood flow in the brain correspond with those of oxy-Hb, and it is thought that a decrease in oxy-Hb concentration causes physiological calming (Hoshi et al., 2001). As a result of evaluating the association between thermal stimulation and brain activity using fMRI, Aizawa et al. (2019) reported that the thermal sensation and whether thermal perception is pleasant or unpleasant may be processed in the insula and medial prefrontal cortex, respectively. Therefore, the response of the prefrontal cortex in this study may be influenced by the pleasantness or unpleasantness induced by WFB. Fujiwara et al. (2020) investigated the effects of thermal stimulation of the lower limbs via NIRS and electroencephalography and reported a decrease in cerebral blood flow in the prefrontal cortex and an increase in α -wave activity. Although the intervention method was different from the present study and was emotionally charged audiovisual stimulation, Matsukawa et al. (2018) employed NIRS and reported that pleasantly charged (comedy) stimulation caused a substantial decrease in oxy-Hb in all regions of the prefrontal cortex. Although various stimulation methods have been tested in previous studies, a common finding is that the relaxation effect significantly reduced the activity of the prefrontal cortex. Since the activity of the prefrontal cortex was also significantly decreased in the present study, we concluded that WFB has a relaxation effect.

Second, the WFB has more of an effect on activation in the left prefrontal cortex than in the right. The laterality ratio score is negative when the increase in the oxy-Hb concentration in the right prefrontal cortex is less than that in the left (Tanida et al., 2004). To date, no studies on the footbath have investigated the differences in left-right prefrontal cortex activities. Although the intervention conditions differed from the present study, Song et al. (2017) found that viewing fresh roses significantly decreased the oxy-Hb concentration in the right prefrontal cortex and increased the perception of feeling "comfortable," "relaxed," and "natural," indicating that viewing fresh roses induces physiological and psychological relaxation. Silveira et al. (2019) reviewed a positive psychological response to exercise and suggested that a higher left prefrontal cortex activation was associated with a positive psychological response to exercise. Tanida et al. (2008) reported that the relaxing effect of fragrances was associated with a change in the dominant activity in the prefrontal cortex from the right to the left side. Our study showed a dominant response in the left prefrontal cortex, which indicates a pleasure-related response suggesting that WFBs have a relaxing effect.

Third, the WFB reduced sympathetic activity without incurring fluctuations in parasympathetic nerve activity. A report of a 10-min footbath suggested that this effect was associated with an increase in HF and a decrease in LF/HF (Saeki et al., 2007). Although the method of footbath and the duration of footbath differed, Yamamoto et al. (2008) compared the use and non-use of a 20-min footbath at 42°C and reported that HF did not show a significant change during the footbath, but the LF/HF ratio significantly reduced. Our LF/HF results agree with the findings of these studies. However, our study examined the gradual changes in WFB and found that a decrease in LF/HF occurred 7 min after the start of WFB. Thus, sympathetic nerve activity significantly decreases 7 min after starting a footbath, and the autonomic nervous system changes to a more relaxed state.

The findings of this study demonstrate that WFBs induce a relaxing effect. Based on the reaction time of prefrontal cortex and sympathetic nerve activities, it can be inferred that the relaxing effect would be highest at 7 min after the start of the footbath. According to descriptive statistics, at 4-10 min during the footbath, HF was higher and LF/HF was lower compared with the control condition, and the laterality ratio score had negative values, suggesting that WFBs might also have a relaxing effect at 4-10 min. However, the mechanism of these responses could not be identified. This study was the first to investigate gradual changes caused by footbaths; if the physiological mechanisms of WFBs were known in more detail, we would be a step closer to identifying the pathway for the relaxing effects of WFBs. Stress is a significant risk factor for various diseases, such as hypertension, heart attack, stroke, and even sudden death (Attar et al., 2021). Although further study is needed to determine the extent to which the relaxing effect of WFBs leads to stress relief, this study provides evidence that WFBs in nursing practices may be beneficial to healthcare.

A significant increase in prefrontal cortex activity immediately after starting the footbath was confirmed only in participants under the WFB condition. Uebaba and Xu (2004) reported that a 38°C footbath did not change the concentration of oxy-Hb in the prefrontal cortex compared with the resting state. In addition to the thermal effect, footbaths contain many stimuli, such as hydrostatic pressure and buoyancy. In our study, we eliminated the effects of hydrostatic pressure and buoyancy by performing the footbath in both the intervention and control conditions. However, it was not clear from this study if the difference from the results of Uebaba and Xu (2004) was due to the hydrostatic pressure and buoyancy. As footbaths include many stimuli, more detailed studies are needed in the future to understand the effects of hydrostatic pressure and buoyancy to strengthen the evidence on the effects of footbaths.

In this study, we focused on the superstructure, prefrontal cortex, and effects of WFB on Ba10 and Ba9/46, and other

brain regions were not individually examined. Additionally, only the oxy-Hb concentrations were analyzed, and data for the deoxy-Hb concentrations and total-Hb concentrations were not considered. To strengthen the evidence for WFB, it is important to elucidate the detailed neural responses and neural mechanisms affected by WFB. Although the magnitude of the effect of WFB on prefrontal activity could not be examined due to the characteristics of the NIRS data, the gradual changes in cerebral blood flow and the left-right superiority of prefrontal activity were confirmed, which will contribute to the development of WFB research in the future.

We were able to assess the response of both prefrontal cortex and autonomic nervous activities to WFB. However, the evaluation of the direct connection between prefrontal cortex activity and autonomic nerve responses remains unsatisfactory. It was not feasible to determine whether cerebral activity affected autonomic nervous activity and vice versa. Furthermore, data were obtained under restricted experimental conditions, and the duration of these effects and their associated changes due to repeated implementation could not be assessed. Further research is needed to determine details such as the appearance time of the footbath effect and the increase or decrease in the effect due to repeated execution.

The present study identified that a WFB evokes significant decreases in prefrontal cortex and sympathetic nerve activities after 7 min. In addition, left-dominant prefrontal responses were observed at all time periods. These findings indicate that WFBs have a relaxing effect, and this effect is highest at 7 min after the start of the footbath. This research contributes to evidence-based nursing practices involving warm footbaths. Furthermore, given the likelihood that these effects are beneficial to health, our outcomes support the use of warm footbaths in nursing practices.

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Author Contributions

Kosuke Maeda: Conceptualization, methodology, validation, formal analysis, investigation, writing-original draft, writingreview & editing, project administration, funding acquisition. Takako Ohba: Formal analysis, investigation, writingreview & editing. Tomofumi Kato: Formal analysis, investigation, writing-review & editing. Akihiro Shuda: Formal analysis, writing-review & editing, supervision.

Declaration of Conflicting Interests

The authors declare that there are no conflicts of interest.

Ethical Approval

The study protocol was explained to the participants verbally and in writing, and written informed consent was obtained from each participant. This research was conducted in accordance with the Declaration of Helsinki, approved by the author's Institutional Ethics Committee (18029), and enrolled in the clinical trial (UMIN-CTR Clinical Trial: UMIN 000033735).

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Data Sharing

Available types of data: Data available upon request from the authors.

Available documents: Study Protocol

Available dates: Beginning 9 mon and ending 36 mon following article publication.

With whom the data are available: Investigators whose proposed use of the data has been approved by an independent review committee identified for this purpose.

Types of analyses the authors are willing to share the data: For individual participant data meta-analysis.

Method of requesting the data: Proposals may be submitted up to 36 mon following article publication. After 36 mon, the data will be available in our University's data warehouse but without investigator support other than deposited metadata. Information regarding submitting proposals and accessing data may be found at https://upload.umin. ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000038467.

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Original Research

Collaborative visits by hospital specialist nurses with homecare nurses: A nationwide, cross-sectional, web-based survey

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Abstract

Objective: Hospital-based specialist nurses (clinical nurse specialists and certified nurses) are increasingly conducting patient home visits along with homecare nurses due to the increasing necessity of home care for persons with multiple medical needs. However, not much is known about such visits. Thus, this study examines collaborative visits by specialist nurses. Methods: A web-based questionnaire survey was sent to specialist nurses in Japan specializing in (1) wound care, (2) cancer palliative care, and (3) chronic disease care. Multiple logistic regression analyses were performed to identify the factors involved in collaborative visits, focusing not only on the individual but also on hospital/community characteristics. Results: Data from 1,027 specialist nurses were analyzed. Among them, 45.6%, 21.4%, and 18.3% of wound care, cancer palliative care, and chronic disease nurses, respectively, conducted collaborative visits. For nurses specializing in wound and cancer palliative care, holding managerial positions was associated with providing collaborative visits. Wound care nurses from hospitals in municipalities with fewer hospital beds per capita tended to conduct collaborative visits, whereas cancer palliative nurses in communities with a higher aging rate provided more collaborative visits. For chronic disease nurses, more working hours as specialists, lower participation rates in community-based multidisciplinary gatherings, and working in hospitals with open community consultation services promoted collaborative visits. Conclusions: Hospital and community factors are associated with collaborative visits, suggesting a need for hospital-wide and policy-supported efforts to further increase collaborative visits.

Keywords

advanced practice nursing, chronic disease, community-institutional relations, community integrated care system, homecare

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Introduction

Considering rapid societal changes, e.g., population aging, nurses in several countries have been exploring new systems of providing nursing services, for example, advanced practice nursing, where registered nurses are provided additional education. Reflecting on the international awareness of and interest in promoting advanced practice nursing, the International Council of Nurses has established a committee on advanced practice nursing (International Council of Nurses, n.

Correspondence: A. Masuda. Email: aruha-masuda@g.ecc.u-tokyo.ac.jp Received: July 19, 2021, Accepted: May 19, 2022, Advance Publication: January 26, 2023, Published: February 17, 2023 Copyright © 2023 The Japan Society of Nursing Research This work is licensed under the Creative Commons Attribution International License (CC BY-NC-SA). d.). Nurses in Japan have also started exploring service provision in the face of rapid population aging.

Several types of additional specialist certification education for registered nurses exist in Japan. Both certified nurses (CNs) and certified nurse specialists (CNSs) are specialist nurses who have received advanced education in a specialty and have been certified by the Japanese Nursing Association. They have at least 5 years of clinical experience as a registered nurse in a particular field and have completed a 2-year master's program (CNSs) or a 6-month certification program (CNs). Their core competencies include (1) high-level nursing practices, (2) the ability to instruct staff nurses, and (3) the ability to provide consultation. CNSs are also expected to take on research and ethical coordination roles (Japanese Nursing Association, 2016). Moreover, about 20,000 CNs and 2,000 CNSs are currently available (Japanese Nursing Association, 2019). CNs may specialize in 21 different fields (e.g., wound, ostomy, and continence care [WOC] nursing, palliative care, and infection control), while CNSs specialize in 13 fields (e.g., oncology, psychiatric/mental health, and critical care). Approximately 90% of CNs and CNSs are working in hospital settings.

Developing new specialist nurses and determining how they should work in the healthcare system are being explored in numerous countries (Donald et al., 2013; Yao et al., 2017; O'Flynn, 2018). Japan is characterized by its extreme increase in the aged population. To meet the healthcare needs of numerous older adults, Japan has recently focused on providing home-based care outside hospital settings (Ministry of Health, Labour and Welfare, 2016a). Further, community dwellers also require advanced medical care. Thus, specialist nurses (SNs), representatively CNs and CNSs, with specific knowledge and skills, are encouraged to provide advanced care in homecare settings (Japanese Nursing Association, 2019). The same trend of SNs working outside the hospital setting is observed in other countries (Adams, 2015; Clevenger et al., 2020). Earlier studies report the benefits of SNs on client outcomes, e.g., decreasing readmission rates and improving quality of life through homecare (e.g., Adams, 2015).

Collaborative visits entail SNs working outside the hospital with homecare nurses. They have been used since 2012 and are reimbursed under the medical insurance system. When a homecare nurse faces difficulties due to client problems, they can request a nearby hospital that employs SNs to conduct a collaborative visit. For example, a WOC SN visits the client with the homecare nurse and provides direct care or consultation when homecare nurses have difficulty in treating their client's pressure ulcer. A regular homecare nursing visit currently costs about \$72/h. For each collaborative visit, an approximately additional \$120 is reimbursed to the hospital to which the SN belongs. This reimbursement is for two specialty areas only: pressure ulcers and colostomy care and palliative care (Ministry of Health, Labour and Welfare, 2012). Care of chronic diseases is not covered.

In countries, e.g., Japan, experiencing rapid population aging, collaborative visits play an important role in optimizing home healthcare. However, few studies have reported on the current status of collaborative visits. The only related survey was conducted in 2016 involving WOC CNs, among whom less than a third had conducted collaborative visits (Kaitani et al., 2017). While the importance of collaboration between SNs and homecare nurses in the community is generally recognized, the prevalence of collaborative visits in each specialty and the factors that encourage those visits remain unclear. To promote collaborative visits in Japan and share experiences of that in other countries, further examination of their characteristics and associated factors would be beneficial. Hence, this study describes collaborative home visits made by hospital SNs from the perspective of those SNs and by linking their descriptions to hospital and community statistics. Both hospital and community characteristics were considered in this study to determine the factors that promote collaborative visits among different hospitals and communities. Examining these factors will help promote the effective functioning of advanced practice nurses not only within the hospital setting but also in the community.

Materials and Methods

Study Design

This study used a web-based, cross-sectional questionnaire survey design.

Participants

The participants of the study were CNs and CNSs employed. All CNs and CNSs all over Japan were invited. As reimbursements for collaborative visits are currently only available for two specialties—pressure ulcers and colostomy care and cancer palliative care (Ministry of Health, Labour and Welfare, 2012) —this study included CNs and CNSs from the following five related fields: WOC, palliative care, cancer pain management, breast cancer CNs, and oncology CNSs. This study also included SNs from the following five specialties for frequent chronic diseases for which reimbursements are not yet available: CNs in diabetes, dialysis, respiratory, and heart diseases, and CNSs for chronic conditions. Nurses who were on leave were excluded from the study.

Data Collection

A web-based questionnaire survey distributed through a link e-mailed to all listed CNs and CNSs (n = 23,201) was used. The participants answered questions anonymously after reading the explanatory document on the survey website and providing informed consent. Once the dataset was constructed, existing community statistics were added to examine possible associations between the provision of collaborative visits and community characteristics. The survey was conducted from August to September 2019.

Measures

The authors used an investigator-developed survey and nationally available statistics. Data on SNs' individual, hospital, and community characteristics as well as whether they had provided collaborative visits in the community were collected.

SN's Collaborative Visits

To examine the prevalence of collaborative visits, the participants were asked: "Have you ever conducted collaborative visits with a homecare nurse?" Response options were "yes" or "no."

SN's Individual Characteristics

Individual demographic variables included specialty, sex, age, completion of additional training for specific medical procedures (*tokutei koi kensyu*), participants' work positions in the hospital, and the hospital department they belonged. Training for specific medical procedures (*tokutei koi kensyu*) is a recently introduced program that enables nurses to conduct a specific treatment without receiving a specific individual order from a physician (Ministry of Health, Labour and Welfare, 2015).

Based on earlier studies (Kaitani et al., 2017; Riordan et al., 2017), a question about work characteristics was also included: full-time work as an SN or not, voluntary participation in community-based multidisciplinary gatherings, voluntary participation in seminars in the community, the presence of independent SN-led clinics within the hospital, and their working hours as SNs.

Hospital Characteristics

The hospital characteristics considered in this study included the number of beds, presence of a consultation counter for community people/professionals, presence of a homecare nurse department in the hospital, presence of a long-term nursing facility on the premises, and advertisement of SNs' practice in the community by posting on websites and creating leaflets.

Community Characteristics

Following a prior study that indicated that the number of hospital beds in the community was related to the utilization of homecare nursing services (Nakanishi et al., 2017), community characteristics were also included in the study. The participants were first asked to name the municipality in which their hospital is located. Next, specific data on municipality type, aging rate, and the number of hospital beds/ population were separately collected. National data on the aging rate and the number of hospital beds/population from the national census and the survey of medical institutions were then obtained (Statistical Bureau of Japan, Ministry of Internal Affairs and Communications, 2015; Ministry of Health, Labour and Welfare, 2016b).

For municipality type, cities were divided into ordinancedesignated cities and others. The former is a large city with a population of 500,000 or more. In this study, the 23 special wards in Tokyo were considered ordinance-designated cities. Tasks concerning social welfare, health and hygiene, and city planning and construction are reassigned from the prefecture to the ordinance-designated cities and the 23 special wards of Tokyo.

Data Analyses

This study classified the 10 SN fields (eight under CN and two under CNS) into three groups: (1) WOC (WOC CNs); (2) cancer palliative care (palliative care, cancer pain management, breast cancer CNs, and oncology CNSs); and (3) care for chronic diseases (diabetes, dialysis, chronic respiratory care, chronic heart failure CNs, and chronic care CNSs). This was done to examine field-related differences and the impact of medical reimbursement availability because medical reimbursement is only available for the first two groups (Ministry of Health, Labour and Welfare, 2012).

Bivariate analyses were first conducted to examine the associations between individual, hospital, and community characteristics with the provision of collaborative visits. For categorical variables, the chi-square test was used. Fisher's exact test was used when the contingency tables had 20% or more of the cells with five or fewer observations. For continuous variables, t and U tests were applied to variables with normal and non-normal distributions, respectively. Subsequently, multiple logistic regression analyses were performed to identify the factors associated with the provision of collaborative visits (dependent variable) by group. Based on earlier studies, the following were considered independent variables: age, working status, work location, working hours as an SN, participation in community-based multidisciplinary gatherings, having a community consultation counter, advertising SNs' practice in the community (Doody et al., 2017; Harvey et al., 2017; Kaitani et al., 2017; McAiney et al., 2017; Riordan et al., 2017; Sevilla et al., 2018), and other variables with p < .05 as a result of bivariate analyses in each group.

The analyses used IBM SPSS 26.0 for Windows, and the significance level was p < .05 (two-tailed). No data were missing in this analysis because the web-based questionnaire prevents respondents from leaving any questions unanswered.

Ethical Considerations

A research ethics committee of the university to which the author is affiliated approved the study. The questionnaire included an explanation of the study's purpose and method

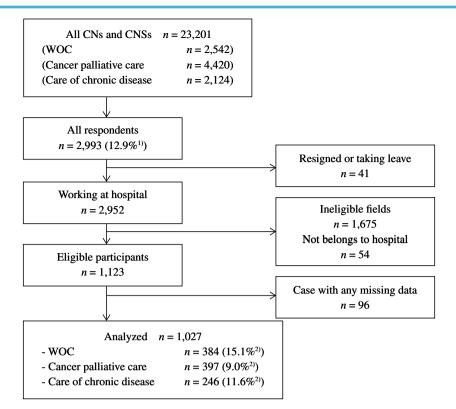


Figure 1. Flowchart of participants in this study

Abbreviations: CNs=Certified nurses, CNSs=Certified nurse specialists, WOC=Wound, ostomy, and continence care. 1) The response rate. 2) The ratio of valid responses.

and the voluntary and anonymous nature of participation, with informed consent obtained before participation.

Results

Of the 23,201 SNs to whom the survey was sent, 2,993 (12.9%) responded. The response rates among CNs and CNSs were 12.4% and 18%, respectively. Based on the inclusion and exclusion criteria, 1,027 cases were analyzed according to the three groups, with 384, 397, and 246 specializing in WOC, cancer palliative care, and care for chronic diseases, respectively, and valid response rates for each group were 15.1%, 9%, and 11.6%, respectively (Figure 1).

More than 90% of the participants were women. Participants' mean ages were 45.7 ± 6.8 , 45.8 ± 6.4 , and 44.4 ± 6.2 for WOC nurses, cancer palliative care nurses, and care for chronic disease nurses, respectively. Among the participants, 17.1% worked full-time as SNs, with the fewest SNs working in care for chronic diseases. Furthermore, 45.6%, 21.4%, and 18.3% of SNs in WOC, cancer palliative care, and care for chronic diseases conducted collaborative visits, respectively. In the bivariate analysis, the factors related to conducting collaborative visits for the WOC group included higher age, completion of training for specific medical procedures (*tokutei koi kensyu*), status as managerial nurses,

more working hours as SNs, participation in communitybased multidisciplinary gatherings, and higher number of hospital beds in the community. In the cancer palliative care group, related factors included completion of training for specific medical procedures (*tokutei koi kensyu*), status as managerial nurses, and participation in community-based multidisciplinary gatherings. In the care for chronic disease group, related factors included more working hours as SNs, higher number of hospital beds in the community, and having a consultation counter for the community (Table 1).

