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Improving the international presence of nursing research in Japan and expectations for the development of *Journal of International Nursing Research*

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With the publication of the *Journal of International Nursing Research* (*JINR*) Volume 2, Number 2, I am very proud to have the opportunity to say some words as the president of the Japan Society of Nursing Research. I am very happy that the first issue of *JINR*, Volume 1, Number 1, was published in February 2022; Volume 2, Number 1 was published in February 2023, and now Volume 2, Number 2 has been published smoothly. On behalf of all the members of the Japan Society of Nursing Research (JSNR), I would like to express my deepest gratitude to the editor-Chief Prof. Naohiro Hohashi and the editorial committee members for their efforts.

So far, *JINR* has received many submissions that have exceeded our expectations. Volume 1, Number 1 contained two review articles, two original research, and one technical report, and Volume 2, Number 1 contains two review articles, seven original research, and one brief report. The research themes that have been published are diverse and suitable for the Japan Society of Nursing Research as an umbrella society of nursing science.

As Prof. Kiyoko Fukai, the former president of JSNR, wrote in the preface to the first issue, "Nursing is a science that contributes to practice (applied science); therefore, papers written in Japanese are useful for busy practitioners. However, if details of high-quality nursing research that contributes to practice can only be read in Japanese, it cannot be utilized as a new finding shared by the entire world of the nursing academia because there are no borders in philosophy." For most of us (nurses), writing a research paper in English is a bit of a hurdle and we may hesitate. However, by publishing papers in English, research papers can have readers spread across the world. I do not think it is easy for most of us, but please continue to try it.

Finally, let us make *JINR* even more exciting, and take a new step in the history of JSNR!

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Editorial

If you decline to conduct peer reviews, then don't submit your paper

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I have often said, "If you publish one paper, you should review two papers by others, because more than two reviewers need to make time to review your paper." The *Journal of International Nursing Research* (*JINR*) has been struggling with problems related to the time-consuming review process, due mainly to a shortage of reviewers. *JINR* is an international journal, and after checking the content of submitted papers, it searches for researchers from around the world who are willing to undertake peer reviews.

JINR has adopted the use of Reviewer Locator, an optional tool of ScholarOne Manuscripts that automatically generates a list of the most suitable reviewers. The Reviewer Locator displays a list of up to 30 candidates who may be suitable to review a submitted paper. The list displays the ORCID ID of the candidate, the DOI of the paper, and other information about the researcher. The list also shows how many papers a researcher has published and how many papers they have reviewed. Some researchers have published numerous papers but only engaged in a small number of peer reviews, which I believe is undercuts the principles of academia.

Finally, I would like to report three updates for *JINR*. First, the Guidelines for Authors and Guidelines for Reviewers were revised on May 29, 2023 to deal with the use of AI tools such as ChatGPT, so please check them carefully.

Second, the four winners of the Outstanding Reviewer Awards for 2023 have been selected. They are introduced on the *JINR* website and in the print version of *JINR*. We hope that more of you will find the awards an incentive to undertake reviews.

Third, from the 2024 fiscal year, authors whose papers are published in *JINR* will be eligible for academic and incentive awards. Details on this will be posted around June 2024.

We at *JINR* look forward, as always, to your submissions.

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Review Article

Treatment engagement: A concept analysis

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Abstract

The concept of "treatment engagement" has been used in many research articles to describe the behavior and process by which patients engage in treatment and medication. However, the term "treatment engagement" is often undefined and used ambiguously, with each researcher using the term, with a different, vague, or broad meaning. Given that many studies have shown that treatment engagement is directly related to clinical outcomes, the concept, should be defined more concretely. This study, therefore, aims to conduct a concept analysis of treatment engagement using Rodgers' evolutionary method of concept analysis. The antecedents of the concept of "treatment engagement" consisted of three elements: individual (i.e., knowledge regarding the disease and treatment, attitudes toward disease and treatment, and acceptance of the disease), situational (i.e., negative experiences in the past and conditions and circumstances that allow patients to focus on treatment), and environmental (i.e., connection with providers, social support, and adaptive treatment system). The attributes of treatment engagement had two elements: behavioral (i.e., initiation of treatment, continuation of treatment, and adherence to recommendations in treatment) and psychosocial (i.e., attitudes that indicate value and expectations toward treatment, cooperation with peers, and collaboration between patient and providers). Consequences of treatment engagement were treatment retention, better clinical outcomes, and coping with disease and treatment. Through this study, we developed the theoretical definition of treatment engagement as the process of initiating and continuing treatment, and adhering to treatment recommendations, in cooperation with peers and in collaboration with supporters, accompanied by a positive attitude toward treatment.

Background

In various health care fields, some recommended treatments are not initiated or, if initiated, a certain number of patients drop out or show noncompliance (Catherine et al., 2013; Colins et al., 2017). The nursing profession has a role to play in providing community-based or patient-focused interventions to promote behavioral change related to treatment compliance. At the same time, there has been a paradigm shift in health care from disease-centered to patient-centered medicine (International Journal of Health Care Quality Assurance, 2002). Recent studies have shown a tendency for patients to communicate better with health care professionals and to refrain from problematic behaviors to prevent relapse

and enhance their quality of life, and actively participate in treatment and undergo new behavioral changes related to treatment and disease prevention (Brenner & Barnes, 2012; Drieschner & Boomsma, 2008; Jochems, 2017). In other words, the perspective of "patient active participation in treatment" has become more important, including patient autonomy, self-determination, and shared decision making (Buckingham et al., 2016). Thus, in terms of treatment, attention is given not only to the behavioral aspects of the patient but also to the psychosocial aspects, both of which are crucial (Buckingham et al., 2016). Instead of merely focusing on aspects of patient behavior, nursing professionals must also contribute to the assessment and intervention in the psychological aspects of the patients' approach to treatment and the social aspects of the patients' relationship with health care professionals and peers (Caplan & Whittemore, 2013; Claborn, et al., 2017). This concept, which encompasses patients' behaviors and cognitions during treatment, is called "treatment engagement" (Buckingham et al., 2016). It is an important concept because it has been shown to affect clinical outcomes (Stanley et al., 2018). Existing models and theories, such as the health belief model, can show what factors are related to a patient's visit, but they cannot capture how patients participate in treatment. Therefore, we now must consider the concept of "treatment engagement."

In the scientific literature, the term "treatment engagement" first appeared in the mid-1980s and has been used increasingly since the 2010s. In the earlier publication, when this term was first used, it referred to the connection between the patient and the health care providers in the context of suicide prevention (Adam, 1985). However, the term is not explicitly defined in recent publications, and even when it is, the definition varies from study to study. For instance, treatment engagement can refer to a variety of behaviors connected to treatment participation or compliance throughout time (Anand et al., 2015), a proactive approach to therapy (Manuel, 2013), or even the therapeutic connection between health care providers (Collins et al., 2017). Additionally, even where treatment engagement refers to the same behavioral aspect, some authors may use it to describe initiating treatment (Colins et al., 2017), whereas others may use it to describe continuing treatment (Catherine et al., 2013); hence, treatment engagement may carry different meanings depending on the context in which it is used. Clarifying the meaning of treatment engagement can contribute to the development of the concept itself and can provide a direction and foundation for future clinical practice and research.

Therefore, the current study aims to identify the definitive attributes, elucidate a more concrete definition of treatment engagement, and develop the conceptual model of treatment engagement.

Methods

1. Concept Analysis

In this study, Rodger's evolutionary method of concept analysis (Rodgers & Knafl, 2000) was used. This method is based on the philosophical foundation that concepts are evolving things that change over time and circumstances, and by focusing on the nature of concepts and how they are used, the method reveals the properties that concepts possess (Rodgers & Knafl, 2000). It is also a method that is not easily influenced by the researcher's preconceptions because of the rigorous and systematic approach (Rodgers & Knafl, 2000). Treatment engagement may hold different meanings or concepts depending on the time, context, and interpretation; therefore, Rodger's evolutionary method of concept analysis was selected as the most appropriate means of analysis.

Rodger's evolutionary method of concept analysis is based on the following steps (Rodgers & Knafl, 2000): (1) Identify the concept of interest and associated expressions (including surrogate terms). (2) Identify and select an appropriate realm (setting and sample) for data collection. (3) Collect data relevant to identify: attributes of the concept and the contextual basis of the concept, including interdisciplinary, sociocultural, and temporal (antecedent and consequential occurrences) variations. (4) Analyze data regarding the above characteristics of the concept. (5) Identify an exemplar of the concept, if appropriate. (6) Finally, identify implications, hypotheses, and implications for further development of the concept. In this study, the concept analysis was also conducted according to these procedures.

2. Data Collection

A literature search of articles written in English was conducted using the academic article databases PubMed, Medline, CINAHL, and PsychINFO. The keywords were (engag*[Title]) AND (treatment[Title]), and only Journal articles published between 2010 and 2020 were included. A total of 1676 articles were retrieved, of which 671 remained after duplicates were excluded. Unavailable articles and those dealing with nonpatient treatment engagements (e.g., family-only treatment engagements) were excluded, and finally, 485 articles were selected. It is recommended that 20% of the selected articles be included in the final analysis (Rodgers & Knafl, 2000); thus, from the 485 articles, 97 were randomly selected using a random number table.

3. Data Analysis

Inductive analysis, which is a flexible method of identifying and analyzing patterns(Braun &Victoria, 2006) within a data set was performed. First, a spreadsheet was created to tabulate the data collected in the analysis. Next, each paper was read carefully, identifying initial codes that were grouped

into tentative categories. Terms that indicate the nature of the concept of treatment engagement in the target literature were designated as attributes, the terms that indicate events that occur before the concept as antecedents, and the terms that indicate events that occur as a result of the concept as consequences. The categories and included codes were further discussed within the researchers with doctoral degrees in nursing and experience in concept analysis. Furthermore, the content of the analysis was reviewed and revised with the supervision of experts in community health and public health nursing. Through the ongoing analysis, the contents of each identified category were further clarified. Second, model cases were identified, and those that illustrate the defining attributes of treatment engagement were examined from the results of inductive analysis. Finally, a conceptual definition and a model of treatment engagement were created from the results of inductive analysis, establishing the occurrence of the attribute in various contexts. Moreover, to ensure reliability, research notes (describing the work process, decision making, interpretation, etc.) were prepared, and detailed notes were kept for each analyzed paper.

Results

1. Domains of the Literature and Existing Definitions

Of the literature retrieved, the mental health domain was the most prevalent, comprising 61 articles, followed by the HIV-related domain with 16, the lifestyle-related domain with 8, and others with 11. There were 24 articles with explicit definitions of treatment engagement. For example, in the case of alcohol and other drug use disorder, treatment engagement was defined as having two or more alcohol and other drug related services within 30 days after initiating treatment (or hospital discharge) (Binswanger et al., 2019). And elsewhere, treatment engagement was defined as a multidimensional construct that includes not only observable behavior but also attitudes, relational aspects, and cognitions (Collins et al., 2017b), and it was also defined smokers' interest and involvement in both motivational and cessation treatments (Pipper et al., 2012).

2. Attributes

Attributes of a concept are those characteristics of the concept under analysis that have been repeatedly described in the literature (Rodgers& Knafl, 2000). The attributes of treatment engagement included, as behavioral elements, "Initiation of treatment," "Continuation of treatment," and "Adherence to recommendations in treatment" and, as psychosocial elements, "Attitudes that indicate value and expectations toward treatment," "Cooperation with peers," and "Collaboration between the patient and providers" (Table 1).

1) Initiation of Treatment

"Initiation of treatment" denoted the connection to medical care or the start of a specific treatment. An example of the connection to medical care is gay men being tested for HIV and other conditions (Anand et al., 2015). Examples of the start of specific treatment are military veterans' visits to outpatient posttraumatic stress disorder clinics (Stecker et al., 2016), the initiation of psychotherapy for veterans (Mott et al., 2014), and the initiation of medication for depressed Hispanic patients (Sanchez et al., 2017).

2) Continuation of Treatment

"Continuation of treatment" referred to multiple medical examinations and treatment-related behaviors. For example, veterans' use of mental health services more than a certain number of times (Catherine et al., 2013), veterans' participation in psychotherapy more than a certain number of times (Mott et al., 2014), smokers' continued smoking cessation (Carpenter et al., 2020), and multiple insulin replacement of patients with diabetes (Goldman et al., 2018).

3) Adherence to Recommendations in Treatment

"Adherence to recommendations in treatment" indicated adherence to recommended behaviors and instructions given by health care providers. Examples include juveniles who had used illegal drugs adhering to the instructions of health care providers (Abdel-Salam et al., 2014) and people of racial/ethnic minorities adhering to treatment plans (Aggarwal et al., 2015).

4) Attitudes that Indicate Value and Expectations toward Treatment

"Attitudes that indicate value and expectations toward treatment" indicated giving meaning to treatment, agency in treatment, and assertiveness about treatment plans. Examples include young people's perceptions of the usefulness of their treatment from mental health services (Yeh et al., 2019), the concentration on treatment among children with behavioral disorders (Lindhelm et al., 2010), the retention of treatment goals among individuals with eating disorders (Darcy et al., 2010), and self-advocacy among youth who use mental health services regarding their treatment or life (Buckingham et al., 2016).

5) Cooperation with Peers

"Cooperation with peers" indicated providing mutual help and support for those who are undergoing similar treatment. For example, "Cooperation with peers" was observed in a person with a personality disorder who supports other participants within a group treatment program (Clarke et al., 2014) or a substance abuser who receives support from peers in the program (Goodson et al., 2019).

6) Collaboration between Patients and Providers

"Collaboration between patients and providers" denoted building trusting relationships between patients and providers and collaborating in treatment decision making. For example, "Collaboration between patients and provides" was observed in young people who used mental health services and had an open relationship with their providers (Bucking-

Table 1. Attributes of treatment engagement.

Characteristics	Examples	References
<Behavioral elements>		
Initiation of treatment	Getting an HIV test (Anand et al., 2014) Seeing a PTDS treatment facility (Stecker et al., 2010) Initiating psychotherapy (Mott et al., 2014) Initiating pharmacotherapy (Sanchez et al., 2017)	Aggarwal et al. 2015; Anand et al. 2015; Becker et al. 2020; Brenner et al. 2012; Carmlin et al. 2019; Catherine et al. 2013; Chen et al. 2017; Collins et al. 2017a; Cowan et al. 2013; Delaney et al. 2013; Drew et al. 2016; Interian et al. 2013; Jin et al. 2019; Kraviz et al. 2013; Lancaster et al. 2019; Marques et al. 2011; McMurran et al. 2010; Mott et al. 2014; Pillai et al. 2016; Roozen et al. 2010; Sampson et al. 2017; Santis et al. 2017; Schoenfelder et al. 2017; Silva et al. 2020; Simeone et al. 2017; Sirey et al. 2013; Skilbeck et al. 2020; Stecker et al. 2010, 2016; Stein et al. 2014; Stubbe et al. 2016, 2019; Tkach et al. 2019; Wilson et al. 2018, 2019; Woodhead et al. 2013
Continuation of treatment	Utilization of mental health services above a certain number of times (Catherine et al., 2013) Participation in psychotherapy more than a certain number of times (Mott et al., 2014) Continuing medication (Solomon et al., 2020) Continuing to quit smoking (Carpenter et al., 2020) Multiple insulin replacement (Goldman et al., 2018)	Acevedo et al. 2012; Albertsa et al. 2018; Binswanger et al. 2019; Buckingham et al. 2016; Busch et al. 2017; Carpenter et al. 2020; Catherine et al. 2013; Cheung et al. 2018; Claborn et al. 2017; Clarke et al. 2014; Delaney et al. 2013; Dillon et al. 2020; Drew et al. 2016; Garnick et al. 2013; Goldberg et al. 2020; Goldman et al. 2018; Gouse et al. 2016; Guerreo et al. 2013; Harris et al. 2010; Heffne et al. 2016; Ho et al. 2019; Houtepen et al. 2020; Interian et al. 2013; Jin et al. 2019; Jonse et al. 2013a; Jonse et al. 2013b; Kelly et al. 2010; Kern et al. 2014; Kline-Simon et al. 2019; Kwan et al. 2010; McMurran et al. 2010; Monney et al. 2017; Mott et al. 2014; Moucheraud et al. 2020; Myers et al. 2017; Nan et al. 2020; Richwood et al. 2020; Rodriguez et al. 2020; Rutkowski et al. 2010; Schoenfelder et al. 2017; Shrestha et al. 2018; Skilbeck et al. 2020; Solomon et al. 2020; Stubbe et al. 2016; Terzian et al. 2011; Travaglinia et al. 2017; Urbanoski et al. 2018; Wild et al. 2016; Woodhead et al. 2013; Woodhouse et al. 2013; Yeh et al. 2019
Adherence to recommendations in treatment	Adhering to staff instructions (Abdel-Salam et al., 2014) Adhering to treatment plans through appointment keeping and use of full treatment utilization (Aggarwal et al., 2015)	Abdel-Salam et al. 2014; Buckingham et al. 2016; Aggarwal et al. 2015; Clarke et al. 2014; Jeager et al. 2013
<Psychosocial elements>		
Attitudes that indicate value and expectations toward treatment	Perceived usefulness of treatment (Yeh et al, 2019) Focused commitment to treatment (Lindhelm et al 2010) Having a goal (Darcy et al., 2010) Satisfaction with treatment (Becker et al., 2014) Advocating for oneself (Buckingham et al., 2016)	Abdel-Salam et al. 2014; Becker et al. 2014; Buckingham et al. 2016; Collins et al. 2017b; Clarke et al. 2014; Darcy et al. 2010; Dillon et al. 2020; Frost et al. 2018; George et al. 2016; Goodson et al. 2019; Hack et al. 2020; Lindhelm et al 2010; Lore et al. 2015; Manuel et al. 2013; Marshall et al. 2018; Pancow et al. 2012; Pipper et al. 2012; Wild et al. 2016; Yeh et al. 2019; Lore et al. 2015
Cooperation with peers	Supporting and helping others in group therapy (Clarke et al., 2014) Receiving support from peers in the program (Goodson et al., 2019)	Clarke et al. 2014; Goodson et al. 2019; Pankow et al. 2012; Woodhead et al. 2013
Collaboration between patients and providers	Having an open relationship with the provider (Buckingham et al., 2016) Collaborating with patients and providers to develop a treatment plan (Aggarwal et al., 2018)	Aggarwal et al. 2015; Becker et al. 2014; Buckingham et al. 2016; Clarke et al. 2014; Clarkson et al. 2014; Collins et al. 2017b; George et al. 2016; Goodson et al. 2019; Kwan et al. 2010; Lore et al. 2015; Stacey et al. 2017; Yeh et al. 2019

ham et al., 2018), and patients and providers collaborated on treatment planning (Aggarwal et al., 2015).

3. Antecedents

Antecedents are preconditions that must exist before the occurrence of a concept (Rodgers & Knafl, 2000). The antecedents of treatment engagement were extracted as follows: the individual elements of "Knowledge and attitudes about the disease and treatment" and "Acceptance of the disease"; the situational elements of "Negative experiences in the past" and "Conditions and circumstances that allow one to concentrate on treatment"; and the environmental elements

of "Connection with providers," "Social support," and "Adapted treatment system" (Table 2).

1) Knowledge about Disease and Treatment

"Knowledge about disease and treatment" referred to the patients' knowledge regarding the disease itself, such as attention deficit hyperactivity disorder knowledge (Schoenfelder et al., 2017), and treatment methods, such as knowledge regarding preventive treatment for AIDS (Monney et al., 2017).

2) Attitudes toward Disease and Treatment

"Attitudes toward disease and treatment" represented a wide range of factors, from negative attitudes, such as negative feelings associated with the current situation and concerns about the future, to positive attitudes, such as perceptions of the need for and usefulness of treatment, and self-determination of treatment. For example, even among abusers of the same substance, one person's treatment was motivated by her guilt and embarrassment over her continued drug abuse (Wild et al., 2016), whereas another person engaged in treatment with a recognition that their illicit drug use is uncontrollable and requires formal intervention (Dillon et al., 2020).

3) Acceptance of Disease

"Acceptance of disease" indicated the outcome of reducing self-stigma and establishing a self-concept, for example, acknowledging one's own mental illness (Singh et al., 2013) and integrating oneself with being a patient with HIV (Ho et al., 2013).

4) Negative Experiences in the Past

"Negative experiences in the past" referred to experiences of failure related to past treatment. For example, an alcoholic's past experience of failure to get sober or the experience of losing a family member due to illegal drug use were antecedents of treatment engagement (Dillon et al., 2020). These negative experiences in the past seemed to influence treatment engagement, as they led to the perception of not wanting to relapse and experience mental distress again (Dillon et al., 2020).

5) "Conditions and Circumstances that Allow Patients to Focus on Treatment"

"Condition and circumstances that allow patients to focus on treatment" connoted that the patient is in a condition to receive treatment or to focus on treatment. For example, women undergoing HIV treatment were more involved if they had milder menopausal symptoms (Solomon et al., 2020). Moreover, patients were more focused on treatment when the well-being of family members supporting them was better (Becker et al., 2020).

6) Connection with Providers

"Connection with providers" indicated contact and a good relationship between the party or family and the providers, such as outreach (Moucheraud et al., 2020) and increased communication between patients and health care providers (Jonse et al., 2013).

7) Social Support

"Social support" referred to patients having support from the people and communities around them. For example, substance users and young people who use mental health services received support from family, friends, and community members (Becker et al., 2020: Kelly et al., 2010).

8) Adaptive Treatment Systems

"Adaptive treatment systems" implied a good treatment environment and treatment that is tailored to the needs of the participants; for example, accessibility of treatment facilities (Acevedo et al., 2012), and treatment content that is tailored to the preferences of the participants (Kern et al., 2014).

4. Consequences

Consequences referred to situations that result from the attributes of a concept (Rodgers & Knafl, 2000). Three categories of consequences of treatment engagement were extracted: "Treatment retention," "Better clinical outcomes," and "Coping with disease and treatment" (Table 3).

1) Treatment Retention

"Treatment retention" indicated the continuation of treatment for a long time; for example, when substance users continued treatment for more than 90 days through treatment engagement (Abdel-Salam et al., 2014).

2) Better Clinical Outcomes

"Better clinical outcomes" referred to health outcomes such as improved symptoms, reduced problem behaviors, and improved quality of life. Examples include improved depressive symptoms in depressed patients (Skilbeck et al., 2020) and reduced illicit drug use in substance users (Lore et al., 2015).

3) Coping with Disease and Treatment

"Coping with disease and treatment" denoted the capacity to see illness and treatment as a personal matter. For example, it was used to refer to the introspection of patients with hepatitis C through psychosocial support (Wild et al., 2015).

5. Conceptual Model of Treatment Engagement

Figure 1 shows the conceptual model of treatment engagement that was clarified in this study. Among the antecedents, individual and environmental elements and attributes are considered to influence each other. Among the attributes, behavioral and psychosocial elements also influence each other (Buckingham et al., 2016; Colins et al., 2017a). For example, Collins et al. (2017a) showed that people living with HIV could connect with other providers after "Initiation of treatment," and it facilitated engagement with new programs. This means that among the antecedents, individual and environmental elements and attributes are considered to influence each other. Additionally, Buckingham et al. (2016) showed that "Continuation of treatment" facilitates "Collaboration between patient and providers" and "Collabora-

Table 2. Antecedents of treatment engagement.

Characteristics	Examples	References
<Individual elements>		
Knowledge about disease and treatment	Knowledge of ADHD (Schoenfelder et al., 2017) Information on preventive treatment for AIDS (Monney et al., 2017)	Anand et al. 2015; Becker et al. 2020; Kraviz et al. 2013; Monney et al. 2017; Richwood et al. 2020; Schoenfelder et al. 2017; Sirey et al. 2013
Attitudes toward disease and treatment	Guilt and shame about continuing to use illegal drugs (Wild et al., 2016) Health concerns (Woodhead et al., 2013) Reduced concern about HIV medication (Jonse et al., 2013a) Perception that drug use cannot be controlled by oneself and requires formal intervention (Dillon et al., 2020) Patients can consider what is important for their health and choose their preferred screening and treatment options (Stacey et al., 2017)	Anand et al. 2015; Becker et al. 2020; Carpenter et al. 2020; Darcy et al. 2010; Dillon et al. 2020; George et al. 2016; Gouse et al. 2016; Ho et al. 2019; Houtepen et al. 2020; Jonse et al. 2013a, 2013b; Kern et al. 2014; McMurran et al. 2010; Richwood et al. 2020; Singth et al. 2013; Stacey et al. 2017; Stecker et al. 2016; Wild et al. 2016; Woodhead et al. 2013
Acceptance of disease	Accepting compulsive hoarding syndrome as a mental illness (Singth et al., 2013) Integrating oneself with being an HIV-positive patient (Ho et al., 2013)	Becker et al. 2020; Buckingham et al. 2016; Hack et al. 2020; Ho et al. 2019; Moucheraud et al. 2020; Sampson et al. 2013; Singth et al. 2013; Schoenfelder et al. 2017
<Situational elements>		
Negative experiences in the past	Loss of family members due to substance use (Dillon et al., 2020) Alcoholic's experience of failure to get sober (Dillon et al., 2020)	Dillon et al. 2020; Woodhead et al. 2013
Conditions and circumstances that allow patients to focus on treatment	Milder menopausal symptoms were more involved in HIV treatment (Solomon et al., 2020) Well-being of family (Becker et al., 2020)	Becker et al. 2020; McMurran et al. 2010; Solomon et al. 2020
<Environmental elements>		
Connecction with providers	Outreach (letters, face-to-face contact, phone calls) (Brenner et al., 2012) Increased communication between patients and health care providers (Jonse et al., 2013a) School and family connections (Becker et al., 2020) Hospitals to assess patients at home after discharge from emergency psychiatric facilities (Brenner et al., 2012)	Aggarwal et al. 2015; Becker et al. 2020; Brenner et al. 2012; Buckingham et al. 2016; Clarke et al. 2014a; Delaney et al. 2013; George et al. 2016; Goldberg et al. 2020; Jonse et al. 2013a, 2013b; Moucheraud et al. 2020; Nan et al. 2020; Singth et al. 2013; Stein et al. 2014; Yeh et al. 2019
Social support	Support from family and friends (Kelly et al., 2010) Support from community members and better local environment (Becker et al., 2020)	Becker et al. 2020; George et al. 2016; Jonse et al. 2013a; Kelly et al. 2010; Monney et al. 2017
Adaptive treatment systems	Accessibility (Acevedo et al., 2012) Treatment adjusted to account for participant preferences (Kern et al., 2014) Use of social media (Knight et al., 2016)	Acevedo et al. 2012; Aggarwal et al. 2015; Becker et al. 2020; Busch et al. 2018; Collins et al. 2017a; Dillon et al. 2020; Goldman et al. 2018; Guerreo et al. 2013; Kern et al. 2014; Knight et al. 2016; Kwan et al. 2010; Lindhelm et al 2010; Richwood et al. 2020; Silva et al. 2020; Singth et al. 2013; Tkach et al. 2019

tion between patient and providers" or facilitates "Attitudes that indicate value and expectations toward treatment" among youth who have mental health problems. This means that behavioral and psychosocial elements also influence each other among the attributes. This conceptual model explains that the process described above eventually leads to treatment retention, better clinical outcomes, and, consequently, coping with the disease and treatment.