Multiple logistic regression analyses for the WOC group showed that the characteristics of nurses significantly associated with conducting collaborative visits included SN's higher age (adjusted odds ratio [AOR], 1.04; 95% confidence interval [CI], 1.01-1.08), completion of training for specific medical procedures (*tokutei koi kensyu*; AOR, 2.76; 95% CI, 1.49-5.09), having a managerial, rather than staff, position (AOR, 1.81; 95% CI, 1.07-3.07), working in a hospital with a home care nurse department (AOR, 2.58; 95% CI, 1.50-4.47), and fewer hospital beds per 1,000 population (AOR, .92; 95% CI, .86-.98). Among cancer palliative care SNs, having a managerial position (AOR, 2.62; 95% CI, 1.40-4.89), working in a hospital with a home care nurse department (AOR, 1.90; 95% CI, 1.03-3.54), and the municipality with higher aging rates (AOR, 1.10; 95% CI,

1,027)
= <i>u</i>)
characteristics
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Table

			Wound	Wound, ostomy, and continence care $(n = 384)$	nd continence 384)	e care	Can	cer palliative	Cancer palliative care $(n = 397)$	()	Care o	Care of chronic disease $(n = 246)$	sease $(n = 2^{2})$	(9)
			Having	Having conducted collaborative visits	sollaborative	visits	Having	conducted (Having conducted collaborative visits	visits	Having c	Having conducted collaborative visits	llaborative	visits
	Variables		All	Yes (n = 175, 45.6%)	No $(n = 209)$		All	Yes (<i>n</i> = 85, 21.4%)	No $(n = 312)$		All	Yes (n = 45, 18.3%)	No $(n = 201)$	
			%) u	<i>n</i> (%) or mean ±	± SD	<i>p</i> value	96) u	<i>n</i> (%) or mean ±	± SD	<i>p</i> value	%) u	<i>n</i> (%) or mean ±	SD	<i>p</i> value
Demographic	Sex	Women	Women 363 (94.5)	169 (96.6)	194 (92.8)	.108 ^b	375 (94.5)	79 (92.9)	296 (94.9)	.323 ^d	222 (90.2)	40 (88.9)	182 (90.5)	.457 ^d
characteristics	Age	Years	45.7 ± 6.8	47.2 ± 6.2	44.5 ± 7.0	<.001 ^{c**}	45.8 ± 6.4	45.7 ± 5.9	45.8 ± 6.5	.935°	44.4 ± 6.2	44.0 ± 6.5	44.5 ± 6.2	.598°
	Training for specific medical procedures (Tokutei kooi kensyu)	Yes	71 (18.5)	50 (28.6)	21 (10.0)	<.001 ^{b**}	8 (2.0)	7 (8.2)	1 (.3)	<.001 ^d **	19 (7.7)	5 (11.1)	14 (7.0)	.253 ^d
	Work position	Staff nurse	130 (33.9)	42 (25.0)	94 (43.5)	<.001 ^b **	152 (38.2)	19 (22.4)	133 (42.6)	.001 ^{b**}	100 (40.7)	13 (28.9)	87 (43.3)	.076 ^b
	Department of work	Inpatient ward	97 (25.3)	30 (16.8)	72 (32.4)	$.001^{b**}$	148 (37.3)	26 (30.6)	122 (39.1)	$.150^{b}$	109 (44.3)	17 (37.8)	92 (45.8)	.329 ^b
Specialist	Fulltime/parttime as specialist nurse	Fulltime	Fulltime 239 (62.2)	121 (69.1)	118 (56.5)	$.011^{b*}$	140 (35.3)	37 (43.5)	103 (33.0)	.072 ^b	42 (17.1)	7 (15.6)	35 (17.4)	.765 ^b
nurses' work characteristics	Participation in community-based multidisciplinary gatherings	Yes 1	110 (28.6)	60 (34.3)	50 (23.9)	.025 ^b *	170 (42.8)	45 (52.9)	125 (40.1)	.003 ^b **	100 (40.7)	13 (28.9)	87 (43.3)	.076 ^b
	Participation in the seminars in the community	Yes 2	297 (77.3)	148 (84.6)	149 (71.3)	.002 ^b **	336 (84.6)	79 (92.9)	257 (82.4)	.017 ^b *	213 (86.6)	40 (88.9)	173 (86.1)	.616 ^b
	Having specialist nurse-led clinic	Yes 2	290 (75.5)	140(80.0)	150 (71.8)	.062 ^b	175 (44.1)	38 (44.7)	137 (43.9)	.896 ^b	131 (53.3)	27 (60.0)	104 (51.7)	.316 ^b
	Working hours as specialist nurse	One day or more (per week)	293 (76.3)	147 (84.0)	146 (69.9)	.001 ^{b**}	215 (54.2)	56 (65.9)	159 (51.0)	.014 ^b *	100 (40.7)	25 (55.6)	75 (37.3)	.024 ^b *
Hospital	The number of beds	Large (400–)	174 (45.3)	69 (39.4)	105 (50.2)	.034 ^b *	212 (53.4)	41 (48.2)	171 (54.8)	.282 ^b	118 (48.0)	28 (62.2)	90 (44.8)	$.034^{b*}$
characteristics	Having consultation counter for the community	Yes	Yes 220 (57.3)	104 (59.4)	116 (55.5)	.439 ^b	216 (54.4)	53 (62.4)	163 (52.2)	.097 ^b	125 (50.8)	30 (66.7)	95 (47.3)	.019 ^b *
	Having home care nurse department	Yes 1:	159 (41.4)	94 (53.7)	65 (31.1)	<.001 ^b **	141 (35.5)	44 (51.8)	97 (31.1)	<.001 ^{b**}	94 (38.2)	25 (55.6)	69 (34.3)	.008 ^b **
	Having long-term nursing facility	Yes	91 (23.7)	50 (28.6)	41 (19.6)	.040 ^b *	85 (21.4)	28 (32.9)	57 (18.3)	.003 ^b **	59 (24.0)	15 (33.3)	44 (21.9)	.104 ^b
	Advertising Specialist nurses' practice to the outside	Yes	334 (87.0)	155 (88.6)	179 (85.6)	.396 ^b	331 (83.4)	74 (87.1)	257 (82.4)	.304 ^b	209 (85.0)	41 (91.1)	168 (83.6)	.202 ^b
Community characteristics	Municipality type	Ordinance- designated city ^a	115 (29.9)	36 (20.6)	79 (37.8)	<.001 ^{c**}	119 (30.0)	15 (17.6)	104 (33.3)	.005 ^c **	79 (32.1)	10 (22.2)	69 (34.3)	.116 ^c
	Aging rate	%	27.0 ± 4.2	27.6 ± 4.0	26.5 ± 4.3	.011 ^c *	26.6 ± 4.1	27.9 ± 4.1	26.2 ± 4.0	.002 ^c **	27.1 ± 3.8	27.9 ± 3.3	26.9 ± 3.9	.079 ^c
	The number of hospital beds per 1,000 persons		9.1 ± 4.1	8.4 ± 3.5	9.7 ± 4.5	.002 ^e **	9.8 ± 5.2	9.4 ± 3.9	9.9±5.5	.357e	9.8 ± 5.3	9.6 ± 5.0	9.9 ± 5.4	.703°
SD = standard deviation	deviation													

 a Ordinance-designated city, includes the 23 special wards. b Chi-square test

°Welch's t-test ^dFisher's exact test °Mann–Whitney U test

p < .05, **p < .01

Table 2. Factors related to collaborative visits by multiple logistic regression analysis.

Variables		WOC <i>n</i> = 384			Cancer palliative care $n = 397$			Care of chronic disease $n = 246$		
		AOR	95% CI	- p value	AOR	95% CI	– <i>p</i> value	AOR	95% CI	- p value
			LL-UL			LL-UL			LL-UL	
Demographic	Age	1.04	1.01-1.08	.034*	.97	.93–1.01	.114	.96	.90–1.03	.227
characteristics	Training for specific procedures (<i>Tokutei kooi kensyu</i>) ^a	2.76	1.49–5.09	.001**						
	Work position ^b	1.81	1.07-3.07	.027*	2.62	1.40-4.89	.003**	1.91	.87-4.20	.109
	Department of work ^c	.82	.43-1.55	.543	.90	.50–1.62	.736	.58	.27-1.28	.178
Specialist	Fulltime/parttime as specialist nursed	1.41	.77–2.61	.269						
nurses' work characteristics	Participation in community-based multidisciplinary gatherings ^a	1.05	.62–1.78	.858	1.36	.79–2.32	.264	.45	.21–.97	.040**
	Participation in the seminars in the community ^a	1.39	.77–2.53	.278	2.31	.89–6.00	.086			
	Working hours as specialist nurse ^e	1.36	.70–2.61	.363	1.57	.89–2.77	.121	2.16	1.06-4.42	.034*
Hospital characteristics	The number of beds ^f	.68	.40-1.14	.143				2.05	.99–4.26	.055
	Having consultation counter for community ^a	1.10	.68–1.77	.701	1.54	.89–2.66	.120	2.08	1.01-4.27	.047*
	Having home care nurse department ^a	2.58	1.50-4.47	.001**	1.90	1.03-3.54	.041*	2.52	1.25-5.07	.010*
	Having long-term nursing facility ^a	.78	.42-1.46	.443	1.63	.82-3.25	.163			
	Advertising specialist nurses' practice in the community ^a	1.61	.78-3.32	.200	1.24	.57–2.69	.588	1.68	.52–5.46	.390
Community	Municipality type ^g	.58	.33-1.01	.056	.59	.29–1.18	.135			
characteristics	Aging rate	1.05	.99–1.12	.120	1.10	1.02-1.18	.012*			
	The number of hospital beds per 1,000 person	.92	.86–.98	.013*						

Dependent variable is having conducted the collaborative visits, yes = 1, no = 0.

WOC = Wound, ostomy, and continence care; AOR = adjusted odds ratio; CI = confidence interval; LL = lower limit; UL = upper limit ^aYes = 1, no = 0

^bHead nurse and vice-head nurse = 1, staff nurse = 0 ^cInpatient ward = 1, others = 0 ^dFulltime as specialist nurse = 1, part time = 0

^e1 day/ week or more = 1, <1 day/ week = 0

^fLarge (400–) = 1, small or medium (0–399) = 0

^gOrdinance-designated cities = 1, other cities = 0

p* < .05, *p* < .01

1.02-1.18) were significantly associated with collaborative visits. Although bivariate analyses showed that the completion of training for specific medical procedures was statistically significant in the cancer palliative care group, it was not included in the logistic regression analyses because the corresponding sample was very small (n = 8). For SNs specializing in care for chronic diseases, lower participation in community-based multidisciplinary gatherings (AOR, .45; 95% CI, .21-.97), the number of working hours as SNs (AOR, 2.16; CI, 1.06-4.42), working in a hospital with a community consultation counter (AOR, 2.08; 95% CI, 1.01-4.27), and working in a hospital with a home care nurse department (AOR, 2.52; 95% CI, 1.25-5.07) were significantly associated with collaborative visits (Table 2).

Discussion

This study investigated the current practice of collaborative visits by hospital-based SNs. This study is believed to be the first study to describe these visits from the perspective of SNs and by linking their descriptions to hospital and community statistics.

A significant number of SNs reported that they provide collaborative visits. Almost half of WOC nurses reported conducting collaborative visits. Nearly one in five SNs specializing in care for chronic disease reported conducting collaborative visits, even though no medical reimbursement available for their visits was observed. These results indicate the growing interest of hospitals and nurses in Japan in the recent promotion of advanced practice by specialists in homecare settings. The rate of WOC nurses who had conducted collaborative visits in a 2016 study was less than a third of the total (Kaitani et al., 2017). Thus, the number of collaborative visits seems to be increasing, probably reflecting the gradual spread of this system. For other societies facing similar challenges of overcoming health systems centered on acute care to ensure optimal homecare, this study's findings are noteworthy in the establishment and promotion of advanced practice nursing for homecare clients.

Several characteristics regarding SNs' working conditions were revealed to be associated with collaborative visits. The number of working hours as SNs was related to the care for chronic disease nurses conducting collaborative visits. Previous studies have reported that SNs' lack of time due to busy work conditions limits their practice (Clevenger et al., 2020; Riordan et al., 2017). Even though SNs would like to conduct collaborative visits, they may not be able to do so due to time constraints. Working in a managerial role was related to collaborative visits conducted by SNs belonging to WOC and cancer palliative care groups. This may mean that nurses in managerial roles have more discretion in their work hours and can provide home visits. Moreover, SNs working as staff are usually engaged in regular staff functions and may have limited discretion and opportunities to use their specialist expertise (Riordan et al., 2017). Both working hours and working status depend on organizational policy, suggesting the importance of organizational support for SNs' collaborative visits.

Training completion for specific medical procedures (tokutei koi kensyu) was associated with collaborative visits for nurses specializing in WOC. A similar trend was also observed in the cancer palliative care group. An earlier study has reported that many hospital nurses are unwilling to practice in homecare settings because of their lack of homecare expertise (Varley et al., 2020). Completion of training for specific medical procedures may have enabled nurses to become confident enough to apply their skills in homecare settings. One of the six specialty packages of the training is aimed at homecare (Ministry of Health, Labour and Welfare, n.d.), although it is unlikely that SNs participated in the training as a result of providing collaborative visits given that the collaborative visit is only a small part of their entire activities as hospital SNs. This training started in 2015 (Ministry of Health, Labour and Welfare, 2015), and more studies are needed to examine its impact on SNs' practice behaviors.

SNs in the care for chronic disease group who participated in community-based multidisciplinary gatherings were less likely to conduct collaborative visits. This result is contrary to previous studies (McDonnell et al., 2015; Restrepo et al., 2001). Without medical reimbursement for collaborative visits, SNs in the chronic disease group may complete their collaboration with community professionals in those gatherings rather than conduct direct visits. However, SNs may need to see clients directly to properly understand their condition (McDonnell et al., 2015). It may thus be necessary to expand medical reimbursement to cover chronic disease care.

Certain hospital characteristics were associated with collaborative visits. Hospitals with a community consultation counter were associated with collaborative visits among the care for chronic disease group. To bridge the existing gap between hospital and home care, a system for care coordination is required and may play an important role (Mackavey, 2016). Similarly, more collaborative visits were conducted across all groups associated with hospitals with a homecare nurse department. Nurses have easier access to and can easily collaborate with colleagues in a hospital, whereas geographical distance separates hospital and homecare and makes it more difficult (Varley et al., 2020).

Furthermore, some community characteristics were related to collaborative visits in WOC and cancer palliative care groups. SNs who worked in municipalities with a high aging rate were more likely to provide collaborative visits, while those who worked in municipalities with a high number of hospital beds per 1,000 population were less likely to conduct collaborative visits. These results suggest that collaborative visits are influenced by the relative availability of community medical resources, and citizens may need more homecare services in such regions. Fewer hospital beds per capita are related to the utilization of homecare nursing services (Nakanishi et al., 2017), and homecare needs are higher in depopulated and aging areas (McDonnell et al., 2015). Thus, more integrated care between the hospital and the community seems to be necessary for municipalities with higher aging rates and where medical services are relatively scarce.

This study has three limitations. First, it had a relatively low response rate. The response rate varied depending on the specialties of CNSs and CNs. The resulting overall response rate became lower because specialties that have a weak affinity with homecare, e.g., intensive care, were included. The average age of participants in this study, about 45.5 years, is almost the same as that of the national registry of SNs. Moreover, the rate of staff nurses in the current study was lower than that in the registry data, suggesting that the current sample over-represents SNs in managerial roles. This should be considered when interpreting the study results. Second, individual collaborative visits could not be investigated and their details elucidated, something which should be evaluated in future studies. Finally, this study was conducted as a cross-sectional survey; therefore, causal relationships between collaborative visits and their related factors could not be determined.

Despite these limitations, this study is the first nationwide investigation that describes collaborative visits made by hospital SNs from the perspective of those SNs and by linking their descriptions to hospital and community statistics. The results underline the importance of organizational and policy support as well as individual SNs' efforts to promote collaborative visits in the community. Additionally, hospital organizations may also need to consider the specific needs of each community to better serve them. In the context of exploring a new system to provide nursing service, collaborative visits under various strategies considering organizational and community factors are expected to offer advanced and specialized care to clients at home. In the future, identifying the mechanisms of collaborative visits and their effects based on client outcomes is necessary. More studies are needed to identify the barriers and facilitators of such visits to further develop an effective practice model of SNs' collaborative visits in the community.

Author Contributions

Aruha Masuda designed and conducted the study, analyzed and interpreted the data, and prepared the manuscript. Mariko Sakka interpreted the data and reviewed the manuscript. Satomi Kitamura interpreted the data and reviewed the manuscript. Ayumi Igarashi interpreted the findings and critically reviewed the manuscript. Maiko Noguchi-Watanabe interpreted the findings and critically reviewed the manuscript. Akiko Araki coordinated the research, interpreted the findings, and critically reviewed the manuscript. Noriko Yamamoto-Mitani coordinated the research, interpreted the findings, and critically reviewed the manuscript.

Declaration of Conflicting Interests

The authors have no conflict of interest to disclose.

Ethical Approval

This study was approved by the research ethics committee of the Graduate School of Medicine at the University of Tokyo [No. 2019050NI-(2)], Tokyo, Japan.

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Informed Consent

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

Note

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Development of a reliable and valid cancer-related communication scale for use between breast cancer survivors and their adolescent children

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Abstract

Objective: This study aimed to investigate the contents of communication between breast cancer survivors and their adolescent children and to develop a reliable and valid communication scale on maternal breast cancer. Methods: The items were extracted from expert and cognitive interviews. The pilot test comprised self-report questionnaires distributed among 97 adolescents aged 12-18 years whose mothers were diagnosed with breast cancer; a retest was conducted on 34 adolescents. Validity was confirmed by testing factorial, known-groups, convergent, and discriminant validity. Reliability was confirmed by measuring internal consistency and test-retest reliability. Results: The mean age of the participants was 14.8 ± 2.0 years, and 51 (52.6%) of them were female. The average age of being informed about maternal breast cancer was 12.5 ± 2.7 years. Confirmatory factor analysis supported 14 items and a 3-factor model, which included expression of negative feelings (first factor), sharing information about breast cancer (second factor), and relationship with the mother (third factor): $\chi^2/df = 1.21$, goodness-of-fit index = .892, comparative fit index = .973, root mean square error of approximation = .047, and Akaike information criterion = 154.074. For convergent validity, the family adaptability, partnership, growth, affection, and resolve scale confirmed weak correlations for the total, second factor, and third factor scores. Cronbach's α for the total, first, second, and third factors were .863, .764, .882, and .810, respectively. Conclusions: The reliability and validity of the communication scale were confirmed. The scale can help nurses understand and evaluate mother-adolescent communication and devise interventions for facilitating informative, effective, and open discussions regarding maternal breast cancer.

Keywords

adolescent, cancer survivors, communication, family nursing

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Introduction

In Japan, approximately 92,000 women were diagnosed with 2021). The first sign of breast cancer occurs when a woman

breast cancer in 2017, and the prevalence of this disease is rapidly increasing worldwide (Cancer Information Service, 2021). The first sign of breast cancer occurs when a woman

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is in her late 40s (Cancer Information Service, 2021). This is commonly the child-rearing stage, and many breast cancer survivors have children below the age of 18. Previous studies have demonstrated that children of mothers with breast cancer reported the adverse effects of the disease on their physical, emotional, and psychological health, including anxiety, depression, fear, distress, anger, fear of being alone, sleeping difficulties, and headaches (Cappelli et al., 2005; Chan et al., 2020; Edwards et al., 2008; Visser et al., 2004; Walczak et al., 2018).

Given the risk of psychological and behavioral problems, adequate communication regarding breast cancer between breast cancer patients and their adolescent children is essential to avoid these negative effects (Cho et al., 2015). Fitch and Abramson (2007) found that adolescent children aged 12-18 years who did not receive adequate communication regarding maternal breast cancer experienced isolation, fear, and anxiety. In addition, previous studies investigating adolescent children of cancer patients have found that effective communication reduced post-traumatic stress symptoms and anxiety levels (Huizinga et al., 2005; Nelson et al., 1994). A qualitative study investigating 11 children whose parents were diagnosed with cancer demonstrated that most participants wanted to communicate with their parents about cancer (Kennedy & Lloyd-Williams, 2009). However, breast cancer survivors find it difficult to talk about cancer with their children. Reasons for the lack of communication include the mothers' desire to protect their children from distress, the wish to retain the normalcy of their usual lives as much as possible, and management of their sense of uncertainty related to the prognosis (Asbury et al., 2014; Stiffler et al., 2008). According to a qualitative study, children aged 8-18 years, whose mothers were diagnosed with breast cancer, have a basic knowledge of the cancer and its treatment (Huang et al., 2017). They acquire this knowledge not only from their families but also from school, books, and online resources. However, their understanding of the cancer is not always accurate. Adolescents often ask many questions owing to their intellectual curiosity. However, at this stage of development, they are reluctant to talk to their parents. Moreover, they not only understand cancer as a disease, but they tend to associate the word "cancer" with death, causing them to become overly anxious and upset (Fitch & Abramson, 2007). Appropriate communication with adolescents about maternal breast cancer can help them understand and deal with the disease, reduce their anxiety and suffering, and contribute to maintaining a stable daily life.

Nurses should promote appropriate communication regarding cancer between mothers and their adolescent children. Before developing an intervention to support cancerrelated communication, developing a scale that would reliably evaluate how adolescents perceive communication (including its contents and frequency) about maternal breast cancer with their mothers is crucial. However, as far as we know, there are no instruments to measure cancer-related communication between cancer survivors and their adolescent children. Although most previous studies used a parent-adolescent communication scale to assess cancer-related communication between both parties (Barnes, 1982; Cho et al., 2015; Huizinga et al., 2005), they did not measure specific factors associated with cancer, including information about the details of cancer (i.e., stage, symptoms, treatment, and side effects) and the respondents' feelings about it. For these reasons, our study aimed to (1) understand the contents of cancer-related communication and (2) develop a reliable and valid scale to measure communication between breast cancer survivors and their adolescent children.

Materials and Methods

This study consisted of item extraction, cognitive interviews, and a pilot test.

Item Extraction

We extracted 19 items from previous studies about cancerrelated communication scales (Kornblith et al., 2006) and websites for cancer survivors and their families (CancerCare, 2018; Cancer.Net, 2018). We conducted expert interviews with 10 participants: 4 doctors, 3 nurses (pediatric, cancer, and breast cancer nurse specialists), and 3 managers of cancer patient associations. From these interviews, two more items (items 20 and 21) were added, and a four-point Likert scale, ranging from *strongly disagree* to *strongly agree*, was applied. We confirmed the surface and content validity of the items. Because the target participants of this study were adolescents, the sentences of the items were modified to use simpler words to make the questions more comprehensible.

Cognitive Interviews

To examine the content validity of the 21 items, we conducted cognitive interviews with 9 adolescents aged 12-18 years whose mothers were diagnosed with cancer. First, one researcher measured the time required to complete the questionnaire, which ranged from 1 to 5 min (average, 3.25 min). The researcher then interviewed the adolescents about their thoughts on maternal cancer and noted if the questionnaire's content evoked any negative feelings. The participants did not report experiencing any such feelings due to the words used or the content of the questionnaire. After completing this process, the final scale was developed.

Pilot Test

Participants

We recruited participants from three hospitals and two cancer patient associations from February to September 2019. The inclusion criteria were as follows: (1) adolescents aged 12-18 years whose mothers were diagnosed with breast cancer, (2) participants with the ability to answer the questionnaire in Japanese, and (3) consent to participate provided by both the adolescents and their guardians. We excluded those adolescents whose guardians considered them unable to participate due to physical or psychosocial disabilities.

Procedure

The researchers explained the study purpose and procedures to the breast cancer survivors whose children met the inclusion criteria. The researchers then asked them to provide informed consent-related documents and questionnaires to their children. Each child answered the questionnaire and returned it to the researchers *via* mail.

The participants were asked if they wanted to participate in the second survey, which was conducted 2 weeks after the first one to verify retest reliability. We gifted a ballpoint pen to the participants as a token of appreciation for their participation.

Measurement

A cancer-related communication scale to be used between breast cancer survivors and their adolescent children was developed based on the results of the item extraction and cognitive interviews. This scale contained 21 items rated on a 4-point Likert scale, with a higher score indicating appropriate communication about breast cancer between breast cancer survivors and their adolescent children.

Family functioning was evaluated using the family adaptability, partnership, growth, affection, and resolve (APGAR) scale (Kokubu & Kamibeppu, 2013; Smilkstein, 1978). A higher score indicates higher satisfaction with family support (competence). Cronbach's α for this scale in the present study was .776.

The demographic data of the participants included their gender, age, and educational level. We also collected data regarding the age at which they were notified about maternal breast cancer; the presence of peer support, trauma, and subjective stress due to maternal breast cancer; and an experience that was more stressful than maternal cancer.

Statistical Analysis

Descriptive statistical analysis was conducted on the demographic characteristics of the participants; means and standard deviations were calculated for continuous variables, and ratios were calculated for discrete variables. The validity of the scale was confirmed by verifying factorial, convergent, and discriminant validity. Through an exploratory factor analysis (EFA), the number of factors was determined using parallel analysis. A confirmatory factor analysis (CFA) was conducted to confirm the goodness-of-fit. The χ^2 /df, goodness-of-fit index (GFI), comparative fit index (CFI), root mean square error of approximation (RMSEA), and Akaike information criterion (AIC) were used as goodnessof-fit indices. To confirm convergent validity, we used the Family AP-GAR family functioning scale. Appropriate communication in the family is associated with better family functioning (Ghandpazi et al., 2020). We hypothesized that the correlation between the cancer-related communication scale and the Family APGAR family functioning scale is positive. Spearman's rank correlation coefficients between the total and subscale scores of cancer-related communication scale and the scores of Family APGAR family functioning scale were calculated. Reliability was confirmed by verifying internal consistency using Cronbach's α , and test-retest reliability was verified using intraclass correlations (ICC).

In addition, we determined whether the scores of the cancer-related communication scale are affected by demographic characteristics. Regarding gender and the presence or absence of a sibling, Welch's *t*-test was conducted. Furthermore, Spearman's rank correlation coefficient between the scores of the cancer-related communication scale and age were calculated.

IBM SPSS 25.0 for Windows (SPSS, Chicago, Illinois, USA) and IBM SPSS Amos version 25.0 (SPSS, Chicago, Illinois, USA) were used for statistical analysis, and p < .05 (two-tailed) was considered significant.

Ethical Considerations

This study was approved by the Ethics Review Committee of the University of Tokyo, School of Medicine [No. 12079-(1)]. Both the adolescents and their guardian(s) provided written informed consent.

Results

Participant Demographics

We distributed the questionnaires to 129 breast cancer survivors. A total of 107 adolescent children of breast cancer survivors submitted their informed consent forms and questionnaires (response rate, 82.9%). After excluding questionnaires with missing values, 97 responses were finally recorded (effective response rate, 90.7%). The retest questionnaires were sent to 45 participants, and 35 responses were obtained (return rate, 77.8%). Responses with missing values were excluded, and 34 responses were finally included in the retest data (effective response rate, 97.1%).

The mean age of the participants was 14.8 ± 2.0 years, and 51 (52.6%) of them were female. The average age of being informed about maternal breast cancer was 12.5 ± 2.7 years. A total of 38 (39.2%) participants experienced trauma due to maternal breast cancer, whereas 34 (35.1%) experienced more stress due to other factors, such as trouble with friends at school, parent-child relationship, and entrance examinations (Table 1).

		Mea	n ± SD [range]] or <i>n</i> (%)
Demographics				
Age (years)			14.8 ± 2.0	[12–18]
Gender	Male		46	(47.4)
	Female		51	(52.6)
Educational level	Junior high school		53	(54.6)
	High school		37	(38.1)
	Other		7	(7.2)
Experiences related to man	ternal breast cancer			
Age at the time of diagr	nosis notification (years)		12.5 ± 2.7	[7–18]
Years passed since noti:	fication		2.2 ± 2.3	[0–9]
Peer support ^a		Yes	11	(11.3)
		No	86	(88.7)
Trauma due to maternal	breast cancer	Yes	38	(39.2)
		No	58	(60.8)
Subjective stress due to	maternal breast cancer ^b		2.4 ± 1.1	[1–5]
Stressful experience gre	ater than maternal breast cancer	Yes	34	(35.1)
		No	53	(64.9)

Table 1. Participants' characteristics (n = 97).

Notes: Missing values were excluded; ^aFriends whose parents were diagnosed with cancer, ^b1 = not stressful at all, 5 = very stressful; SD = standard deviation.

Validity

Factorial Validity

Based on the parallel analysis, three factors were extracted. We conducted an EFA using the principal factor method and promax rotation. Furthermore, we selected items based on factor loadings of ≥ 0.4 . Because items 2-5 included content regarding communication and expression of negative feelings about maternal breast cancer, such as I cannot talk about cancer with my mother because I get too upset (cry, get angry, panic) (inverted term) and I do not tell my mother how scared I am because she has breast cancer (inverted term), this first factor (F1) was named "expression of negative feelings." Items 6-16 included content regarding communication and shared information about maternal breast cancer, such as My mother explains her treatment plan and how it will affect my life in words that I can understand and My mother and I talk about our worries about whether her treatment will work. This second factor (F2) was named "sharing information about breast cancer." Items 19-21 included content regarding mother-adolescent relationship, such as I feel trusted by my mother. This third factor (F3) was named "relationship with mother." Items 1, 7, 17, and 18 were deleted as they did not fit within the purview of any factors (Table 2).

A CFA was conducted on the 17 items and 3-factor model of the scale. The GFI did not show sufficient values in this model. Therefore, three items (5, 6, and 15), which had a factor loading of .5 or less, were excluded. After confirming that the GFI showed a good value, a 14-item 3-

factor model was adopted: $\chi^2/df = 1.21$, GFI = .892, CFI = .973, RMSEA = .047, and AIC = 154.074 (Table 3, Figure 1, 2).

Convergent Validity

The total score and F2 "sharing information about breast cancer" and F3 "relationship with mother" scores were significantly correlated with the score of the Family APGAR scale (Table 4).

Reliability

Regarding internal consistency, Cronbach's α for the total, F 1, F2, and F3 scores were .863, .764, .882, and .810, respectively. In the retest analysis, the interval between testing and retesting was 16-53 days (average, 28.3 days) for the 34 respondents. The ICC was .748 for the 14 items and .618, .756, and .794 for F1, F2, and F3, respectively (Table 5).

Demographics Related to the Scores of the Cancer-related Communication Scale

For the total score, the mean score (45.2) of the female group was significantly higher than that of the male group (41.7; p = .02). Similarly, the mean score of F2 "sharing information about breast cancer" was significantly higher in the female group (23.8) than in the male group (21.0; p = .02). Regarding the presence or absence of sibling, the absence group tended to have higher scores. For the score of F 3 "relationship with mother," the mean score (10.9) of the absence group (9.8; p = .03; Table 6). No significant correlation was observed between the total and subscale scores and age.

Table 2. Exploratory factor analysis: principal factor method and promax rotation (n = 97).

#		Items	F1	F2	F3
Exp	ressio	n of negative feeling (F1) Cronbach's $\alpha = .664$			
4	☆	My mother does not talk about cancer with me because she does not want me to get upset (i.e., cry, get angry, panic).	.926	.149	049
3	☆	I cannot talk about cancer with my mother because I get too upset (i.e., cry, get angry, panic).	.691	.000	.036
2	☆	My mother gets upset when I talk about my feelings about her having cancer.	.568	.008	072
5	☆	I do not tell my mother how scared I am because she has cancer.	.425	.091	.091
Sha	ring ir	formation about breast cancer (F2) Cronbach's $\alpha = .880$			
8		We discuss/discussed what treatment she is getting.	.106	.828	254
10		I talk with my mother about how cancer treatment changed her body (e.g., removal of breast, hair loss, dietary changes).	005	.810	010
14		My mother explains her treatment plan and how it will affect my life in words that I can understand.	.030	.758	00
12		I talk with my mother about what to do if her condition becomes significantly worse.	074	.680	.03
11		I talk with my mother about how I feel about the way cancer treatment changed her body (e.g., remov- al of breast, hair loss, dietary changes).	033	.653	.10
9		My mother and I talk about our worries about whether her treatment will work.	.051	.613	00
16		When I ask about cancer, she provides gentle and honest answers.	.121	.597	.12
13		I participate in my mother's care (e.g., nurse her, go to the hospital).	080	.596	.13
6		I can tell my mother anything that is on my mind about her having cancer.	.084	.445	.04
15		I know when my mother wants to talk about cancer and when she does not.	303	.431	.08
Rela	ationsl	nip with mother (F3) Cronbach's $\alpha = .810$			
19		My mother still listens to me, even after her cancer diagnosis.	.059	077	.83
20		I am satisfied with the communication I have had with my mother since I learned she had cancer.	.117	.140	.70
21		I feel trusted by my mother.	043	.207	.60
1		My mother understands how I feel about her having cancer.	116	.308	.13
17	☆	When it comes to cancer, I only tell my mother what she wants to hear.	.342	336	.06
18	☆	My mother does not ask me how her having cancer affects my life.	.280	.063	.17
7		I confide in my friends more than my mother about her having cancer.	261	.237	20
		% Variance explained by factor	11.7	26.1	4.8

Notes: \rightleftharpoons inverted terms; F1 = First factor, *expression of negative feelings*; F2 = Second factor, *sharing information about breast cancer*; F3 = Third factor, *relationship with mother*.

Table 3. Comparison of goodness-of-fit index (n = 97).

	χ^2/df	GFI	CFI	RMSEA	AIC
Model 1 (17 items)	1.36	.849	.936	.061	233.251
Model 2 (14 items)	1.21	.892	.973	.047	154.074

Notes: GFI = goodness-of-fit index, CFI = comparative fit index, RM-SEA = root mean square error of approximation, AIC = Akaike information criterion; Model 2: Excluded items 5, 6, and 15 from Model 1.

Discussion

This study demonstrated the contents of cancer-related communication and developed a reliable and valid scale to measure cancer-related communication between breast cancer survivors and their adolescent children. The results of this study indicated that cancer-related communication comprised 14 items and a 3-factor structure, including "expression of negative feelings," "sharing information about breast cancer," and "relationship with the mother." Moreover, the results of internal consistency and test-retest reliability were

satisfactory.

As a result of the EFA, a three-factor structure was extracted. The main contents of communication about cancer were expression and sharing of feelings as well as provision and sharing of information (Barnes et al., 2000; Fitch & Abramson, 2007; Huang et al., 2017; Kennedy & Lloyd-Williams, 2009; Semple & McCance, 2010). These contents were included in F1 "expression of negative feelings" and F 2 "sharing information about breast cancer," respectively. F3 "relationship with the mother" included contents regarding the relationship with the mother, and two out of three items were added based on expert interviews. Furthermore, this factor is essential for indicating whether the motheradolescent relationship was well established through communication, from the time the mother was diagnosed with breast cancer to the present. The scale had to be reduced from 21 to 14 items to ensure optimal model goodness-of-fit by CFA. However, the final 14 items cover the indispensable elements for effective communication, serving as a reliable measure in communication about maternal cancer.

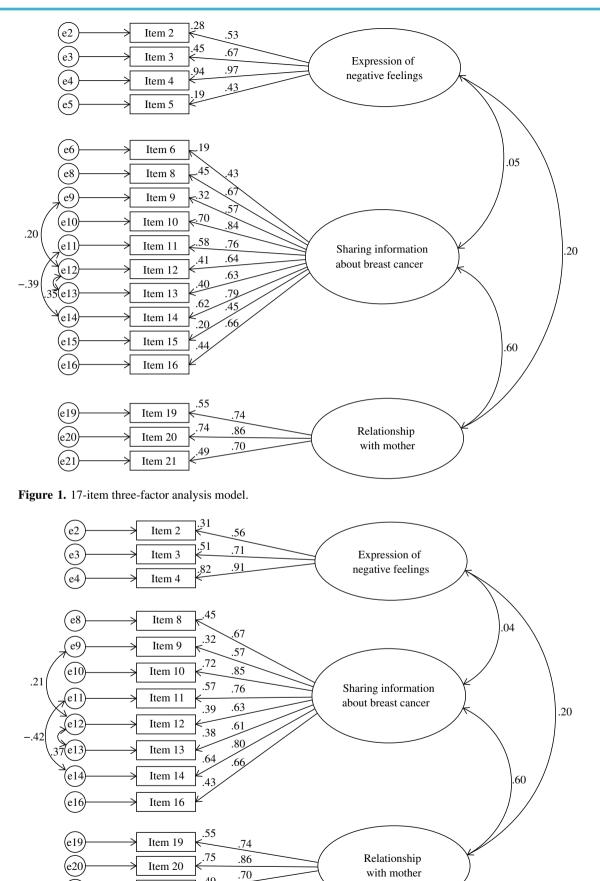


Figure 2. 14-item three-factor analysis model.

Item 21

e21

.49

Regarding convergent validity, the total score and F2 and F3 subscale scores had weak correlations with Family AP-GAR. Previous studies have demonstrated that effective communication in the family improves family functioning (Ghandpazi et al., 2020). Our hypothesis was supported by results of this study, except that for the subscale of F1. F1 comprised the expression of negative emotions. Based on the characteristics of the family (Wright & Leahey, 2012), when the breast cancer survivor fails to accept the emotions of the adolescent about maternal breast cancer, she experiences pain and depression. This situation causes the adolescent to also experience guilt and pain. These feelings may increase and create a vicious cycle. A breast cancer survivor

Table 4. Convergent	validity	of	the
communication scale	(n = 97).		

	Family APGAR
Total (14 items)	.341**
F1 (3 items)	017
F2 (8 items)	.345**
F3 (3 items)	.262**

Notes: APGAR = adaptability, partnership, growth, affection, and resolve; F1 = First factor, *expression of negative feelings*; F2 = Second factor, sharing *information about breast cancer*; F3 = Third factor, *relationship with mother*. ** p < .01

Table 5. Internal consistency and test–retest reliability of the communication scale.

	Cronbach's α (<i>n</i> = 97)	ICC $(n = 34)$
Total (14 items)	.863	.748
F1 (3 items)	.764	.618
F2 (8 items)	.882	.756
F3 (3 items)	.810	.794
F3 (3 items)	.810	.794

Notes: ICC = Intraclass correlation coefficients; F1 = First factor, *expression of negative feelings*; F2 = Second factor,*sharing information about breast cancer*; <math>F3 = Third factor,*relationship with mother.*

and her adolescent child may unintentionally hurt each other when the adolescent expresses his/her negative emotions about maternal breast cancer, thus leading to impaired family functioning. Therefore, no correlation between F1 and family functioning was observed.

Regarding the demographics associated with cancerrelated communication, the female group obtained higher mean total and F2 scores than the male group. Previous studies have demonstrated that male family members hesitate to talk about breast cancer openly because breasts are associated with sexuality and femininity (Fitch & Allard, 2007). In addition, men aged 12-18 years are sexually sensitive; they may be less likely to share information about symptoms, treatment, progress, and side effects of maternal breast cancer with their mothers. The absence of sibling group tended to have higher scores than the presence of sibling group. Adolescent children without siblings may have more time for one-on-one communication with their mothers. However, further research is needed to elucidate the factors that influence cancer-related communication.

Implications for Nurses

For breast cancer survivors/patients, one of the most crucial areas of concern is communicating with their adolescent children about breast cancer. Breast cancer survivors/patients require support from their healthcare professionals to be able to effectively communicate with their adolescent children (Sinclair et al., 2019). This cancer-related communication scale can help nurses understand and evaluate mother-adolescent communication about maternal breast cancer. Furthermore, nurses can devise interventions for facilitating informative, effective, and open discussions regarding maternal breast cancer by using this scale.

Limitations

This study has some limitations. First, the study participants (adolescents) were given the questionnaires by breast cancer survivors, which could indicate that they had a good and open relationship with them. Therefore, adolescents who had

Table 6. Comparison of the scores of cancer-related communication scale by gender and the presence or absence of a sibling.

			Ger	nder					Sibling		
		Fema (<i>n</i> = 2		$Ma = \frac{1}{2}$			Abse (n =		Prese $(n = 1)$		
	Range	Mean	SD	Mean	SD	р	Mean	SD	Mean	SD	- p
Total (14 items)	14–56	45.2	6.2	41.7	8.4	.02	45.8	6.6	42.9	7.6	.10
F1 (3 items)	3-12	11.0	1.2	11.0	1.7	.93	11.3	0.9	11.0	1.6	.37
F2 (8 items)	8–32	23.8	5.2	21.0	6.5	.02	23.7	5.7	22.1	6.1	.28
F3 (3 items)	3-12	10.4	1.7	9.6	2.4	.08	10.9	1.4	9.8	2.2	.03

Notes: SD = standard deviation; F1 = First factor, *expression of negative feelings*; F2 = Second factor, *sharing information about breast cancer*; F3 = Third factor, *relationship with mother*.

problems communicating with the survivors may have been unintentionally excluded, thus introducing a selection bias. Second, EFA and CFA were conducted using the same data to confirm factor validity. In the future, the validity of factors will need to be confirmed using different data. Third, the cancer-related communication scale in this study does not include items related to positive aspects, such as awareness and positive emotions experienced by a mother diagnosed with breast cancer, including coping and health management efforts. Future studies could measure cancer-related communication between breast cancer survivors and their adolescent children more accurately by considering the aforementioned aspects.