6. Exemplar

To illustrate the concept of treatment engagement, we identified a pertinent exemplar, drawing on qualitative studies by Buckingham et al. (2016) and Colins et al. (2017a). The exemplar is a combined story created with reference to prior research to illustrate treatment engagement. Lucas (Alias) was advised by his family to use mental health services to

Table 3. Consequences of treatment engagement.

Characteristic	Examples	References
Treatment retention	Substance users stay in treatment for more than 90 days (Abdel-Salam et a., 2014)	Abdel-Salam et al. 2014; Clarkson et al. 2014; Collins et al. 2017a; Moucheraud et al. 2020
Better clinical outcomes	Improved depression in patients with depression (Skilbeck et al., 2020) Reduced illegal drug use among substance abusers (Gouse et al., 2016) Enhanced quality of life for girls detained in jail (Lore et al., 2015)	Brenner et al. 2012; Garnick et al. 2013; Gouse et al. 2016; Goodson et al. 2019; Harris et al. 2010; Kwan et al. 2010; Lindhelm et al 2010; Lore et al. 2015; Nan et al. 2020; Simeone et al. 2017; Skilbeck et al. 2020
Coping with disease and treatment	Introspection of patients with hepatitis C through psychosocial support (Woodhouse et al., 2013)	Kraviz et al. 2013; Woodhouse et al. 2013
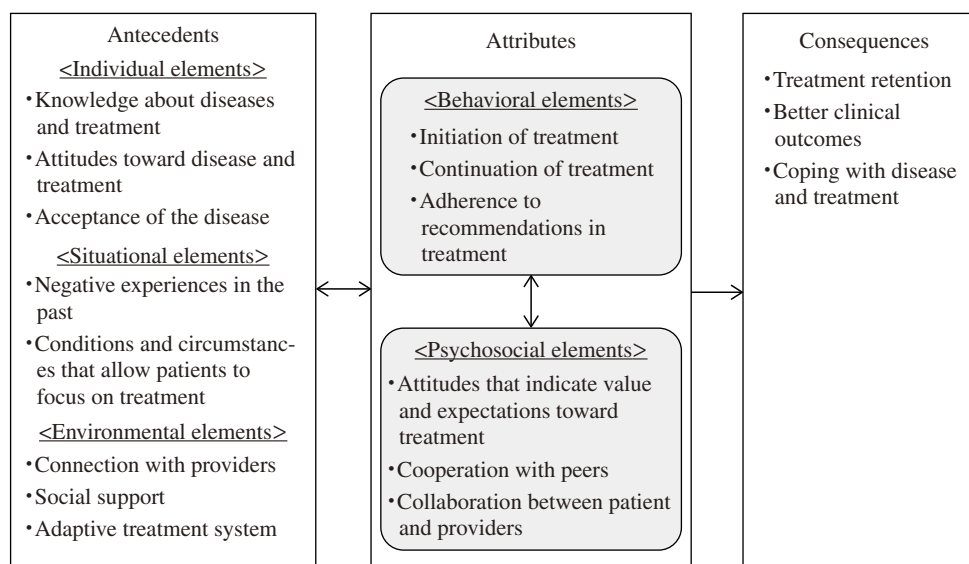
Figure 1. Results of the concept analysis of treatment engagement.

treat his drug addiction. At first, he was reluctant to use mental health services because he was concerned about what others would think. However, he gradually developed attitudes that indicate value and expectations toward treatment, wanting to change his situation and communicating his needs to his supporters. Additionally, he set goals for his treatment with his health care providers and shared his plans with them. In this way, he continued his treatment for more than 3 months while following the instructions of the medical staff and is now living independently in the community without using illegal drugs.

7. Related Terms and Surrogate Terms

Related terms refer to concepts that are related in some way to the target concept but do not share the same attributes (Rodgers & Knafl, 2000). As related terms for treatment engagement, "Adherence," "Patient participation," and "Patient engagement" were identified (Drew et al., 2016; Kern et al., 2014; Shrestha et al., 2017). "Adherence" is defined as "the

extent to which a person's behavior-taking medication, following a diet, and/or executing lifestyle changes corresponds with agreed recommendations from a health care provider" (WHO, 2003). "Adherence" is similar to treatment engagement in that it focuses on treatment behaviors such as medical examinations, taking medication, and self-management and emphasizes the psychological aspect of a positive attitude toward treatment and relationships with health care providers (WHO, 2003). Conversely, "Adherence" has a strong connotation of continuation of treatment behavior because it targets chronic diseases for which treatment is relatively long-term, whereas treatment engagement often targets populations for which it is difficult to initiate treatment, and it is about not only the continuation of treatment but also the initiation of treatment. Hence, treatment engagement encompasses both continuation and initiation of treatment. Therefore, although treatment engagement and adherence are related, they are considered to be different concepts.

"Patient participation" is defined as a "patient's rights and

opportunities to influence and engage in the decision making about his care through a dialogue attuned to his preferences, potential and a combination of his experiential and the professional's expert knowledge" (Castro et al., 2016). "Patient participation" is similar to treatment engagement in that it emphasizes the psychological aspect of a positive attitude toward treatment and the relationship with health care providers (Castro et al., 2016). Conversely, "Patient participation" does not include the behavioral elements of the patient among its attributes, whereas treatment engagement differs in that it includes the behavioral elements of initiation or continuation of treatment. Additionally, although "Patient participation" focuses on decision making in treatment (Castro et al., 2016), treatment engagement is different in that it focuses on receiving treatment. Therefore, although treatment engagement and "Patient participation" are related, they are considered to be distinct concepts.

"Patient engagement" is defined as "the desire and capability to actively choose to participate in care in a way uniquely appropriate to the individual in cooperation with a healthcare provider or institution for the purposes of maximizing outcomes or experiences of care." (Higgins et al., 2016). "Patient engagement" is considered to be similar to treatment engagement in that it emphasizes the psychological aspect of a positive attitude toward treatment and the relationship with health care providers (Higgins et al., 2016). Conversely, "Patient engagement," like patient participation, does not include patients' behavioral elements among its attributes, whereas treatment engagement differs in that it includes the behavioral elements of initiation and continuation of treatment. Therefore, although treatment engagement and "Patient engagement" are related, they are considered to be different concepts.

Additionally, a surrogate term refers to a semantic means of expressing a concept in a language other than the one chosen for analysis (Rodgers, 2000). Because treatment engagement was found to be a multidimensional and comprehensive concept, no adequate surrogate terms were identified.

Discussion

1. Theoretical Definition

In this study, we conducted a concept analysis of treatment engagement using Rodger's evolutionary method of concept analysis (Rodgers & Knafl, 2000). Consequently, the attributes of treatment engagement were extracted as behavioral elements, initiation of treatment, continuation of treatment, and adherence to recommendations in treatment, and as psychosocial elements, attitudes that indicate value and expectations toward treatment, cooperation with peers, and collaboration between patients and providers. Based on these results, treatment engagement was defined as "the process of

initiating and continuing treatment, and adhering to treatment recommendations, in cooperation with peers and in collaboration with supporters, accompanied by attitudes that indicate value and expectations toward treatment," This definition indicates that treatment engagement is a comprehensive and multidimensional concept that includes many elements.

2. Characteristics of the Concept

The six attributes of treatment engagement were divided into two dimensions, namely, behavioral and psychosocial elements. Many of the previous studies analyzed targeted the behavioral elements, and because these behavioral elements are factors that directly affect clinical outcomes (Brenner et al., 2012; Colins et al., 2017), they are considered to be important for explaining treatment engagement.

Regarding the psychosocial elements of the attribute, "attitudes that indicate value and expectations toward treatment," was extracted and bore similarities to the individual element among the antecedents of "attitude toward disease and treatment." The difference between the two is that only positive content was extracted for the attribute attitudes that indicate value and expectations toward treatment, whereas a content, both positive and negative, was extracted for the antecedent. Therefore, the characteristics of treatment engagement, in terms of patient attitudes toward treatment and disease, encompass both positive and negative attitudes in the process toward reaching a point of treatment engagement, but when patients are engaged in treatment, the characteristics are accompanied by positive attitudes.

Additionally, studies by Buckingham et al. (2016) and Colins et al. (2017) have shown that behavioral and psychosocial elements influence each other, and these elements are considered to be dynamic and contextual in nature. Therefore, as indicated in the previous definition, treatment engagement may be a process rather than a state at a single point in time. Given this, future studies should examine in detail the attributes as they relate to the process of treatment engagement.

Furthermore, a unique aspect of the concept of treatment engagement is that the behavioral component includes "initiation of treatment" and "continuation of treatment," which carry meanings particular to different contexts. In the articles extracted for this study, only a few references used "initiation of treatment" and "continuation of treatment" together within their concept of "treatment engagement" (e.g., Catherine et al., 2013), and most articles focused on one or the other. In many articles, the context in which each element is used varies. For example, "initiation of treatment" is an attribute of treatment engagement used in situations where treatment is unlikely to be initiated, and "continuation of treatment" is used in situations where treatment is unlikely to be continued treatment engagement attribute used

in situations where treatment is difficult to continue. In other words, the fact that they have multiple attributes with different contexts of use also suggests that their meaning may not be understood by the reader if they are just described as treatment engagement. Therefore, it was believed that treatment engagement should be explicitly defined, especially for studies that are focused on such behavioral elements of the concept.

3. Related Theories

Theories related to treatment engagement include those related to health behavior, such as the health belief model, the theory of planned behavior, and empowerment theory (Dillon et al., 2020; Stecker et al., 2010). In the health belief model and the theory of planned behavior, patients' attitudes toward disease and treatment are considered to be among the factors that explain health behaviors such as willingness to undertake medical examinations, which is consistent with the results of this study. Additionally, empowerment theory captures the concept of patients' positive attitudes toward treatment and their relationships with health care providers, which is consistent with the results of this study. However, these theories do not comprehensively explain the antecedents, attributes, and consequences of treatment engagement, and the construction of a theory unique to the concept of treatment engagement is required in the future.

4. Application to Clinical Practice and Further Research

Concept analysis clarifies the structure of a concept, which in turn elucidates what antecedents are necessary to promote the attributes that are the central properties of the concept. Among the antecedents described in this study "building relationships between patients and health care providers" is the foundation of treatment engagement, which promotes the achievement of patient goals and well-being (George et al., 2016). Nurses have a role to play in supporting treatment engagement through health screenings, medical examinations, and outpatient settings (Whittemore, 2013). Therefore, it was considered important for nurses to build a trusting relationship with patients and encourage them to build positive attitudes and behaviors toward treatment collaboratively.

Although the qualitative contents of treatment engagement were clarified and a theoretical definition of that was outlined in this study, this concept should be measurable for further research. Measuring the extent of this qualitative content of treatment engagement will help to clarify its relationship with other concepts. This process is a necessary part of testing theories or models of treatment engagement. Developing the scale of treatment engagement will be also useful for nursing practice, as it can serve as an indicator for evaluating treatment engagement in specific intervention programs. There are several measures of treatment engagement that have been developed, including the Service En-

gagement Scale (Tait et al., 2002), which measures engagement with community mental health services, and the Treatment Engagement Rating Scale (Drieschner & Boomsma, 2008), which measures offender treatment engagement. However, both of these are assessed by professionals. A scale that incorporates subjective evaluations of treatment engagement by the patients would be appropriate, because, in this study, we extracted attributes of treatment engagement that included the patients' perspective, such as positive attitudes toward treatment.

Additionally, most articles analyzed in this study focused on the attributes and antecedents of treatment engagement and did not examine what might happen after treatment engagement was achieved. Thus, examining the consequences of treatment engagement will contribute to the development of the concept in the future.

5. Limitations

This study was conducted using English-language articles only, which may have restricted the scope of the literature retrieved. There is a possibility of expanding the scope of the study beyond English language publications and deepening our understanding of the concept of treatment engagement as it applies to specific cultural contexts.

Moreover, it may be necessary to be careful in applying these results in various fields because there was a significant proportion of papers in the mental health field. This implies that the final concept and model may be useful for such a population.

Additionally, this study did not evaluate the quality of each article that was included in the final analysis. In the future, it may be beneficial to consider the quality of the collected literature to maintain the accuracy of the concept analysis.

Conclusion

In this study, we conducted a conceptual analysis of treatment engagement. Consequently, six attributes, eight antecedents, and three consequences were extracted. Treatment engagement was defined as "the process of initiating and continuing treatment, and adhering to treatment recommendations, in cooperation with peers and in collaboration with supporters, accompanied by attitudes that indicate value and expectations toward treatment." In clinical practice, our deepened understanding of the concept of treatment engagement suggests the important role that nurses and other health care workers have in building trusting relationships with patients and encouraging positive behavioral and psychosocial aspects of treatment.

least one of the following criteria [recommended by the IC-MJE (https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html)]: substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; drafting of the article; or critical revision of the ariticle for important intellectual content.

Declaration of Conflicting Interests

The authors have no conflicts of interest that are directly relevant to the content of this article.

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Review Article

Nursing care for people with concurrent heart failure and diabetes: A scoping review

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Abstract

There has been an increasing number of people with heart failure (HF) and with diabetes mellitus (DM). The number of people with concurrent HF and DM (HF-DM) is also expected to increase because of the strong relationship between both diseases. Several systematic reviews and meta-analyses have evaluated nursing care for each HF and DM, but none have been retrieved on nursing care for people with HF-DM. This study reviewed and categorized the literature on nursing care for people with HF-DM and aimed to identify the scope of further research that is still required. A scoping review was conducted following the framework of Arksey and O'Malley (2005). A broad range of keywords was used to systematically search the PubMed, MEDLINE, CINAHL, and Ichushi-Web databases for topics on nursing care for people with HF-DM. A total of 957 articles were retrieved, and 11 papers were ultimately accepted. Three of the 11 papers were randomized controlled trials (RCTs), which used integrated program interventions for people with HF-DM to some efficacy. For the remaining papers, a qualitative synthesis of the data identified six categories. Although a program integrating HF-DM presented a certain level of effectiveness, many of the nursing suggestions lacked specificity. Moreover, few RCTs have been conducted, which indicates the need for further research. This study also indicated the importance of collecting practical knowledge from advanced nurse practitioners and developing guidelines on nursing assistance for HF-DM.

Worldwide, the number of people with diabetes mellitus (DM) is increasing every year. In 2021, 537 million people were expected to have DM, and by 2045, the number is expected to increase to 784 million people (International Diabetes Federation, 2021). In Japan, the number of people with DM is also increasing, with the number of "persons strongly suspected of having DM" estimated at approximately 10 million (Ministry of Health, Labour and Welfare, 2017). The number of people with heart failure (HF) is also on the rise. The current 5.7 million people with HF in the United States are projected to increase to more than 8 million by 2030, whereas prevalence is expected to increase by 46% (Virani et al., 2021). The number of people with HF in Japan is similarly increasing and is estimated to reach 1.3 million by 2035 (Okura et al., 2008). The relationship between HF and DM is profound, with the incidence of chronic HF in people with DM being twice as high in men and five times higher in women than in people without DM

(Kannel et al., 1974). In an HF cohort study that includes both HF with reduced ejection fraction and HF with preserved ejection fraction, the prevalence of DM was reported to range from 10% to 47% (From et al., 2006; Shindler et al., 1996; Cleland et al., 2003; Dei Cas et al., 2014; Sandesara et al., 2018). The frequency of complications of DM was 30.7% in Japan (Hamaguchi et al., 2009). In people with DM, the prevalence of HF ranged from 9% to 22%, which was four times higher than that in people without DM (Nichols et al., 2004). Against the background of increasing figures for both HF and DM, those for HF-DM are also expected to increase globally.

To prevent exacerbations of both HF and DM, self-care is necessary, and people must maintain good glycemic control to prevent exacerbations of HF (Kishimoto et al., 2014). The American College of Cardiology (ACC) and American Heart Association (AHA) HF stages define HF as the stage at risk for HF, such as DM or ischemic heart disease. However, in stages C and D, which are symptomatic HF, physical function is compromised and symptom management is required; doing self-care is even more important to prevent recurrence. DM requires management of a DM diet, DM medication, monitoring of blood glucose levels, daily physical activity, monitoring of hypoglycemic symptoms, and foot care (Kerr et al., 2007). Additionally, HF requires following a low-sodium diet, taking HF medications, performing and interpreting daily weight measurements, engaging in physical activity, and monitoring symptoms of dyspnea, fatigue, and edema (Heart Failure Society of America, 2010). Nevertheless, approximately half of the people with DM have inadequate glycemic control (Japan Diabetes Clinical Data Management Study Group, 2019) and low self-care adherence (Peyrot et al., 2005), which suggests difficulties in implementing self-care. Moreover, people with HF have a high rate of rehospitalization within a year after discharge, and inadequate self-care to prevent the worsening of symptoms is a problem (Tsutsui et al., 2006). These indicate that the current situation makes self-care challenging for people with HF or DM alone. When both diseases are present, self-care behaviors become more complex, especially competing recommendations for diet, medications, and symptom management (Cha et al.,2012). Furthermore, the presence of HF may lead to a reduction in self-care priorities and capabilities for DM (Kerr et al., 2007). For these reasons, it is not easy for people with HF-DM to balance the self-care behaviors of both diseases, and it is important to support people by viewing them as people with HF-DM. Nursing includes the promotion of health, prevention of illness, and the care of ill, disabled, and dying people (International Council of Nurses, 2023). Therefore, for those with complex self-care requirements, nurses are the optimal self-care providers, and the care they provide, nursing care, is important for people with HF-DM.

Several systematic reviews and meta-analyses have separately evaluated nursing care for people with HF and DM (Daly et al., 2017; Lambrinou et al., 2012; Niu et al., 2021; Qiu et al., 2021; Rice et al., 2018; Son et al., 2020; Welch et al., 2010; Yu-Mei Chen et al., 2019). Nevertheless, nursing care for people with HF-DM is yet to be evaluated by studies. The American Heart Association and the HF Society of America summarizes the epidemiology, pathophysiology, and impact of DM on HF outcomes in people with concurrent type 2 DM and HF and also reviews the evidence for pharmacotherapy, such as hypoglycemic agents, the effects of exercise therapy, and the need for team-based care (Dunlay at al., 2019). However, it was not a focused analysis of nursing care. Thus, this study reviewed and organized the existing literature on nursing care for people with HF-DM and aimed to identify the scope of further research that is still required.

Methods

A scoping review was used as the research method. A scoping review adopts a broad view of the nature of the research topic, integrates existing knowledge without being bound by the research design, and maps differences and deficiencies in existing research findings (Munn et al., 2018). This study followed the framework of Arksey and O'Malley (2005), which implements the following steps: 1) identifying the research question; 2) identifying relevant studies; 3) selecting studies; 4) charting the data; 5) collating, summarizing, and reporting the results. We used the Population/Concept/Context (PCC) framework for this review. The PCC framework is recommended by the Joanna Briggs Institute, which is developing guidance for scoping reviews, to identify the main concepts in our primary review questions (Joanna Briggs Institute, 2020). The framework was defined as follows: Population: people with HF-DM; Concept: nursing care; and Context: any hospital department, including outpatient, inpatient, and community. HF was defined as symptomatic HF, that is, ACC/AHA HF stages C and D. Additionally, nursing care was defined as care practiced by nurses for people.

Identifying the Research Question

Primary review questions were defined according to the PCC framework that was set.

"What is effective nursing care and suggestions for people with HF-DM?"

Identifying Relevant Studies

To identify relevant studies, we searched the PubMed, MEDLINE, and CINAHL (for European literature) and Ichushi-Web (for Japanese literature), the latter of which is updated by the nonprofit, nongovernment organization Japan Association for Medical Abstracts. A literature search was

conducted on these databases on January 22, 2021. The following search formulas were used:

a) PubMed/MEDLINE/CINAHL: "TI diabetes" AND ("TI Heart failure" OR "TI heart disease") AND ("care" OR "nurse" OR "nursing"); and

b) Ichushi-Web: "TI tonyobyo (diabetes)" AND {"TI shinfuzen (heart failure)" OR "TI shinzobyo (heart disease)"} AND {"kango (nurse or nursing)" OR "kea (care)"}.

Selecting Studies

In selecting studies in a scoping review, the adoption criteria are set before the start of the study, and two reviewers independently decide whether to adopt the article. The same procedure was followed in this study. Based on the established PCC framework, the inclusion criteria were a) described nursing care for people with HF-DM, b) research article, and c) published in English or Japanese, regardless of the type, quality, or location of the study (outpatient, ward, community, etc.). The exclusion criteria were a) abstract not registered in the database and b) article not available.

For the primary screening, two researchers independently checked whether the retrieved articles met the criteria for inclusion based on the title and abstract of the article. The results of the two researchers were cross-checked, and if their opinions differed, a third researcher was consulted to discuss the results with the other two and decide whether to include the article. In cases where no clear decision could be made, the article was included. In the secondary screening, the full text was obtained, and two researchers independently confirmed whether the inclusion criteria were met. If the two researchers disagreed, the third researcher was again consulted to determine the final articles to be included.

Charting the Data

The data extracted were as follows: author, year of publication, country, purpose, study design, participants, sample size, and major findings in the study. Additionally, descriptions and implications regarding effective nursing care for people with HF-DM were extracted from the sections corresponding to the results, discussion, and conclusions of the research article. For randomized controlled trials (RCTs), the data extracted were the intervention content, eligibility criteria, exclusion criteria, outcome measures, and effect of the intervention. Two researchers independently confirmed the data extraction, and in cases of disagreement, a third researcher was called in to discuss and decide on the data extracted.

Collating, Summarizing, and Reporting the Results

For RCTs, the extracted data were summarized. Additionally, we decided to examine the effectiveness of the RCTs by critically evaluating them according to the Mixed Methods Appraisal Tool (MMAT, version 2018), which was de-

veloped to critically appraise different study designs (Hong et al., 2019). The MMAT allows for a critical appraisal process in reviews of systematic mixed studies, by providing methodological quality criteria for different study designs, within a single tool.

For other studies, qualitative integration of the data was performed. All the data obtained from the search results were carefully read to extract statements on the implications of nursing care for people with HF-DM. The results of the extracted studies were categorized according to similarity.

Results

Identification of the Relevant Studies and Eligibility

Figure 1 shows the flow diagram of the article selection process. In this study, 957 articles were retrieved: 352 from MEDLINE, 442 from PubMed, 154 from CINAHL, and nine from Ichushi-Web. Of 485 valid papers, we excluded 472 duplicates to include a final total of 11 papers (Table 1). Ten papers were published in English, whereas one was published in Japanese. The types of studies included nine quantitative studies, one qualitative study, and one mixed study, of which three were RCTs. All participants were patients. Furthermore, nine of the 11 papers were published after 2014.

Data Charting and Reporting

Summarizing the RCTs

Of the three RCTs, the Reilly et al. (2015) study was a secondary analysis of the Dunbar et al. (2015) study; thus, two of the studies actually implemented interventions. Two screening questions obtained from the MMAT manual were applied to two RCTs, that is, "Are there clear research questions?" and "Do the collected data address the research questions?"; all of the RCTs satisfied the two screening questions. Regarding MMAT scores, the Dunbar et al. (2014) study was Yes (4/5) and Cannot tell (1/5), whereas the Dunbar et al. (2015) study was Yes (4/5) and Cannot tell (1/5).

The participants were people with HF-DM who were either hospitalized or attending outpatient clinics. The interveners were trained nurses, and the interventions were not stand-alone but were delivered on multiple occasions on an ongoing basis. The interventions were conducted with individual education and counseling, phone calls, with both studies further conducting home visits. The educational tools were designed to integrate data on HF-DM and written at the elementary school reading level. They also included information on the pathogenesis and interactions of HF-DM, diet, activities, medications, oral care, foot care, smoking, and self-monitoring. Knowledge, self-efficacy, self-care behaviors, and quality of life (QOL) were the outcome measures used by Dunbar et al. (2014), whereas QOL, 6-minute
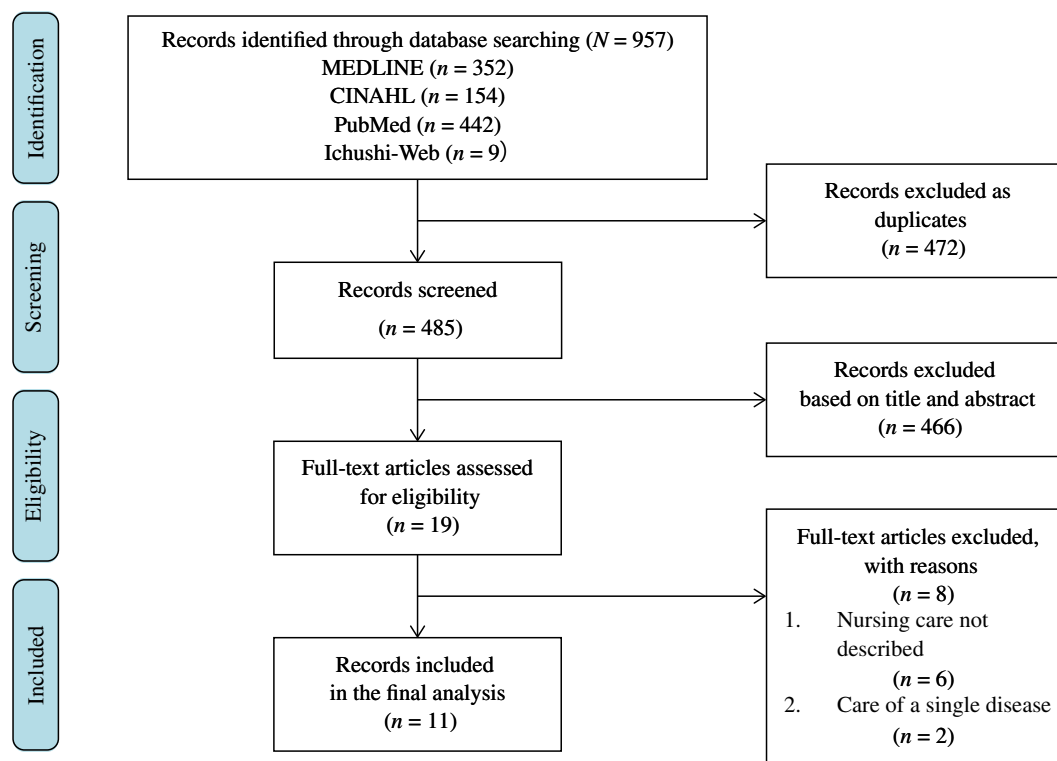
Figure 1. Flow diagram of the study selection process.

walk test (6MWT), Community Healthy Activities Model Program for Seniors were used by Dunbar et al. (2015). Alternatively, Reilly et al. (2015) used resource use and cost determination and effectiveness measures. The effects of the intervention in the Dunbar et al. (2014) study were HF knowledge at 30 days after intervention, improved HF self-care maintenance at 30 days after intervention and sustained to 90 days after intervention, improved self-care management at 90 days after intervention, improved DM self-efficacy at 30 and 90 days after intervention, improved self-reported general diet and exercise at 30 days after intervention, and improved foot care by 90 days after intervention. However, no effects were observed on DM knowledge, DM-specific QOL, and HF self-efficacy. Moreover, the effects of the intervention in the Dunbar et al. (2015) study included greater improvements in HF total, physical, and emotional QOL and general QOL. The effects of the interventions were also observed in improved physical function, as measured by the 6MWT and self-reported physical activity. However, no effects on DM QOL were observed. The study by Reilly et al. (2015) demonstrated dominance in lowering costs without sacrificing quality-adjusted life years.