Conclusion

This study developed a valid and reliable scale to evaluate and assess cancer-related communication between breast cancer survivors and their adolescent children. It is proposed that the findings of this study could help devise psychosocial interventions to support breast cancer survivors and their families.

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Author Contributions

R.O. and K.K. contributed to the conception and design of this study; R.O., M.T., K.T., J.T., and H.Y. conducted data collection; R.O. performed the statistical analysis and drafted the manuscript; M.T., K.T., J.T., H.Y., and K.K. critically reviewed the manuscript and supervised the whole study process. All authors read and approved the final manuscript.

Declaration of Conflicting Interests

The authors declare that there are no conflicts of interest.

Ethical Approval

This study was approved by the Ethics Review Committee of the University of Tokyo, School of Medicine [No. 12079-(1)].

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Mental health status of public health nurses and its related factors under the coronavirus disease 2019 pandemic in Japan

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Abstract

Objective: The purpose of this study is to investigate the mental health status of public health nurses (PHNs) in public health centers (PHCs) and to clarify its related factors during the coronavirus disease 2019 (COVID-19) pandemic in Japan. Methods: Participants were 1.320 full-time PHNs in PHCs, and self-administered structured questionnaire regarding individual factors, work environment factors, and mental health status measured using the 12-item General Health Questionnaire (GHQ-12) was surveyed. The survey period was from June 10 to July 15, 2021. We asked the respondents for a response regarding the situation during the fourth wave of COVID-19 infectious spread. For analysis, participants were divided into two groups according to a cut-off point of the GHQ-12 score, and the χ^2 test was conducted. Afterward, stepwise logistic regression analysis was conducted. **Results:** The data of 640 participants were analyzed (valid response rate: 48.5%). Of the 640 participants, 64.2% worked in the infectious diseases section. Among the participants, 63.6% reported working overtime every day, and 38.3% reported working every weekend. Regarding the mental health status, the mean GHQ-12 score was 6.3±3.4, and 75.5% of the participants had a higher level of psychological distress. As shown in the result of the logistic regression analysis, the items "belonging to the infectious disease section" (OR = 1.73), "frequency of working overtime" (OR = 2.23), "frequency of working on the weekends" (OR = 2.11) and "workplace social support" (OR = 0.31) affected the PHNs' mental health. Conclusions: This study revealed that the mental health status of PHNs was at a critical level during the COVID-19 pandemic, and the needs for immediate mental health support for PHNs was suggested.

Keywords

COVID-19, pandemic, public health nurses, mental health, related factors

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Introduction

Coronavirus disease 2019(COVID-19), which was first reported in Wuhan City, Hubei Province, China, in December 2019, soon spread across the world; The World Health Organization (WHO) declared COVID-19 a worldwide pandemic on March 11, 2020 (WHO, 2020). For approximately

two years since the emergence of the disease, efforts to develop a coronavirus vaccine have been ongoing as vaccination is a major means of containing the COVID-19 infection rate. However, owing to the spread of various of COVID-19 variants, there still seems to be no prospects for the end of COVID-19. In Japan, COVID-19 has spread steadily since the first wave of the COVID-19 pandemic (between April

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and May 2021). The total number of infected individuals reached more than 2.6 million. Furthermore, more than 18,000 people have died as of January 31, 2021 (Ministry of Health, Labour and Welfare, 2022).

Given this critical situation, many concerns regarding the pandemic's impact on the mental health of health professionals who have been working to prevent the spread of the infection have been raised because they have been facing continuous exhaustion and intense stress. In fact, a study on the mental health of Japanese medical professionals during the COVID-19 pandemic showed that more than 60% of the participants had mental health problems (Tahara, 2021). Several overseas surveys have also clarified that medical professionals are experiencing stress reactions such as anxiety, depressive symptoms, and mental distress during the COVID-19 pandemic (Anliu, 2020; Si, 2020; Suryavanshi, 2020).

Under the Japanese public healthcare system, public health centers (PHCs) situated at the prefectures, ordinancedesignated cities, core cities, special wards and other designated cities are responsible for conducting COVID-19related work (e.g., active epidemiological investigation, hospitalization adjustments, and telephone counseling for residents). However, after the establishment of the Community Health Act, the number of PHCs decreased from 847 to 469 between 1994 and 2020. Currently, this has caused a yearly decrease in the number of staff members working in PHCs (Ministry of Health, Labour and Welfare a; b). Given this situation, PHC staff members have been experiencing exhaustion. Approximately half of PHC staff members in one domestic PHC have been found to have mental health problems such as insomnia, mental distress, post-traumatic stress disorder, depression, and anxiety during the COVID-19 pandemic (Usukura, 2021). However, the number of participants number in this survey was 23, which is very small sample.

Currently, among PHC staff members, public health nurses (PHNs) are playing a central role in COVID-19related work (Honda, 2021). PHNs conduct regular work as well as COVID-19-related work (Kanzaki & Ijima, 2020), so they are forced to work overtime or work on weekends in to handle the large volumes of work in this pandemic-period (Sato, 2020). Furthermore, PHNs have been facing slander from infected persons, their families, and residents, who are opposing their COVID-19-related work (Sato, 2020). These facts demonstrate the harsh conditions faced by PHNs who have been working to contain the COVID-19 pandemic. A survey in the Philippines showed that, compared to nurses, PHNs were more fearful regarding facing discrimination because of their involvement in COVID-19-related work. This was because PHNs' work includes dealing with individuals regardless of whether such individuals are infected (Labrague, 2021). Considering these working conditions and the characteristics of PHNs' work, it could impact the mental health of PHNs during the COVID-19 pandemic in Japan is affected. PHNs perform important roles related to maintaining and promoting the health of the community health (Ministry of Health, Labour and Welfare, 2013). Thus, the functioning of PHNs is directly related to the health of the community.

Some previous studies have examined the mental and psychological statuses of PHNs in emergency situations. They examined PHNs' lack of confidence in controlling a severe acute respiratory syndrome (SARS) outbreak in Taiwan (Chih, 2006) and the physical and mental health problems of PHNs who were dispatched to provide disaster support after the East Japan Great Earthquake (Yoshida, 2017). Few studies have examined the mental health status of PHNs during nonemergencies, Imai reported that PHNs involved in mental health care showed a higher prevalence of burnout compared with other PHNs who were working on other assigned sections (Imai, 2006). Furthermore, half of all PHNs who were working on other assigned sections experienced burnout symptoms (Imai, 2006). However, other studies showed that the rates of psychological distress tended to be low (Yamada, 2013), and results regarding PHNs' mental health status varied. To date, many studies have shown that individual and work environment factors can affect PHNs' mental health.

Among individual-level factors, age (Lee, 2002; Saito, 2016; Yamada, 2013), years of experience as a PHN (Lee, 2002; Saito, 2016), years of being employed at the current local government (Saito, 2016), and years of experience as a clinical nurse (Lee, 2002) have shown that young PHNs tend to have mental health problems. Moreover, it has been found that work environment factors, including frequency of working overtime and hours of working overtime (Saito, 2016; Yamada, 2013), taking breaks while at work (Saito, 2016), and lower levels of continuous education (Lee, 2002), are related to critical impacts on mental health. Furthermore, social support in the workplace has provided a buffer effect on mental health (Ozaki, 2014). In brief, these results showed that a heavy workload and the lack of opportunities to maintain motivation negatively affected mental health and that mental health can be maintained if good relationships are maintained in the workplace.

Considering these circumstances, PHNs have supposedly faced mental health problems under the COVID-19 pandemic conditions. If many PHNs have mental health problems, such psychological issues could interfere with their regular work as well as their COVID-19-related work. Therefore, it is necessary to help PHNs take measures to maintain good mental health. For this purpose, we must perceive PHNs' mental health status and reveal what factors could affect it.

On the basis of the abovementioned considerations, the current study investigated the mental health status of PHNs in PHCs and analyzed any related influencing factors during the COVID-19 pandemic.

Materials and Methods

Participants

The study participants included 1,320 full-time PHNs working in PHCs across Japan.

Stratified sampling was used to select the study participants, and 469 PHCs were divided into two groups based on the presence or absence of certain emergency declarations. These emergency declarations included "a declaration of a state of emergency," "a state of semi-emergency related to coronavirus measures," and "a state of prefecture-specific emergency." Subsequently, 165 PHCs were selected from each group using random sampling. We asked the supervising PHNs to select four PHNs (one PHN, 1-5 years of experience; two PHNs, 6-20 years of experience; and one PHN, more than 21 years of experience) per PHC. This was conducted to reflect the previous study's result of clarifying that "years of experience as a PHN" was related to the mental health status, especially for PHNs who have been working for 1-5 years (Saito, 2016) and the age composition of the statistical population in the participation of this study.

Survey Methods

This study employed a quantitative and descriptive study method. An anonymous self-administered structured questionnaire was distributed by mail. We mailed the questionnaires to supervising PHNs and asked them to distribute a survey cooperation request document, questionnaire, and return envelope to the four PHNs. The participants returned the questionnaire using the provided return envelope. The survey was conducted from June 10 to July 15, 2021.

Survey Contents

The survey included individual factors, work environment factors, mental health status, and free description regarding difficulties during the COVID-19 pandemic. The respondents were asked to respond to the situation during the fourth wave of the COVID-19 infectious spread from April to May 2021. Furthermore, a pretest was conducted for 14 PHNs to help in revising the questionnaire.

Individual Factors

Attributes of the Municipality to which the Participants Belonged

The items included the type of municipality to which the participants belonged; announcement of "a declaration of a state of emergency," "a state of semi-emergency coronavirus measures," or "a state of prefecture-specific emergency,"; and the state of occurring clusters in the PHCs' district areas.

Individual Characteristics

The items were sex, age, assigned section, years of experi-

ence as a PHN, job position, marital status, presence of family members who are living together, presence of someone whom the participants could consult for advice regularly regardless of someone in the workplace, and occurrence of life events from April to May 2021.

Work Environment Factors

Working Conditions

The items were frequency of working overtime, mean time of working overtime per month from April to May 2021, frequency of working on the weekends, engaging in telephone counseling during night shifts, existence of workers who are on administrative leave, and taking breaks.

Degree and Impact of Involvement in COVID-19-related Work

The items were degree of involvement in COVID-19-related work, impact of COVID-19 on regular work, and degree of interaction with nonregular staff members.

Social Support in the Workplace

The scale of social supports in the workplace (Komaki, 1994) was used to measure workplace social support. This scale has 14 items, including 8 items related to emotional support and 6 items related to instrumental support. The responses to this scale are marked on a five-point Likert scale, including responses such as "I don't think so," "I don't think that it says either," "Neutral," "I think that it says either," and "I think so." Social support is evaluated based on the total score of all items (minimum = 14, maximum = 70). A high total score indicates that the participants have social support in the workplace.

The current author developed the scale used in this study by modifying the original scale (Komaki, 1993), but he did not verify its reliability and construct validity after making the modification. However, this scale has specific contents regarding workplace social support and some previous studies on nurses have also used it (Yamamoto, 2020). Hence, the scale was used in this study. In the survey data, the Cronbach's α coefficient of the social support scale was 0.95.

Mental Health Status

To assess mental health status, the 12-item General Health Questionnaire (GHQ-12), which was shortened GHQ (Goldberg, 1972) and was translated into Japanese by Nakagawa (1995), was used. This scale was scored by using the GHQ method and evaluated based on the total scores of all items (minimum = 0, maximum = 12), with a cut-off point of 4 (Honda, 2001). A high total score indicated a higher level of psychological distress. The GHQ measure assesses nonspecific mental distress and has been verified to have high reliability and construct validity.

Many scales have been developed to measure mental health status, but the GHQ-12 can measure mental health status comprehensively and easily. Furthermore, several studies have used the GHQ-12 to measure the mental health status of medical staff during the COVID-19 pandemic (Dai, 2020; Nie, 2020). Thus, the GHQ-12 was also used in this study.

Definition of Terms

Mental Health

In this study, mental health was defined as a "situation that did not cause strong mental and psychological symptoms" following the measure method of the GHQ.

Social Support in the Workplace

In this study, social support in the workplace was defined as "empathy, acknowledgment, and cooperation in the workplace" based on the contents of the workplace social support scale (Komaki, 1994).

Statistical Analysis

In this survey, quantitative data and quantitative data by free description were obtained. However, only quantitative data were used in the analysis in this study to statistically examine the related factors for mental health, and all quantitative data were used.

First, descriptive statistics were conducted on the individual factors, work environment factors, and GHQ-12 score. Second, on basis of the mental health status, two groups were created using the cut-off points: the "no higher level of psychological distress" group and the "higher level of psychological distress" group. Next, the χ^2 test was used to examine the differences between these two groups and each item of the individual factors, work environment factors, and GHQ-12 score.

To conduct the χ^2 test, each item was divided as follows. Regarding "announcement of a declaration of a state of emergency," as well as items such as "a declaration of a state of emergency," "a state of semi-emergency coronavirus measures," and "a state of prefecture-specific emergency," the response was "announced," and "no declaration" was "not announced." Regarding the state of occurrence of the clusters in PHCs' district areas, items such as "large clusters" and "clusters" were indicated with "clusters occurred," and the presence of "no clusters" was indicated with "clusters did not occur." Furthermore, items related to years of experience as a PHN were divided into three groups: "1-5 years" was indicated with "new period"; "6-10 years," "11-15 years," and "16-20 years" were indicated with "midcareer period"; and "more than 21 years" was indicated as "management period." Regarding frequency of working overtime, "everyday" and "about 2-3 times a week" were indicated as "high frequency of working overtime" and "about once a week" and "none" were indicated as "not high frequency of working overtime." Furthermore, the mean time of working overtime per month was divided into two groups with 45 h per month, which is the limit on working overtime, as prescribed by Labor Standards Act. Regarding the

"about 2-3 times a month" were indicated as "high frequency of working on weekends" and "about once a month" and "none" were indicated as "not high frequency of working on weekends." The items related to taking breaks were divided into two groups: "no break" and "took time to have lunch" were indicated as "did not take break," and "took time to have lunch and relax" and "took as usual" were indicated as "took break." Furthermore, regarding the degree of involvement in COVID-19-related work, the items of "100%," "90%-80%," and "70%-60%" were indicated with "strongly involved"; the items of "50%-40%," "30%-20%," and "10% or no involvement" were indicated with "did not become strongly involved." Regarding the degree of COVID-19's impact on regular work, the items of "disrupted regular work" and "rather disrupted regular work" were indicated with "strongly influenced" and the items of "rather un-disrupted regular work" and "un-disrupted regular work" were indicated with "did not strongly influence." The item related to the degree of interaction with nonregular staff members was divided into two groups: "interacted as a task manager," and "not a task manager but interacted frequently" were indicted as "strongly interacted," and "not a task manager but interacted sometimes" and "did not interact" were indicated as "did not strongly interact." The social support score was divided based on "the group had social supports in the workplace" and "the group did not have social supports in the workplace."

frequency of working on weekends, "every week" and

Finally, logistic regression analysis using the stepwise method was conducted. Items with significant differences based on the χ^2 test were used as independent variables, namely, sex, and age after checking for multicollinearity among items with significant differences, and the two mental health status groups were used as the dependent variables. The significance level was less than 5% with regard to two-tailed tests, and IBM SPSS 28 was used for the analysis.

Ethical Considerations

Documents regarding this survey's purpose and the method of data collection and publication were provided to the participants. Moreover, the participants were assured that participation in the survey was voluntary, that they would not incur any disadvantages even if they did not participate, and that their answers would be regarded as consent.

Furthermore, this study was approved by the Medical District Department Ethical Review Board of Kyushu University (Approval number: 2021-82).

Results

Of the 1,320 participants, 733 responded to this survey (response rate: 55.5%), and the data of 640 participants were

analyzed (valid response rate: 48.5%).

Individual Factors

The individual factors of the participants are presented in Table 1. The rate of PHNs who "worked in regions where a declaration of a state of emergency was announced" was 70.3%, whereas the rate of "large-scale clusters or clusters" that occurred in jurisdictional areas was 79.1%.

Among the participants, gender-wise, females formed 91.9% of the sample and 30.0% of the total participants were in their 20s. Furthermore, 64.2% of the participants were working in the infectious diseases section.

Work Environment Factors

The work environment factors of the participants are shown in Table 2. Among the participants, the rate of working overtime "everyday" was found to be 63.6%, the rate of working on "every weekend" was 38.3%, and the rate of working overtime "about 2-3 times a week" was 48.1%. Furthermore, the average amount of hours working overtime per month was 52.9±45.0 h, and the rate of working overtime for more than 45 h a month, which is the limit on working overtime, as prescribed by Labor Standards Act, was 51.7%. Regarding taking breaks at work, 13.1% of the participants took a break "as usual" and 53.4% of the participants took time "to have lunch and relax" (53.4%). Moreover, 69.4% of the participants responded that their regular work had been affected by their involvement in COVID-19-related work. Incidentally, 95.9% of PHNs working in the infectious disease section worked overtime high frequently, and 72.9% of PHNs in the other sections did. The mean score for social support in the workplace was 53.9±10.4.

Mental Health Status of PHNs during the COVID-19 Pandemic

Figure 1 shows the state of the GHQ-12 score.

In this study, the mean score of GHQ-12 was 6.3 ± 3.4 (minimum score = 0, maximum score = 12). After the GHQ-12 score was divided based on the cut-off points, 157 participants (24.5%) were placed in the "no higher level of psychological distress" group and 483 participants (75.5%) were placed in the "higher level of psychological distress" group.

Related Factors of PHNs' Mental Health Status during the COVID-19 Pandemic

Results of the Relationship between the GHQ-12 Score and Factors Based on the χ^2 Test

The results of the relationship between the GHQ-12 score and factors based on the χ^2 test are shown in Table 3, 4.

Among the individual factors, the items of "a declaration of a state of emergency was announced" and "assigned sec-

Table 1. Participant characteristics.

	n = 640
Items	n (%)
Attributes of the municipality to which the participants be	elong
Type of municipality to which the participants belong	
Prefectures	517 (80.8)
Ordinance-designated cities	25 (3.9)
Core cities	84 (13.1)
Special wards	9 (1.4)
Other designated cities	5 (0.8)
State of declaration of emergency	
The state of declaration of state of emergency	213 (33.3)
The state of semi-emergency coronavirus measures	109 (17.0)
The state of prefecture-specific state of emergency	128 (20.0)
None	190 (29.7)
State of occurring clusters in PHC's district area.	
Large clusters	68 (10.6)
Clusters	438 (68.4)
None	134 (20.9)
Individual characteristics	
Sex	
Female	588 (91.9)
Male	52 (8.1)
Age	
20s	192 (30.0)
30s	165 (25.8)
40s	114 (17.8)
50s	166 (25.9)
60s	3 (0.5)
Assigned section	
The section of infectious disease	411 (64.2)
The section other than the section of infectious disease	229 (35.8)
Years of experience as a public health nurse	
1–5 years	187 (29.2)
6–10 years	119 (18.6)
11–15 years	71 (11.1)
16–20 years	62 (9.7)
More than 21 years	201 (31.4)
•	201 (31.4)
Job position	
Staff	271 (42.3)
Chief class	133 (20.8)
Subsection chief class	103 (16.1)
Assistant director class	84 (13.1)
Manager class	85 (13.1)
Marital status	
Unmarried	249 (38.9)
Married	391 (61.1)
Presence of family living together	. ,
Yes	472 (73.8)
No	472 (75.8) 168 (26.2)
Existence of someone to whom participants were able	100 (20.2)
to go for advice regularly	(00 (0(0)
Yes	620 (96.9)
No	20 (3.1)
Occurrence of life events from April to May 2021	1.40 (21.0)
Yes	140 (21.9)
No	500 (78.1)

	n = 640
Items	n (%)
Working condition	
Frequency of working overtime	
Everyday	407 (63.6)
About 2–3 times a week	154 (24.1)
About once a week	57 (8.9)
None	22 (3.4)
Mean time of working overtime per month from April	52.9±45.0
to May, 2021	
>45 h	299 (48.3)
≦45 h	320 (51.7)
>80 h	441 (71.2)
≦80 h	178 (28.8)
Frequency of working on weekends	
Every week	245 (38.3)
About 2–3 times a month	308 (48.1)
About once a month	59 (9.2)
None	28 (4.4)
Engaging telephone counselling in night shift	
Yes	396 (61.9)
No	244 (38.1)
Existence of workers on administrative leave	
Yes	238 (37.2)
No	402 (62.8)
Taking break	
Took as usual	84 (13.1)
Took time to have lunch and relax	116 (18.1)
Took time to have lunch	342 (53.4)
No break	98 (15.3)
Degree and impact of involvement in COVID-19 relate	d work

Degree and impact of involvement in COVID-19 related work

Degree of involvement in COVID-19 related work

100%	153 (23.9)
80%-90%	202 (31.6)
60%-70%	121 (18.9)
40%-50%	62 (9.7)
20%-30%	83 (13.0)
10% or no involvement	19 (3.0)
Impact of COVID-19 on regular	
Disrupted regular work	444 (69.4)
Rather disrupted regular work	160 (25.0)
Rather un-disrupted regular work	25 (3.9)
Un-disrupted regular work	11 (1.7)
Degree of interaction with nonregular staff	
Interacted as a task manager	97 (15.2)
Not a task manager but interacted frequently	138 (21.6)
Not a task manager but interacted sometimes	192 (30.0)
Did not interact	213 (33.3)
Mean of social support score	53.9±10.4

tion" were significantly different. Furthermore, the participants who "worked overtime" frequently had a long "mean time of working overtime per month," "worked on the weekends" frequently, had a frequent "degree of involvement in COVID-19-related work," experienced a strong "impact on regular work" because of COVID-19, and had a frequent "degree of interaction with nonregular staff members." Furthermore, the items of workplace social support significantly differed.