Qualitative Categorization and Nursing Suggestions for People with HF-DM

Six categories were generated by categorizing the descriptions of nursing suggestions for people with HF-DM extracted from eight studies (excluding RCTs) according to similarity (Table 2).

Development of Education Guidelines that Integrate HF-DM Management

The need to develop education guidelines that integrate HF and DM management, rather than separate them, was mentioned.

A study examining the follow-up of people with HF-DM found that DM management should be given the same importance as HF management due to the lack of professional intervention for DM both during hospitalization and after discharge (Wu et al., 2018). Conversely, the study also found that people with HF-DM comorbidities who participated in the HF-only program had better DM self-care behaviors. This suggests that as people with HF age and develop more comorbidities, such as DM, an important strategy for improving the treatment of HF-DM is to consider HF disease management (Ware et al., 2006). The need for integrated interventions focusing on HF-DM was also described in a study that investigated self-care determinants in people with HF-DM (Aga et al., 2019) and in another that identified predictors of DM self-care behavior (Ausili et al., 2016). Nevertheless, although the abovementioned studies emphasized the need for integrated interventions for HF-DM, they did not mention specific interventions.

In the aim to describe more specific nursing suggestions, the authors found that people with HF-DM had a significantly lower carbohydrate intake but a higher sodium intake than people with HF alone and consequently proposed the need to develop standardized dietary guidelines for people

Table 1. Studies included in the scoping review.

Author (s) (Year)	Country	Study design	Purpose	Participants (n)	Major findings
Ware et al., 2006	USA	Single-center, prospective observational study	To test the hypothesis that a focus on HF care may be associated with inadequate DM care	Patients with DM enrolled in an HF disease management program ($n = 78$)	Ninety-five percent of patients had hemoglobin A1c levels measured within 12 months, and 71% monitored their glucose at least once daily. Most patients received counseling regarding a diabetic diet and exercise, and approximately 80% reported receiving regular eye and foot examinations. The mean hemoglobin A1c level was 7.8% ± 1.9%. Patients in an HF disease management program demonstrated levels of diabetic care close to American Diabetes Associations' goals.
Cha et al., 2012	USA	Cross-sectional, correlational design	To explore the need for self-monitoring and self-care education in patients with HF-DM by describing cognitive and affective factors to provide guidance in developing effective self-management education	NYHA Class II & III persons with HF ($n = 116$; HF, $n = 70$; HF-DM, $n = 46$)	Patients with HF-DM were older, heavier, had more comorbidities, and took more daily medications than HF patients. High self-efficacy on medication and low sodium diet was reported in both groups with no significant difference. Although HF-DM patients took more daily medications than HF, both groups exhibited high HF medication-taking behaviors. The HF-DM patients consumed significantly lower total sugar than HF patients, but clinically higher levels of sodium.
Dunbar et al., 2014	USA	Randomized controlled trial	To develop and test an integrated self-care education and counseling program for its short-term effects on self-care antecedents and behaviors; to examine the feasibility of such an integrated intervention	Patients with HF-DM (aged 21–80 years) ($n = 65$; usual care, $n = 19$; intervention, $n = 46$)	An integrated HF-DM self-care intervention was effective in improving essential components of self-care and had sustained (90 days) effects on selected self-care behaviors. The data revealed that the integrated HF-DM self-care intervention conferred effects on HF knowledge at 30 days, improved HF self-care maintenance at 30 days and sustained to 90 days, improved self-care management at 90 days, improved DM but not HF self-efficacy at 30 and 90 days, improved self-reported general diet and exercise at 30 days, and improved foot care by 90 days.
Dunbar et al., 2015	USA	Randomized controlled trial	To test an integrated self-care intervention on outcomes of QOL, physical function, and physical activity in HF and DM	Patients with HF-DM (aged 21–80 years) ($n = 134$; usual care, $n = 64$; intervention, $n = 70$)	An integrated HF and DM self-care intervention improved perceived HF and general QOL but not DM QOL. Improved physical functioning and self-reported physical activity (PA) were also observed with the integrated self-care intervention. Those who received an integrated self-care intervention experienced greater improvements in HF total, physical, and emotional QOL, and general QOL, but not DM QOL, when compared with a usual care attention control group. Additional effects observed included improved physical function as measured by the 6-minute walk test and self-reported PA.
Reilly et al., 2015	USA	Randomized controlled trial (secondary analysis of data)	To conduct a prospective cost-effective analysis of a randomized clinical biobehavioral trial focused on improving comorbid self-care for people with HF-DM	Same as S. Dunbar et al. (2015)	The self-care intervention demonstrated dominance in lowering costs without sacrificing quality-adjusted life years.
Ausili et al., 2016	ITA	Secondary analysis of data from a multicenter cross-sectional study	(1) To compare self-care maintenance, self-care management, and self-care confidence of patients with HF-DM versus patients with HF without DM; (2) To determine whether the presence of DM influences self-care maintenance, self-care management, and self-care confidence of HF patients; and (3) To identify sociodemographic and clinical determinants of self-care maintenance, self-care management, and self-care confidence in patients with HF-DM	Adults with a confirmed diagnosis of HF ($n = 1,192$; with DM, $n = 379$)	Self-care was poor in patients with HF-DM. Statistically significant differences were found in self-care maintenance, self-care management, and self-care confidence in patients with HF with and without concurrent DM. The presence of diabetes did not influence self-care maintenance, self-care management, or self-care confidence. Age, number of medications, presence of a caregiver, family income, and self-care confidence were determinants of self-care maintenance. Sex, number of medications, and self-care confidence were significant determinants of self-care management. The number of medications and cognitive function were determinants of self-care confidence.

Table 1. Studies included in the scoping review (continued).

Author (s) (Year)	Country	Purpose	Study design	Participants (n)	Major findings
Wu et al., 2018	UK	(1) To assess the differences in the number of hospital readmissions between patients with HF and patients with HF-DM; (2) To assess the use of an integrated care approach for patients with HF-DM during the index HF-related admission; and (3) To explore patient experiences of admissions	Mixed methods approach	(1) Patients with HF (n = 370; with concurrent DM, n = 172); (2) Both conditions of DM and HF; ≥18 years old; with an ejection fraction of <45% at the index HF admission (n = 72); (3) Patients with HF-DM who had current or recent admissions (n = 14)	Over a 12-month period, patients with HF-DM had more HF-related accident and emergency attendance episodes and hospital readmissions than patients with HF. We reviewed 72 medical records, which met the inclusion criteria during admission. Most of them were reviewed by HF specialists, but less than one-third were reviewed by DM specialists. The interview respondents addressed the need for better integration and coordination of care.
Aga et al., 2019	USA	To describe sociodemographic, clinical, and psychosocial correlates of DM self-care behaviors in adults with HF-DM	Cross-sectional, correlational design (Secondary analysis of data)	Patients with HF-DM (aged 21–80 years; n = 180)	The number of comorbidities > 2 (p <.001), having more than a high school education (p <.05), and African American ethnicity (p <.05) predicted better exercise, SMBG, and foot care behaviors, respectively. The use of an aldosterone inhibitor (p <.05) predicted worse exercise performance, higher Charlson Comorbidity Index scores (p <.01) worse SMBG, and treatment with diet plus medication (p <.05). Dyslipidemia (p <.001) predicted worse foot care.
McCants et al., 2019	USA	To determine the impact of integrated case management services versus treatment as usual for patients diagnosed with HF-DM	A retrospective, descriptive, and comparative analysis	Patients diagnosed with HF-DM (n = 68)	In the integrated case management group, 18.4% were readmitted, whereas 81.6% were not. In the treatment as usual group, 52.6% were readmitted and 47.4% were not. Integrated case management services were statistically significant in reducing readmission for the sample.
Yamazaki et al., 2019	JPN	To clarify the experiences associated with the care behaviors of patients with HF-DM with poor glycemic control	A qualitative study; semi-structured interviews	Patients with HF-DM with poor glycemic control (n = 10)	For the experiences associated with self-care behaviors, 14 categories were obtained, including "struggling to balance the different and conflicting treatment behaviors of diabetes and heart failure," "equating treatment behaviors of diabetes and heart failure," "judging criteria for treatment behaviors based on changes in numerical values and subjective symptoms," and "priority for heart failure based on severe physical symptoms and awareness of death."
Aga et al., 2020	USA	To describe sociodemographic and clinical correlates of DM self-efficacy in T2D adults with comorbid HF	Correlational design (secondary analysis of data)	Same as F. B. Aga et al. (2019)	Good self-rated health and the presence of an implantable cardioverter-defibrillator had significant positive relationships with DM self-efficacy. Conversely, taking both oral anti-glycemic medication and insulin, a history of depression, having a cardiac pacemaker, and taking digitalis were negatively correlated with DM self-efficacy. Patients of African American descent with HF-DM had significantly lower diabetes self-efficacy scores compared with their White counterparts. A significant negative correlation was found between LVEF and DM self-efficacy scores. Patients with HF-DM without end-organ failure had significantly higher mean DM self-efficacy scores compared with those with end-organ failure.

HF: heart failure; DM: diabetes mellitus; T2D: Type II diabetes; HF-DM: heart failure with diabetes mellitus; SMBG: self-monitoring blood glucose; LVEF: left ventricular ejection fraction.

with HF-DM (Cha et al., 2012). Additionally, Yamazaki et al. (2019) revealed the experience of HF-DM who try to find commonalities and perform them in a simplified manner without distinguishing them rather than considering and executing self-care behaviors for both diseases individually. They also recognized the need to help simplify self-care behaviors for both diseases by integrating self-monitoring tools that record the results of measurements, such as weight and blood glucose levels, and by focusing on the treatment methods common to both diseases, such as diet and exercise.

Consideration for Contradictions and Conflicts Between HF and DM Management

The need for consideration of the different and sometimes conflicting management methods for HF-DM was identified.

Cha et al. (2012) found that people with HF-DM tended to have a significantly lower carbohydrate intake but a higher sodium intake than people with HF alone. Accordingly, they stated that nurse educators need to realize this gap and assess people's current knowledge, confidence, skills, and behaviors related to the requested treatment regimens for both conditions. They further suggested that strategies to solve problems and barriers should be included in self-management education. Yamazaki et al. (2019) described the self-care experience of people with HF-DM who struggled to balance the conflicting self-care behaviors required to control HF and DM respective diseases. The study also recommended the fact that people are required to undergo conflicting treatments and are easily confused in their perception of their disease.

Individualized Approach

The need for an individualized approach, rather than a one-size-fits-all one, to people with HF-DM was recognized.

An investigation on the predictors of DM self-care behaviors in people with HF-DM suggests the importance of using the available resources for self-monitoring of blood glucose (SMBG) and tailoring DM self-care education to the people's level of understanding, considering that higher education is associated with higher rates of SMBG implementation (Aga et al., 2019). Based on the self-care behavior experiences of people with HF-DM, Yamazaki et al. (2019) highlighted the need to understand how people deal with HF-DM and what their current perceptions are of the "disease trajectory," as well as to understand the disease phase of the people through sufficient dialog. They also mentioned the need to strengthen DM self-care support using numerical values and subjective symptoms, as well as to help people take an interest in their own bodies.

Interventions Based on Appropriate Screening for Self-Care Risks

The need to intervene after screening people with HF-DM for risks that may affect self-care was cited.

In a study investigating self-care among people with HF-

DM, the determinants of self-care maintenance, self-care management, and self-care confidence, each of which constitutes self-care in people with HF, were identified (Ausili et al., 2016). Age, number of medications, presence of a caregiver, family income, and self-care confidence were determinants of self-care maintenance. Gender, number of medications, and self-care confidence were determinants of self-care management. Number of medications and cognitive function were determinants of self-care confidence. These findings indicate that systematic assessment, especially assessment of self-care confidentiality, is important to identify people at risk for inadequate self-care. The results further showed that the rate of SMBG implementation decreased with increasing comorbidity, suggesting that DM self-care management becomes more complex with more comorbidities, which increase the psychological and economic burden and predisposition to depression (Aga et al., 2019). Moreover, a study that investigated the relationship between DM self-efficacy and health status revealed that DM self-efficacy was higher in people with a higher self-evaluation of their health status, suggesting that people with low health awareness need special support to increase their DM self-efficacy (Aga et al., 2020). The study also stated that depressive symptoms should be regularly assessed and alleviated since they are associated with DM self-efficacy.

Professional Cooperation and Collaboration Between HF and DM Teams

For people with HF-DM, the respective teams for HF and DM should not only be involved with the people separately but also need to cooperate and collaborate. Furthermore, nurses need to coordinate between the two teams.

A study assessing the current status of people with HF-DM after discharge from the hospital found that 69.4% of people were followed up in the HF clinic after discharge, but only 2.8% were referred to the DM clinic (Wu et al., 2018). The results also indicate that professionals from multidisciplinary teams need to take a coordinated and integrated approach to people with HF-DM. Furthermore, considering that people with HF-DM have self-care behavior experiences that require support from others, including healthcare providers, the paper described the need for nurses to facilitate a multidisciplinary team collaboration that includes physicians, rehabilitators, and pharmacists and to serve as intermediaries to maintain good people-healthcare provider relationships (Yamazaki et al., 2019). Furthermore, the importance of case management was discussed based on the results of an integrated case management service for people with HF-DM that reduced readmissions (McCants et al., 2019).

Development of Social Support and Resources

Besides direct support for people with HF-DM, social support and resources must also be developed.

Yamazaki et al. (2019) investigated the experiences asso-

Table 2. Nursing suggestions for people with heart failure and diabetes.

Nursing suggestions	Descriptions
Development of Education Guidelines that Integrate HF-DM Management	As the HF population ages and comorbidities such as diabetes become more prevalent, HF disease management should be considered an important strategy to improve both cardiac and diabetic care. (Ware et al., 2006)
	A future study should revisit these findings to explore the powers of specific and achievable objectives and to develop standardized dietary guidelines for HF-DM patients. (Cha et al., 2012)
	Finally, integrated methods and interventions, focusing both on heart failure and diabetes, should be tested to enhance self-care in this unique and growing patient population. (Ausili et al., 2016)
	The in-depth examination of inpatient care processes and the exploration of patients' views on their admissions suggest diabetes management should be considered as important as heart failure management during their admissions (Wu et al., 2018)
	Nurses who are involved in caring for people with both heart failure and diabetes must provide them with sufficient education and support addressing both conditions, as well as liaising with other healthcare team members during their admission. (Wu et al., 2018)
	Given the expected rise of T2D-HF in the foreseen future, increased research on self-care interventions that incorporate an integrated approach will be vital for improving clinical outcomes in the management of complex and coexisting chronic conditions. (Aga et al., 2019)
	It is effective to provide support to simplify treatment behaviors for both diseases, such as a single tool for self-monitoring to record measured values and guidance that focuses on treatment methods such as diet and exercise that are common to both diseases. (Yamazaki et al., 2019)
Consideration for Contradictions and Conflicts Between HF and DM Management	Diabetes educators need to be aware of potential conflicts of treatment regimens to manage two chronic diseases. (Cha et al., 2012)
	The results of this study revealed that having both diabetes and heart failure, which have different self-care behaviors, causes not only a sense of psychological burden but also a confusing experience in the perception of the illness. Confusion in the perception of illness may lead to incorrect self-care behavior, suggesting the importance of confirming the level of understanding of each self-care behavior. (Yamazaki et al., 2019)
Individualized Approach	Evaluating available resources, identifying barriers to self-care, and tailoring diabetes self-care education to the patient's level of understanding is essential for better management and preventing complications associated with T2D. (Aga et al., 2019)
	It may be effective to strengthen diabetes self-care support using numerical values and subjective symptoms, as well as approaches to help people take an interest in their own bodies. It may be effective to strengthen diabetes self-care support using numerical values and subjective symptoms, as well as approaches to help people take an interest in their own bodies. (Yamazaki et al., 2019)
	The process of how patients are dealing with chronic diseases such as diabetes and heart failure and how they are currently perceiving the disease as an "illness trajectory" through sufficient dialog should be understood. Then, it would be effective to intervene on that basis. (Yamazaki et al., 2019)
Interventions Based on Appropriate Screening for Self-Care Risks	We recommend that clinicians systematically evaluate these risk factors to identify patients at risk. Particularly, we recommend an evaluation of self-care confidence, because interventions aimed at improving confidence may be particularly effective in improving self-care. (Ausili et al., 2016)
	It is possible that each additional chronic illness may potentially complicate diabetes self-care management, increase psychological and financial burden, and have reduced motivation for performing diabetes self-care. Greater disease burden likely contributed to increased depressive symptoms and lower perceived health status among our participants. (Aga et al., 2019)
	Alleviating depressive symptoms could help to enhance patients' confidence and attention and ultimately Improve diabetes self-efficacy. Our findings also suggest that addressing treatment and comorbidity burden and alleviating depressive symptoms could help us to Improve diabetes self-efficacy in adults with T2D and comorbid HF. (Aga et al., 2020)
	Findings from this study indicate that lower perceived health status in particular may provide an opportunity to examine the person's confidence in performing self-care behaviors such as medication and dietary adherence essential for better health outcomes in T2D and HF. Therefore, future interventions aimed at enhancing the self-efficacy of patients with T2D-HF should give special emphasis to those with lower perceived health status. (Aga et al., 2020)
Professional Cooperation and Collaboration Between HF and DM Teams	In future practice, healthcare professionals from all the relevant teams must take a collaborative and integrative approach for patients with both heart failure and diabetes. (Wu et al., 2018)
	This retrospective, descriptive, comparative analysis study confirms that case management services in comparison with treatment as usual for hospitalized individuals diagnosed with HF and diabetes are effective in reducing readmissions. (McCants et al., 2019)
	Extending the length of stay for patients who are not medically ready for discharge should be considered because there is a cost difference, as there is evidence of readmission reduction. (McCants et al., 2019)
	Nurses must coordinate collaboration between the multidisciplinary team, including doctors, rehabilitation, and pharmacists, and act as intermediaries to maintain good patient-provider relationships. (Yamazaki et al., 2019)
Development of Social Support and Resources	For persons with T2D-HF without adequate social support, educational groups that promote observational learning and utilize positive role models may be beneficial for improving participation and adherence to diabetes self-care and clinical outcomes. (Aga et al., 2019)
	It is important to help create a supportive environment by checking the patient's surroundings, including how they feel about supporting others; whether they have support from family, friends, and others; and whether they are considering introducing care services. (Yamazaki et al., 2019)

ciated with self-care behaviors of people with HF-DM and found that although the people were prepared to manage their disease by themselves without depending on others, they also felt the need for support. The study described the importance of support in assessing the people's situations and creating a supportive environment. The study assessed how people felt about supporting others; whether they had support from family, friends, and others around them; and whether they were considering availing of nursing care services. Furthermore, for people without adequate social support, such as from family and friends who are successfully managing DM, encouraging observational learning and education with positive role models can be effective (Aga et al., 2019).

Discussion

Only 11 articles on nursing care for people with HF-DM were included for analysis. Of these, only one was published in Japan, making this scarcity of studies particularly striking. Nevertheless, the rapid increase in the number of research papers since 2014 indicates that the field of nursing care for people with HF-DM is beginning to attract attention.

The present review suggests that RCTs with quality assessment by MMAT have shown that programs integrating HF-DM have some effectiveness. These findings clearly indicate the importance of providing nursing interventions that integrate HF-DM rather than nursing interventions for each disease. Notably, the educational tool was designed to integrate HF-DM data, and the intervention was delivered by trained nurses. As mentioned earlier, self-care behaviors are complicated when both HF and DM are present. Furthermore, the management of both diseases can be conflicting. Thus, education for each disease was not expected to solve the problem. The current review has shown the effectiveness of using educational tools that integrate HF-DM data, and the use of integrated educational tools may help address the complexity and conflict of self-care behaviors in people with HF-DM. It is also important that the effectiveness of these RCTs was produced by interventions by trained nurses. However, it was suggested that nursing care for people with HF-DM requires particular training, whereas the RCTs in this review did not identify specific training content. Another future research question for effective nursing care for HF-DM patients is what type of nurse education to provide.

One of the challenges is also the small number of RCTs. Only three RCTs were retrieved in this review, all of which were conducted in the United States. Moreover, because the studies were conducted by the same research group, the regions sampled were limited. As healthcare systems differ around the world (Mossialos et al., 2016), programs tailored to the healthcare systems of each country and region are necessary. Additionally, since various factors, such as poverty, education, race/ethnicity, age, and disability, may affect the health literacy of individuals (Kutner M et al., 2006), programs that match the health literacy issues of each country and region must be established. More studies on nursing care, including qualitative studies, are needed for the development of a program for HF-DM and based on the results, which is important to develop and evaluate programs. Moreover, to clarify the effectiveness of an integrated program for HF-DM, conducting more RCTs and accumulating the results of these RCTs are essential in order to create a program that meets the challenges of healthcare systems and health literacy around the world. Furthermore, since no RCTs evaluating people with HF-DM have been conducted in Japan, programs that are tailored to the Japanese healthcare system must urgently be developed, and more studies on nursing care for people with HF-DM are needed.

The current review generated six categories of suggestions for nursing care for people with HF-DM. The identification of these suggestions for nursing care was very helpful in examining effective care for patients with HF-DM. Nevertheless, a challenge is the lack of specificity in these suggestions. "Development of education guidelines integrating HF-DM management" only described the necessity of such guidelines and did not provide specific directions for nursing assistance, as was observed in several cases. The specific suggestions presented were the need for standardized dietary guidelines for HF-DM, unification of self-monitoring tools, and common treatment methods for both diseases related to diet and exercise. Nonetheless, further research is required to clarify specific nursing assistance, and guidelines that reflect the opinions of experts must be developed. "Interventions based on appropriate screening for self-care risks" indicated the need for the assessment of self-care confidence, self-efficacy, and depressive symptoms. However, the contents of these screenings were inadequate and did not constitute a systematic risk assessment. Additionally, since self-care risk may differ across countries and regions, more encompassing research on self-care risk in people with HF-DM must be conducted, and a specific and systematic self-care risk assessment index tailored to each country and region should be developed. "Professional cooperation and collaboration between HF and DM teams" suggested that team-based care for people with HF-DM requires collaboration between the HF and DM specialist teams rather than independent intervention. An important premise of the chronic care model is team-based care, which usually includes physicians and advanced practice providers, nurses, pharmacists, nutritionists, social workers, and community health workers (Proia et al., 2014). However, even in these respects, differences exist among national and regional healthcare systems, and each may have its own challenges. Hence, a policy for professional collaboration that is appropriate for each coun-

try and region must be developed, and the impact of team medicine practices on people's outcomes should be investigated. Moreover, to determine how exactly HF-DM teams should collaborate, as well as to establish the role of nurses in initiating team medicine, further research is needed.

Another challenge is the lack of established guidelines for nursing assistance integrating HF-DM. In this review, six categories were presented as suggestions for the nursing care of people with HF-DM. However, these suggestions were not adequately reflected in the RCTs. The contents of these nursing suggestions may be important factors in providing appropriate care for people with HF-DM. Hence, specific nursing assistance guidelines for people with HF-DM that incorporate these nursing suggestions should be developed. Moreover, we believe that the practical knowledge possessed by nurses in the field of HF or DM can contribute to the development of these integrated nursing assistance guidelines for people with HF-DM. Among other things, we believe that practical knowledge by advanced practice nurses who have received advanced education in nursing care can contribute to these efforts. In the United States, the clinical nurse specialist (CNS) certification is issued for advanced practice nurses (National Association of Clinical Nurse Specialists, 2021). In Japan, similar certifications for advanced practice nurses are also issued, such as Certified Nurse Specialist and Nurse Practitioner (Japan Association of Nursing Programs in Universities, 2021). We believe that the nursing practice of these advanced practitioners for people with HF-DM should be refined. Therefore, we will not only compile examples of advanced nursing practices but also conduct interviews with many advanced practice nurses to clarify the structure and direction of their practice, which will facilitate the development of assistance guidelines.

Limitations

This review investigated the implications of nursing care for people with HF-DM, clarified the scope of the study, and provided baseline information for future research. Nevertheless, the results were derived from a small number of studies. Moreover, submission of this review was long a time from the date of the search (January 22, 2021). This may not reflect the most recent situation, as the number of articles has been increasing since 2014. Furthermore, as characteristic of a scoping review, a quality assessment of the studies was not conducted. These attributes may thus limit the reliability of the study results.