Factors Related to the Mental Health Status of PHNs Based on Logistic Regression Analysis Using the Stepwise Method The results of the logistic regression analysis using the stepwise method of factors related to the mental health of PHNs are shown in Table 5.

Among the items that showed significant differences based on the χ^2 test, sex, and age, the items "belonging to the infectious disease section" (OR = 1.73), "frequency of working overtime" (OR = 2.23), "frequency of working on weekend" (OR = 2.11), and "social support score" (OR = 0.31) showed significant differences.

Discussion

Characteristic of the Study Participants

Regarding individual factors, 70.3% of the municipalities to which the participants belonged declared a state of emergency, and the rate of "large-scale clusters or clusters" that occurred in jurisdictional areas was 79.1%. This showed that many study participants worked in the regions that witnessed a severe outbreak of COVID-19. Regarding individual characteristics, the ratio of men to women was the same as that of the statistical population (Ministry of Health, Labour and Welfare, 2019). Furthermore, in this study, the rate of participants who were in their 20s was higher than that of the statistical population (Ministry of Health, Labour and Welfare, 2020); this affected the high rate of new period PHNs and general staff members. Moreover, 64.2% of the participants belonged to the infectious disease section. The participants in this survey were involved in COVID-19related work under conditions of severe infection spread, and the proportion of participants in the younger generation was higher than that in the statistical population.

Regarding work environment factors, over 85% of the participants frequently worked overtime and on weekends. Furthermore, in this study, the rate of working overtime for more than 45 h a month was 30% higher than the figure provided by a survey of Japanese workers in 2019 (Recruit Works Institute, 2019). The rate of working overtime for more than 80 h a month, which may have caused death from overwork, was approximately 20% higher than the figure provided by a survey of local government workers in 2015 (Ministry of Internal Affairs and Communications, 2015). These results showed that the participants worked in

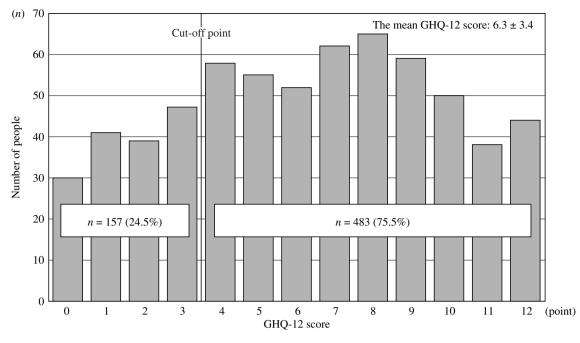


Figure 1. Distribution of the GHQ-12 score showed the mean GHQ-12 score and the number and rate of "higher level of psychological distress" and "no higher level of psychological distress."

oppressive working conditions during the COVID-19 pandemic. Regarding taking breaks at work, approximately 70% of the participants did not rest at work, and this result reflected the present situation where the PHNs managed to take breaks (Sato, 2020). Furthermore, over 90% of the participants responded that their regular work was affected by their involvement in COVID-19-related work. This showed that their regular work had been accumulating because of their involvement in COVID-19-related work; this rise led to severe working conditions.

The mean score for workplace social support was 53.9± 10.4; this finding matched that of a previous study that examined nurses (Yamamoto, 2020). Many previous studies have investigated workplace social support using various social support scales. These results showed that nurses' social support scores were higher than those of other professionals (Hu, 2018; Temam, 2019), thus indicating that nurses had social support in the workplace. Under critical situations, such as the COVID-19 pandemic, there have often been concerns regarding confusion in the workplace and difficulty of obtaining social support. However, the social support score of the PHNs matched that of the nurses in the previously mentioned study, so PHNs were found to have received workplace social support during the COVID-19 pandemic. Lanzetta proved that people in groups with burdens (for example, a time limit or some difficulty in communication with other members) took cooperative attitudes to conduct problem solving in the relevant situations (Lanzetta, 1995). The participants had to solve problems in a group that received a heavy burden, and this may have affected the

social support scores in this study.

Mental Health Status of PHNs during the COVID-19 Pandemic

Several studies have examined the GHQ-12 score of PHNs during normal times. In this study, the GHQ-12 score had a mean of 6.3 ± 3.4 , and the rate of "higher level of psychological distress" was 75.5%. These results showed that the mean GHQ-12 score was higher than 3 points and the rate of "higher level of psychological distress" was over 30% higher than that of PHNs during normal times (Saito, 2016; Yoshida, 2017).

Moreover, it was revealed that the rate of "higher level of psychological distress" for medical professionals was 25.1% to 51.1% during the COVID-19 pandemic (Del Piccolo, 2021; Nie, 2020). Compared to these findings, the rate of "higher level of psychological distress" observed in this study was higher.

Furthermore, several studies have examined the mental health status of healthcare professionals in critical situations. These studies showed that the rate of "higher level of psychological distress" was 32.7% during the East Japan Great Earthquake (Suzuki, 2014) and 21.9% during the Nepal Earthquake (Shrestha, 2015). Different mental health scales were used to determine this finding. These results indicate that preserving PHNs' mental health status during the COVID-19 pandemic is of critical significance.

The effort-reward imbalance model (Siegrist, 1996) is a useful framework for interpreting the results of the study. This model showed that an imbalance between the efforts

Table 3. Results of the relationship between the GHQ-12 score and factors based on the χ^2 test (individual factors).

	Mental health status			
Items	No higher level of psychological distress group n = 157	Higher level of psychological distress group $n = 483$	p value	
Attributes of the municipality to which the participants be	elong			
Type of municipality to which the participants belong				
Prefectures	131 (83.4)	386 (79.9)	.34	
Ordinance-designated city	2 (1.3)	23 (4.8)		
Core city	20 (12.7)	64 (13.3)		
Special ward	2 (1.3)	7 (1.4)		
Other designated cities	2 (1.3)	3 (0.6)		
State of declaration of emergency during the 4 th wave of t	the COVID-19 infectious sprea	ad		
Announced	100 (63.7)	350 (72.5)	<.05	
Not announce	57 (36.3)	133 (27.5)		
State of occurring clusters in public health centers' distric				
Clusters occurred	121 (77.1)	385 (79.7)	.48	
Clusters did not occur	36 (22.9)	98 (20.3)		
		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		
Individual characteristics Sex				
Female	143 (91.1)	445 (92.1)	.68	
			.08	
Male	14 (8.9)	38 (7.9)		
Age	50 (21.0)	142 (20.4)	12	
20s	50 (31.8)	142 (29.4)	.13	
30s	46 (29.3)	119 (24.6)		
40s	28 (17.8)	86 (17.8)		
50s	31 (19.7)	135 (28.0)		
60s	2 (1.3)	1 (0.2)		
Assigned section				
The section of infectious disease	79 (50.3)	332 (68.7)	<.01	
The section other than the section of infectious disease	78 (49.7)	151 (31.3)		
Years of experience as a public health nurse				
New period	138 (28.6)	49 (31.2)	.18	
Mid-career period	184 (38.1)	68 (43.3)		
Management period	161 (33.3)	40 (25.5)		
Job position				
Staff	74 (47.1)	197 (40.8)	.68	
Chief class	32 (20.4)	101 (20.9)		
Subsection chief class	23 (14.6)	80 (16.6)		
Assistant director class	18 (11.5)	66 (13.7)		
Manager class	10 (6.4)	39 (8.1)		
Marital status				
Unmarried	57 (36.3)	192 (39.8)	.44	
Married	100 (63.7)	291 (60.2)		
Presence of family living together	. ,	. /		
Yes	123 (78.3)	349 (72.3)	.13	
No	34 (21.7)	134 (27.7)		
Existence of someone to whom participants were able to				
Yes	155 (98.7)	465 (96.3)	.12	
No	2 (1.3)	18 (3.7)	.12	
Occurrence of life events from April to May 2021	2 (1. <i>J</i>)	10 (3.7)		
Yes	31 (19.7)	109 (22.6)	.46	
No	126 (80.3)	374 (77.4)	.+0	

(01)

Table 4. Results of the relationship between the GHQ-12 score and factors based on the χ^2 test (work environment factors).

			n (%)	
	Mental he	Mental health status		
Items	No higher level of psychological distress group n = 157	Higher level of psychological distress group $n = 483$	p value	
Working condition				
Frequency of working overtime				
High frequency of working overtime	116 (73.9)	445 (92.1)	<.01	
Not high frequency of working overtime	41 (26.1)	38 (7.9)		
Mean time of working overtime per month from Apr	il to May 2021			
> 45 h	84 (56.8)	215 (45.6)	<.05	
\leq 45 h	64 (43.2)	256 (54.4)		
Frequency of working on the weekends				
High frequency of working on weekend	117 (74.5)	436 (90.3)	<.01	
Not high frequency of working on weekend	40 (25.5)	47 (9.7)		
Engaging telephone counselling in night shift				
Yes	89 (56.7)	307 (63.6)	.12	
No	68 (43.3)	176 (36.4)		
Existence of workers on administrative leave				
Yes	55 (35.0)	183 (37.9)	.52	
No	102 (65.0)	300 (62.1)		
Taking break				
Took break	74 (47.1)	126 (26.1)	<.01	
Did not take break	83 (52.9)	357 (73.9)		
Degree and impact of involvement in COVID-19 rela	ated work			
Degree of involvement in COVID-19 related work				
Strongly involved	95 (60.5)	381 (78.9)	<.01	
Not strongly involved	62 (39.5)	102 (21.1)		
Impact of COVID-19 on regular work				
Strongly influenced	142 (90.4)	462 (95.7)	<.05	
Not strongly influenced	15 (9.6)	21 (4.3)		
Degree of interaction with nonregular staff				
Strongly interacted	41 (26.1)	194 (40.2)	<.01	
Did not strongly interact	116 (73.9)	289 (59.8)		
Social support score				
Group had social support in the workplace	122 (77.7)	253 (52.4)	<.01	
Group did not have social support in the workplace	35 (22.3)	230 (47.6)		

expended toward working and the rewards obtained because of work could cause mental health problems. A previous study on nurses' burnout indicated that nurses who experienced imbalance between the efforts expended toward working and the rewards felt more emotional exhaustion compared with nurses who did not (Bakker, 2000). The survey's administration period coincided with the fourth wave of the COVID-19 infection spread. The number of infected patients increased, and PHCs were recruited to manage such patients or conduct follow-ups with patients undertaking selfisolation. On the basis of the work conditions for those working overtime or on the weekends, it was assumed that PHNs would have to make efforts to deal with this work. However, some patient deaths had been caused by their inadequate management of infected patients, and PHNs were often allegedly slandered by mass media and the residents (Sato, 2020). This situation shows that PHNs did not receive sufficient rewards for their efforts. During the COVID-19 pandemic, PHNs worked under stressful conditions including the tension of dealing with emergencies, and they often experienced an imbalance between the efforts that they expended toward their work and the rewards that they received for working. This situation may have affected their mental health status.

Items	Regression Coefficient	Odds Ratio (95% CI)	<i>p</i> value
Assigned section	0.55	1.73 (1.14-2.63)	<.01
Frequency of working overtime	0.80	2.23 (1.24-4.02)	<.01
Frequency of working on weekend	0.75	2.11 (1.21-3.69)	<.01
Social support	-1.17	0.31 (0.20-0.48)	<.01
Hosmer-Lemeshow test	$\gamma^2 = 3.579$ (H	F=4) $p = .466$	

Table 5. Factors related to the mental health status of PHNs based

 on stepwise logistic regression analysis.

Factors Related to Mental Health Status during the COVID-19 Pandemic

Logistic regression analysis showed that the items belonging to the infectious disease section, frequency of working overtime, working on weekends, and workplace social support affected the PHNs' mental health.

PHNs working in the infectious diseases section experience a large psychological load because of official responsibilities and pressures, and this could have affected their mental health. In previous studies, healthcare workers working on the front line in Turkey had high risks of mental health problems during the COVID-19 pandemic (Sahin, 2020). The PHNs working in the infectious disease section had to work on the front line during the COVID-19 pandemic, so it was affected their mental health. In addition, the number of infected people increased in the fourth wave of the spread of COVID-19 infection, and many PHNs from other sections were also involved in COVID-19-related work during this period. The PHNs dispatched from other sections became involved in COVID-19-related work temporarily, and PHNs working in the section related to infectious diseases had to continuously engage themselves in COVID-19related work and were thus exposed to the official responsibilities imposed upon PHNs as well as other pressures on a long-term basis (Honda, 2021). These situations increased their psychological load and it affected their mental health.

The extracted frequency of working overtime as a related factor was found to match that found in previous studies. Dnder the COVID-19 pandemic situation, working over 48 h per week was associated with a higher risk of depression for health care workers in Latvia (Valaine, 2021) and working over 8 h a day was one of the risk factors for anxiety for physicians in Bangladesh (Khatun, 2021). Working on week-ends was also extracted as a related factor in this study. Several studies on other occupations showed that working conditions included "working for more than 8 h a day" and "working for more than 5 days per week"; these were related to mental health (Proctor, 1996). This study's results thus affirmed that conditions involving excessive and hard-

work affected PHNs' mental health.

Furthermore, this study found that workplace social support was related to the mental health status of PHNs; this finding matched those of previous studies on PHNs in a nonemergency situation (Ozaki, 2014). In addition, during the COVID-19 pandemic, it was revealed that perceived social support affected the mental health status of healthcare workers (Schug, 2021). Many international studies have shown that workplace social support provides a buffer effect against occupational stress (Fenlason, 1994; Komatsu, 2010). This study thus demonstrated the importance of maintaining good relationships in the workplace.

Suggestions for Mental Health Care of PHNs

This study found that the mental health status of PHNs during COVID-19 was critical; this indicated the necessity of immediately conducting mental health care for PHNs.

Overload situation needs to be improved to maintain mental health. It may be necessary to have a temporary period of time away from COVID-19 duties by strengthening the employment of part-time staffs, especially for PHNs in the infectious disease section. Furthermore, this study also found that workplace social support affected the mental health status of PHNs during the COVID-19 pandemic. Administrators are expected to ensure that peer support is available.

Limitations of this Study

In this study, the response rate was 55.5%, and the valid response rate was 48.5%. Thus, it cannot be said that this study's result reflected the entirety of the concerns of PHNs. Furthermore, this survey was conducted after the spread of COVID-19. Therefore, lack of time and energy of the PHNs may have affected the response rate of the survey.

This cross-sectional survey-based study was conducted during the fourth wave of the COVID-19 pandemic. Subsequently, the public health situation has changed because of the outbreak of the fifth and sixth waves of the COVID-19 infection and the initiation of vaccination efforts, as well as the development of oral anti-COVID-19 drugs. These new developments could have also affected the mental health status of PHNs. Moreover, many participants were working in PHCs at regions with severe infections or in harsh working conditions; this probably affected the results regarding PHNs' mental health status. Furthermore, as this was a cross-sectional survey-based study, the results of this study did not establish a causal relationship between PHNs' mental health status and related factors.

Regarding the workplace social support in this study, the veracity of the interpretation of the results was limited because the validity of the scale has not been examined and has not been used for PHNs.

Despite these limitations, this study was the first to inves-

tigate the mental health status of PHNs and its related factors during the COVID-19 pandemic. Therefore, this study could form the basis for developing provisions for PHNs' mental health care.

Conclusion

This study aimed to clarify the mental health status of PHNs and its related factors during the COVID-19 pandemic. Consequently, the mental health status of PHNs was found to be critically affected by items belonging to the infectious disease section, frequency of working overtime, working on weekends, and the workplace social support; these were extracted as related factors.

Considering these related factors, the provision of mental health care for PHNs should be undertaken urgently.

Author Contributions

Karen Tsuruda and Yoko Hatono contributed to the conception and design of this study, performed the statistical analysis, drafted the paper, revised it critically, and approved of the final version to be published.

Declaration of Conflicting Interests

We have no conflict of interest to disclose.

Ethical Approval

This study was approved by the Medical District Department Ethical Review Board of Kyushu University [No. 2021-82].

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Original Research

Factors interfering with behavioral change in patients with non-alcoholic fatty liver disease: An ethnographic study

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Abstract

Objective: The reason behind the constant denial to accept any kind of behavioral changes among non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH) patients even after counseling and why behaviors that lead to disease progression are maintained is unclear. This study aimed to describe the daily living behaviors of NAFLD/NASH patients and elucidate the reasons behind their inability to change their routines, which are problematic as they lead to disease progression. **Methods:** A qualitative study was conducted using an ethnographic design. The data collection methods included participatory observation, field note-taking, and semistructured interviewing of eight NAFLD patients in their daily lives at their homes and workplaces. SpradleyJINRJJ-15s Developmental Research Sequence method was employed to analyze the data. This paper conforms to the standards for reporting qualitative research. **Results:** Four themes were generated: (1) health beliefs built in the family, (2) difficulty in systematizing health knowledge, (3) dependence on food, and (4) social disadvantages. **Conclusions:** NAFLD patients had negative influences from the family environment from childhood, lacked integrated knowledge about the risk factors, and developed food addiction. Furthermore, social disadvantages, such as a stressful environment, an environment where there was less chance to have significant others to support their treatment, financial difficulties, and lower educational background, influenced all factors.

Keywords

ethnography, behavioral change, NAFLD, reduced inequality, qualitative research

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Introduction

Non-alcoholic fatty liver disease (NAFLD) or its severe form, non-alcoholic steatohepatitis (NASH), is the hepatic manifestations of metabolic syndrome that has become the most prevalent chronic liver disease worldwide (Younossi et al., 2016). The number of patients with NAFLD/NASH has increased worldwide, primarily due to unhealthy food habits and sedentary lifestyles. Japan is not an exception regarding the NAFLD/NASH epidemic. In Japan, the prevalence rates of NAFLD and NASH are estimated to be around 29.7% (Eguchi et al., 2012) and 3% (Estes et al., 2018), respectively. NAFLD/NASH has also been linked to obesity and insulin resistance (Koda et al., 2007; El-Serag, Tran, & Everhart, 2004). Since 2008, specific health guidance has been provided to persons predisposed to high risk of meta-

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bolic syndrome. Despite the health guidance, the current obesity ratio (approximately 33% for men and 22.3% for women) has not changed in women but significantly increased in men between 2013 and 2020 (Ministry of Health, Labor and Welfare, 2020). Because obesity is the most important factor in the onset of NAFLD/NASH (Koda et al., 2007), the prevalence of NASH is expected to increase further in the future. In Japan, 9.1% of cirrhosis is related to NASH (Enomoto et al., 2020), and the liver carcinogenesis rate from NASH was reported to be 5.29/1000 person-years compared with 0.44/1000 person-years in NAFLD (Younossi et al., 2016).

The medical treatment for NAFLD/NASH mainly focuses on the management of the risk factors, such as diabetes, dyslipidemia, hypertension, and lifestyle changes (The Japanese Society of Gastroenterology and Japanese Society of Liver, 2020). Weight reduction due to diet and exercise therapy has been reported to improve the progression of NAFLD/NASH (Musso et al., 2012). Several studies have demonstrated that the effects of lifestyle improvement interventions could be as short as 6 to 12 months (Promrat et al., 2010; Wong et al., 2013). For example, an initial body weight reduction of 7%-10% was observed in a span of 1 year with the intervention of dietary, exercise, and behavioral therapies that lead to better liver condition and improvement in steatosis (Promrat et al., 2010).

It has been reported that promoting behavioral changes among obese people is difficult (Kimura, 2012). This suggests that to achieve a successful lifestyle intervention in these people, we need to focus on their individual personality and social circumstances.

People with severe obesity also suffer from eating disorders, depression, and anxiety (Canivet et al., 2020).