Conclusion

A scoping review of effective nursing care for people and suggestions for people with HF-DM found three articles on integrated HF and DM self-care interventions in RCTs,

which extracted and summarized content of the three articles and found improvements in essential elements of self-care such as HF knowledge, self-care, QOL, DM self-efficacy, physical function, self-reported physical activity, and demonstrated dominance in lowering costs without sacrificing quality-adjusted life years but no improvement in DM QOL. Additionally, six categories were generated by categorizing the descriptions of nursing suggestions for people with HF-DM extracted from eight studies (excluding RCTs): "Development of Education Guidelines that Integrate HF-DM Management," "Consideration for Contradictions and Conflicts Between HF and DM Management," "Individualized Approach," "Interventions Based on Appropriate Screening for Self-Care Risks," "Professional Cooperation and Collaboration Between HF and DM Teams," and "Development of Social Support and Resources." However, many of the suggestions lacked specificity and few RCTs have been conducted. It was suggested that more research should be conducted on nursing care for people with HF-DM in order to develop programs and nursing assistance guidelines for them and to proceed with RCTs based on these guidelines.

Author Contributions

Yusuke Yamazaki designed the study, and Sumie Kuroda supervised the analysis and critically revised the work. Yusuke Yamazaki and Misaki Sawaoka equally contributed to the literature search and data analysis. Yusuke Yamazaki drafted the article. All authors reviewed and accepted the final form.

Declaration of Conflicting Interests

Ethical Approval

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Original Research

Typology of hunger sensation perception in patients with type 2 diabetes

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Abstract

Objective: This study is aimed to identify how patients with type 2 diabetes perceive hunger using a questionnaire based on the results of a previous study and characterize how they perceive hunger. **Methods:** First, we drafted a 46-item questionnaire based on previous studies. Next, we subjected the draft questionnaire to exploratory factor analysis and assessed its reliability based on item validity and internal consistency. Finally, we confirmed the possibility of classification through hierarchical cluster analysis and determined whether the classified types were related to HbA1c and body mass index, which are indicators of diabetes control. The inclusion criteria involved participants who were 20 years of age or older, outpatients at a hospital or clinic, and diagnosed with type 2 diabetes for at least 6 months. **Results:** The participants were 147 patients with type 2 diabetes, with a mean age of 59.5 ± 12.7 years. We developed a 25-item, six-factor questionnaire to assess hunger perception in patients with type 2 diabetes mellitus. Afterward, the construct was compared with previous studies. The cumulative contribution of the six factors was 53.7%, with a Cronbach's alpha coefficient of reliability of 0.875 for the full questionnaire. A hierarchical cluster analysis based on the factor scores of the questionnaire showed that there were two groups, namely, an "all factors high score group" and an "all factors low score group." Notably, HbA1c was significantly higher in the "all factors high score group." **Conclusions:** In this study, a questionnaire based on previous research allowed us to typify how patients with type 2 diabetes perceive hunger.

Introduction

In order to achieve treatment goals while maintaining effective behavioral management and psychological health, interventions, such as diabetes self-management education and support, are important (American Diabetes Association, 2021). Good glycemic control requires self-management be-

haviors, and theory-based self-management education is effective in improving HbA1c, self-efficacy, and diabetes knowledge (Zhao et al., 2016). Nevertheless, reportedly, it takes 2-8 months to change behavior after education. This is especially the case with diet-related behaviors, which has a low implementation rate of approximately 30% of 7 days (Marinho et al., 2018; Alhaiti et al., 2020), and many pa-

tients struggle with diet management (Schmidt et al., 2020; Polhuis et al., 2020). Particularly, according to studies, patients with type 2 diabetes often fail to take action, even when they understand dietary knowledge (Willig et al., 2014). Moreover, notably, diet restricts dietary freedom and is most implicated in reduced quality of life (Shim et al., 2012).

These are reported difficulties in managing behavior and maintaining psychological well-being, which patients with diabetes must now continue to do for the rest of their lives. In a previous study, patients with type 2 diabetes experienced challenges and exhaustion when attempting to adhere to and continue with their diets, with a common theme of "I understand the need, but I can't do it." That is, patients felt hunger, which required the coping behavior of endurance. In this context, the causes of difficulty in attempting to follow a diet can be explained in two ways including "I don't have enough patience" and "the condition of diabetes is affecting me." (Nagamune et al., 2020). Furthermore, based on the experience developed through diabetes education and treatment, patients lived with the physical sensation of "not knowing" whether their hunger was "intolerable" or "affected by the pathophysiology of diabetes." It was inferred that the patients felt ambiguity in their own "physical sensation" of hunger because of their diabetes. Thus, we focused on the feeling of hunger in patients with type 2 diabetes.

Hunger sensation, along with satiety, has been studied since it relates to eating (Ogden et al., 2013; Pritchard et al., 2014; Rogers et al., 2016). Blood glucose levels and blood concentrations of free fatty acids stimulate the satiety and feeding centers, which results in feelings of satiety and hunger. It is generally regulated by homeostatic and cognitive mechanisms. Moreover, it is regulated by signals from the gastrointestinal tract and central nervous system (Davis, 2018), particularly ghrelin, which is derived from the gastrointestinal tract and acts on the central nervous system to promote appetite and increase food intake and is involved in both homeostatic feeding and preferences and nonhomeostatic feeding, including pleasure eating (Davis, 2018; Howick et al., 2017). Ketone body formation increases hunger between meals and at night in compensated type 2 diabetes, whereas the lack of ketone body formation increases daytime hunger in noncompensated type 2 diabetes (Cugini et al., 1996). Additionally, insulin hypersecretion is associated with increased leptin levels, with higher leptin levels in high insulin resistance (Wauters et al., 2003) and lower leptin levels in nonobese individuals with diabetes (Mohammadzadeh et al., 2013). Hence, endocrine metabolism and circadian rhythms may affect diabetes mellitus. Furthermore, hunger sensation is viewed as one of the internal senses that make us aware of body homeostases, such as pain, itchiness, thirst, and muscle and visceral sensations (Sherrington, 1906; Craig, 2003). Besides the aforementioned homeostatic

and nonhomeostatic eating, hunger as an endogenous sensation varies widely among individuals because of multidimensional factors including genetic factors, health factors such as obesity and eating habits, psychological and neurodevelopmental factors, psychological factors including depression and eating disorders, and cognitive factors such as the ability to consciously regulate eating and eating motivation. Nevertheless, measurement tools have been noted to lack validity (Stevenson et al., 2015). From the above, hunger and satiety have been studied from a physiological perspective. However, no studies on hunger in the context of diabetic recuperation exist.

Thus, the researchers focused on how patients with type 2 diabetes perceive hunger. Based on the results of previous studies, it was hypothesized that the way patients with type 2 diabetes perceive hunger is an evaluation of their own behavior and perceptions of their bodies, which occurs as patients receive diabetes education and build up their medical care. This study aimed to clarify how patients perceive hunger by typifying the feeling of hunger using a questionnaire based on previous research.

By clarifying the feeling of hunger, which patients themselves express as "I do not know," through a questionnaire that takes into account the patient's medical treatment lifestyle, we thought it would be a way of finding new dietary support for dietary therapy based on how patients perceive hunger sensations.

Materials and Methods

Research Design

This study was a cross-sectional one that used an anonymous self-administered questionnaire method.

Study Participants

The study population involved patients who met the following criteria: aged 20 years or older, were attending a hospital or a clinic, and were diagnosed with type 2 diabetes for at least 6 months. The exclusion criteria were as follows: unable to independently answer the self-administered questionnaire and highly obese based on a body mass index (BMI) of 35 kg/m² or more (considered to be different in pathogenesis, treatment, and management from those with obesity based on a BMI of 25-35 kg/m² or less, who often have psychological and/or social problems) (Japan Society for the Study of Obesity, 2016). Participants were recruited with the consensual assistance of medical personnel working at the cooperating facilities.

Preparation of a Draft of the "Questionnaire for Perception of Hunger Sensation in Patients with Type 2 Diabetes"

To understand how patients with type 2 diabetes perceive hunger sensation, we developed a 46-item draft question-

naire based on information from a previous study (Naga-mune et al., 2020) in which patients were found to cope with hunger in their daily lives. The draft questionnaire included questions that included elements such as "it is because I do not have enough patience" and "it is because my diabetes condition is affecting me," which were the results of previous studies, as well as the perception, evaluation, and feelings about their own medical treatment behavior and their body with diabetes. To avoid simple "not think" and "think" responses, a 5-point Likert-type scale ranging from 1 (never think) to 5 (always think) was chosen. We also asked seven nursing experts in diabetes and five nurses, for their opinions on whether the items were appropriate for understanding how patients with type 2 diabetes perceived hunger. Subsequently, we reexamined the appropriateness of the content and wordings of all items (Table 1).

Data Collection

Data were collected using a self-administered questionnaire developed by the researcher, with items including basic attributes, factors related to how hunger was perceived, and glycemic control indices. Participating facilities were recruited among hospitals and clinics with accreditation from the Council for the Promotion of Diabetes Control in Region A. Of these, three medical institutions agreed to cooperate in this study; the researcher or a medical worker at the institution explained the purpose of the study and the details of cooperation to the participants orally and in writing and then distributed questionnaires to those who gave their consent. To collect the questionnaires, either the researcher directly visited the medical facilities to pick them up or the survey collaborators sent them in a return envelope to the researcher. The data collection period lasted from July 2020 to June 2021.

Survey Items

The survey items included basic attributes, factors related to how hunger was perceived, and diabetes control indices (HbA1c and BMI).
Basic Attributes
There were seven items in this section, with answer options including fill-in-the-blank and choice selection (i.e., gender, age, duration of illness, presence or absence of co-residents, presence or absence of complications, treatment method, and presence or absence of diabetes education experience).
Diabetes Control Indices
Based on test results from the day of the study explanation or within the last month, the participants were asked to write down their HbA1c levels. To ascertain their degree of obesity, they were also asked to state their heights and weights to calculate BMI.

Analysis Method

Statistical methods were used for analysis, with a significance level of $p < .05$. All analyses were performed using The Statistical Package for the Social Sciences (SPSS) version 27.0 (IBM Corp, Armonk, NY).
Development of the "Questionnaire for Perception of Hunger Sensation in Patients with Type 2 Diabetes"
Item Analysis
The 46 items of the draft "Questionnaire on Perceived Hunger in Patients with Type 2 Diabetes" were checked for the ceiling (mean + standard deviation [SD] > 5) and floor effects (mean − SD < 1) before analysis with item-total correlations (I-T analysis). Subsequently, items with low correlations ($|rs| < 0.20$) were discarded by item-total correlations (I-T analysis), and items inappropriate for factor analysis were deleted (Streiner et al., 2015).
Extraction and Naming of Factors
We conducted an exploratory factor analysis (EFA) via the principal factor method (Costello et al., 2005) to understand the indicators that characterized how patients with type 2 diabetes perceived hunger. Using Promax rotation, factor analysis was performed. For each item, we compared the factor loadings of each factor matrix; the factor structure was constructed by assigning the item with the largest absolute value to the corresponding factor. The criterion for factor loadings was set at 0.4 or higher (Costello et al., 2005), whereas the Kaiser-Meyer-Olkin (KMO) measures of sample adequacy and Bartlett's sphericity tests were used to determine the appropriateness of the factor analysis.
Confirmation of Construct
After extracting the factors, we calculated a Pearson's product-moment correlation coefficient for the correlation coefficients of each factor. After adopting the factor structure, we compared the results with those obtained in previous research (Nagamune et al., 2020).
Examination of Internal Consistency
To calculate Cronbach's alpha coefficients for the entire questionnaire and each factor, we performed a reliability analysis. Additionally, we generated standardized factor scores (mean = 0, SD = 1) from the final factor solutions and used these in subsequent analyses.
Cluster Analysis of the Participants
Based on the factor scores obtained for the "Questionnaire for Perception of Hunger Sensation in Patients with Type 2 Diabetes," the participants were classified through a hierarchical cluster analysis using the Ward method. This analysis was conducted to identify similarities in the perception of hunger among patients with type 2 diabetes (Mojena, 1977; Blashfield, 1980). Furthermore, we performed a discriminant analysis to confirm the validity of the cluster classification by calculating the discriminant hitting rate of the discriminant function obtained from the data. Next, we compared

Table 1. Questionnaire draft items and statistics.

Perception	Item	Mean	SD	Corrected item-total correlation
Awareness of hunger	1. I feel hungry before meals.	3.6	1.1	.32**
	2. I feel like I can eat even if I am not that hungry.	3.7	1.0	.25**
	3. I feel hungry between meals.	3.0	1.1	.34**
	4. I feel hungry when I see other people eating.	2.2	0.9	.51**
	5. I feel hungry when I smell or see food.	2.6	1.1	.45**
	6. I feel hungry after eating a meal.	1.9	1.0	—
	7. This hunger is unique to patients with diabetes.	2.0	0.9	.43**
	8. Only I feel this hunger.	2.1	1.0	.44**
	9. I feel that my hunger has become stronger since I was diagnosed with diabetes mellitus.	2.0	0.9	.54**
	10. I have to live with this feeling of hunger all my life.	2.6	1.2	.52**
Verbalization approval	11. I may talk to a healthcare provider about hunger.	3.0	1.3	.58**
	12. I may talk to my family about hunger.	3.1	1.3	.62**
	13. I may talk to people other than medical professionals and family members about hunger.	3.0	1.3	.56**
	14. I think people will listen to me seriously about my hunger.	2.5	1.0	.45**
	15. This feeling of hunger is not my only problem.	2.6	1.1	.54**
Countermea-sures and tolerance	16. Hunger can be suppressed without a strong will.	3.1	1.2	.10
	17. It is difficult to tolerate hunger, even in one's own body.	2.5	1.2	.40**
	18. Hunger does not have to be tolerated.	2.9	1.1	.45**
	19. It is okay to eat a little to satisfy one's body and feelings.	3.4	1.0	.47**
	20. I can consult with medical professionals for advice and support.	2.8	1.1	.40**
	21. I may talk to express my opinion about the family's cooperation.	3.4	1.1	.26**
Justification	22. Stress in diabetes is caused by this hunger.	2.2	1.0	.54**
	23. One never gets used to the feeling of hunger in diabetes.	2.6	1.0	.45**
	24. Blood glucose control does not work well due to diabetes.	3.1	1.1	.41**
	25. Blood glucose control does not work well because of old age.	2.8	1.0	.41**
	26. I get hungrier when my blood sugar is high.	2.3	1.0	.47**
	27. I need not be driven by the state of my blood sugar control and my eating behavior.	3.0	1.0	<.01
	28. It is my body, but I am having difficulty controlling my blood sugar.	3.3	1.1	.46**
	29. I reflect on my life and acknowledge that my body is working hard enough.	2.9	1.0	<.01
	30. I do not have to think that my hunger is because I am restricting myself with food.	2.9	0.9	.19*
Competence evaluation	31. My efforts are not reflected in my weight and HbA1c.	2.5	1.0	.22**
	32. When my blood glucose control is not good, I have to adjust my own diet.	3.9	0.8	.18*
	33. If my healthcare provider suggests that I have a problem, I must take action to address it.	4.1	0.7	.14
	34. When the test results show that my blood sugar control is not good, the medical profes-sional will say, "That is because you are eating too much," and I will think that myself.	4.0	0.8	.38**
	35. I am not able to resist eating just on my own.	2.8	1.0	.47**
	36. My blood sugar control is not working because I am eating too much.	3.7	1.0	.36**
	37. I am not able to control my diet as well as I used to.	2.7	1.0	.33**
	38. I am less able to control my blood sugar than I used to be.	2.8	1.1	.40**
	39. I am not as good at controlling my weight as I used to be.	2.8	1.1	.37**
Result	40. I do not feel hungry between meals.	3.2	1.0	<.01
	41. I do not feel hungry from after dinner until bedtime.	3.4	1.0	<.01
	42. I do not feel hungry at night (when sleeping).	3.9	1.1	<.01
	43. I am able to have good blood sugar control.	2.7	1.0	−.22**
	44. I am able to control my weight.	2.8	1.0	−.27**
	45. I am able to manage my diabetes based on my doctor's expectations.	2.6	1.0	−.18*
	46. I am able to manage my diabetes based on my family's expectations.	2.6	1.0	<−.01

Note. Items with |rs|<.20 were excluded. Floor effects excluded one item.

*p<.05   **p<.01

N = 147, SD = standard deviation.

data for which normality was found by cluster using the Student's t-test and compared data for which normality was not found by cluster using the Mann-Whitney U test.

Analysis of the Relationship between Clusters of Patients with Type 2 Diabetes Classified by Hunger Perception Factors and Diabetes Control Indices

Cluster analysis was used in this study as a means of interpreting how patients with type 2 diabetes perceive hunger. The Mann-Whitney U test was used for the relationship between clusters of participants classified based on hunger and HbA1c/BMI.

Ethical Approval

At each cooperating institution, the study procedures were either conducted by a researcher or healthcare worker after providing written explanations of the purpose to all participants. This study was conducted anonymously. All participants provided consent through the questionnaires. Additionally, we explained that there would be no disadvantage in medical treatment due to nonparticipation. We carefully protected the privacy of all participants through anonymity and by strictly managing and storing their data. This study was approved by the Ethics Review Committee of his institution.

Results

Of the 200 questionnaires distributed, 175 were collected, with a collection rate of 87.5%. The number of valid responses was 147, with a valid response rate of 84.0%. Besides the previously mentioned inclusion and exclusion criteria, we excluded questionnaires with missing values on the hunger perception section and those from respondents who were taking immunosuppressive drugs. The effect of missing values in deriving the results of the analysis was only present in one patient, who did not fill in HbA1c. Thus, missing values were treated as missing values.

Basic Attributes

Of the analyzed respondents, 104 were males (70.7%) and 43 were females (29.3%), and respondents were aged 20-85 years (mean of 59.5 ± 12.7 years). Table 2 lists other relevant items.

Development of the "Questionnaire for Perception of Hunger Sensation in Patients with Type 2 Diabetes"

Item Analysis (Table 1)

One item was deleted due to the floor effect, whereas 11 items were deleted due to I-T correlations below 0.2.

Examination of Construct Validity, Extraction, and Naming of Factors (Table 3)

Following the factor analysis, the KMO measure of sample adequacy was 0.798, whereas Bartlett's sphericity test showed a significant probability of 0.000, indicating that it was proper to use the factor analysis. Initial eigenvalues of 1.000 or more were adopted and confirmed via the Kaiser-Guttman criteria and scree plots. In the second and subsequent factor analyses, items with factor loadings of less than 0.4 and items with factor loadings of 0.4 or more for two or more factors for one item were deleted to discard items. Finally, the questionnaire had a 25-item, six-factor structure. The cumulative contribution rate after rotation was 53.7%. The first factor consisted of six items, including "competence evaluation" and "results" from the original proposal. Most respondents assessed their own ability to manage themselves and felt that self-management was challenging. As such, this factor was named a "sense of lack of self-control." The second factor consisted of five items, including "verbalization approval" and "countermeasures and tolerance" from the original proposal. Most items were related to discussions with others about hunger. As such, this factor was named "verbal affirmations of hunger." The third factor consisted of five items, including "awareness of hunger" and "justification" from the original proposal. Most were based on the sense of a relationship between diabetes and hunger or that hunger had changed as a result of diabetes. As such, this factor was named "acceptance of diabetes-specific hunger." The fourth factor consisted of four items, including "awareness of hunger" and "justification" from the original proposal. Most items were based on the feeling that one was aware of a hunger situation. As such, this factor was named "hunger awareness." The fifth factor consisted of two items, including "justification" from the original proposal. Here, the reason for poor glycemic control is not one's behavior but one's body. As such, this factor was named "feeling physically dependent when blood sugar control is poor." Finally, the sixth factor consisted of three items, including "countermeasures and tolerance" and "ability assessment" from the original proposal. In response to hunger, participants felt that it was suitable to eat a little. As such, this factor was named "tolerance of food intake."

Examination of Internal Consistency (Table 3)

The Cronbach's alpha coefficient for the entire questionnaire was 0.875. Table 3 shows the coefficients for each factor. The factor analysis showed that five of the six factors had at least three items, with factors containing three or more items being stable and desirable (Costello et al., 2005). However, given the results of previous qualitative research (Costello et al., 2005), we believed that the two items from Factor 5 concerning physical sensation during poor glycemic control should be retained.

Cluster Classification of Patients with Type 2 Diabetes According to the Six Factors of Hunger Perception (Figure 1, Table 4)

We calculated factor scores based on the six factors of hunger perception in patients with type 2 diabetes, and respondents were classified via cluster analysis (Ward method).

Table 2. Basic attributes.

		n (%)	Mean ± SD	Range
Sex	Male	104 (70.7)		
	Female	43 (29.3)		
Age (years)			59.5 ± 12.7	20–85
	20s	2 (1.4)		
	30s	5 (3.4)		
	40s	28 (19.0)		
	50s	37 (25.2)		
	60s	42 (28.6)		
	70s	25 (17.0)		
	80s	8 (5.4)		
Duration of disease (years)			12.2 ± 9.3	0.7–45
	Less than 1 year	2 (1.4)		
	Less than 5 years	31 (21.1)		
	Less than 10 years	29 (19.7)		
	Less than 20 years	54 (36.7)		
	Less than 30 years	19 (12.9)		
	Less than 40 years	9 (6.1)		
	Less than 50 years	3 (2.0)		
HbA1c (%)		146 (99.3)	7.4 ± 1.1	5.7–12.2
BMI (kg/m^2)		147 (100)	25.8 ± 3.9	18.5–34.4
Living situation	Living alone	21 (14.3)		
	Living with family	126 (85.7)		
Treatment (Multiple answers)	Tablets	137 (93.2)		
	Insulin	35 (23.8)		
	GLP-1	5 (3.4)		
	Diet therapy only	7 (4.8)		
Diabetic complication (Multiple answers)	Diabetic neuropathy	10 (6.8)		
	Diabetic retinopathy	12 (8.2)		
	Diabetic nephropathy	4 (2.7)		
	Periodontal disease	8 (5.4)		
	Vascular complication	7 (4.8)		
Diabetes education	Educated	125 (85.0)		
	Never educated	18 (12.2)		
	Do not know	4 (2.7)		

Note. SD = standard deviation.

The number of groups was determined by referring to the dendrogram of the two groups that were most suitable for interpretation. There were 38 and 109 individuals in clusters A and B, respectively (Figure 1). The discriminant success rate (cross-confirmed) was 93.2%. To characterize the six factors among the clusters, the factor scores were compared. The data showing normality were tested using the Student's t-test, whereas data that did not show normality were tested using the Mann-Whitney U test. The six-factor scores for Cluster A were (Factors 1-6) 0.698, 0.241, 0.950, 0.972, 0.381, and 0.633, respectively. The six-factor scores for Cluster B were (Factors 1-6) −0.243, −0.084, −0.331, −0.339, −0.133, and −0.221, respectively. Although the second factor, "verbal affirmations of hunger," was not significantly different between the two groups, the other factors were significantly different (Table 4). As for the characteristics of the perception of hunger, Cluster A had high scores on each factor and was thus named the "high score group for all factors." By contrast, Cluster B had low scores on each factor and was thus named the "low score group for all factors."

Characteristics of Diabetes Control in Patients with Type 2 Diabetes in Each Cluster (Table 5)

We analyzed the relationship between HbA1c and BMI with two clusters classified based on the six factors of hunger perception.

HbA1c

This characteristic was 7.8% in the all-factor high score

Table 3. Factor loadings of the "questionnaire for perception of hunger sensation in type 2 diabetes patients".

Factor	1	2	3	4	5	6
Factor 1: Sense of lack of self-control						
43.*I am able to have good blood sugar control.	.817	.057	−.091	.034	.153	−.205
38. I am less able to control my blood sugar than I used to be.	.791	−.148	.059	−.054	−.049	.209
39. I am not as good at controlling my weight as I used to be.	.754	.050	.062	.011	−.013	−.072
44. *I am able to control my weight.	.726	.220	−.032	−.034	−.048	−.194
37. I am not able to control my diet as well as I used to.	.682	−.211	−.045	.011	.020	.251
35. I am not able to resist eating just on my own.	.442	−.028	.245	.075	−.015	.212
Factor 2: Verbal affirmation of hunger						
12. I may talk to my family about hunger.	−.041	.912	−.045	.070	.060	.070
13. I may talk to people other than medical professionals and family members about hunger.	.073	.883	.056	−.067	−.004	.028
11. I may talk to a healthcare provider about hunger.	.093	.865	.051	.025	−.031	−.019
21. I may talk to express my opinion about the family's cooperation.	−.065	.454	−.133	.004	.062	.117
14. I think people will listen to me seriously about my hunger.	−.094	.405	.312	−.042	−.095	.108
Factor 3: Awareness of hunger						
9. I feel that my hunger has become stronger since I was diagnosed with diabetes mellitus.	−.064	−.075	.781	.162	−.024	.028
8. Only I feel this hunger.	.163	−.034	.683	−.058	−.079	−.138
7. This hunger is unique to patients with diabetes.	−.082	.041	.663	−.125	−.013	−.018
22. Stress in diabetes is caused by this hunger.	.028	.101	.558	.105	−.005	.016
26. I get hungrier when my blood sugar is high.	−.055	−.016	.473	−.108	.321	.124
Factor 4: Acceptance of diabetes-specific hunger						
5. I feel hungry when I smell or see food.	−.127	.005	−.079	.820	−.002	.065
1. I feel hungry before meals.	.130	.018	−.126	.654	−.130	−.008
4. I feel hungry when I see other people eating.	.042	.071	.052	.610	.066	.015
3. I feel hungry between meals.	−.017	−.076	.160	.512	.091	−.080
Factor 5: Feeling physically dependent when blood sugar control is poor						
25. Blood glucose control does not work well because of old age.	.088	−.024	.070	.045	.834	−.125
24. Blood glucose control does not work well due to diabetes.	−.019	0.072	−.128	−.037	.757	.140
Factor 6: Tolerance of food intake						
19. It is okay to eat a little to satisfy one's body and feelings.	−.027	.030	.013	.049	.028	.622
18. Hunger does not have to be tolerated.	−.098	.179	−.009	−.024	.004	.600
34. When the test results show that my blood sugar control is not good, the medical professional will say, "That is because you are eating too much," and I will think that myself.	.296	.140	−.148	−.030	−.019	.459
Cronbach's α coefficient for each factor	.868	.852	.764	.734	.763	.634
Overall Cronbach's α coefficient			.875			
Factor correlations (*r*)	1	2	3	4	5	6
	1.000	.250	.337	.305	.244	.458
		1.000	.236	.326	.084	.275
			1.000	.422	.297	.423
				1.000	.175	.345
					1.000	.326
						1.000

Note. *Reverse-scored item.

N = 147, factor loading ≧ .40
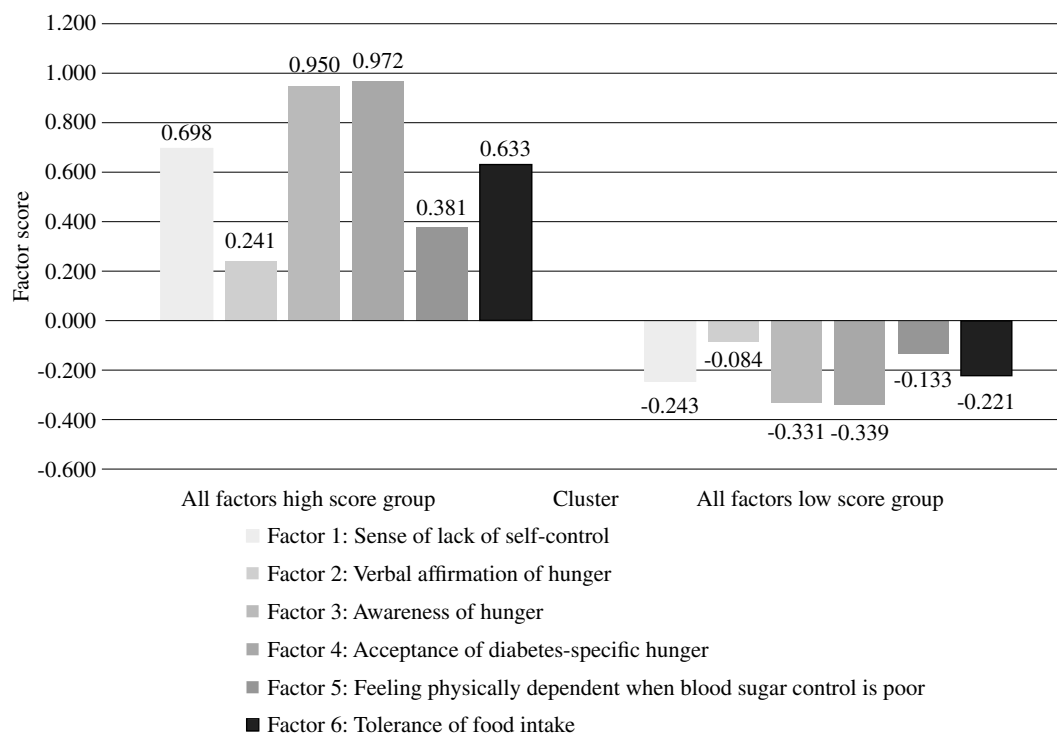
Figure 1. Cluster classification of patients with type 2 diabetes according to the six factors of hunger perception.

Table 4. Statistics for each factor of hunger perception classified into two groups.

						$N = 147$
	t	*df*	*Z*	*p*	95%CI	*r*
Factor 1 "Sense of lack of self-control"	−5.83	145	−	.000**	[−1.261, −0.623]	.44
Factor 2 "Verbal affirmations of hunger"	−	−	−1.695	.090	−	−.14
Factor 3 "Acceptance of diabetes-specific hunger"	−	−	−7.322	.000**	−	−.6
Factor 4 "Hunger awareness"	−11.812	91.33	−	.000**	[−1.531, −1.090]	.78
Factor 5 "Feeling physically dependent when blood sugar control is poor"	−3.098	145	−	.002*	[−8.41, −0.186]	.25
Factor 6 "Tolerance of food intake within the group"	−	−	−5.384	.000**	−	−.44

Note. SD = standard deviation.

*p<.05   **p<.001

※Factor 1, 4, and 6: The Student's t-test

※Factor 2, 3, and 5: The Mann-Whitney U test

Table 5. Characteristics of diabetes control in patients with type 2 diabetes in each cluster.

	N	*n*	All factors high score group	*n*	All factors low score group	*Z*	*p*	*r*
HbA1c (%; mean ± SD)	146	38	7.8 ± 1.1	108	7.3 ± 1.1	−3.120	.002*	−.05
BMI (kg/m²; mean ± SD)	147	38	26.2 ± 4.2	109	25.6 ± 3.7	−0.602	.547 (ns)	−.26

Note. Mann-Whitney U test; *p<.05; SD = standard deviation; BMI = body mass index.

group and 7.3% in the all-factor low score group, a significant difference ($z = −3.120$, $p < .05$, $r = −.05$). HbA1c was significantly higher in the high score group compared to the low score group for all factors (Table 5).

BMI

This characteristic was 26.2 kg/m² in the group with high scores for all factors and 25.6 kg/m² in the group with low scores for all factors, with no significant difference ($z =$

−0.602, *p* = .547, *r* = −.26) (Table 5).

Discussion

"Questionnaire for Perception of Hunger Sensation in Patients with Type 2 Diabetes"

Content and face validity were ensured in the process of drafting the questionnaire. It used a six-factor, 25-item structure obtained through EFA. The Cronbach's alpha coefficient of the sixth factor was 0.634, which is slightly low, but not below 0.5 (Bujang et al., 2018), and the overall Cronbach's alpha coefficient was 0.875, which confirms the internal consistency of the questionnaire as a single 25-item measure. Additionally, the cumulative contribution of the six factors after rotation was 53.7%.

Hara et al. (2011) found that a "sense of self-control" was associated with self-regulated eating behavior and HbA1c levels. Peyrot and Rubin (1994) divided internal control in patients with diabetes into "autonomy" and "self-responsibility" components, finding that autonomy was associated with positive outcomes and self-responsibility with negative outcomes. Factor 1 thus indicates that patients have difficulty protecting their autonomy and that they live with the thought that they are unable to tolerate hunger in their lives. Moreover, the contribution rate of the first factor, "sense of lack of self-control," was 24.1%, indicating that it is an important factor in the perception of hunger sensation.

In Factor 2, "verbal affirmations of hunger," patients reported that having diabetes changed their relationships with their surroundings and were frustrated with interventions regarding their food choices (Willig et al., 2014). Elements of stigma for patients with diabetes include others being prejudiced against the patient's food choices because of diabetes, imposing excessive dietary restrictions when the patient does not want them, and changing relationships with those around them because of diabetes (Browne et al., 2016). In other research, patients were also hesitant to discuss hunger and eating problems with their families or healthcare providers (Nagamune et al., 2020). Although the second factor in this study did not capture the relationship with family members, surrounding others, or medical professionals, the patients' ability to talk about their hunger and express their opinions to others is related to their hunger. Nevertheless, the second factor could not be categorized as something that all patients had, and thus, there were no significant differences between groups.

Factors 3, 4, and 5 consisted of "awareness of hunger" and "justification," which were original items. Posey (2006) defined symptom perception as "the belief an individual has about what a particular symptom means (cognitively and emotionally), the appraisal of the symptom based on past and present knowledge and experience, and the response or action of the individual based upon that meaning and appraisal." This implies that patients make their own meanings of diabetes and hunger, in which case they may perceive hunger as a symptom of diabetes.

Finally, the sixth factor corresponds to items from a previous study, including "I physically feel that I cannot do it, but I do not think the medical staff understands me" and "coping with passive endurance" (Nagamune et al., 2020). As a novel contribution, the researchers reported that patients felt glycemic control was directly related to eating but still tolerated eating to some extent.

Characteristics of Subjects Classified from the "Questionnaire for Perception of Hunger Sensation in Patients with Type 2 Diabetes"

The "Questionnaire for Perception of Hunger Sensation in Patients with Type 2 Diabetes" was used to divide the subjects into two groups. The all factors high score group had a higher HbA1c than the all factors low score group, and there was a significant difference between the two groups. Comparing the two clusters, the all factors high score group tended to have particularly high scores on Factor 3: "diabetes-specific hunger approval," Factor 4: "hunger awareness," Factor 1: "Sense of lack of self-control," and Factor 6: "Tolerance of food intake within the group." Furthermore, the results of this study showed that the characteristics of each factor score of the clusters revealed that the ideas "it is because I do not have enough patience" and "it is because my diabetes condition is affecting me" are not stronger in one and weaker in the other. Therefore, the perception of hunger in patients with type 2 diabetes should be based on two concepts: "it is because I do not have enough patience" and "it is because my diabetes condition is affecting me." Moreover, we believe that support is required to help patients feel that they are in control of themselves while satisfying the sense that it is okay to eat.

Additionally, in this study, both groups scored low on Factor 2: "verbal affirmations of hunger." Relationships and communication with family, surroundings, and healthcare providers have been shown to be related to motivation and self-management behaviors (Parkin et al., 2003; Heisler et al., 2003). Moreover, a previous study (Nagamune et al, 2020) found that patients are hesitant to discuss hunger and eating with their families, people around them, and healthcare providers. Hence, we believe that the content of the second factor was not significantly different between the two groups; the results in Figure 1 indicate that the participants in this study tended to be less positive about verbalizing their feelings and were "patient" about verbalizing their feelings regarding their bodies. Therefore, we believe that besides "helping patients feel in control while satisfying their sense that it is safe to eat," healthcare professionals, family members, and others around them should start by "listening" to the "hunger" that patients are feeling, rather than looking

for the cause of hunger.

Moreover, the present results confirmed that the all factors high score group had higher HbA1c than the all factors low score group. Likewise, reportedly, the sense of self-care burden and behavioral changes associated with diabetes affect glycemic control (Roy et al., 2020). In summary, too high physical sensations related to hunger may negatively impact the ability to self-manage, which results in poor glycemic control.

Considering the above, we believe that this study is novel because it clarified the "feeling of hunger" as perceived by patients. We believe that this research can be used to support the self-management of diet therapy in terms of predicting how patients feel about hunger and how they live their lives under medical treatment according to how they perceive hunger.

Limitations

The study had several limitations. First, given that this is a cross-sectional study that investigates the relationship between hunger and two specific diabetes control measures (HbA1c and BMI), whether changes in control measures would result in changes in how hunger is perceived is unclear. Second, only patients with type 2 diabetes attending hospitals and clinics as outpatients were involved. Therefore, the study may not apply to patients with diabetes who are hospitalized. Third, HbA1c may be lower in patients with nephropathy due to progressive anemia. Therefore, the study may not apply to patients with diabetes who are hospitalized. Fourth, the age of the subjects was younger than the average age for patients with diabetes in Japan in general, and few patients had complications.

This study should be retested to determine whether reliability can be ensured with different subjects.

Conclusion

In this study, it was investigated how patients with type 2 diabetes perceive hunger using a 25-item, six-factor structured questionnaire. Based on the six factors of hunger, participants were divided into two groups: the "all factors high score group" with high scores on all items and the "all factors low score group" with low scores on all items. Additionally, the all factors high score group had significantly higher HbA1c than the all factors low score group. The results of this study allowed the categorization of how patients with type 2 diabetes perceive hunger.

Author Contributions

All authors contributed to the conception and design of this study. Nagamune acquired and analyzed the data and drafted the manuscript. Okuwa and Inagaki were major contributors to the analysis and interpretation of the data. Okuwa, Ina-

gaki, Tasaki, Horiguchi, and Asada critically reviewed the manuscript and the entire research process. The final manuscript was read and approved by all authors.

Declaration of Conflicting Interests

We have no conflicts of interest to disclose.

Ethical Approval

Approval code issued by the Institutional Review Board: 967-2

The name of the institution that granted the approval: Medical Ethics Committee of Kanazawa University

Informed Consent

All participants involved in this study provided informed consent.

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Original Research

Development of the prenatal positive experience scale for men in Japan: A cross-sectional scale development study

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Abstract
Objective: The aim of this study was to develop and validate a scale to measure the positive experiences of men during their partner's pregnancy. **Methods:** Scale items were developed in consultation with the literature. The content and surface validity were assessed by experts and the public. Exploratory factor analysis, convergence validity, and internal consistency of the scale were analyzed. Data were collected using the Quality Marriage Index, responsibility and happiness numerical rating scales, and Center for Epidemiologic Studies Depression Scale. Multiple regression analysis was performed to identify relevant variables. **Results:** A total of 267 expectant fathers were sampled. The final scale was composed of 28 items and 3 factors, namely, 1, increased awareness of becoming a father; 2, self-growth through becoming a father; and 3, comprising positive emotional responses to pregnancy events. Cronbach's alpha was .98 for the entire scale and ranged from .88 to .97 for the three factors. Regarding convergent validity, a significant moderate positive correlation with other scales was found. Significantly related variables included number of weeks pregnant, age of wife, positive emotional response at pregnancy announcement, and risk of depression. **Conclusions:** The 3 factors and 28-item Prenatal Positive Experience Scale for Men were confirmed to have sufficient reliability and validity. More advanced gestational weeks, a younger partner, positive emotional response at pregnancy announcement, and no risk of depression were associated with more positive emotional experiences. On the basis of these results, nursing interventions promoting positive emotions should be provided for men during pregnancy.

Keywords
adoption, expectant fathers, experience, positive emotions, prenatal

Introduction

The transition to parenthood requires physical, psychological, and social adaptation. During gestation, women undergo physical changes, whereas men do not; thus, psychological and social adjustment is important for men during this period. In a systematic review of anxiety in men during pregnancy, the incidence of anxiety in men whose partner is pregnant increased from the time of conception to the time of delivery, and the incidence was reported to be 3.4%-25% (Philpott et al., 2019). In other review articles, the prevalence of anxiety disorders in men whose partners are pregnant has been reported to range from 4.1% to 16% (Leach et al., 2016). A meta-analysis of prenatal depression in expectant fathers also reported a prevalence of paternal depression of approximately 10% (Cameron et al., 2016; Paul-

son & Bazemore, 2010; Rao et al., 2020). In addition, high stress levels in men during pregnancy have been shown to have an impact on mental health, including anxiety, depression, distress, and fatigue (Philpott et al., 2019). In a qualitative study of men's psychological transition to fatherhood from gestational age to the time of birth, the partner's pregnancy was also described as the most demanding period in terms of psychological reorganization of the self (Bäckström & Hertfelt Wahn, 2011; Genesoni & Tallandini, 2009).

However, several studies have reported experiences with positive emotions, such as increased feelings of being happy because of a partner's pregnancy, building a relationship with the fetus, and deepening attachment (Golian Tehrani et al., 2015; Poh et al., 2014). It is expected that the positive emotions of men during pregnancy will have a positive impact on mothers and children.

The broaden-and-build theory (Fredrickson, 2001) expands thought-action repertoires, functions as antidotes for the lingering effects of negative emotions, enhances psychological resiliency, and triggers upward spirals toward improved emotional well-being. Don et al. (2021) reported that men's positive emotions during pregnancy increased their postpartum marital satisfaction and perceptions of positive support and decreased their perceptions of negative support, indicating that positive emotions also have a positive impact during the transition to parenthood. In summary, it is expected that positive emotions will help reduce negative emotions, such as anxiety, depression, and stress, in men during pregnancy. It is also expected that such emotions have a positive effect during the child-rearing period. As a measure of men's positive emotions during pregnancy, Don et al. (2021) used the Profile of Mood States, but this scale assesses mood state at particular times and has limitations in assessing positive emotions specific to the pregnancy period.

A qualitative research study by Yashima et al. (2021) explored the positive emotions of men during pregnancy. This study identified 10 related themes, namely, 1, the achievement of a role as a man; 2, the joy of pregnancy itself; 3, caring for pregnant wife; 4, an increasing interest in pregnancy, childbirth, and childcare; 5, valuing relationships and time with wife; 6, the joy of becoming a father; 7, happy to feel the presence of my child; 8, affirming visualizations of child or family; 9, positive recognition of changes related to becoming a parent; and 10, gratitude for supportive environment. This qualitative research indicates that men have very specific experiences related to pregnancy. It would be possible to evaluate men in transition to parenthood by assessing whether these experiences are occurring in men during their partners' pregnancy; however, there is no simple quantitative measure that can be used to quantify these experiences.

This study aimed to develop and validate a scale to measure men's experiences of positive emotions during their part-

ner's pregnancy. In addition, we examined the factors associated with men's experiences of positive emotions for antenatal childcare. We hypothesized that men who experience positive emotions during pregnancy will experience better mental health and participate in childcare and will eventually have a positive effect on mothers and children. If we can evaluate men's positive emotions during the pregnancy period, we will be able to better provide psychosocial support to men, support the adoption of the fatherhood role, and encourage increased involvement from the antenatal period.

Material and Methods

Participants

The eligibility criteria for the participants were men over the age of 20 years and whose wife or partner is pregnant with their first child. Men who previously had children (including adopted children) were excluded from this study. The sample size required to verify the structural validity of the scale was set to 300. This sample size was selected because it is five times the number of scale items and more than 100 people are considered an appropriate sample size for scale development (Mokkink et al., 2010). In addition to that criterion, the number of inappropriate responses, such as the same number for all items, was estimated to be approximately 10%; thus, the number was set at 300.

Data Collection

Data collection was conducted in March 2018 by an online research company (Cross Marketing Co., Ltd.). The research company invited participants in the company's database who met the eligibility criteria to participate in the study via email. Participants were invited to read the research information sheet, which outlined the research purpose and ethical considerations, on a web page, accept the contents, and then proceed to the questions. Consent was obtained by pressing the research participation consent button. This study was approved by the institutional review board of [name and reference number removed].

Measurements

Prenatal Positive Experience Scale for Men
This scale development study was conducted according to the scale development procedure outlined by DeVellis et al. (2016).

Determine what to measure: This scale measured men's experiences of positive emotions during pregnancy. Positive emotions were defined in our study as experiences of joy and happiness, comfort and enjoyment, self-growth and responsibility, and expectations and compassion, based on the emotions addressed in Fredrickso's (1998) broaden-and-build theory.

Generate an item pool: The draft of this scale has 57 items with 43 subcategories developed from the qualitative research by Yashima et al. (2021), which results based on interviews of positive experiences during wife's pregnancy conducted with a total of 9 men from 17 weeks gestation to 4 months postpartum with their first child, and 14 subcategories added from the literature review (Kamiike et al., 2018), which results derived from 41 Japanesel and Englich literature aimed at identifying positive emotions and experiences of men during the pregnancy period.

Reviewed by experts and cognitive interviewing: These items were evaluated in an expert meeting with three nursing specialists and two nursing students. Six men and four women of reproductive age were included to strengthen the content and surface validity.

Determine the format for measurement: Responses to the scale were rated on a 6-point Likert scale, ranging from not applicable or /not experienced at all (0) to very applicable (5). Higher scores indicated a more positive emotional experience.

Marital Satisfaction
The Quality Marriage Index (QMI), with six items, was used to assess the quality of the marital relationship (Moroi, 1996; Norton, 1983). Responses were rated on a 4-point Likert scale ranging from strongly disagree (0) to strongly agree (4). The score range was 0-24 points, and the higher the score, the more satisfactory was the marital relationship. This scale was used to verify the concurrent validity of the scale developed in this study.

Responsibility and Happiness
Using the numerical rating scale (NRS), we measured the participant's current sense of responsibility within his family and current sense of happiness in his life. Responses were rated on a 10-point Likert scale ranging from not at all (0) to very much (10). This scale was used to verify the concurrent validity of the scale developed in this study.

Depression
The Center for Epidemiologic Studies Depression Scale (Radloff, 1977; Shima et al., 1985) was used to measure depression. This 20-item Likert scale measures the degree of depressive symptoms within the past week. The scale asks participants to rate their mood based on items related to depressive symptoms. The items pertain to the mood of the participants and include depressive and physical symptoms, interpersonal relationships, and positive emotions. Responses were rated on a 4-point Likert scale ranging from rarely or none of the time (<1 day) to most or all of the time (5-7 days). The score range was 0-60 points. The scale has a cut-off score of ≥16, which indicates greater symptoms of depression. A score of <16 indicates no risk of depression (Radloff, 1977; Shima et al., 1985).

Demographic Information
The following demographic details were sought: age, age of partner, number of weeks pregnant, employment status, individual annual income, annual family income, family structure, educational background, morning sickness, presence or absence of infertility treatment, and emotional response to pregnancy announcement.

Analysis

The analysis procedure was performed according to the scale development guidelines described below (DeVellis et al., 2016). The data were analyzed using SPSS ver. 26 (IBM Software Group, Chicago, IL, USA) (with $p = .05$).

Exploratory Factor Analysis
The ceiling and floor effects were analyzed for each item of the Prenatal Positive Experience Scale for Men. Moreover, exploratory factor analysis (maximum likelihood method, and Promax rotation) was performed to validate the scale. The item exclusion criteria were items having a factor loading of <.400 and those with two or more factors having a factor loading of ≥.300. After item exclusion, the item meanings and item-total correlation were confirmed among the researchers. Items with duplicate contents were excluded. Finally, the researchers interpreted the meanings of the items and named the extracted factors.

Reliability Analysis
The internal consistency of the scale was calculated using Cronbach's α coefficient to test the interitem consistency.

Pearson's Correlation Coefficient
Pearson's correlation coefficient was used to analyze the concurrent validity between the total score of the Prenatal Positive Experience Scale for Men and QMI and happiness and responsibility NRS.

Multiple Regression of Related Factors
Multiple regression analysis was performed to investigate the related factors in the Prenatal Positive Experience Scale for Men. The total score of the scale was the dependent variable. The independent variables included the number of weeks of gestation, participant's age, wife or partner's age, emotional response to pregnancy announcement, infertility treatment, and the risk of depression.

Results

Participants' Characteristics

The characteristics of the subjects are shown in Table 1. Of the 300 participants, 31 respondents had inappropriate responses, such as answering the same number for all items, and 2 respondents reported that their partners were at <5 weeks of gestation. These participants were excluded from the sample. A final total of 267 participants were included in the analysis. The mean age of the participants was 38.1 years with a standard deviation of 8.2 years. The mean age of the participants' partners was 34.0 years with a standard deviation of 5.5 years. Regarding the participants' educa-

Table 1. Characteristics of the participants (n = 267).

	Mean (SD)
Age (years)	
Male	38.1 (8.2)
Partner	34.0 (5.5)
Gestational week (weeks)	21.7 (9.9)

	n	%
Education		
<16 years	81	30.3
>16 years	186	69.7
Occupation		
Yes	263	98.5
No	4	1.5
Annual income		
<4 million yen	77	28.8
4–8 million yen	139	52.1
>8 million yen	36	13.5
No response	21	7.8
Pregnancy period		
1st trimester (–12 weeks)	57	21.3
2nd trimester (13–27 weeks)	124	46.3
3rd trimester (28 weeks–)	87	32.5
Infertility treatment		
No	195	72.8
Yes	72	27.2
Feelings at the pregnancy announcement		
Very happy	179	67.0
Unexpected but happy	57	21.3
Unexpectedly surprised/confused	9	3.4
Nothing in particular	22	8.2
Risk of depression		
Yes	123	46.1
No	144	53.9

SD, standard deviation

tional and employment background, 186 (69.7%) participants were university graduates or above and 263 (98.5%) were employed. Most participants (n=139, 52.1%) had an average annual income of ≥4 million yen to <8 million. The average number of weeks of pregnancy for the participants' partners was 21.7 weeks. The ratio of first trimester of pregnancy (<13 weeks) was 57 (21.3%), second trimester of pregnancy (13-28 weeks) was 124 (46.3%), and third trimester of pregnancy (≥28 weeks) was 87 (32.5%). A total of 179 (67%) participants were very happy when they found out that they were pregnant. Seventy-two (n=72, 27.3%) participants were on fertility treatment, and 123 (46.1%) participants were at risk of depression.

Exploratory Factor Analysis

First, the two items with ceiling and floor effects were excluded from the item analysis. An exploratory factor analysis (maximum likelihood method and Promax rotation) was performed on 55 items. Three factors were extracted and are shown in Table 2. Items were deleted in accordance with the exclusion criteria. After the exclusion, 32 items remained. We confirmed the meaning and content of each item in an expert meeting. During this process, we excluded four items that had overlapping meanings and content. After this process, the final scale consisted of 28 items, which covered three factors. The Kaiser-Meyer-Olkin measure was .969, Bartlett's spherical was p <.001, and the cumulative contribution rate was 76.3%.

The first factor, increased awareness of becoming a father, consists of 13 items. This factor measures feelings of contentment related to having a baby, sense of family responsibility, and awareness of becoming a father. The second factor, self-growth through becoming a father, consists of 10 items. This factor measures positive emotions associated with life changes and the increased sense of social responsibility related to becoming a father. The third factor, comprising positive emotional responses to pregnancy events, consists of five items. This factor determines and measures the type of positive reactions to events related to their partner's pregnancy, such as feeling the movement of the fetus, healthcare checkups, childcare products, and childbirth.

Reliability Analysis

Cronbach's α coefficient was .98, .97, .97, and .88 for the entire scale and the first, second, and third factors, respectively. These results indicate sufficient internal consistency.

Pearson's Correlation Coefficient

Examining the concurrent validity, the correlation with the Prenatal Positive Experience Scale for Men was r =.477 (p <.001), for QMI; r =.419 (p <.001) for happiness NRS; and r=.516 (p <.001) for responsibility NRS. A significant, moderate positive correlation was found between these scales.

Multiple Regression

In Table 3, multiple regression demonstrated a significant association between the Prenatal Positive Experience Scale for Men and the number of weeks of pregnancy (β= .14, p = .019); the age of the wife (β =−.20, p = .008); positive emotional response at pregnancy announcement (β =.246, p <.001); and risk of depression (β =−.18, p = .003) (adjusted R^2 = .143, p <.001). No significant correlation was observed in relation to infertility treatment, despite previous studies noting a significant relationship.

Discussion

Validity and Reliability of the Prenatal Positive Experience Scale for Men

In this study, we developed and validated the Prenatal Positive Experience Scale for Men. The developed scale con-

Table 2. Exploratory factor analysis of the prenatal positive experience scale for men (*n* = 267).