Recently, Sugiyama et al. (2018) reported that psychological stress could induce binge-eating and lead to increased body mass index (BMI) in female NAFLD patients. However, it is unknown why NAFLD/NASH patients overeat to cope with psychological stress. No studies have elucidated why behavioral changes do not occur and why behaviors that lead to disease progression are maintained, even when educated about lifestyle-related improvements. In addition, as background information on "why patients continue to have unhealthy lifestyles," the patient's previous growth environment, habits, and experiences cultivated in the environment affect the recognition and understanding of illness. Therefore, this study aimed to describe the daily living behaviors of NAFLD/NASH patients, identify their recognition, and understand the underlying factors that disturb behavioral change from occurring and the processes that cause disease progression. Greater awareness of these behaviors among nurses would help them consider a holistic approach and be more proactive in managing NAFLD/NASH patients, which will help prevent further progression of these conditions.

Materials and Methods

Study Design and Setting

We employed the micro-ethnography approach (Roper, & Shapira, 1999) to gain a deeper insight into the knowledge and perceptions of NAFLD/NASH from the perspective of patients who are unable to pursue their medical treatment. The micro-ethnography approach was selected as it focuses on the unique issues of small groups of people and the generated knowledge that could be applied to healthcare practices (Roper, & Shapira, 1999). The study was conducted between November 2015 and December 2016 in Hiroshima, Japan.

Participants and Recruitment

The participants were outpatients (male and female, aged \geq 20 years) diagnosed with NAFLD/NASH. They were referred to the outpatient clinic by their general practitioner.

To recruit a broad range of NAFLD/NASH patients, purposive sampling was employed. Among the sample participants, we aimed to achieve a large range in terms of age, gender, and BMI. Purposive sampling was used to select participants so as to understand what contributed to the nonadherence to medical treatment. The numbers of the participants were not predetermined, and no specific criteria were set for exclusion.

Procedure (Participant Observation and Interviews)

The interview and participant observation were conducted by the principal investigator (PI) (the first author, a master's program student who took a qualitative research methodology class and concurrently worked as a nurse at the gastroenterology and metabolism department) and the second author (a nursing faculty specializing in chronic care nursing). After obtaining consent, the PI and co-researcher visited once or twice the participants' home and/or designated places where they spend most of their time, places for their dinning and grocery shopping, and work places for data collection.

We observed numerous aspects of the participants' behavior that might influence the onset and progression of NAFLD/NASH, such as daily activities, dietary habits, cooking methods, lifestyle habits, and stress-coping strategies. We also monitored the daily lives of the family members who lived with the participant, and they were also asked some questions about their lifestyle habits.

During the participant observation, we set semistructured interviews using an open-ended protocol. The interviews were designed to elicit the participants' opinions about their health, awareness and understanding of the illness, how to cope with the illness, family relationships, the presence or

Table 1. Interview guide.

Educational background

• Please tell me about your final educational background.

- Occupation
- Please tell me about your current occupation and working style.
- Please tell me about your past occupations.

Eating habit

- Please tell me about your current and past eating habits.
- (number of meals per day, meal time, presence or absence of snacks, meal content)
- How much do you spend on meals?
- Do you go out to eat? Where are the menu selection criteria?
- Is there any reason to take the dietary habit?
- What and what criteria do you buy when shopping?

Family

- Please tell me about your family structure.
- Please tell me about your family's illness, eating habits, and body shape.
- Are there any critical situations in your relationship with your family?
- How did you get over it?

Illness

- Do you know about your own illness?
- Please tell us about your treatment so far. (Opportunity for consultation, hospitalization history, experience of worsening medical condition)
- Do you know about the problems that illness causes to your body? (If you don't know the problem, why don't you?)
- Do you understand the treatment and test values for your own illness?
- Have you ever received medical treatment guidance? Did you understand it? Has there been any change in yourself due to the medical treatment guidance?
- Did the illness affect your daily life and work?
- Do you know what kind of medicine you are taking?
- What is the reason why the medical treatment behavior can be continued/cannot be continued?
- What do you think of your body shape? Why do you think so?
- Are you using folk remedies?

absence of illness in their family, and their life history (Table 1). Furthermore, specific questions such as information on family size and members, age, gender, occupation, comorbidities, and educational background were gathered. Probing and active listening were adopted during the interview to collect information (asked when a question arises during behavioral observation). The set interviews lasted from 30 to 50 min and were conducted in places where the participants always visited. Field notes were taken, and the interviews were recorded using a digital recorder with the consent of the participants.

Data Analysis

The analysis followed Spradley's Developmental Research Sequence (Spradley, 1980). We started data analysis as soon as the first participant observation was performed. The recorded interviews were transcribed verbatim after repeatedly listening to the contents. The accuracy of the transcripts was assured by the two researchers who were involved in the home visits. The field notes were also used to strengthen data interpretation. These notes and dataset transcripts were manually assessed using a thematic approach. We conducted a domain analysis to find semantic relationships through a

close reading of the field notes and verbatim interview transcripts and discovered cultural domains. A domain is a category of cultural meaning. Next, we conducted taxonomic analysis to determine how the domains are organized. Then, we conducted a componential analysis to identify the meanings and relationships among the terms that make up the core domains. Subsequently, cultural themes related to NAFLD/NASH behaviors were discovered while elucidating the relationships among the domains. Final themes were based on whether they addressed our research questions related to NAFLD/NASH behaviors or not. In addition, we analyzed the similarities and differences between the domains and how they relate to medical treatment adherence. Any discrepancy in the identification of the domains and themes was resolved by discussion and consensus. The participants were indicated as "Participants A, B, C, D, E, F, G, and H."

Trustworthiness

We used the "strategies to guarantee the truth" of the qualitative study (Holloway, & Wheeler, 1996). Combining the observation and interview data (triangulation), the participants were asked to listen and review their statements

Partici- pant	Age (year)	Medical history	Educational back- ground (highest)	Occupation	BMI (kg/m ²)	Family medical history
А	60	DM, HT, colorectal polyps, hypopharyngeal cancer, cataracts, hepatitis C	University Under graduate	Unemployed (on welfare support)	23.7	Unknown
В	30	DM	Dropout of high school	Dispatch clean- ing services	48.2	Grandfather: DM
С	60	DM, HT	High school	Factory worker	30.0	Father: DM Brother: DM
D	70	DM, HT, dyslipidemia, chronic renal failure	High school	Clerical work	32.4	Father: DM Brother: Pancreatic cancer
Е	80	DM, HT, dyslipidemia	High school	Unemployed	23.5	Mother: DM, cerebral infarction Brother: DM, cerebral infarction
F	50	DM, HT, DM nephropathy, DM retinopathy	Junior college	Public servant	36.9	Father: DM Mother: DM, HT
G	40	Chronic heart failure, atrial fibrillation, sleep apnea syndrome	High school	Factory worker	68.4	Father: DM, myocardial infarction Mother: Stroke
Н	50	DM, dyslipidemia, left-lower extremity arteriosclerosis obliterans	High school	Unemployed (on welfare support)	38.4	Mother: DM Grandmother: DM

Table 2. Basic attributes of the participants.

Abbreviation: BMI = body mass index; DM = diabetes mellitus; HT = hypertension

(checking participants), and discussion with seven certified nurses specializing in chronic care nursing (expert review) were used as the basis for qualitative research evaluation.

Ethics Statement

The study protocol was approved by the Ethics Committee for Epidemiological Research of Hiroshima University (E-81). The aim of this study was explained to every participant, and written informed consent for participation was obtained from each of them. This study was conducted in accordance with the Declaration of Helsinki.

Results

Description of the Participants Involved in This Study

Data from eight participants were analyzed (two men and six women; age range: 30-80 years). Seven participants (88%) had a history of diabetes, and four (50%) had hypertension (Table 2).

From the participant observations and semistructured interviews, we found four cultural themes: 1) health beliefs built in the family, 2) difficulty in systematizing health knowledge, 3) dependence on food, and 4) social disadvantage (Table 3).

The processes involved in generating these cultural themes are described in the following sections. In addition, illustrative quotes are included in the text.

Theme I: Health Beliefs Built in the Family

The participants felt that lifestyle-related illnesses, such as obesity, were hereditary and thus tended to ignore the importance of taking preventive actions. Participant E said, "I have a family history of being overweight." The participants reported witnessing that some of their family members lived comfortably despite "Having lifestyle-related diseases in the family." Being raised with beliefs that lifestyle-related illnesses are hereditary and therefore inevitable made participants casual about the danger of sickness and obesity. The participants were not worried about the obesity of their spouses and children. "The body image built within the family" diminished the perception of criticism and made it difficult to recognize it as a problem.

Participant C's father also had high blood pressure. "My father had high blood pressure, I heard it was around 180 mmHg. If my blood pressure was around 160 mmHg, I can go for work." Participant D stated: "My family and I do not think that blood pressure of 150 mmHg or higher is a problem. I heard that my father had upper side (systolic) blood pressure of 200 mmHg but he did not care about it." When we asked Participant G if she had ever thought about taking care of her health in an environment where her family members were obese or had lifestyle-related diseases, she responded that she was fine because she had no symptoms compared with her family members ("Comparing themselves to their families").

It is important to note that several participants lacked

Theme	Domain		
TT 1/1 1 1' 01 '1/ ' /1	Having lifestyle-related diseases in the family		
Health belief built in the family	Body image built within the family		
	Comparing themselves to their families		
	Difficulty in interpreting health information		
	Lack of awareness of the disease/its severity		
Difficulty in systematizing health knowledge	Difficulties in correctly judging the received health information		
	Denied having health issues (denial behavior)		
	Visiting a doctor is a treatment		
	Taking medicine is a treatment		
	Habitual behavior in family eating patterns		
Dependence on food	Routine eating behavior		
	Eating improves mental health		
Social disadvantages	Changes in the living environment		
	Educational background		
	Financial difficulties		
	Family relationship		
	Lack of support from others		
	Dependence on others		

Table 3. Theme and domain.

knowledge about the disease and its causes. Therefore, their decisions about their health were solely based on comparison between themselves and their family members.

Theme II: Difficulty in Systematizing Health Knowledge

All participants received medical care and guidance, but they were unable to systematically understand the information. Because of "difficulty in interpreting health information," they were not able to integrate clinical and biological parameters to the severity of their condition.

Participant A said: "Till now, I cannot interpret liver function tests data, I judge them using my weight, whether my weight is heavy or light." When the researchers asked her whether she understood the information about nutrition provided in the outpatient setting, Participant A replied, "Is sodium a salt? My interpretation is that foods with less energy tend to have more sodium." When asked about the medical guidance received at the hospital, participant B said, "I don't remember. I didn't know anything about HbA1c." Participant B also stated: "You can treat diabetes by just reducing your weight, right! So, diabetes is not scary to me." Participant B made her own interpretation and thought that if she just needed to lose weight, she could cure herself without seeing a doctor. This leads to a lack of a sense of urgency and self-suspension from seeing a doctor.

Participant C said: "It's good that I don't know the numbers."

Participant C cited her lack of understanding of the test values as the reason why she did not feel threatened and did not change her behavior. It was difficult for them to integrate their knowledge and data with their physical condition. Moreover, they interpreted the data in their own way and lacked awareness of the disease and its severity ("Lack of awareness of the disease/its severity" and "Difficulties in correctly judging received health information"). Furthermore, even though a physician pointed out their health problems, they simply "Denied having any health issues."

Participant F said: "My lab test results showed some abnormalities, but my doctor did not point it out. So, this is ok" (the fact is that the physician explained to him the anomaly). Participant D and G emphasized the reasons why they did not take care of their health: "I'm young, so absolutely okay," and "I have no symptoms, so it's okay."

Seven of the eight participants stated that they continued to consult their physicians without interruption since the first consultation; this is because they believed that "Visiting a doctor is a treatment" and "Taking medicine is also a treatment." The following expressions also indicated their denial of health issues:

Participant C said: "I regularly drink beer even though I have gout. The medication helped me to heal my gout without quitting alcohol. For blood pressure, I just go to the hospital and take medicine. Only anti-hypertensive drugs can cure blood pressure. If I take my medicine, I do not need to change my lifestyle because of my liver problem."

Indeed, even when participants got health explanations from physicians, the health education was not accepted as knowledge.

On the other hand, some participants talked about changes in their behavior, even though it was hard to understand. Participant A said: "I started to buy healthy foods after being instructed by the nutritionist at the outpatient clinic." Participant A was observed to actually purchase the instructed menu items when accompanied on shopping trips. After receiving nutritional guidance at the hospital, Participant D bought a measuring scale and measured rice at home. In the refrigerator at home, there was also rice that was measured and divided into small portions. With guidance, they were able to implement simple things such as measuring quantities. They were able to take action on simple things that were easy to implement in their real lives, such as choosing foods and measuring quantities, when instructed. They recognized that it was good for their bodies.

Theme III: Dependence on Food

The participants reported that the family environment influenced their food habits, i.e., their dietary habits were similar to those of their family. For example, Participant B said: "I was in a family of four, but the amount of food was quite excessive for the consumption of four persons during each meal." In Participant E's home, there was always juice that she would get from relatives and sweets for snacking that her husband also liked. Participant F said that his father liked to eat excessive fat, and his sons grew up on the same diet, which indicated the habitual eating behaviors developed in the family. The persons in charge of purchasing and preparing the food were also responsible for influencing the food choices. There was a common bias to choose foods that were high in sugar and calories. The eating habits observed in the participants were similar to those of their family members, and by sharing these eating habits from childhood, the eating habits of the family members were passed on to the participants ("Habitual behavior in family eating patterns").

The participants also had a habit of eating the same food repeatedly from a fixed menu ("Routine eating behavior"). In Participant A's home, there was a large amount of retort food of the same type. When the researchers accompanied her on shopping trips, the stores we went to, the route we took at the stores, and the products we bought were all the same and fixed each time. When we accompanied Participant A to dine out, he often chose the same restaurant and mostly ordered hamburgers. He said he had never paid attention to calories or nutritional balance. Participant B said: "I can eat similar meal every day without thinking about the nutritional balance, if I find it delicious." When the researchers accompanied them on their shopping trips, they bought bread, juice, fried foods, and sweets. At the supermarket, they bought cheap junk food and high-calorie foods. Participant F said: "I'm a picky eater. I would eat what I liked, but if I don't like something, I wouldn't eat it." She talked about her dietary preferences. In the kitchen of Participant G, there were sweet breads and crackers. Participant G said: "I like sweets, so I always have sweet breads and crackers in my kitchen to eat." Thus, the participants' eating habits were biased toward carbohydrates and high-energy items, and they repeatedly consumed such food articles. Participants who had economic hardships did not have many options; they had to buy cheaper food.

In addition, the participants reported that "Eating improves their mental health." They found that binge-eating helped them cope with stress.

Participant G said: "During stressful situations, eating helps me feel comfortable. As a result, I used to eat right after getting frustrated."

Participant B said: "I calm down when I have food in front of me. I just like to eat. I want to eat without stress."

Participants had developed food and eating addictions with unhealthy eating schedules.

Theme IV: Social Disadvantages

Participant D was in debt, divorced, and sold her house to pay off the debt. After the divorce, Participant D got an office job but was not financially able to afford it. Participant E was forced to lower her standard of living due to the impact of her husband's failure in business. Participant G was a single mother who managed to make a living by working as a cleaner. Similarly, there was a possibility that occupational instability, low wages, and irregular work, such as night shifts, had adversely affected their living environment along with their medical treatment. Unstable occupations forced them to change work places, and becoming unemployed and being on welfare support have changed their lives ("Changes in living environment."). Their "Educational background" had an effect on their employment and became the reason behind their poor economic conditions. Three participants reported that "Financial difficulties" caused their children to give up on going to school, and they were aware of the fact that their parents' declining economic conditions would also affect their lives.

The participants noted needs that were not being met in their daily lives. They were unmarried, divorced, or bereaved and lacked support from others ("Family relationships"), i.e., no family or friends to help them understand potential health risks. For instance, Participant A was single and described her experience of not being in contact with friends: "I had nowhere to go, and I spent most of my time alone in my studio. I do not get support from anybody."

Two single mothers, Participants D and G, complained about the lack of help and support from society:

"I have a small child, I have to work, and I haven't thought about myself for almost 10 years." (Single mother D)

"If something happens, I have to cope with the challenges without support from anybody. At home, my children are fighting all the time. My daughter became an adult and left home, and I miss her every day." (Single mother G)

They suffered from lack of cooperation with their fami-

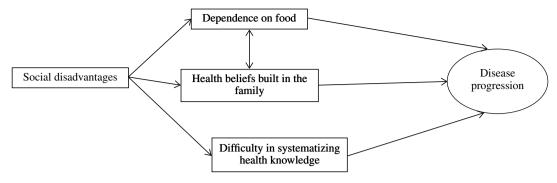


Figure 1. Relationship of cultural themes to the processes leading to the progression of NAFLD/NASH. : Cultural theme, : Progression of NAFLD/NASH, ->: Order of influence.

lies. The women speaking here considered that "the lack of support from others" and the lack of family support tended to affect them both mentally and financially.

In the following excerpt, a woman (Participant E) described losing motivation to change her lifestyle and eating unhealthy food as she saw her husband eating junk food: "Even though I have a family, I get little support from my husband. My husband always drinks his favorite juice and sweets beside me, and I succumb to the temptation to eat the same unhealthy foods."

On the other hand, it was observed that the participants' behaviors changed with the support from others. For Participant A, an encounter with a physician has stimulated behavioral change focusing on treatment, and Participant H was able to continue losing weight with the cooperation of her husband, family members, and others. She observed changes that drove her to continue medical treatment. The participants' behavior depended on others for positive changes or for negative influences ("Dependence on others"). The existence of significant persons in the participants' lives and the presence or absence of their support had an effect on the medical treatment and behavioral changes.

This kind of social disadvantage made it difficult to pay attention to one's health and promoted overeating habits as a coping strategy.

Discussion

We demonstrated the perspectives and daily life behaviors of NAFLD/NASH patients. In addition, we generated cultural theme and domains linked with the development of unhealthy behaviors, which potentially contribute to disease progression. We interpreted the relations among the themes and discussed the process presented in Figure 1. This understanding is vital to identifying opportunities for new therapeutic measures that can be provided to NAFLD/NASH patients.

Factors That Inhibit Patients from Adhering to Therapeutic Education to Modify Their Lifestyle

Negative Influences from the Family Environment and Lack of Integrated Knowledge about the Risk Factors of NAFDL/ NASH

We found that perceptions and food habits within the family influenced the lifestyle of the family and that of NAFLD/ NASH patients. The participants were reluctant to improve their lifestyle because many of them had flawed interpretations of their illnesses and lacked adequate knowledge that could help them connect their condition and risk factors. In addition, due to lack of knowledge, they made judgments about their health status based on comparisons with their family members. For instance, the participants interpreted that obesity was not regarded as a health problem. They compared themselves with obese people in their family; most participants believed that obesity is only hereditary. This view of health was largely shared by participants and their families, which means that the family environment is paramount in influencing personal health outcomes. This finding may have important implications for nurses to engage family for health education. This view is in line with previous studies suggesting the necessity of involvement of family members in medication adherence when caring for patients with low health literacy (Lauffenburger, Khan, Brill, & Choudhry, 2019).

Food Addiction

Our study also highlighted that addiction to unhealthy foods was common. This dependence on unhealthy foods was based on eating habits shared within the family from childhood. Their eating habits consisted of choosing foods high in sugar and calories and ordering the same food repeatedly from a fixed menu. One factor that makes it difficult to break out of this eating habit is food addiction formed from such a habit. High-fat foods, such as junk food, are highly addictive (Berthoud, Lenard, & Shin, 2011). Indeed, intake of high-fat and high-calorie foods can result in obesity and leptin resistance. Leptin resistance is implicated in the gene-

sis of disrupting mechanisms that control eating (Considine et al., 1996), i.e., leptin resistance stimulates appetite, leading to excessive calorie consumption and obesity, which leads to a vicious circle. Intake of high-fat and high-calorie food stimulates the reward system in the brain, resulting in a rewarding effect, such as euphoria (Berthoud et al., 2011). Considering that food addiction is based on the eating habits ingrained in the family from childhood, it is difficult to stop overeating even if one's diet is restricted. As a result, it is very difficult to break this vicious cycle. Therefore, prevention requires dietary education from early childhood and education not only for patients but also for their families. Furthermore, it is important to note that NASH patients tend to be depressed, which negatively affects their dietary habits (Elwing, Lustman, Wang, & Clouse, 2006), and that bingeeating disorder is common among NAFLD patients (Zhang et al., 2017). The participants in this study also experienced stressful environments due to social factors and ate large quantities of food to cope with stress. This allowed them to maintain a good mental state. This type of behavior creates a vicious cycle that promotes eating addictions, which, in turn, lead to the onset and exacerbation of the disease.