No.	Item	Factor (factor loading)			
		1	2	3	Communality
Factor 1 [increased awareness as a father] (Cronbach's alpha = . 97)					
25	I am grateful to my pregnant partner.	**.987**	.023	−.150	.811
3	I'm glad to know about my partner's pregnancy.	**.978**	−.101	−.018	.793
5	I am looking forward to the birth of my child.	**.923**	−.063	−.032	.726
27	As my child is born, I feel more responsible for my family.	**.917**	.144	−.190	.801
34	I am relieved that the baby my partner is carrying is fine.	**.858**	−.100	.142	.786
36	I am happy to realize the existence of a baby in my partner's stomach	**.827**	−.030	.146	.831
35	I adore my baby.	**.814**	.043	.098	.845
23	I feel that my family ties are deepening, including with the baby that will be born.	**.675**	.218	.056	.791
37	I feel close to my baby.	**.666**	.047	.246	.796
22	I enjoy the time my partner and I have until childbirth.	**.660**	.165	.061	.692
20	I have a growing interest in childcare that stems from conversations with my partner.	**.615**	.209	.082	.708
16	I strive to maintain fetal health.	**.606**	.206	.051	.649
4	I am in awe of the mystery of life because of my partner's pregnancy.	**.560**	.129	.153	.605
Factor 2 [self-growth by becoming a father] (Cronbach's alpha = .97)					
50	My view point has expanded since I became a parent.	−.041	**.954**	−.051	.788
48	By becoming a parent, I became more enthusiastic about my life.	.037	**.938**	−.090	.812
46	Being a parent has increased my flexibility.	−.069	**.894**	.073	.807
44	Being a parent has increased my inner strength.	−.061	**.877**	.062	.772
47	Becoming a parent has increased my compassion for women and vulnerable people.	.129	**.847**	−.070	.801
43	I enjoy becoming a father.	.073	**.790**	.046	.772
49	Being a parent has increased my sense of social responsibility.	.267	**.762**	−.122	.785
55	I feel a connection with my parents because my partner is pregnant.	.113	**.662**	.091	.669
40	I enjoy imagining the specific characteristics of my baby.	.043	**.645**	.252	.771
52	I feel relieved by the information about pregnancy and the reaction of surrounding people.	.012	**.594**	.226	.617
Factor 3 [comprising positive emotional responses to pregnancy events] (Cronbach's alpha = .88)					
38	I enjoy feeling the baby respond to me when I touch my partner's stomach	−.228	.237	**.862**	.790
32	I enjoy feeling the fetal movement of my baby.	.126	−.055	**.834**	.786
9	I'm glad that my partner's morning sickness and dietary restrictions have been resolved.	.077	−.033	**.656**	.471
6	There is a sense of relief with a release of pressure on the wife to get pregnant.	.136	−.022	**.610**	.482
19	I think the performance of ultrasound machines and the functionality of childcare products are amazing.	.238	.077	**.467**	.492
Interfactor correlations					
	Factor 1	-	.733	.702	
	Factor 2	-	-	.719	

Note. Exploratory factor analysis (maximum likelihood method, Promax rotation); Cronbach's α (full scale) = .98, Kaiser–Meyer–Olkin, .969; Bartlett's spherical, *p* <.001; the cumulative contribution rate was 76.3%.

sisted of 28 items encompassing three factors: 1., increased awareness of becoming a father; 2, self-growth through becoming a father; and 3, comprising positive emotional responses to pregnancy events. The reliability of the scale was analyzed using the internal consistency of the conceptual composition of each factor and the entire scale. The cutoff for Cronbach's α coefficient was set at .80. These results confirm the reliability of each factor and the internal consistency of the concept of the Prenatal Positive Experience Scale for Men (Polit-O'Hara & Beck, 2008). We examined surface validity through a review of the questions by experts and the public during the drafting stage. Questions were

modified for clarity and readability. The validity of the construct was further determined by extracting the factors using exploratory factor analysis and examining their meanings.

Concurrent validity was analyzed by finding the correlation between existing measuring tools and the newly developed scale. We noted that if there was a high positive correlation, the validity of each scale was strengthened (Burns & Grove, 2005). The QMI measured marital satisfaction (Moroi, 1996). We hypothesized a positive correlation between the QMI score and happiness related to pregnancy, as marital satisfaction may impact men's emotional response to pregnancy announcement. In addition, we hypothesized that

Table 3. Factors related to men's prenatal positive experiences (*n* = 267).

	β	t	*p*	95.0% Confidence interval for regression coefficient	
				Lower bound	Upper bound
(Intercept)		8.404	.000	3.403	5.486
Gestational week	.135	2.351	.019	.003	.029
Age	.050	.656	.512	−.014	.028
Partner's age	−.204	−2.685	.008	−.075	−.012
Feelings at the pregnancy announcement[a]	.246	4.045	.000	.455	1.318
Risk of depression[b]	−.176	−3.020	.003	−.672	−.142
Infertility treatment[c]	.060	1.024	.307	−.145	.458

Note. Multiple regression analysis, forced entry, was conducted.

Adjusted R-squared, .143; F-statistic, *p* < .001; Durbin–Watson = 1.917

[a]0 = Unexpectedly surprised/confused, nothing in particular; 1 = Very happy, Unexpected but happy

[b]0 = <16 of CES-D score; 1 = >16 CES-D score

[c]0 = no; 1 = yes

β, Standardized coefficient beta

the happiness NRS would be positively correlated as it measures levels of happiness felt related to pregnancy and imagining the birth of the child. The sense of responsibility NRS was also hypothesized to be positively correlated as it measures the increased sense of responsibility for the family and society. As expected, a significant positive correlation was obtained with all these measures. Moreover, concurrent validity was confirmed.

Factor Structure of the Prenatal Positive Experience Scale for Men

The first step related to parental development is accepting pregnancy and preparing to become a parent. Preparing for changes in the parents' relationships and lifestyle involves imagining the birth of a child and becoming a parent (Galinsky, 1987). The first factor, increased awareness of becoming a father, includes items related to the man's emotional response to their partner's pregnancy, physical experience of the child through the changes in their partner's body, and interest in childcare. The first factor includes the experiences of a man who is preparing to become a parent, as they imagine becoming parents through their partner. In addition, the first factor measures experiences unique to men, which are different from the positive experiences of pregnant women (Takeishi et al., 2011), such as feelings of gratitude toward their partner and increased sense of responsibility toward their family.

The second factor, self-growth through becoming a father, measures the individual growth of men into fatherhood such as increased flexibility, broadened horizons, deepened affection, awareness of the importance of social connections, and stepping into a parenting role. Previous research has reported that fathers' experiences of self-growth related to childcare are related to increased flexibility, deepened love

for family, and broadened horizons. Our study notes that self-growth begins from the pregnancy period. Kikoshi and Tomari (2006) argue that the process of acquiring the role of a father starts as an emotional response toward fatherhood and then they form an image of fatherhood, which includes increased responsibilities. Our study measured the formation of the image of fatherhood. We postulated that being aware of the connection with the surroundings and sense of social responsibility are experiences related to pregnancy that are unique to men who see high social status as a male role (Watanabe, 2017).

The third factor, comprising positive emotional responses to pregnancy events, includes physical experiences of pregnancy through feeling fetal movements and emotions (i.e., joy and relief) related to witnessing physical changes in their partner associated with pregnancy. Men's experiences of pregnancy and fetal growth are moderated through their partner's body. Seeing the physical changes in their partner's body, feeling the fetal movements, and seeing the fetus through an ultrasound at a health checkup are important aspects of men's experiences related to pregnancy. Our findings demonstrated that the process of buying, feeling, and preparing childcare products promote positive feelings related to pregnancy. One study postulates that men have a good scientific understanding (Wakabayashi et al., 2006), such as the performance of medical devices and the functionality of childcare products. This study states that men systemize their understanding of pregnancy and childbirth. Our scale recognized the experiences related to pregnancy that are unique to men. With the development of medical equipment, through ultrasound examinations, expectant parents can see the fetus clearly and realize its presence and its growth early in the pregnancy. Yet, it may be difficult to answer all items of this scale early in the first trimester.

Variables Related to the Prenatal Positive Experience Scale for Men

The Prenatal Positive Experience Scale for Men was significantly associated with the number of weeks of gestation, partner's age, emotional response to pregnancy announcement, and risk of depression. As the number of weeks of gestation elapses, physical changes associated with pregnancy become more apparent and fetal movement can be felt from the abdominal wall. These changes allow the father to have a physical experience of the pregnancy, which assists them in stepping into a father's role (Iwata & Mori, 2004). In this process, men may accumulate experiences that are accompanied by positive emotions.

Our findings demonstrate that pregnancy is associated with fewer positive emotions if the man's partner is older. Previous research has demonstrated that advanced maternal age pregnancy is at higher risk for complications, such as miscarriage and preeclampsia (Hashimoto et al., 2003; Furukawa, 2016). As such, men with older partners may have increased anxiety surrounding the pregnancy, which may lower their scores.

Some studies have stated that women who reported feeling "confused and perplexed" during pregnancy struggle to transition into motherhood compared with those who reported feeling "happy" during pregnancy (Kondo et al., 2005). Drawing on this research, we proposed that men who report feelings of joy during pregnancy easily transition into fatherhood. We also found that men at risk of depression reported having fewer positive experiences of pregnancy than men at no risk of depression. Consequently, our scale could lead to early screening for the risk of depression by measuring positive emotions associated with their partner's pregnancy (Watson et al., 1988).

Limitations and Future Research

One significant limitation of this study was that the participants were not representative of the broader Japanese population. The participants were older than the average age of first-time fathers in Japan, which is 32.8 years. Considering the university entrance rate is 56.6% for men in Japan (Ministry of Education, 2018), the participants in this study had a higher degree of education. Our sample included many participants with high socioeconomic status. These participants may have more positive emotional experiences than the general population because they have greater access to financial and social resources. Therefore, future studies should include participants with high social risk, such as those belonging to low educational background and lower socioeconomic status. In addition, majority of the participants were in the second trimester of their partner's pregnancy, and few of the participants were in their first trimester. Although there is a greater risk of pregnancy complications in the first trimester, such as imminent miscarriage, the midpregnancy period is generally considered stable with minimal risk for miscarriage. This may have resulted in higher scores for positive emotions. In addition, some items are difficult to answer immediately after the discovery of pregnancy and may not be accurately assessed as early as the first trimester, and an assessment based on the number of weeks of gestation would be necessary.

Conclusions

In this study, we developed and validated the Prenatal Positive Experience Scale for Men. Therefore, 28 items belonging to three factors were extracted and named as the first (increased awareness of becoming a father), second (self-growth through becoming a father), and third (comprising positive emotional responses to pregnancy events) factors. This study demonstrated that the scale had sufficient reliability and validity. The Prenatal Positive Experience Scale for Men allows for a quantitative evaluation of the positive experiences of men during their partner's pregnancy. This scale could be used for developing psychosocial support for expectant fathers and to encourage and strengthen their participation in postpartum childcare activities. This study is the first to develop and validate a quantitative scale on men's positive experiences during their partner's pregnancy. Our study demonstrated that positive experiences of men during their partner's pregnancy were associated with a young partner, a positive emotional response to pregnancy announcement, and experiencing the pregnancy progress. In the future, it is expected that this scale will be used to examine the effects of interventions for men during pregnancy and the relationship between postpartum participation in childcare and motivation to work.

Author Contributions

YN, YT, and TY were involved in study conception and design; YN, YT, TO, MA, and NY were involved in data interpretation and analysis; and MK, MY, and TY contributed to the interpretation of the results and critically reviewed the manuscript. All authors revised and approved the manuscript to be published and agreed to be accountable for all aspects of the work, ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. They also critically revised the report.

Declaration of Conflicting Interests

The authors declare no conflict of interest associated with

this study.

Ethical Approval

Ethics Committee Tohoku University Graduate School of Medicine (2018-1-821)

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Development of a weight loss intervention by mothers for adults with severe intellectual disabilities and autism

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Abstract

Objective: Obesity is highly prevalent among people with intellectual disabilities (ID) and autism. Programs to reduce obesity, however, are currently underexplored. Furthermore, people with severe ID and autism are highly dependent on their family members for a healthy lifestyle; therefore, behavioral changes within the family, especially in mothers, are necessary to reduce their obesity. This study aimed to develop a diet-centered obesity reduction program by mothers that can cater to people with severe ID and autism. **Methods:** The study used an AB design, with A as the baseline and B as the intervention. An intervention based on "behavior analysis" and the "obesity acceptance process of mothers" was conducted with nine mothers and adults (age range: 20-46 years) with severe ID and autism from different day centers. The primary outcomes were weight and waist circumference. The secondary outcomes were the occurrence of desirable maternal behavior, the scores of the children's inflexible adherence to target foods, and target food intake. The outcomes were analyzed at the individual and group levels. **Results:** Seven adults lost weight, with five losing ≥3%. During the follow-up, six adults continued losing weight. The rate for implementing behaviors related to at least one target food was approximately ≥80% for all mothers. The adults' resistance scores were generally low, and six people scored 0 points. The Friedman test revealed significant decreases in weight and waist circumference. **Conclusions:** The program effectively decreased the weight of people with severe ID and autism through changes in maternal behavior. The children's low resistance reinforced maternal behavioral changes.

Keywords

obesity, intellectual disability, mother, behavior analysis, autism

Introduction

What Is Already Known

Obesity is highly prevalent among people with intellectual disability (ID) and autism.

Weight loss programs for adults with ID focus on the cognition and behavior of individuals with disabilities and target people with mild or moderate ID.

To date, studies on weight loss in this group have been more effective for people with mild or moderate ID.

What This Paper Adds

This was the first weight loss program specifically for adults with severe ID and autism and the first study aimed at their mothers.

The weight loss program reduced the body weight of adults with severe ID and autism.

The dietary intervention of mothers modified the routine diet of adult children with ID and autism.

According to the American Psychiatric Association (APA), the prevalence of ID in the general population is approximately 1%. Severity levels for ID are classified as mild, moderate, severe, and profound, and the prevalence of severe ID is approximately 6 per 1000 in the general population (APA, 2013). One of the mental and neurodevelopmental disorders that most commonly co-occur with ID is autism (APA, 2013). Many studies have reported that the high prevalence of obesity in people with ID and autism leads to premature mortality (George et al., 2011; Ha et al., 2010; Phillips et al., 2014). People with ID who live at home are more likely to be obese than those who live in institutions (Bhaumik et al., 2008). In Japan, approximately 90% of people with ID live with their families (Cabinet Office, 2019), and >60% of caregivers of people with disabilities are mothers (Kyosaren, 2010). Individuals with severe ID require support in all daily living activities (APA, 2013). Their mothers are often responsible for weight control through diet and exercise. Many such mothers are very positive about supporting the components of healthy eating, such as good food selection and regularity (George et al., 2011; Sakuda et al., 2013). However, mothers of people with ID also maintain close relationships with their children (Ueto, 2012) and believe that eating is enjoyable for them (Arai et al., 2011; Nonaka et al., 2019). Many people with autism demonstrate excessive adherence to routines and resistance to change (APA, 2013), making it extremely difficult to provide dietary support to people with ID who also have autism (Tanabe et al., 2012). Among adolescents with developmental disabilities, adolescents with autism had the highest prevalence of obesity in a national sample of the United States (Phillips et al., 2014).

Globally, the few intervention programs that address obesity among people with ID are limited in scope, targeting only those with mild or moderate disabilities (Harris et al., 2018; Nonaka & Furuta, 2017). Previous study on weight loss, including ones on individuals with severe ID living at home, suggested that existing interventions were likely to be more effective for people with mild or moderate ID (Melville et al., 2011). To address obesity in people with severe ID and autism, the behavior of family members, especially mothers, needs to be changed; more specifically, interventions should be made in the psychologies of mothers of people with severe ID and autism to address obesity in this group. This study aimed to develop a diet-centered obesity reduction program for children with severe ID and autism, performed by their mothers. It aims to help health professionals, such as nurses, to instruct mothers to manage their children's weight without conflict and help mothers accompany their children to hospitals or elsewhere and use paid carers. People with severe ID and autism would thus have more opportunities to go out and for leisure activities, have better access to medical care, and be better equipped to pre-

vent lifestyle-related diseases and extend their healthy life span.

The rest of the study is organized as follows. Section 2 provides an overview of the study design and method, Section 3 presents the results, and Section 4 discusses them and ends with a conclusion.

Materials and Methods

Study Design

This study used an AB design, with A as the baseline and B as the intervention, with follow-ups.

Participants

The inclusion criteria were certification of severe ID and autism; aged ≥18 years, BMI ≥25, and residing with family at home. The exclusion criteria were certification of physical or mental disability by Japanese law, receiving dietary guidance from experts within the last 6 months, and mother's age ≥75 years. The WHO defines BMI 30 as obese, but in Japan, BMI ≥25 is considered obese because Japanese people are more likely to develop diseases with mild obesity than Westerners (Japan Society for the Study of Obesity, 2000). The age of the mothers was also limited to ≥75 years to be more accurate in running and recording the program. Individuals who met the criteria were recommended by day center directors in Japan, and 10 pairs of mothers and children from 10 different day centers ultimately consented to participate. One dropped out; the remaining nine pairs remained until follow-up.

This study was conducted in accordance with the Helsinki Declaration of 2013 (World Medical Association, 2013). The purpose and methods of this study and the confidentiality of personal information were explained orally and in writing to all participating mothers, and written consent was obtained from all mothers. These matters were also explained orally and in writing to these mothers' adult children with severe ID and autism while they were with their mothers in ways that were tailored to their abilities, and consent was obtained in writing from the children or their mothers. This study was approved by the Research Ethics Review Board of Aichi Prefectural University (31aikendaigakujo dai1-7gou).

Intervention

The authors developed a diet-centered "Conflict-free Weight loss Program for Adults with Severe ID and autism" based on the "obesity acceptance process of mothers" (Nonaka et al., 2019) and "behavior analysis." According to the former, mothers faced dietary and hyperkinetic issues caused by their children's disabilities, owing to which they provided them with scheduled meals—which included the same foods, the same number of foods, and foods of the same color—to avoid conflict with their children, which conse-
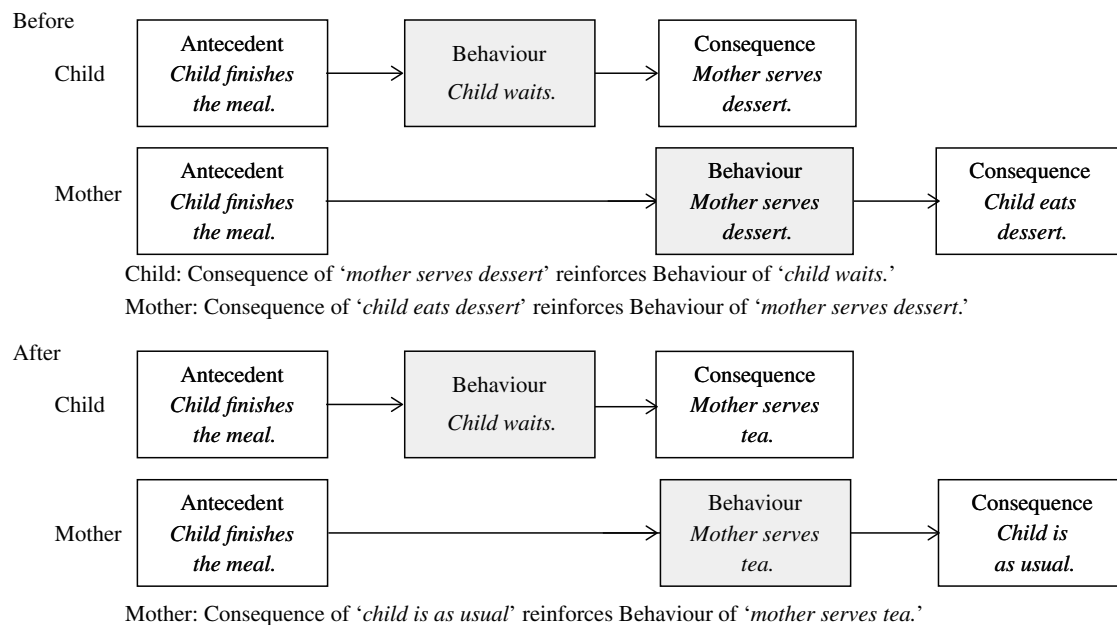
Figure 1. An example of the principle of reinforcement in behavioral analysis for mother and adult with severe ID and autism.

quently led to obesity. Mothers worried about the adverse effects of obesity and tried to assist their children in losing weight, but such efforts were often abandoned. They resumed providing scheduled meals and accepted their children's obesity because they were attached to their children who had difficulty being independent. The key to the program was for mothers to avoid conflict with their children. Figure 1 shows an example of the principles of reinforcement in behavioral analysis for mothers and their adult children with severe ID and autism. In "behavior analysis," behavior is influenced by antecedents and consequences (ABC analysis) (Cooper et al., 2007). Reinforcement is the most important principle of behavioral analysis (Cooper et al., 2007); it is the process in which a behavior is strengthened by the immediate consequences that reliably follow its occurrence (Miltenberger, 2015). The program was designed to use a "behavior analysis" framework to allow mothers who were closely associated with their children to change their behaviors, maintain changes in their behaviors through the consequence "child is as usual," and reduce their children's food intakes. Interventions were individually conducted on mothers by a researcher at day centers or participants' homes. The intervention included two 70- to 90-min sessions aimed at changing mothers' behaviors and daily records and 60-min monthly sessions for encouragement and advice to help mothers maintain their good behaviors.

In Session 1, mothers were given a lecture on the "obesity acceptance process of mothers" (Nonaka et al., 2019) to help them objectively understand their experiences. They then scored their children's inflexible adherence to daily routine foods and selected low-score target foods. During Session 2, the mothers learned "behavior analysis." By conducting an ABC analysis of their children's behaviors when they sought to obtain target foods, mothers realized that their children's behaviors were reinforced by the acquisition of particular foods and that their own behaviors were reinforced by their children's consumption of these foods. The mothers decided how they could behave to reduce their children's target food intakes and implemented these behaviors at home. Further, they recorded their children's resistance scores, weights, target food intakes, and whether they themselves implemented their plans to change their behaviors. They submitted this information to a researcher at each session. The researcher highlighted any changes in the behaviors of the mothers and the children, confirmed whether they had lost weight as planned, and guided mothers in how to overcome barriers at monthly sessions. A researcher called mothers twice a month to monitor whether they were experiencing difficulties and provide encouragement.

Measures

Data were collected from June 2019 to August 2020. The primary outcomes were children's weight and waist circumference, a convenient measure of visceral fat accumulation leading to lifestyle-related diseases. They were measured weekly during a 2-week baseline, monthly during the 4-month intervention, and once 3 months after the intervention. Weight (kg) was measured using the HD-366 scale (Japan, Tokyo, Tanita), and waist circumference (cm) was measured at the height of the navel of the standing participant. Secondary outcomes were target food intake, inflexible adherence score (0 = as usual; 10 = occurrence of problem

Table 1. Participants' characteristics at baseline start.

Participants	Mothers	Adults with ID		
	Age	Age	Gender	BMI (kg/m^2)
1	63	30	M	33.2
2	68	36	F	35.7
3	55	22	M	46.5
4	56	27	M	26.2
5	71	40	M	28.1
6	55	22	M	27.5
7	61	34	M	36.1
8	47	20	M	25.1
9	72	46	M	26.8
Average	60.9	30.8		31.7

BMI, body mass index

M, male; F, female

ID, intellectual disabilities

behavior), and occurrence of desirable maternal behavior. As confounding factors, at baseline, intervention, and follow-up, the children's physical activity over 1 week was measured using Active Style Pro HJA-750C (Japan, Kyoto, Omron Healthcare) and their diet for 1 day was recorded by their mothers. Additionally, as qualitative data, the researcher recorded the remarks of the mothers and the states of the mothers and children during the sessions in field notes.

Data Analysis

For the primary outcomes, individual trends were first visually analyzed using line graphs. Collective data were analyzed using the Friedman test and multiple comparisons (Tukey's test). The level of statistical significance was <5%, and statistical analysis was performed using IBM SPSS Statistics for Windows, version 23 (IBM Corp., Armonk, NY, USA). For secondary data, weekly mean values were used and visually analyzed using line graphs. Confounding factors were determined from dietary records, time by activity intensity, average daily steps, steps per hour, and interviews with mothers about changes in diets and physical activity. Narrative data were used to explore factors for primary and secondary outcomes.

Results

Table 1 presents the characteristics of the nine pairs of participating mothers and their adult children. At baseline, the average age of the mothers and children was 60.9 and 30.8 years, respectively, and the mean BMI of the children was 31.7 kg/m^2.

Seven of the nine adult children experienced weight loss; five and one of them lost ≥3% and >10% of their weight, respectively. During the follow-up, six children continued to lose weight. All mothers were able to intervene for at least one target food, on average, approximately ≥80% per week. Even with their mothers' interventions, the children did not resist much and were able to reduce their intake.

Results of Individuals

Figures 2.1, 2.2 show the individual results. Because of space limitations, only six of the nine cases are explained in detail as follows.

P2: On weekdays, the child bought breakfast, supper, snacks, and juice at a convenience store with their mother and consumed them alone. The child made coffee with milk and lots of sugar every morning and drank cola and juice after their bath. The mother only served them holiday meals and some drinks. The target foods were sugar, cola, and juice. As the children always used both spoons in the container, the mother decided to reduce the amount of sugar and the number of spoons and change to zero-calorie cola and juice. The mother's implementation rate was 100% for sugar, but she could not stop the child from choosing hot chocolate over cola and the regular-calorie juice. The child's inflexible adherence was 0. The child's weight increased by 2.8% and sugar intake did not decrease. The confounding factor was that holiday meals prepared by the mother increased.

P3: The mother said that her child's weight had increased from 14 to 15 kg over the last 3 to 4 years, with a similar increase at baseline. She mentioned that the father liked to cook and served the food to the children. Target foods were rice and meat for breakfast; the mother decided to reduce these foods. Her implementation rates were >80%. The average daily intake per week was similar. The child's inflexible adherence was within 2. The child's weight and waist circumference did not increase initially but slightly increased thereafter. During the follow-up period, the child and his father consumed after-dinner snacks more frequently and the COVID-19 pandemic prevented the child from going out with helpers.

P5: The mother could not stop buying her favorite snacks, so the target foods were four kinds of snacks that her child liked, dinner rice, breakfast fruits, and bread. In the first month, however, she was warned by a family doctor that her child might be hospitalized for diabetes. The mother then stopped buying all snacks. She bought snacks only when shopping with her child on holidays. The mother's implementation rates were 100% for fruits and bread, 50%-100% for rice, and 14%-100% for snacks. The child sometimes sought snacks at home but did not become angry when he could not find them. The inflexible adherence was 0. The child's weight loss was 13% at postintervention but 11.5% at follow-up. The confounding factor did not change. The mother said that she wanted to buy snacks but would refrain postinterview.