Disadvantageous Social Situation and Behavior Toward Medical Treatment

Our findings also indicated the negative effects of "social disadvantages" on factors that impede the treatment behavior of NAFLD/NASH patients, i.e., family-established views on health and food addiction.

In this study, the participants were facing financial difficulties, and the economic situation was affecting their diet and education. Regarding this effect, the 2018 National Health and Nutrition Survey (Ministry of Health, Labor and Welfare, 2020) reported that low-income households eat fewer staple foods, entrees, and side dishes than highincome ones, and their nutritional balance is low. In addition, the Cabinet Office (2018) reported that the college and other education rate for households on welfare support is 36% (72.9% for all households). Ochanomizu University (2018) reported that family economic status and children's academic performance are strongly correlated. Low-income individuals have lower academic performance, which affects their career path. A similar situation was observed in the participants in this study. Financial distress led to loss of food choices and opportunities for learning. Loss of dietary choices affects good eating habits, and loss of access to education makes it difficult to understand and build health information, leading to disease awareness and the formation of a view of health. Incomprehension of information from health professionals leads to "overconfidence in medical treatment" rather than controlling behavior by oneself, leading to a stop of thinking that "it is okay if I receive treatment/medication." This recognition or psychological defense mechanism, such as denial, makes it difficult for the patients

to initiate their behavioral change.

Socioeconomic conditions affect health behavior and create health inequalities. It was also reported that the lower the socioeconomic status, the lower the social support (Saito et al., 2005). Furthermore, it was observed that our participants were also more socially isolated. For those who tend to depend on others, the situation where it is difficult to obtain support from the surroundings is a factor that hinders adherence to therapeutic education or medical treatment behaviors. Social situations, such as divorce and bereavement, are stressful experiences that impair people's mental wellbeing, making it difficult to pay attention to one's health and thus leading to overeating as a coping mechanism against stress; indeed, this is how food addiction is formed.

In this way, social conditions affect health perceptions, eating behaviors, and medical treatment environment. These, in turn, affect the onset, progression, and medical treatment behavior of NAFLD/NASH. The World Health Organization (Wilkinson, & Marmot, 2003) has shown that social determinants are involved in the health status of an individual. Therefore, the social situation has a great influence on one's view of health, which is the basis of rehabilitation behavior, and has also hindered it or one's adherence to treatment.

To Achieve High Levels of Adherence to Medical Treatment

Eliminating Health Disparities

Our findings indicate that adverse social situation caused health disparities and, as a consequence, impeded adherence to treatment procedures or lifestyle changes in NAFLD/ NASH patients. To improve the outcomes, healthcare professionals need to understand the patients' situation and give advice that is easy to implement both economically and competently. Foods that are less harmful to one's health can be selected regardless of the economic situation. Measures need to be taken to allow people to stay healthy without being affected by the social situation and home environment. Suggestions for Nursing Care and Patient Education

During the interview, one participant changed his behavior due to a positive relationship with his physician (driven by his sincere attitude toward the patient). Furthermore, some participants were able to adhere to healthier food choices as they were taught in a step-by-step manner how to purchase groceries. From these points, nurses need to build relationships of trust with patients and have a collaborative discussion and easy, step-by-step guidance on patients' behavioral changes.

Our findings also indicated that the participants did not have sufficient social support, making it difficult to follow and continue with medical advice. It is necessary to create an environment in which family members and supporters are involved in the patients' treatment and provide support. Efforts to support continued behavioral changes through telenursing and/or home-visit nursing between consultations are also considered effective. This can help patients adhere to treatment.

Limitations of This Study

Qualitative methods have limitations in terms of generalizability. Because six of the eight participants were women, it is unclear whether our results are generalizable to men with NAFLD/NASH. In terms of BMI, this population is representative of the NAFLD/NASH patients. In this study, it was difficult to obtain consent from working men, because visiting participants at home and attending interviews caused time constraints. Therefore, it is necessary to verify whether similar results can be obtained by conducting a study on men in the future. For future studies, it would be better to also consider the illness duration and differences in the illness duration among participants, which might yield useful information about adherence levels.

Conclusion

NAFLD/NASH patients had a belief about health that had been constructed during the course of their upbringing, which was mainly governed by the perspective of their family members. It was also observed that dependence on food formed based on shared eating habits within the family. This health belief and dependence on food along with social factors, such as financial difficulties and educational background, had a significant influence on their views about health that subsequently hindered their behavioral changes. Thus, it is necessary to understand the social situation of NAFLD/NASH patients so as to change their stance about health and health behaviors. Measures and a support system that can assist NAFLD/NASH patients in a better way are highly recommended. For future studies, it is necessary to verify whether similar results could be obtained by conducting a study on men and to also consider the illness duration and differences in the illness duration among participants.

Author Contributions

Study conception and design: T.K. and M.M, Data collection: T.K. and M.M, Data analysis and interpretation: T.K., M.N., M.M. and B.A.M, Drafting of the article: T.K., M.N., M.M. and B.A.M, Critical revision of the article: T.K., M. M. and B.A.M. All authors have read and agreed with the final submitted version of the manuscript.

Declaration of Conflicting Interests

We have no conflict of interest to disclose.

Ethical Approval

The protocol of this study was approved by the Ethics Committee for Epidemiological Research of Hiroshima University (E-81).

Informed Consent

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

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Brief Report

Effectiveness of a cervical cancer prevention program to improve health literacy among Japanese undergraduate females in their 20s: A quasiexperimental study

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Abstract

To improve health literacy (HL) regarding cervical cancer prevention, a health program for females in their 20s was previously developed. The present study aimed to examine the effectiveness of that program. We conducted a quasi-experimental study (with control groups) on female undergraduate students in a private university in Japan. In total, 15 and 60 students were categorized into the experimental and control groups, respectively. Intergroup pair-matching using the identified variables yielded a final assessment population of 28 students (n = 14 in each group). The data analysis consisted of group comparisons of the participants between baseline and final assessment using the Wilcoxon signed-rank sum test and McNemar's test. Experimental group comparisons revealed a significant difference in median HL scale scores (baseline, 57.0; final assessment, 66.0; p = .002), median women's health knowledge test scores (baseline, 14.5; final assessment, 16.0; p = .029), and the percentage of participants who felt confident explaining their own body to a medical practitioner (baseline, Y = 14.3, N = 0.0; final assessment, Y = 100.0, N = 0.0; p<.001); however, no significant difference was found for cervical cancer screening behavior. No changes were seen in any of the variables between baseline and final assessment in the control group. These results indicated that our program was effective for improving HL, confidence in explaining one's own body to a medical practitioner, and women's health knowledge test scores, but not for changing cervical cancer screening behaviors. Further research is needed to determine how to provide more appropriate health programs for females in their 20s.

Trial Registration: University Hospital Medical Information Network Clinical Trial Registry (Trial No.UMIN 000032444).

Keywords

cervical cancer prevention program, female undergraduate students, health literacy

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Introduction

In Japan, cervical cancer rate among women aged 20-30 years has been rising (Foundation for Promotion of Cancer Research, Japan, 2021). However, cervical cancer is prevent-

able, which means that women should undergo regular screening. Since 2008, the Japanese government has been conducting a cervical cancer screening for women with ages 20-years and over. However, despite the Japanese government's efforts, the cervical cancer screening rate remains

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Session	Topic	Contents	Materials
	1. Introduction	Explain educational objectivesMorbidity of cervical cancer	Slides delivered via presentation software
Group lecture (one time)	lecture	• Menstrual periods	 Slides delivered via presentation software Basal body thermometer, graph, and vaginal discharge model
3. Preventi	3. Preventing cervical cancer	Cervical cancer screeningCommunication about condom use with partners	• Slides delivered via presentation software
	4. Gynecological exams and consultations	Overview of a gynecological examinationHow to choose female health information	Participants' mobile phonesA worksheet simulating a gynecological exam
Follow-up (once a month for 3 months)	Topics 2 to 4	• Education sent as e-mails; one topic was sent at a time	• Participants' mobile phones

Table 1. Contents of the cervical cancer prevention program aimed at improving the female Japanese undergraduate students' health literacy.

around 40%, which is low compared with the nearly 70%-80% as observed in other Organization for Economic Cooperation and Development member countries (Foundation for Promotion of Cancer Research, Japan, 2021). Since 2012, the Japanese government has refrained from promoting Human papillomavirus (HPV) vaccination, however, have resumed in 2022 (Ministry of Health, Labor and Welfare, 2021). Increasingly, stakeholders have been highlighting the importance of cervical cancer screening for women.

HPV is highly transmissible and now considered the most common sexually transmitted infection (STI) in most populations (Castellsagué, 2008). Regarding STIs, the World Health Organization (WHO) recommends providing a cultural and age-appropriate programs to sexually healthy boys and girls (World Health Organization, 2014). However, in most Asian cultures, many parents are reluctant to educate their children on sexual health topics because sexuality is a societal taboo (Lee et al., 2013); Japan is no exception to this rule. Additionally, few opportunities regarding sex education are provided to students after graduating from high school. In disproportion to such few opportunities, a previous study found that approximately 50% of Japanese women pursue university education (Gender Equality Bureau, Cabinet Office, Government of Japan, 2019). As part of the WHO's cervical cancer control, secondary prevention with a focus on screening is recommended for people with ages 30-years and below. Female undergraduate students are at the beginning of sexual maturity period, which makes it an important time to focus on the prevention of cervical cancer.

Given this background, it seems important to provide the Japanese women who are in their early 20s, who may be enrolled in a university, with a standardized and ageappropriate sex education. Correlatively, a concept on health literacy (HL), which is defined as one's capacity to obtain,

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process, and understand both the basic health information and services that allow one to take appropriate health decisions (Berkman et al., 2010), has been shown to play an important role in women's general health care. A systematic review of HL and cervical cancer screening found that HL was linked to cervical cancer screening behavior (Kim & Han, 2016). Regarding the methods on HL enhancement, another review suggested that HL can be improved by providing people with an adequate information, effective communication, and structured education program (Nutbeam et al., 2018); doing so may help improve the Japanese women's HL and promote cervical cancer prevention among high risk group. In spite of this, there is no current study that demonstrates the effects of a program which aims to improve HL to prevent cervical cancer among female Japanese university students. To address this gap in knowledge, a health education program was previously developed to improve the HL in female Japanese undergraduate students who are in their 20s (Kawata & Saito, 2018). The present study aimed to examine the effectiveness of an HL program for cervical cancer prevention among female Japanese university students.

Cervical Cancer Prevention Program and Methods

The program contents are shown in Table 1. The program lasts about 50 minutes and consists of a group lecture and a demonstration to provide knowledge on the following: (i) use of basal body temperature thermometer and vaginal discharge model to understand one's own menstrual cycle; (ii) gynecological disease cases (e.g., general STIs, cervical cancer) to learn about the recent trends in, and the prevention of, gynecological diseases; and (iii) using one's own smart-

phone to access health resources and worksheets regarding gynecological examinations and consultations. The teaching materials used in the program were created using Power-Point 2013 (Microsoft, Redmond, WA, USA). We utilized this method for the teaching materials based on a literature review on HL and women's health (Corrarino, 2013), which suggested that readability, layout, and design were key components in developing effective print materials for learning. In the original study in which we developed the program, all the participants that were reported to have a higher level of satisfaction and understanding of the materials commented that the level of difficulty was appropriate for the curriculum. Moreover, after the program completion, they showed improved HL and women's knowledge on health. However, three of the 14 participants thought the program lasted too long (Kawata & Saito, 2018). Therefore, the time was shortened. Additionally, after a group lecture, we sent e-mails containing the contents of the group lectures via their smartphones once a month for 3 months to promote knowledge retention. Therefore, we changed the present study evaluation period to 6 months because of the addition of the emails, and adjusted the events with the cooperating university. The present program was carried out by a researcher and a public health nurse who had practical experience and received training in our previous study.

Study Design, Participants, and Setting

We conducted a quasi-experimental study with intervention and control groups after recruiting participants from a private university in one region of Japan. We asked a private university association in a convenient region of Japan to provide us a corporate university that would be eligible for participation. The selected university has two campuses. To avoid cross-contamination of information between groups, as designated by the cooperating university, the study participants were recruited from both campuses. Posters requesting the student participation were placed in both campuses. The inclusion criteria for both groups were as follows: (i) currently a female Japanese undergraduate student, and (ii) ages 20-years or above. The sample size for the present study was based on our previous study (Kawata & Saito, 2018): the effect size (r = 0.88) was calculated based on a Zstatistic of 3.12 with a difference of 8 mean points pre-post intervention and 13 participants. It was designed with a power of 80%, a significance level of 5%, and an effect size of 0.8, and there were 14 or more participants. This study was conducted from March to October 2015. The start of the program was scheduled to coincide with the participants' course registration and health checkups. This study was approved by the Research Safety and Ethics Committee of the Tokyo Metropolitan University Arakawa Campus 2014 (approval No. 14104). We informed all participants, both in verbal and written form, about the purpose of this study, and assured them that their personal information would be protected. We also informed them that their participation in this study was voluntary. All participants provided written consent prior to participation.

Instruments and Study Protocol

We conducted an anonymous self-administered questionnaire survey and managed the data using concatenate numbers. The study variables were the participants' basic attributes, HL variables, and women's knowledge on health. The participants' basic attributes consisted of age, gynecological history, final sex education history, and cervical cancer screening history.

The HL variables comprised HL scale scores, confidence in explaining one's own body with a medical practitioner (Y/N), questions to test participants' cervical cancer screening behaviors (Y/N), and (only for those with no cervical cancer screening history) intention to undergo cervical cancer screening in the future (Y/N). The assessment of cervical cancer screening behavior indicated whether the participants had undergone screening within 6 months after the start of the program (Y/N). To assess HL scale scores, we used a tool previously developed by one of the authors (Kawata et al., 2014). This tool is composed of 21 items, with each item scored on scale ranging from 1 (extremely low) to 4 (excellent). Cronbach's α of the original tool was 0.88.

To assess women's health knowledge (20 items), we used an original test previously developed with reference to the preceding studies on women's health (Dimmitt Champion et al., 2013; Sandfort & Pleasant, 2008). As our study had a quasi-experimental design, we performed pair-matching at the final assessment to control the confounding factors namely HL scale scores at the baseline. The evaluation protocol is shown in Figure 1.

Statistical Analysis

The data were analyzed using SPSS (version 23.0 for Windows; SPSS, Inc., Chicago, IL, USA). Statistical significance was set at p<.05. The statistical analyses consisted of calculating the basic statistics and conducting comparisons of each group regarding the participants' basic attributes and HL variables, as well as women's health knowledge and cervical cancer screening behavior at the final assessment using the Wilcoxon signed-rank sum test, Fisher's exact test, and McNemar's test. We selected the nonparametric test in consideration of the possibility that a normal distribution could not be secured because of the small number of samples.

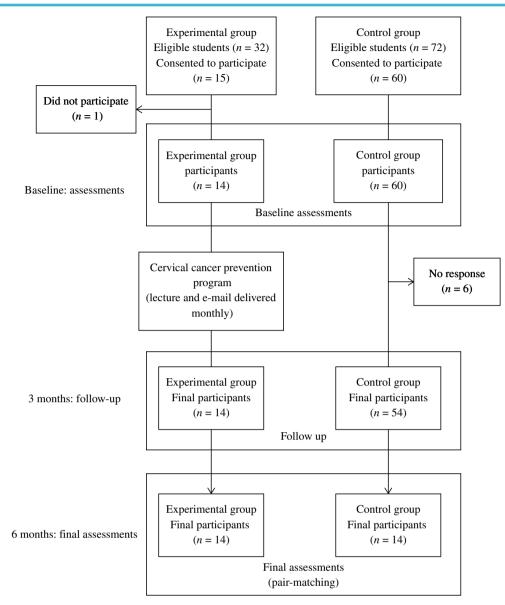


Figure 1. Evaluation protocol for both groups

Evaluation protocol for both groups, including the number of participants and assessment periods for each group. Each group was assessed before (baseline) and at 3 months (follow-up) and 6 months (final assessment) after the start of the program. As our study design did not include randomized group allocation, we had to control the confounding factors and conduct intergroup pair-matching at the final assessment of HL scale scores at baseline.

Results

Participants' Characteristics

In total, 14 of the 32 students (43.8%) eligible for the intervention group and 60 of the 72 (83.3%) students eligible for the control group agreed to participate in the study. At follow-up, 14 (100%) students participated in the intervention group, whereas only 54 (90.0%) participated in the control group.

In this study, pair-matching was conducted at the final assessment using data from the baseline survey. This procedure yielded a final population of 28 participants (n = 14 in each group), all of whom had their data analyzed. The results of group comparisons regarding the participants' basic attributes after pair-matching at the final assessment were not significant (Table 2).

Comparisons of Each Group between Baseline and Final Assessments

Comparisons of each group between baseline and final assessments are shown in Tables 3 and Table 4. In the experimental group, significant differences were found in median

Variables	Catagory	Experimental group $(n = 14)$	Control group $(n = 14)$	<i>p</i> -value
variables	Category	n (%)	n (%)	
Age (years)		20.7 (0.7)	20.8 (0.8)	.807ª
Gynecological history	Yes	4 (28.6)	1 (7.1)	.163 ^b
	No	10 (71.4)	13 (92.2)	.103
Einel con advection history	Junior high school	5 (53.7)	4 (28.6)	.500 ^b
Final sex education history	High school	9 (64.3)	10 (71.4)	.500°

Table 2. Comparisons of participants' basic attributes after pair-matching in each group.

Note. Results tested by at-test and bFisher's exact test.

Data are expressed as mean (standard deviation), n (%)

Table 3. Comparisons of the health literacy (HL) scale and women's health knowledge at baseline and final assessment after pair-matching in each group.

Variable	Experimental group $(n = 14)$		n voluo	Control gro		
variable	Baseline Final assessment		<i>p</i> -value	Baseline	Final assessment	- <i>p</i> -value
HL scale	57.0 (51.3-60.0)	66.0 (62.0-71.0)	.002	57.0 (51.3-60.0)	58.0 (51.3-61.5)	.861
Women's health knowledge	14.5 (13.8–15.3)	16.0 (15.0–17.0)	.029	15.0 (13.5–16.0)	13.5 (12.5–15.3)	.107

Note. Results tested by the Wilcoxon signed-rank sum test.

Data are expressed as median (interquartile range)

HL: Health literacy

Table 4. Comparisons of participants' confidence in explaining and health behavior at baseline and final assessments after pair-matching in each group.

Variable Category		Final assessment						
		Category		Experimental group $(n = 14)$		Control group $(n = 14)$		
			Yes	No	<i>p</i> -value	Yes	No	<i>p</i> -value
Confidence in explaining one's		Yes	2 (14.3)	0 (0.0)	< 001	3 (21.3)	1 (7.1)	> 000
body to a medical practitioner		No	12 (85.7)	0 (0.0)	<.001	1 (7.1)	9 (64.5)	>.999
Health behavior	-							
Cervical cancer screening	Baseline	Yes	2 (14.3)	0 (0.0)	.500	1 (7.1)	0 (0.0)	>.999
		No	2 (14.3)	10 (71.4)	.500	0 (0.0)	13 (92.9)	>.999
Intention to undergo cervical		Yes	4 (28.6)	0 (0.0)	.063	2 (14.3)	1 (7.1)	.219
cancer screening in the future		No	5 (35.7)	5 (35.7)	.005	5 (35.7)	6 (42.9)	.219

Note. Results were tested using McNemar's test. Data are expressed as n (%).

HL scale scores (baseline, 57.0; final assessment, 66.0; p = .002), and women's health knowledge (baseline, 14.5; final assessment, 16.0; p = .029), and the percentage of participants who felt confident explaining their own body to a medical practitioner (baseline, Y = 14.3, N = 0.0; final assessment, Y = 100.0, N = 0.0; p < .001). No significant differences were found in regard to cervical cancer screening behavior or future intention to modify health behavior.

Discussion

This study found that the investigated health education pro-

gram was effective in improving women's HL and knowledge on health. As similar in Korea, a previous study reported that a cervical cancer prevention program had positive effects on cervical cancer knowledge for female university students (Mo et al., 2013). Namely, both previous findings and present studies indicate that receiving sex education at university age is important for expanding sexual knowledge among undergraduate students.