P7: Target foods were rice and a main dish for dinner.
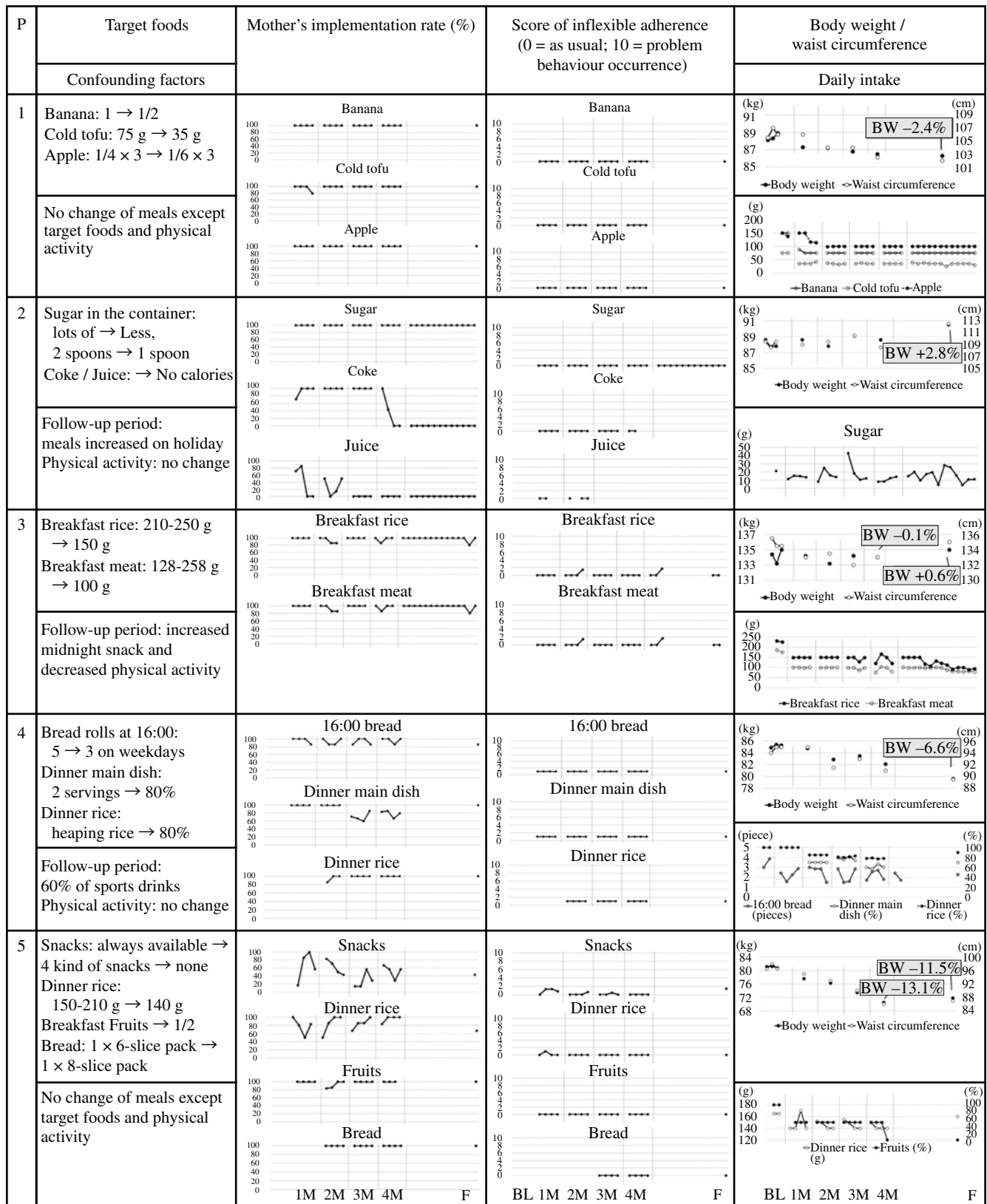
Figure 2.1. Individual results.

Note. P, participant; BL, baseline; M, month; F, follow-up; BW, body weight.

P	Target foods / Confounding factors	Mother's implementation rate (%)	Score of inflexible adherence (0 = as usual; 10 = problem behaviour occurrence)	Body weight / waist circumference / Daily intake
6	Sausage: at breakfast/dinner, 1 each → 1/2 each. Dinner rice: 120 g × 2 → 100 g × 2 → 80 g × 2 or noodles + rice 80 g × 2 → noodles + rice 50 g × 2. Saturday lunch: Yakisoba + noodles 2/3 + rice 80g × 2 → Yakisoba + noodles 2/3 + rice 50 g × 2 Decrease in side dishes and treats availability. No change in physical activity	Sausage; Dinner rice; Lunch staple food	Sausage; Dinner rice; Lunch staple food	BW −4.0% (Body weight; Waist circumference); Lunch rice (g); Dinner rice (g); Sausage (number)
7	Dinner rice: 120 g-240 g → 120-150 g. Dinner maindishes: 2 servings → 1 serving Intervention period: decrease in holiday snacks. Follow-up period: breakfast decreased, physical activity increased	Dinner rice; Dinner main dish	Dinner rice; Dinner main dish	BW −6.9% (Body weight; Waist circumference); Dinner rice; Dinner main dish
8	Breakfast rice: 1 cup → 0.7 cup (1 cup is 180 mL). Snacks: 2 boxes → 2 individually wrapped Follow-up period: dinner rice on days with many snacks was reduced. No change in physical activity	Breakfast rice; Snacks	Breakfast rice; Snacks	BW −7.2% (Body weight; Waist circumference); Breakfast rice (cup); Snacks (box)
9	16:00 sugary drink: 1 cup × 4 days/week → Tea. Soy milk after bath: 1 bottle → None Intervention and follow-up period: dinner rice on days with many snacks was reduced. Physical activity: significantly reduced in 4th month, decreased in follow-up period	16:00 sugary drink; Soy milk after bathing	16:00 sugary drink; Soy milk after bathing	BW −1.9% (Body weight; Waist circumference); 16:00 sugary drink; Soy milk after bathing

1M 2M 3M 4M F　BL 1M 2M 3M 4M F　BL 1M 2M 3M 4M F

Figure 2.2. Individual results.

Note. P, participant; BL, baseline; M, month; F, follow-up; BW, body weight.

The mother's implementation rates were 80% for rice and approximately ≥50% for main dishes, although sometimes this rate was 30%. Inflexible adherence was 0. The child lost 6.9% of their weight, and intakes were reduced. The confounding factors were that holiday snacks and breakfast decreased and physical activity increased.

P8: Target foods were snacks and rice for breakfast. The mother decided to reduce snacks from two boxes to two individually wrapped snacks and rice from one cup to 0.7 cups (one cup = 180 mL). The mother's implementation rates were 100% for rice and 30% for snacks, especially during the follow-up, as the child's parents and brother

Table 2. Standardized body weight/standardized waist circumference friedman test.

	Baseline (*n* = 9)	Postintervention (*n* = 9)	Follow-up (*n* = 9)	*p*
Body weight[*1]	1	0.978 (0.869–1.006)	0.960 (0.885–1.028)	.045
Waist circumference[*2]	1	0.965 (0.887–0.994)	0.960 (0.897–1.031)	.013

[*1] [*2] The mean of the three baselines was set to 1, and the postintervention and follow-up values were divided by the baseline mean.

※Notation is shown by median (total range = minimum value − maximum value).

bought snacks. The inflexible adherence was low—0 for breakfast and 2 for snacks in the second month. The child's weight reduced by 7.2%, and their intake of rice and snacks was the same as the mother's implementation. As a confounding factor, the mother reduced the quantity of rice served at dinner on the day the child consumed many snacks.

P9: The target foods included a sugary drink at 16:00 and soy milk after a bath. At first, the child hated drinking tea at 16:00; hence, the mother served coffee with honey. However, a few days later, the child started drinking tea or whipped green tea. The mother's implementation rate was ≥80%, and inflexible adherence was almost 0. Three months later, the child's weight decreased by 2 kg and their waist circumference decreased by 1.5 cm. However, during the fourth month, the child's day center closed because of COVID-19; consequently, physical activity decreased drastically, weight increased, and the ultimate decrease in the child's weight was 1.9%.

Statistical Analysis of Primary Outcomes

As Table 2 shows, the standardized body weight (median [minimum-maximum]) with a baseline mean of 1 was 0.978 (0.869-1.006) at postintervention and 0.960 (0.885-1.028) at follow-up. The standardized waist circumference (median [minimum-maximum]) was 0.965 (0.887-0.994) at postintervention and 0.960 (0.897-1.031) at follow-up. Weight was significantly reduced from baseline at follow-up, and waist circumference was significantly reduced from baseline at postintervention and follow-up.

Mothers' Remarks and the States of the Mothers and Children

Some children voluntarily weighed themselves at the sessions or at home. Some even mirrored their mothers' expressions of happiness or disappointment with their weights. Because of severe ID, mothers usually had much less communication with their children, and therefore, some mothers were pleased with this new communication. Certain mothers recognized that their children either "accepted" or "did not notice" that they were given inflexible adherence scores of 0. Reflecting on their behavior, some mothers reported the following: "My child didn't want them, but I bought them. I

was bad" (mother 8). "I thought deeply that my child was satisfied with just this amount" (mother 1). "If I don't give a side dish or snacks, my child won't want it. It was weakening" (mother 7). "I was glad that the program was easy" (mother 9).

Discussion

This was the first weight loss program specifically for adults with severe ID and autism and the first study aimed at their mothers.

Effect of the Intervention on the Mothers

The results suggest that the program allowed the mothers to continuously intervene in and address their children's obesity. The mothers' implementation rates were approximately ≥80% for at least one target food. As is the case with the larger public, interventions in balanced diets with limited energy levels (Melville et al., 2011) and high-volume and low-calorie foods (Saunders et al., 2011) are encouraged for people with intellectual or developmental disabilities. However, it may be difficult for mothers who believe that their children's enjoyment comes from meals to intervene in the diet of individuals with severe ID who themselves have difficulty understanding a healthy diet. In this program, target food selections that did not conflict with children when intervening based on the "obesity acceptance process of mothers" (Nonaka et al., 2019) and an objective view of the children's behaviors using the "behavior analysis" framework appear to have modified the mothers' behaviors. Additionally, postintervention, the mothers' behaviors were reinforced and maintained by the fact that their "children were as usual" and the achievement of weight loss. Mothers' remarks such as "my child didn't want them (target foods)" and "I thought deeply that my child was satisfied with this amount" also showed that this program was feasible for mothers.

Effect of the Intervention on the Children

This study succeeded in reducing the children's intakes of the target foods selected by their mothers with little or no resistance from the children. Additionally, regarding the confounding factors, the children did not increase their levels of

food consumption, which contributed to their weight loss. Other home-based weight loss programs for adults with ID focus on the cognition and behavior of individuals with disabilities and target people with mild or moderate ID (Bergström et al., 2013; Martínez-Zaragoza et al., 2016; Pett et al., 2013). To date, studies on weight loss in this group have been more effective for people with mild or moderate ID (Melville et al., 2011).

People with severe ID and autism frequently have obsessions with specific foods (APA, 2013) and highly regularized eating behaviors (George et al., 2011; Sakuda et al., 2013). "Conflict-free" food selection was an effective way to encourage healthy dietary changes in individuals with severe ID and autism by working with their mothers. The program was also accepted by the children, as some of them voluntarily tried to weigh themselves and seemed to "accept" or "not notice" that their mothers had intervened in their diets. It is important to note here that if the target foods that children accept are low in calories, they may lose weight as a result of such repeated diets.

The results also suggest that individuals other than mothers who are familiar with the children benefit from weight loss. In individuals with mild to moderate ID and autism, however, the impact of their own meals is likely greater, so their own interventions would be necessary, and thus, the effects of the program may be limited.

Factors Related to the Intervention Effect

If the child is relatively independent and the mother's involvement in the diet is minimal, the program's effect may be limited, as was true in the case of P2. Additionally, the physical activity of adults with severe ID can be affected by a lack of available support and whether their parents have the time and physical strength to assist them (Arai et al., 2011; Spanos et al., 2013). Therefore, spending time at day centers and going out with helpers are valuable physical activities for this group. If these activities are reduced, as was the case with P3 and P9, the program's effect may be diminished. Further, it may be difficult to maintain plans if they significantly change the mother's diet, as in the cases of P5 and P8.

Conclusions

The limitations of this study were its small sample size and adaptation of the AB design, given that using the ABA design would have been unethical. The results demonstrate that the program increased the mothers' abilities to appropriately intervene in their children's weight to help them lose weight with little or no resistance from the children. The two sessions allowed mothers to appreciate their impact on their children's weight gain. The low resistance of the children and application of praise reinforced good behavioral change in the mothers. In future research, it will be necessary to increase the number of cases and confirm the effectiveness of the program by including people with severe ID without autism.

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Original Research

Cognitive behavioural therapy for mood and anxiety disorders delivered by mental health nurses: Outcomes and predictors of response in a real-world outpatient care setting

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Abstract

Objective: The need for mental health nurses (MHNs) to incorporate psychological techniques into their nursing practice has been recognised worldwide. Further evidence from real-world settings is necessary to demonstrate that MNH-led cognitive behavioural therapy (CBT) is an effective approach that can be used in clinical practice. This study aimed to explore the clinical effectiveness and predictors of MNH-led CBT for mood and anxiety disorders in routine outpatient care settings in Japan. **Methods:** This retrospective study collected data through a medical record review of 69 participants who underwent MHN-led CBT between January 2015 and December 2019. **Results:** Participants who received MHN-led CBT demonstrated significant improvements in depressive/anxiety symptoms, health-related quality of life and primary psychiatrists' impressions of condition severity (all $p <$ .001). At the end of therapy, more than half of the participants (56.5%) showed positive clinical significance (recovered/improved) based on cutoff points and reliable change indices of validated depression and anxiety measurement scores. Furthermore, an increase in the baseline anxiety score predicted lower odds of achieving positive clinical significance (odds ratio = 0.87, 95% confidence interval = 0.79-0.96). **Conclusions:** Despite several limitations, mainly owing to its single-group retrospective design, this real-world evidence of MHN-led CBT bridges the gap between research and clinical practice, contributing to the widespread use of MHN-led CBT in mental health services worldwide.

Introduction

Cognitive behavioural therapy (CBT) has been consistently effective in treating mood and anxiety disorders (Butler et al., 2006; Hofmann et al., 2012; Wakefield et al., 2021). Although psychotherapy is preferred over medication by most patients, insufficient provision of such therapy is a major problem in several countries (Kazdin & Blase, 2011; McHugh et al., 2013). Efforts to improve mental health services worldwide have identified the need for mental health nurses (MHNs) to incorporate evidence-based psychosocial interventions in their clinical practice (Hurley et al., 2020a; Hurley et al., 2020b; The Psychological Professions Network, 2018).

Since nurses constitute the largest group of healthcare professionals, the use of psychosocial intervention techniques by MHNs is expected to improve/expand mental health services. MHNs play a vital role in the dissemination of CBT. In the UK, MHNs received systematic CBT training and primarily provided CBT to neurotic individuals. These trained MHNs were as effective at delivering CBT as other professionals such as psychiatrists and psychologists (Bird et al., 1979). A follow-up study of British MHNs providing CBT further demonstrated a significant contribution to mental health service provision, particularly in community care settings (Gournay et al., 2000). Several studies have confirmed the efficacy of MHN-led CBT for various mental disorders (Nance, 2012; Turkington et al., 2006). According to a report from the European Psychiatric Nurses (Horatio), most (90%) CBT therapists in the UK presently have a background in psychiatric nursing (Horatio: European Psychiatric Nurses, 2012). Furthermore, CBT is the psychological intervention technique most frequently administered by MHNs in outpatient settings (Ameel et al., 2019). In Japan, CBT for mood disorders was included in the National Health Insurance in Financial Year (FY) 2010, marking an important milestone for Japanese mental health services, which are otherwise dominated by pharmacotherapy. However, service users' access to CBT in Japan is generally suboptimal owing to the scarcity of CBT providers under the health insurance scheme, which requires CBT to be only provided by skilled and experienced psychiatrists (Ono, 2011). Research has shown that psychological treatments, predominantly CBT, for anxiety are more effective when they are delivered by a psychiatrist or clinical psychologist than when delivered by MHNs (Parker et al., 2021). However, to improve access to CBT in Japan, the subsequent FY 2016 revision of medical fees expanded the range of eligible CBT providers to include MHNs. Therefore, further evidence from real-world outpatient care settings is necessary to demonstrate that MHN-led CBT for mood and anxiety disorders is an effective treatment that can be used in clinical practice. Our previous study reported the results of the routine clinical outcomes of MHN-led CBT (Yoshinaga et al., 2022), but this study included a heterogeneous population that included all types of mental disorders; thus, real-world outcomes focusing on a more homogeneous population, especially common mental disorders (i.e. a range of mood and anxiety disorders), are needed. Furthermore, it is essential to identify people who require an adapted treatment strategy and to specify the predictors of MHN-led CBT responses.

Thus, this study aimed to analyse the clinical effectiveness of MHN-led CBT for mood and anxiety disorders in routine outpatient care settings and investigate whether sociodemographic and clinical characteristics are predictive of differential therapeutic responses to CBT. Accordingly, clinical data were collected retrospectively from former patients, in Japan, who had received MHN-led CBT for mood and anxiety disorders.

Materials and Methods

Study Design and Sample

This study employed a retrospective cohort design and included patients with mood and anxiety disorders referred to MHNs for CBT at two psychiatric outpatient clinics in Japan. We retrospectively collected data through medical record reviews of former patients who had received individual face-to-face CBT between January 2015 and December 2019. The Ethics Committee of the University of Miyazaki reviewed and approved all aspects of this study (approval number: O-0442) and waived the requirement to prospectively obtain informed consent from the participants due to the retrospective nature of this study. In addition, we placed posters/leaflets at the study institutions and their websites to inform participants that they could withdraw from the study at any point.

The inclusion criteria for this study were as follows: (1) patients who had a primary diagnosis of mood or anxiety disorders based on the 10th revision of the International Classification of Diseases (ICD-10) or the 4th/5th editions of the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV/DSM-5) and (2) those who had received individual face-to-face MHN-led CBT (at least one session) between January 2015 and December 2019. The diagnostic assessment/classification was conducted by their primary psychiatrist at the study institution.

A total of 121 patients were referred to MHNs for CBT during the observation period, 52 of whom were excluded (31 did not meet the inclusion criteria for diagnoses, 12 did not start CBT and 9 did not attend the initial assessment). The remaining 69 participants with mood or anxiety disorders (n = 47 [68.1%] and 22 [31.9%], respectively) received individual CBT of at least one session by an MHN (Figure 1).

Intervention

CBT was delivered by three MHNs (mean age = 34.7 years [SD = 2.1]) working at the study institution. On average, they had clinical experience of 8.9 years (SD = 0.5) in psychiatric nursing and 4.9 years (SD = 1.5) in CBT. All MHNs had completed a formal, multi-professional CBT training programme in Japan (including onsite workshops and online case supervision), which was organised by the Center for the Development of Cognitive Behavior Therapy Training.

Under routine clinical settings, CBT was conducted as a structured, individual face-to-face session containing components of CBT-related techniques. If available, therapists fol-
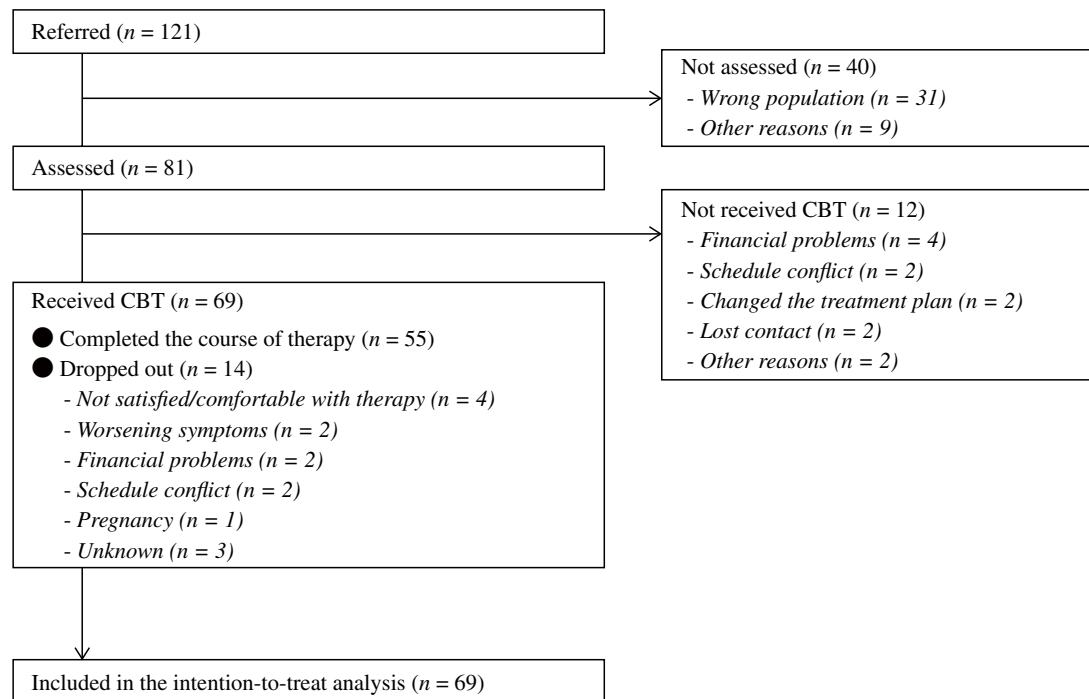
Figure 1. Flow of participants.
Abbreviations: ITT: intention to treat.

lowed standardised Japanese CBT protocols/manuals for each disorder. Most sessions lasted approximately 40-60 min.

Outcomes

Depressive Symptoms (Patient Health Questionnaire-9 Item: PHQ-9 [Self-rated])
The PHQ-9 was used to evaluate the severity of depressive symptoms (Kroenke et al., 2001). It is a self-administered questionnaire comprising nine items that measure the frequency of depression symptoms (e.g. depressed mood, sleep difficulties and feelings of worthlessness or guilt). Responders scored each item based on their experience over the previous 2 weeks, on a 4-point Likert-type scale. The total score ranges from 0 to 27, the clinical cutoff for significant depressive symptoms is ≥ 10 points, and a difference of ≥ 6 points between assessments indicates a reliable change (reliable improvement/deterioration). The Japanese version of the PHQ-9 is valid and reliable for use with Japanese university students and primary care patients (Muramatsu et al., 2018; Umegaki & Todo, 2017).

Anxiety Symptoms (Generalized Anxiety Disorder-7 Item: GAD-7 [Self-rated])
The GAD-7 was used to evaluate the severity of anxiety symptoms (Spitzer et al., 2006). It is a self-administered questionnaire comprising seven items that measure the frequency of generalised anxiety symptoms (e.g. feeling nervous, being unable to stop or control worrying and having

trouble relaxing). Responders scored each item based on their experience over the previous 2 weeks, on a 4-point Likert-type scale. The total score ranges from 0 to 21, and a clinical cutoff of ≥ 8 points and a difference of ≥ 5 points between assessments indicate a reliable change. The Japanese version of the GAD-7 is valid and reliable for use with Japanese patients with depression or anxiety disorders (Doi et al., 2018).

Clinical Significance Based on the PHQ-9 and GAD-7 Scores (Primary Outcome)
Participants were classified as *recovered*, improved, *no reliable change (unproblematic or problematic)* or *deteriorated* based on the established cutoff points and reliable change indices of the PHQ-9 and GAD-7 (Clark et al., 2018). More details on how clinical significance was determined from the conjunction of these scales are as follows:

- *Recovered*: Patients who improved reliably (PHQ-9 and/or GAD-7) and whose final observed scores (PHQ-9 and GAD-7) were below the cutoff point
- *Improved*: Patients who improved reliably (PHQ-9 and/or GAD-7) but whose final observed scores were above the cutoff point (PHQ-9 and/or GAD-7)
- *No reliable change (unproblematic)*: Patients who showed no reliable change (PHQ-9 and/or GAD-7) and whose final observed scores were below the cutoff point (PHQ-9 and GAD-7)
- *No reliable change (problematic)*: Patients who showed no reliable change (PHQ-9 and/or GAD-7) but whose

last observed scores were above the cutoff point (PHQ-9 and/or GAD-7)

- *Deteriorated*: Patients who reliably showed score changes in the opposite direction (PHQ-9 and/or GAD-7)

Health-related Quality of Life (EuroQol 5-dimension 5-level Questionnaire: EQ-5D-5L [Self-rated])

The EQ-5D-5L was used to measure health-related subjective quality of life (QoL) (Herdman et al., 2011; van Hout et al., 2012). This questionnaire comprises five dimensions of mobility, self-care, usual activities, pain/discomfort and anxiety/depression and is rated using five response options: 1 (no) to 5 (extreme problems). These results were converted into a single figure, that is, the health utility value. The range is between 0 (dead) and 1 (full health), and a value less than 0 represents a status worse than death. The Japanese version of the EQ-5D-5L is reliable for the general population (Shiroiwa et al., 2016).

Clinicians' Impressions of Condition Severity (Clinical Global Impression of Severity: CGI-S [Clinician-rated])

The CGI-S was used by primary psychiatrists at the study institutions to assess the severity of the clinician's impressions of the patient's condition (Busner & Targum, 2007). The CGI-S is a single item that asks the clinician one question: 'Considering your total clinical experience with this particular population, how mentally ill is the patient at this time'? This question was rated on a 7-point Likert scale ranging from 1 (normal, not at all ill) to 7 (among the most extremely ill patients). The rating is based on observed and reported symptoms, behaviour and function in the past 7 days.

Statistical Analysis

All statistical analyses were performed using JMP Pro version 15.2.0. The statistical significance threshold was set at a bilateral alpha level of 0.05. We compared the baseline and endpoint scores (PHQ-9, GAD-7, EQ-5D and CGI-S) using paired t-tests based on the intention-to-treat principle, assuming that the missing values randomly occurred. We calculated the Hedges' g within-group effect sizes to determine the magnitude of the effect of MHN-led CBT. A within-group effect size of 0.20-0.49 was considered small, 0.50-0.79 was medium, and ≥ 0.80 was large. Moreover, we evaluated the differences in the daily doses (mg/day) of concurrent psychotropic medications (imipramine-equivalent dose of antidepressants, diazepam-equivalent dose of anxiolytics and chlorpromazine-equivalent dose of antipsychotics) between the assessment points in the same manner.

Multivariate logistic regression models were used to examine the predictors of positive clinical significance status (*recovered* or *improved*) at the endpoint. First, we examined the crude (unadjusted) association between each factor and the odds of positive clinical significance. Second, we examined the adjusted associations for possible confounders using multivariable logistic regression models with all factors included. Thirteen possible predictor variables were selected: (1) age (continuous), (2) sex (female or male), (3) marital status (single or married), (4) employment (employed or unemployed), (5) primary diagnosis (mood or anxiety disorders), (6) duration of illness (continuous), (7) comorbidity (yes or no), (8) psychotropic medications (yes or no), (9) baseline PHQ-9 score (continuous), (10) baseline GAD-7 score (continuous), (11) baseline EQ-5D-5L score (continuous), (12) baseline CGI-S score (continuous) and (13) weeks of treatment (continuous). The associations were presented as odds ratios (ORs) with 95% confidence intervals (CIs).