However, no association was found between HL and cervical cancer screening behavior. There are four possible reasons for this. First, the participants' cervical cancer screening behavior was evaluated too early; the year-round Japanese cervical cancer screening schedule goes from April to the end of March of the following year (2016), and this variable was evaluated in the middle of 2015. Therefore, a methodological review is warranted to appropriately assess this variable. Second, Japanese women can receive a free cervical cancer screening only in the location where they are registered as a resident. University students in Japan often stay in accommodations near their universities without changing their resident registration; therefore, it is inconvenient to visit a clinic which is far from home or school. Corroborating this notion, a previous report states that inaccessible clinics, inconvenient locations, and appointment times were barriers in cervical cancer screening participation (Chorley et al., 2016). Third, with regards to the possibility of improving the female Japanese undergraduate students' cancer screening behaviors, previous studies have discussed the influence of a primary physician's recommendations. Additionally, a study conducted to examine the relationship between HL and recommendation adherence to undergo breast cancer screening among Japanese women found that breast and/or cervical cancer screening behavior is associated with both receiving a recommendation and having a primary care from a physician (Goto et al., 2019). However, this is only considered to be partly true due to the lack of a general primary care physician system in Japan. In other words, these studies indicate that a healthcare worker's recommendations and encouragements may promote awareness to cancer risk, and it is necessary to periodically provide women with an age-appropriate and up-to-date health education. Finally, the emotional barriers may contribute to poor cervical cancer screening behavior. A previous study reported that statements related to "fear of pain" and "embarrassment" seemed to be more prominent among Asian women than among other ethnic minorities (Marlow et al., 2015). The results of that study suggest that many women think that undergoing cervical screening for the first time will be painful and uncomfortable. Thus, it seems necessary to foster an environment that promotes a perception of comfort toward the procedure wherein women can comfortably undergo cervical cancer screening. Regarding such participation, in Japanese culture, knowledge about the health of Japanese women may be empirically conveyed from mothers and grandmothers; correlatively, in Korea, a study that provided a health education on cervical cancer prevention for mothers was shown to be effective in improving their cervical cancer and Pap test knowledge, as well as their confidence in communication with their daughters (Kim et al., 2017). The heightened self-efficacy then led them to recommend cervical cancer screening to their daughters. A possible method to overcome these emotional barriers may be the provision of education program contents that are culturally relevant; for example, contents that promote the inclusion and participation of young women's mothers in their cervical cancer screening and sex education. However, to overcome the behaviors on cultural barriers related to cervical cancer prevention, it is necessary to consider the contents that allow students who have undergone cervical cancer screening to be involved as a peer-support staff.

The present results suggest that HL might not have a direct effect on health behavior. Further research is needed to determine how to provide a culturally- and age-appropriate sex education to improve HL among female undergraduate students in Japan. In Japan, a high percentage of students pursue higher education. In light of this, universities and other institutions of higher learning are the best places to provide health education to young women in their early 20s. Additionally, The Japanese education system offers regular health checkups. We recommend that female undergraduate students take these opportunities in order to raise awareness about the risk of cervical cancer and the benefits of screening.

This study had several limitations. First, although we established the sample size for each group based on a preceding study, the sample size was small for a quasiexperimental design. Second, our results are based on data from students attending a single university in Japan; all participants had a history of sex education up to high school, and it can be said that this is a general situation for Japanese women. However, the results may not be generalizable to all undergraduate females in Japan. Therefore, we believe a randomized controlled trial with a larger sample size is necessary to confirm the causal effects between the variables analyzed in the present study. This study is a reanalysis and revision of doctoral dissertation data.

Author Contributions

SK and ES conceived of the study and study design; SK collected the data; SK and ES analyzed and interpreted the data, drafted, and critically revised the manuscript for important intellectual contents. All authors read and approval the final manuscript.

Declaration of Conflicting Interests

The authors declare that they have no competing interests.

Ethical Approval

This study was approved by The Research Safety and Ethics Committee of the Tokyo Metropolitan University Arakawa Campus (approval no. 14104).

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Informed Consent

We informed all participants, both in verbal and written form, about the purpose of this study and assured them that their personal information would be protected.

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Possibilities and challenges of dialogic approach training for child guidance center staff

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Abstract

Parenting support and abuse prevention are pressing agendas in Japan. In the 1980s, open dialogue (OD) has emerged as a treatment option for mental illnesses in Finland. We held six training sessions using the OD approach at a child guidance center from 2017 to 2019. Each session consisted of a lecture and role-plays, and participants' reflections were gathered through a feedback sheet after each session. Moreover, we interviewed one staff member after the training. Our OD training with the child protection staff is reported, and the possibilities and challenges are discussed. The participants were 104 staff members of the child guidance center, and in total, 73 feedback sheets informed us regarding the achievements and concerns of our training session. The categories of awareness, new experiences, and trust to therapists emerged as achievements, whereas categories of questions, difficulties, uncertainty, and the need for further learning emerged as concerns. From a 102-min interview with one child guidance staff, we acquired his interest in dialogue, impressions, and feedback on our training. He informed us of the difficulties in dialogue between the families and facilities with authority, necessity of early contact, possibilities of OD in child protection, and suggestions for OD training. Our training was part of an exposure program. However, the participants deepened their understanding of the dialogic approach. As per our findings, we realized that OD and its training were suitable for the field of parenting support. The conditions of organizational training, such as costs, timing, location, and resource availability, should thus be improved.

Keywords

open dialogue, training, reflecting, child protection, parenting support

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Background

In 2020, over 200,000 child abuse cases were reported in Japan (Ministry of Health, Labour and Welfare, 2021). Parenting support and abuse prevention remain pressing issues in Japan. In fact, child protection staff is often exhausted from handling abuse cases. In previous studies, we examined the feelings of a mother whose child had been taken away by the authorities due to suspected child abuse. She emphasized that she strongly wanted the child protection staff to hear of

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her parenting challenges (Kadoma et al., 2020). Family care requires a partnership between parents and dialogue.

In the 1980s, open dialogue (OD) emerged as a treatment option for mental illnesses in Finland. We have been interested in this approach for several years. Some studies have clarified its effectiveness for psychosis, particularly schizophrenia (Bergström et al., 2018; Freeman et al., 2019; Seikkula et al., 2003). However, the application of OD to clients outside the medical field is limited, and only a few cases have been reported. In Spain, OD was used for family therapy with multiple families (Putman & Martindale, 2021, p. 212).

Family care requires partnerships with parents and dialogue. In OD studies, both clients' and therapists' perspectives and experiences are deemed essential. Tribe et al. (2019) explored the experiences of networking meetings service users and clinicians during the implementation of OD for a UK-based mental health service. Holmesland et al. (2010) described the challenges associated with the transformation and emergence of professional identity in transdisciplinary multiagency network meetings and the use of OD.

However, OD has a simple principle. Putman and Martindale reported that a very good outcome of OD was obtained from high-quality training programs (Putman & Martindale, 2021, p. 107). Originating in Western Lapland, OD training typically requires 3-4 years. In recent years, it has also been conducted in Europe, including Scandinavian countries (Putman & Martindale, 2021, pp. 107-139). In Japan, the Open Dialogue Network Japan is known to hold training sessions for professionals by inviting trainers from Finland.

Although various studies have been conducted on the OD, few have been conducted on training participants' feedback or reflections. It is essential to understand a trainee's perspectives of the achievements and concerns regarding OD training to investigate the possibilities and challenges of the OD approach and training.

We tried OD training with child guidance center staff for 3 years. Although we have reported the outline and the contents of our training (Hosokawa et al., 2020), we had not qualitatively analyzed the reflection of the participants including personal interview data.

Aim

In this study, we aimed to (1) report our OD training with child protection staff and reflection of the participants/trainees and (2) discuss the possibilities and challenges of using this approach or training.

Methods

Study Participants

The study participants were child protection staff workers

who attended our training sessions. The number of participants in each session ranged from 9 to 31, and the total was 104. All staff of the child guidance center was deemed eligible to attend. They attended the training as much as their work schedule had allowed. Of these participants, one was interviewed after the training.

Data Collection

We held six training sessions at a Child Guidance Center in a city from 2017 to 2019. This city was urban and located in the Tokai area of Japan. Data was collected through 73 feedback sheets submitted by the training attendees and an in-depth interview with one training attendee. The child guidance center distributed and gathered feedback sheets after every training. The attendees responded to the feedback sheets anonymously. We received them from the child guidance center with the attendee's permission.

After six training sessions, we collected data through an interview with a child guidance staff member who had attended the training. The interviewee was a primary worker who handled the case which we modeled in our role-play. He was dedicated to family care and interested in dialogue, so we thought that he was an appropriate person who could talk about experiences related to our research aim. The first author asked him to reflect on our activity/training, his daily work to support the family, and his thoughts regarding the dialogical approach for a family with challenges. This interview was held at the first author's institute for 102 min in March 2019.

Regarding Our Training

The training consisted of a lecture on OD and conversations (Table 1). They included the principles and key elements of OD (Olson et al., 2014). The participants role-played imaging families for whom the staff members cared for. The staff played the roles of the client, family, related people surrounding the clients, and facilitators. The role-play included conversations using open-ended questions and responding to the clients' utterances. Each session lasted 120-180 min. Although OD training typically requires 3-4 years, our training was adopted as a part of the professional development efforts at a child guidance center. Therefore, it was not intensive or long term. The researchers were trainees of various backgrounds and specialties: three public health nurses, a pediatric nurse, a psychiatrist, a psychological therapist, and a cultural anthropologist. Some members were theoretical and methodological leaders of dialogic approaches in Japan.

Data Analysis

Data analysis in this current study consisted of three steps: (a) organizing feedback comments, (b) constructing categories based on similarities and differences, and (c) finding achievements and concerns related to the training program.

Table	1.	Contents	of the	training	sessions.

Session	Month/Year	Contents	Number of Participants	Number of Responses
1	Feb-17	Welcome, Lecture, Reflection exercise	16	6
2	Jul-17	Role-play to become clients and families	20	12
3	Jan-18	Facilitation exercise	31	27
4	Aug-18	Reflection exercise	9	8
5	Oct-18	Practice of open dialogue	18	13
6	Mar-19	Role-play of open dialogue	10	7

Table 2. Reflections of the participants in our training.

Achievements	Concerns				
<awareness></awareness>	<questions></questions>				
Participants realized the unique characteristics of the open dialogue	Participants raised practical questions.				
approach that emphasizes respect and dialogue.	<difficulties></difficulties>				
<new experience=""></new>	They expressed challenges in the technical aspects of the open dia- logue approach.				
They had new experiences of imagining the clients' situations.					
<trust therapists="" to=""></trust>	<uncertainty></uncertainty>				
They developed trust in the therapists.	Some felt uncertain regarding the characteristics of OD being tolerant of ambiguity.				
	<need for="" further="" learning=""></need>				
	They expressed interest in learning more about OD.				

In addition, we analyzed the interview data for the essence of the informants' narratives. We highlighted the importance of his experiences and thoughts regarding our study aim through the transcript. The informant who participated in the personal interview checked the validity of our analysis.

Ethical Consideration

Participation in the training sessions was voluntarily, and the privacy of the participants was ensured. Informed consent was obtained from all participants involved in this study. This study was approved by the Institutional Research Ethics Committee of the first author's university (ID-16019-4).

Results

Participants' Reflections on Our Open Dialogue Training

The 104 participants (in each session ranged from 9 to 31) included psychotherapists, child welfare specialists, social workers, and other professionals at the child guidance center. The number of participants depended on the availability of the staff. Sometimes, they were absent from the sessions due to the unpredictable nature of their jobs. In total, 73 feedback sheets informed us regarding the achievements and concerns of our training sessions. Table 2 shows the categories and subcategories of the comments from the participants.

Achievements

As an achievement, the categories of awareness, new experience, and trust to therapist emerged.

Awareness

This category meant that the participants realized the unique characteristics of the OD approach that emphasized respect and dialogue. The participants said, "I gained multiple perspectives," "I can apply this great skill to day-to-day counseling," and "I learned that there is no immediate solution."

New Experience

They had new experiences imagining the clients' situations, such as a parent struggling. They noted that fresh perspectives would help them to offer better counseling. They said, "I found reflection helped me have an internal dialogue, which I had never had before."

Trust to Therapist

The participants developed trust in the therapists. They said that "I enjoyed calm and direct conversations through therapists/facilitators" and "Therapists collaborate in responding to client's concerns."

Concerns

Conversely, the participants also raised concerns; we thereafter categorized them into questions, difficulties, uncertainty, and need for further learning.

Questions

The participants raised practical questions, such as "I don't know if I can apply OD to my cases" and "facilitator's skills vary greatly."

Difficulties

They expressed challenges in the technical aspects of the OD approach. Their comments included, "effects of reflection are hard to understand" and "it is difficult to discuss the client's issues in front of her."

Uncertainty

The participants understood some features of OD and felt anxiety simultaneously. Some felt uncertain as regards the characteristic of OD being tolerant of ambiguity. They said, "I am not certain about conversation without goals," and "I am not sure about discussing without purposes and directions."

Need for Further Learning

The participants expressed interest in further learning. Their comments were as follows: "I want to observe the actual practice of OD" and "I want to learn more about the theoretical background of OD."

A Child Protection Staff's Feedback Gained from a Personal Interview

The informant was a child protection staff member in his 30s and had a social welfare license. He previously worked at a hospital as a medical social worker. After that, he worked for several years at a child guidance center. He was the primary caseworker, who we role-played during the training. The first author conducted a 102-min interview with the informant. Questions were based on his interest in dialogue, impressions, and feedback on the training.

He mentioned the "difficulties of dialogue between the families and facilities with authority," "necessity of early contact," "possibilities of OD in child protection," and "suggestion for OD."

Difficulties of Dialogue between the Families and Facilities with Authority

He said that "we have the authority to prohibit undesired behavior from parents and children." Therefore, "the relationship between the worker and client is hierarchical." Through the training, he realized that he had authoritatively communicated with his colleagues. He raised examples of these behaviors, such as not being willing to wait and talk, talking about the clients without them, focusing on the risk rather than parent-child strength, and overemphasizing organizational solutions, rather than parents and children understand-

ing each other's feelings.

Necessity of Early Contact

The social worker wished he could have provided continuous support rather than short-term advice. He told us "our guidance on how to discipline children is only temporary, and therefore, we cannot follow our advice. I am afraid that the child-parent relationships at home would be as bad as before." In addition, he wanted to contact the family earlier. He said, "If we could engage with them earlier, the family might have become happier." Through our training, he was able to realize that early conversations with parents regarding the problems could prevent abuse.

Possibilities of Open Dialogue in Child Protection

The informant expressed his impressions regarding OD as follows: "I felt that OD gave me diverse perspectives. I found it interesting to see that two or more facilitators listen to parents' concerns. But we should be doing it already. A facilitator's role is important." He understood the features of the family that were being challenged, "Parents are willing to open themselves to concerned people" and "When parentchild relationships are difficult, the family cannot discuss their problems by themselves." Therefore, he thought that "OD was suitable for less serious service facilities rather than child protection offices." "Responding to mothers' SOS by using OD may help avoid temporary protection and keep their daily life going." These narratives suggested the possibility of OD.

Suggestions for Open Dialogue Training/Practice

He mentioned ideas for understanding OD and promoting training. He said, "It was important for supporters to get a better image of OD and role-play the situation." Therefore, he proposed that an "image movie" would help us understand how we start an OD session. In addition, he said that "people from outside, such as researchers, rather than child protection staff, should take the role of facilitators." He concluded by saying, "We should reach out to families and have dialogue in a daily living context."

Discussion

Studies on dialogic approach in child protection remain to be limited; thus, we tried to practice and conduct research in this field. As mentioned above, our training was part of an exposure program for the child protection center staff, and it was not intensive or engaging. However, we received some suggestions on the possibilities and challenges of our OD training.

First, as possibilities, the participants deepened their understanding of the dialogic approach. They realized the unique characteristics of OD, such as respecting multiple

perspectives. Participants experienced clients' situations through role-plays and reflection, which resulted in internal dialogue. We think that this promotes support workers' continued interest in collaborating with clients. In our research, participants developed trust to therapists/facilitators through conversations in OD. Putman and Martindale (2021, p. 111) also suggested observation/reflection on the importance of trust within teams. Stockmann et al. (2019) reported trainees' perspectives on training and peer-supported OD in the UK. They found that the trainees were able to develop positive changes in their personal attitudes toward their clinical work (Stockmann et al., 2019). The trainees in our study also reported awareness of their clients' situation. We received suggestions from the interviewees that early conversations using OD could open the clients' minds and, in turn, prevent abuse. Therefore, we suggest that OD might be suitable for support centers that are popular among parents. In Putman and Martindale (2021), it is said that the OD training process could be called unlearning and healing (p. 123). In addition, Putman thought it was more accurate to speak of "releasing" rather than "unlearning" (Putman & Martindale, 2021, p. 108). Putman emphasized that OD training helped participants in becoming more flexible and creative in their work (Putman & Martindale, 2021 p. 111). Our training participants cultivated their self-awareness and developed their unique perspectives.

Second, as challenges, the participants raised issues of the difficulty and uncertainty in OD. "Uncertainty" was a key element of OD, and the participants learned this vital feature of OD in our limited training. They wondered whether they could apply OD to their cases. They felt anxiety regarding the tolerance of uncertainty, dialogue without a goal, and the meaning of reflection. In Stockmann et al.'s study, promoting dialogue, not change, was something that participants struggled with. Additionally, tolerance of uncertainty was also found to be difficult and in conflict with their work (Stockmann et al., 2019). These findings were consistent with our findings on trainees' anxiety. OD is not a method, but an attitude (Olson et al., 2014). Therefore, exercises to improve listening skills and promote reflection are needed. We gained suggestions through personal interviews and found that communication between the parents and child protection staff tended to be vertical. Thus, the staff members should consider a horizontal and understanding communication approach with parents. This approach was supported by the "not-knowing" approach (Anderson & Goolishian, 1992) that "the client was the expert" in their experiences. The need for early contact with the family can be addressed by the concept of "early dialogue." It is another dialogic approach developed in Finland (Arnkil & Erickson, 2009). Its dialogic approach suggests early conversation, not intervention among the family and related people.

This research has limitation, that is, only one facility par-

ticipated in the training, and only one staff member participated in the personal interview.

Our training is one of the trial cases of a dialogic approach that addresses the issue of community-based child abuse. The OD approach may be suitable for parenting support and child protection. We believe this approach supports both parents with various challenges and child protection staff. The conditions of organizational training, such as costs, timing, location, and resource availability, should be improved.

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Author Contributions

Akiko Kadoma designed and conducted the study and prepared the manuscript. Midori Asano, Mami Yamamoto, Koji Shiraki, Rikuya Hosokawa, and Hirofumi Sato contributed to the concept and design of the study, data collection/analysis, and detailed interpretation. Hitomi Nakahata and Mari Kato analyzed the data, interpreted the findings, and critically reviewed the manuscript. All authors critically reviewed the manuscript and confirmed the final manuscript.

Declaration of Conflicting Interests

The authors declare that there are no conflicts of interest.

Ethical Approval

This study was approved by the Institutional Research Ethics Committee of Nagoya City University Graduate School of Nursing (ID: 16019-4).

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Informed Consent

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

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Kuramoto, N., Watanabe, Y. (2022). Effectiveness of using near-infrared vein visualizers by nurses in promoting successful peripheral venous catheterization in patients receiving chemotherapy. *Journal of International Nursing Research*, *1* (1), e2021-0014. https://doi.org/10.53044/jinr.2021-0014

In the above-mentioned article, Table 3 unfortunately contained errors. The asterisks given for p value appeared incorrectly. The correct table should be shown as follows. The authors regret the errors.

NIR vein visualizer group							
Vein characteristic	Suc	Success $(n = 20)$		Failure $(n = 14)$			p value
characteristic	Mean	SD	Median	Mean	SD	Median	-
Thickness	7.65	3.15	9.00	9.43	1.02	10.00	.05
Elasticity	7.45	2.56	8.00	9.07	1.21	10.00	.06
Tortuous veins	8.05	2.26	9.00	9.21	1.31	10.00	.07
Rolling veins	7.35	2.64	8.00	8.29	2.05	8.50	.30
Visibility	7.45	3.02	9.00	9.14	1.99	10.00	.02
Palpability	6.95	3.07	7.00	9.21	1.31	10.00	.01

Note. Results showed by Mann-Whitney U tests

p < .05; a score of 10 is more difficult than a score of 1 Abbreviations: NIR, near-infrared; SD, standard deviation

 Table 3. Vein characteristics in the NIR vein visualizer group.

JINR Journal of International Nursing Research Outstanding Reviewer Awards in 2023

The individuals named below have been recognized as recipients of Outstanding Reviewer Awards in 2023

The editors of the *Journal of International Nursing Research (JINR)* wish to express gratitude to the individuals named below for their efforts in reviewing manuscripts on behalf of *JINR*.

Their invaluable contributions in the form of thorough reviews and constructive comments toward improvement of numerous manuscripts are greatly appreciated.

Along with our sincere thanks for their participation in peer reviews, we at JINP look forward to working with them in the future.

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The Editorial Committee members express their gratitude to the following individuals, who served as reviewers of manuscripts for the *Journal of International Nursing Research* between April 2022 and March 2023.

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