Results

Baseline Sociodemographic and Clinical Characteristics

Among the 69 participants who received at least one session of CBT by an MHN, the mean age was 35.9 years (SD = 10.8) and 31 participants (44.9%) were female. The mean duration of the primary diagnosis of mood or anxiety disorders was 8.1 years (SD = 7.6) and 24 participants (34.8%) had comorbid mental disorders. In addition, 52 participants (75.4%) received concurrent psychotropic medications (antidepressants, anxiolytics, or antipsychotics) at baseline. Table 1 shows the other baseline sociodemographic and clinical characteristics.

Intervention Received

Among the 69 participants who underwent CBT, 55 (79.7%) completed the course of treatment (dropout rate = 20.3%). On average, 12.8 sessions (SD = 7.6) were conducted over 24.3 weeks (SD = 20.3).

As stated, 75.4% of the participants were prescribed psychotropic medications concurrently at baseline; however, throughout the observation period, there were no significant differences in the average daily doses of concurrent psychotropic medications.

Outcomes

Regarding clinical significance based on PHQ-9 and GAD-7 scores (primary outcome), 27 participants (39.1%) were considered to have *recovered* and 12 (17.4%) *improved* (i.e. 39 [56.5%] participants demonstrated positive clinical significance). The remaining 27 participants (39.1%) were judged to have *no reliable change* (n = 13 [*unproblematic*] and 14 [*problematic*]) and 3 (4.3%) had *deteriorated* (n = 3). In terms of the difference in clinical significance between the mood and anxiety disorder subgroups, 24 out of 46 (52.1%) in the mood disorder subgroup and 15 out of 23 (65.2%) in the anxiety disorder subgroup met the criteria for positive clinical significance (see Tables S1, S2 for details).

Table 2 presents the results of other secondary outcome measures (PHQ-9, GAD-7, EQ-5D-5L and CGI-S). Statisti-

Table 1. Baseline sociodemographic and clinical characteristics (*n* = 69).

Variable		Value
Age, years, mean (SD)		35.9 (10.8)
Sex, *n* (%)		
Female		31 (44.9)
Male		38 (55.1)
Marital status, *n* (%)		
Single	Never married	40 (58.0)
	Divorced	4 (5.8)
	Total	*44 (63.8)*
Married	Married	22 (31.9)
	Living as married	3 (4.3)
	Total	*25 (36.2)*
Employment status, *n* (%)		
Employed or student	Full time	17 (24.6)
	Part time	9 (13.0)
	Student	6 (8.7)
	Total	*32 (46.4)*
Unemployed	Sick leave from work/school	17 (24.6)
	Unemployed/homemaker	20 (30.0)
	Total	*37 (53.6)*
Primary diagnosis, *n* (%)		
Mood disorders	Major depressive disorder	39 (56.5)
	Bipolar I/II disorder	7 (10.1)
	Persistent depressive disorder (dysthymia)	1 (1.4)
	Total	*47 (68.1)*
Anxiety disorders	Social anxiety disorder	15 (21.7)
	Generalised anxiety disorder	6 (8.7)
	Agoraphobia	1 (1.4)
	Total	*22 (31.9)*
Duration of primary diagnosis, years, mean (SD)		8.1 (7.6)
Comorbidity, yes, *n* (%)		24 (34.8)
Baseline concurrent psychotropic medications, yes, *n* (%)		52 (75.4)
Baseline antidepressant (imipramine equivalent), mg/day, mean (SD)		43.6 (55.2)
Baseline anxiolytic (diazepam equivalent), mg/day, mean (SD)		7.9 (13.6)
Baseline antipsychotic (chlorpromazine equivalent), mg/day, mean (SD)		10.3 (43.5)

cally significant improvements were also found in all secondary outcome measures (all $p < .001$). The within-group effect sizes for the PHQ-9, GAD-7 and CGI-S were large (Hedges' g = 0.84, 0.90 and 0.91, respectively), and that for EQ-5D-5L was medium (Hedges' g = 0.52).

Predictors of Positive Clinical Significance

All potential predictors were entered into a logistic regression model with a positive clinical significance status (*recovered* or *improved*) at the endpoint as the outcome. Only the baseline severity of anxiety symptoms (GAD-7) predicted the likelihood of positive clinical significance, with an increase of one point in the baseline GAD-7 score predicting lower odds of achieving positive clinical significance (OR = 0.87, 95% CI = 0.79-0.96). None of the other predictors were statistically significant. The area under the receiver operating characteristic curve was 0.74 (see Table S3).

Discussion

This study investigated the real-world clinical effectiveness of MHN-led CBT conducted in routine clinical settings for mood and anxiety disorders, along with the baseline predictors of CBT outcomes. The results yielded three key findings. First, in routine care settings, MHN-led CBT for common mental disorders resulted in remarkable improvements in all clinical outcome measures. Second, more than half of the participants either recovered or improved after receiving CBT, with only a few participants who deteriorated or dropped out. Third, CBT outcomes were affected by baseline anxiety symptoms in participants (less severe anxiety at baseline was associated with better outcomes).

The key strength of our study is the high external validity observed in the results based on real-world data derived from routine clinical practice. As stated in the introduction, evidence from highly controlled efficacy studies (e.g. randomised controlled trials) often has low external validity. Thus, the findings of this study using real-world data have significant implications for the dissemination of MHN-led CBT in routine practice. Furthermore, a previous study indicated that CBT for anxiety disorders is more effective when provided by psychiatrists or clinical psychologists than when provided by MHNs (Parker et al., 2021). Despite this, in terms of within-group effect size, our results were comparable to those of other studies in which mental health professionals other than MHNs delivered psychological interventions (including CBT) in a routine care setting. For example, several previous studies investigated the effectiveness of psychotherapy delivered by clinical psychologists in routine outpatient care, demonstrating within-group effect sizes of 0.42-1.34 on the severity of depression and anxiety symptoms (Cahill et al., 2010; Richards & Borglin, 2011; von Brachel et al., 2019; Westbrook & Kirk, 2005). These were close to the effect sizes of MHN-led CBT on the severity of depression and anxiety symptoms observed in our study (Hedges' g = 0.84-0.90). Similarly, the effect size of CBT on QoL in our study (Hedges' g = 0.52) was comparable to the effect size reported in the previous meta-analysis based on randomised controlled trials of CBT for depression and anxiety (Hedges' g = 0.63) (Hofmann et al., 2017).

Furthermore, we found that less severe anxiety at baseline was positively associated with better clinical outcomes, suggesting that MHN-led CBT may be more effective for mild to moderate anxiety. These results are largely consistent with findings from other studies that have investigated predictors

Table 2. Changes in outcome measures ($n = 69$).

	Mean (SD)		t	p	Effect size
	Pre	Post			g
Depression (PHQ-9)	13.13 (5.84)	8.16 (5.90)	7.90	< .001*	0.84
Anxiety (GAD-7)	10.81 (5.43)	6.19 (4.71)	6.23	< .001*	0.90
Quality of life (EQ-5D-5L)	0.68 (0.12)	0.75 (0.15)	−4.97	< .001*	0.52
Clinician's impressions of patients' condition severity (CGI-S)	3.96 (0.92)	3.00 (1.19)	7.78	< .001*	0.91

Note. t and p values of paired t-test. *p < .01

Abbreviations: EQ-5D-5L, EuroQOL 5-dimensions 5-level; PHQ-9, Patient Health Questionnaire-9; GAD-7, Generalized Anxiety Disorder-7; CGI-S, Clinical Global Impressions-severity of illness

of CBT outcomes in younger adults. The number of sessions, homework completion and baseline severity of depression and anxiety symptoms predicted treatment outcomes (Kampman et al., 2008). However, another study focusing on older adults (Wetherell et al., 2005) reported that greater baseline severity of anxiety symptoms was positively associated with better clinical outcomes. This contradicts our findings, which may have been influenced by the young age of the participants. Further research is required for a detailed examination of the relationship between symptom severity and clinical outcomes among individuals with mood and anxiety disorders undergoing MHN-led CBT.

This study had some limitations. First, the most significant limitation was the lack of a control or comparison group. Therefore, we could not determine whether MHN-led CBT itself or other nonspecific factors (e.g. natural time trends) contributed to the considerable clinical effectiveness observed in our study. This was an unavoidable limitation because our study was conducted in a routine outpatient care setting. Second, the sample size was relatively small because the study was conducted at two sites within a limited geographical area. Third, only a small number of MHNs provided CBT, primarily due to the limited number of MHNs specifically trained in CBT in the country.

Overall, our findings demonstrate that MHN-led CBT can be delivered with strong positive outcomes in routine clinical settings and will contribute to the spread of CBT worldwide. To disseminate CBT, evidence (e.g. clarification of mechanisms of action, various targets and delivery methods, cost-effectiveness and establishment of evidence in clinical settings) must be established. This is also recommended by the guidelines, which require public administrative support. It also requires training tailored to the therapist's skill level (e.g. simple and flexible interventions that can be used in clinical practice and education for various professions), along with ongoing evaluation and validation in routine clinical practice (Holmes et al., 2018). Furthermore, the Japan Health Care Policy Institute recently released a proposal outlining the requirements for further dissemination of CBT, based on the concept of implementation science in Japan.

These recommendations emphasise the need for public normalisation and awareness of mental health problems (including treatment) and the development of a delivery system (using information and communication technology and applications), as stigma against psychiatry persists in Japan (Japan Health Policy NOW, 2021). In summary, our real-world evidence undoubtedly supports and encourages the use of MHN-led CBT in mental health services, narrowing the gap between clinical research and practice; however, Japanese MHNs, researchers and policymakers also need to take additional measures to disseminate CBT across Japan.

Conclusions

In psychiatric outpatient routine care settings, CBT provided by MHNs is effective for individuals with mood and anxiety disorders to improve their depressive and anxiety symptoms, QoL and clinicians' impressions of condition severity. The CBT response change was affected by baseline anxiety symptoms in the participants. Our findings bridge the research-practice gap and will contribute to the widespread use of MHN-led CBT in routine clinical settings worldwide.

Author Contributions
HT and NY contributed to the conception and design of this study. YH merged the dataset. HT analysed the data and drafted the first manuscript. All authors collected and interpreted the data, critically revised the first manuscript for important intellectual content, and approved the final manuscript.

Declaration of Conflicting Interests
The authors declare that there are no conflicts of interest.

Disclaimer

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Learning needs of family caregivers in the Japanese working generation who care for community-dwelling people with dementia: A qualitative research study

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Abstract

Objective: This study investigated and described the learning needs experienced by family caregivers in the Japanese working generation who care for community-dwelling people with dementia (PWD). **Methods:** This qualitative descriptive study conducted semi-structured in-depth interviews to explore the learning needs experienced by the family caregivers of PWD. 18 family caregivers were recruited via purposive sampling (age range 30-60 years) from two medical facilities, two self-help groups, and 10 prefectural-sponsored counseling facilities in Japan. The collected data were subjected to a qualitative content analysis. Then, the derived learning needs were independently reviewed by two nursing researchers with expertise in qualitative research and family nursing. The Standards for Reporting Qualitative Research (SRQR) recommendations were followed. **Results:** Four main categories and 20 subcategories were derived to clarify the learning needs of family caregivers in the Japanese working generation who care for community-dwelling PWD. The four main categories included (a) increasing long-term care literacy, (b) dispelling the negative images associated with dementia and long-term care, (c) working on long-term care as a unified team that handles issues concerning caregiving for dementia, and (d) promoting an active role as a member of society. **Conclusions:** This study clarified specific learning needs that family caregivers in the Japanese working generation experience when caring for community-dwelling PWD, thus, contributing to a more thorough understanding of the associated challenges. In addition, the structured list of learning needs should aid health professionals when conducting assessments and planning interventions, especially when framing these issues from the cultural perspective.

Keywords

dementia, family caregiver, learning need, working generation, qualitative research

Introduction

There are approximately 50 million people with dementia (PWD) worldwide, with current numbers expected to be more than tripled by 2050 (World Health Organization, 2020). This constitutes a serious international health problem, as the behavioral and psychological symptoms of dementia (BPSD) affect interpersonal relationships and the ability to perform activities of daily living; even more problematically, the various issues stemming from COVID-19

have increased neuropsychiatric symptoms in many PWD. Thus, this highlights the urgent need for interventions to improve support for caregivers (Wei et al., 2022).

In Japan, the number of PWD is expected to exceed seven million by 2025 (Ministry of Health, Labour and Welfare, 2019). Japanese tradition entails that families are responsible for caregiving duties. To date, official reports show that approximately 54% of family caregivers with community-dwelling people are below 60-years-old in Japan (Statistics Bureau of Japan, 2019). The situation in Japan is continually worsening, with 99,000 individuals quitting their jobs due to long-term care needs on an annual basis (Ministry of Internal Affairs and Communications, 2018).

Dementia care makes it especially difficult to balance work requirements. Reports have shown that social isolation due to turn over leads to other problems, such as the abandonment of care and elder abuse (Leung et al., 2017). While the Japanese long-term insurance system assists people with these types of care needs (Iwagami & Tamiya, 2019), cognitive symptoms have become more difficult to manage due to issues, such as the COVID-19 pandemic and certain lifestyle restraints, including restrictions on going out and service usage and communication with others (Ministry of Health, Labor and Welfare, 2021). In summary, the current conditions have increased the burden of long-term care, thus making the problem more serious.

Research shows that individuals who care for PWD with high long-term care needs are especially hindered in their work due to heavy caregiving burdens (Gordon et al., 2012; Fujihara et al., 2019). Further, individuals in the working generation are more likely to develop depression because they must work and provide care without help from family members or formal services (Juratovac & Zauszniewski, 2014; Eguchi & Wada, 2018). Moreover, family caregivers in the working generation are greatly affected by the burdens associated with long-term care.

Despite these issues, caregivers may benefit by employing some helpful strategies. For example, Baharudin et al. (2019) reported that pre-planned care positively influenced the relationship between BPSD and caregiver burden. In addition, research shows that caregivers undergoing educational programs/courses feel more confident about dementia care because they help reduce stress and dissolve feelings of concern and promote empathy and understanding. (Klimova et al., 2019). In this regard, family caregivers in the working generation may balance their work and care duties by learning more about the caregiving process itself. This should be complemented by dementia education programs, which are facilitated through goal setting (Resciniti et al., 2020). Assessing the learning needs of trainees is an essential element of effective teaching and is becoming increasingly formalized as a part of continuing professional development (McKimm & Swanwick, 2009). Grant (2002) reported that

published classifications of learning needs include felt needs and expressed needs. Hence, these needs must be identified to understand learning needs. Furthermore, Watanabe (2002) reported that "apparent learning needs" that appear in learner's words and actions, such as "I want to learn," do not adequately reflect their true learning needs. Ergo, she highlighted the need to focus on "in apparent learning needs," such as "feelings about learning" and "important things," that the learners themselves were not aware of and did not verbalize. In other words, clarifying learning needs is necessary for designing an educational program for family caregivers in the Japanese working generation who care for community-dwelling PWD. However, education on dementia care tends to focus on formal caregivers (Resciniti et al., 2020). While a previous study described the learning needs of individuals who care for PWD (Yoon & Kim, 2019), it did not focus on the needs of individuals in the working generation. Dilworth-Anderson et al. (2020) critiqued the current frameworks on education for caregivers and found them limiting; he called for reworking the framework to include diversity, inclusivity, and intersectionality. The general lack of evidence in this area highlights the need to clarify specific learning needs and support strategies for these caregivers, especially considering the rapid rate of population aging in Japan. This study aims to understand the learning needs of family caregivers in the Japanese working generation who provide care to community-dwelling PWD and build support to balance work and long-term care with peace of mind. Sakanashi and Fujita (2017) reported that empowering caregivers provides them continuous physical and mental stability and confidence in caregiving. Hence, this study's theoretical perspective is empowerment. Therefore, this study conducted interviews with diverse family caregivers of PWD from the working generation in Japan, revealing and describing relevant learning needs based on their direct experiences. The results may help develop an additional dimension for empowerment—the empowerment of caregivers through their knowledge and experiences. Here we define the working generation in Japan as individuals between 30 and 60 years of age who have work experience and are currently responsible for work duties.

Materials and Methods

Study Design

This study employed a qualitative descriptive design (Sandelowski, 2000) to gain a rich understanding of learning needs that pertain to family caregivers in the Japanese working generation who provide care to community-dwelling PWD.

The learning needs in this study were defined as including both of the following: apparent learning needs that family caregivers in the Japanese working generation who care for community-dwelling PWD felt and expressed, and inap-

parent learning needs that they themselves were not aware of and did not verbalize through their caregiving experience.

Reporting follows the Standards for Reporting Qualitative Research (SRQR; O'Brien et al., 2014).

Population and Sample

To include a wide range of caregivers, we recruited 18 family caregivers of PWD through two medical facilities, two self-help groups, and 10 prefectural-sponsored counseling facilities in Japan. The inclusion criteria were family caregivers of PWD, aged between 30 and 60 years of age and ability to speak fluent Japanese. We used purposive sampling (Sandelowski, 2000) to recruit a wider range of caregivers (e.g., men and women, husbands and wives, sons and daughters), caregiving durations, and types of dementia diagnoses. This ensured robust sample representativeness across study sites. Long-term participation in the field and assiduous observation yield reliable information (Flick, 2011). Thus, before conducting the interviews, we participated in the self-help groups to develop relationships with potential participants.

We provided each medical facility, self-help group, and prefectural-sponsored counseling facility with adequate information regarding the study purpose and procedures. Following this, we provided all participants with the relevant information and obtained their informed consent.

Data Collection

We collected data through semi-structured interviews with all 18 participants between January 2019 and February 2020. To identify their apparent and inapparent needs, we asked caregivers what difficulties they faced when caring for a family member with dementia, how they dealt with them, and what they were careful about and valued when caring for their families. We also asked what they wished to learn about caring for a family member with dementia.

We also collected demographic characteristics, including gender, age, employment status during caregiving, relationship with the PWD, family cohabitation status, dementia type, duration of caregiving, and level of caregiving. The interviews were conducted in the one-on-one semi-structured format and held in comfortable, safe environments—such that all participants were encouraged to engage both openly and freely. After obtaining their respective consent, the audio from each interview session was digitally recorded. Meanwhile, we documented their expressions and movements in the field notes. The interviews ranged from 45 to 150 minutes (M = 91.2 min). Signed consent forms cannot be linked with interview content and informant names were neither requested nor recorded.

Analysis

Interviews were transcribed anonymously by an independent professional. We employed the qualitative content analysis method (Elo & Kyngäs, 2008) after transcribing the interviews verbatim. During the first phase, the first author familiarized with the data and led the initial analysis. The author repeatedly read each interview transcript, identified the participant's learning needs, and recorded codes. At this stage, the codes were documented onto coding sheets, which were then used to generate subcategories. Following this open coding process, the subcategory lists were grouped under higher-order codes. First, each subcategory was named using content-characteristic words. Then, subcategories with similar contents and incidents were grouped. During the second phase, another researcher read through the transcripts and verified the data categorizations. During the third phase, the results of both analyses were discussed to develop the learning needs. Finally, two nursing researchers with expertise in both qualitative research and family nursing and who were not otherwise involved in this study double-checked the analysis to ensure rigor.

Ethical Considerations

This study was approved by the ethical review board at a university affiliated with one of the authors. All participants were informed of the study purpose and procedures, potential for publication, and confidentiality of their data. All participants were informed regarding their right to refuse participation and provided their written informed consent prior to interview engagement.

Results

Participant Characteristics

Table 1 shows relevant characteristics of the 18 participants. Their mean age was 52.0 years (range of 31-60 years); 14 were women, 8 were full-time workers, 12 were daughters of the care recipient, 11 cared for patients with Alzheimer, 8 of the care recipients required extensive caregiving, and 8 reported caregiving durations >10 years.

Category Descriptions

Table 2 shows a list of learning needs extracted during the analysis, including four main categories and 20 subcategories. Specific examples from participants' responses are included below to illustrate some subcategories. Case identifiers are denoted by "[Mr./Ms., family caregiver]."

Main Category: (a) Increasing Long-term Care Literacy

This main category—investigated through seven subcategories—reflects that caregivers must collect/utilize appropriate information and locate the various tools/networks designed to support them in providing long-term care.

Prior to caring for PWD, the interviewees did not believe that either dementia or long-term care was relevant to their lives. Therefore, "Understanding that care is not a problem

Table 1. Demographic characteristics of the caregivers of people with dementia (*n* = 18).

No.	Age	Sex	Employment status during caregiving	Relationship with the person with dementia	Sex of person with dementia	Age of person with dementia	Type of dementia	Caregiving required	Duration of caregiving (years)
A	Late 40s	Female	Full-time worker	Daughter	Male	Late 70s	Dementia with Lewy bodies	Extensive	8
B	Early 50s	Female	Retired	Daughter-in-law	Female	Early 80s	Alzheimer's disease	Mild	2.5
C	Early 60s	Female	Part-time worker	Spouse	Male	Late 60s	Young onset dementia	Extensive	10
D	Early 30s	Female	Full-time worker	Daughter	Male	Late 60s	Young onset dementia	Extensive	10
E	Early 50s	Female	Part-time worker	Daughter	Female	Late 70s	Alzheimer's disease	Extensive	10
G	Late 50s	Female	Full-time worker	Daughter	Female	Late 80s	Alzheimer's disease	Mild	2
H	Late 50s	Female	Full-time worker	Daughter	Female	Early 80s	Alzheimer's disease	Extensive	12
I	Late 50s	Female	Full-time worker	Daughter	Female	Late 80s	Alzheimer's disease	Moderate	5
J	Early 50s	Female	Full-time worker	Daughter	Female	Late 70s	Alzheimer's disease	Mild	3
K	Early 60s	Male	Retired	Son	Male	Early 90s	Alzheimer's disease	Extensive	5
L	Late 30s	Male	Retired	Son	Male	Early 70s	Dementia with Lewy bodies	Moderate	0.9
M	Late 30s	Female	Full-time worker	Daughter	Female	Late 70s	Frontotemporal dementia	Moderate	14
N	Early 50s	Female	Part-time worker	Daughter	Female	Early 80s	Frontotemporal dementia	Moderate	6
O	Late 50s	Male	Retired	Son	Male	Early 90s	Alzheimer's disease	Dead	12
P	Late 50s	Male	Full-time worker	Son	Female	Late 80s	Alzheimer's disease	Extensive	17
Q	Late 50s	Female	Retired	Daughter	Male	Late 80s	Vascular dementia	Dead	5
R	Early 50s	Female	Retired	Daughter	Male	Late 70s	Vascular dementia	Dead	2.5
S	Late 50s	Female	Retired	Daughter	Female	Late 80s	Alzheimer's disease	Moderate	8

Table 2. Learning needs of family caregivers in the Japanese working generation who care for community-dwelling people with dementia.

Main Category	Subcategory
Increasing long-term care literacy	Understanding that care is not a problem for others but is a problem for me
	Understanding that learning by myself is a shortcut to solving problems
	Understanding the correct treatment and communication methods
	Choosing quality services that match the personalities of people with dementia
	Using social services that make full use of knowledge and information
	Learning how to control my emotions
	Understanding how to anticipate and act
Dispelling the negative images associated with dementia and long-term care	Understanding that various treatments and courses exist for dementia
	Understanding the people with dementia who suffer from difficulties in daily and social life
	Understanding that dementia is only an illness
Working on long-term care as a unified team that handles issues concerning caregiving for dementia	Sharing long-term care life with the entire family
	Acquiring the help of trusted specialists
	Selecting an appropriate consultant according to the content
	Understanding the benefits of long-term care for your family
	Understanding that each family member has different thoughts and perceptions
Promoting an active role as a member of society	Understanding the responsibility of playing an active role as a member of society
	Establishing one's own life to maintain a balance between work and long-term care
	Supporting changes in the image of dementia and the long-term care society
	Promoting and disseminating useful information about dementia and long-term care
	Increasing family involvement to improve the nature of care and the welfare service system

for others but is a problem for me" was necessary. Additionally, they also did not know who to talk to—or where to obtain information from—when suddenly confronted with the need to provide care. Therefore, "Understanding that learn-

ing by myself is a shortcut to solving problems," "Understanding the correct treatment and communication methods," "Choosing quality services that match the personalities of people with dementia," "Utilizing social services that make

full use of knowledge and information," "Learning how to control my emotions," and "Understanding how to anticipate and act" were also crucial. Below are the characteristic subcategories and specific examples.

(1) Understanding that "Care Is Not a Problem for Others but a Problem for Me"

This subcategory indicates family caregivers recognizing their caregiving responsibilities. Mr. K had an active career in the metropolitan area and lived a fulfilling life with his wife. He was willing to take care of his parents if they required it but was actually not prepared for the work. Being unable to cope, Mr. K lost his employment and home:

Before I started caring, I had a vague feeling that I [would have] to go back to my parents' house and take care of them someday. However, I don't think I fully understood that caregiving was my problem. So, I did not know what to prepare, I did not prepare for anything [Mr. K, family caregiver].

(2) Utilizing Social Services that Fully Utilize Knowledge and Information

This subcategory refers to obtaining knowledge and information about caregiving to receive effective support. Mrs. C's husband developed young-onset dementia. Childcare is a unique challenge for family caregivers with young-onset dementia. While working part-time, she raised three children, a college student and a high school student. She was initially worried about the situation but learned that she could receive her disability pension with the help of a self-help group's supporters. Since then, she has received a lot of information on her own:

I did not understand anything at first. However, I realized that it is important to always go to the city hall and look for useful information. It is necessary to talk to various people and get information for yourself [by asking questions such as] "What is that?" There is no support unless you study or ask people. It is both mental and economically important [Mrs. C, family caregiver].

Main Category: (b) Dispelling the Negative Images Associated with Dementia and Long-term Care

This main category—investigated through three subcategories—indicates that caregivers perceive the care recipient as a self-respecting person.

The interviewees did not initially understand that the treatments, processes, and reasons for the illness' onset differ on a case-to-case basis. Thus, "Understanding that there are various treatments and courses for dementia" was necessary. Further, they were prejudiced against dementia and held negative perceptions of PWD due to the belief that interpersonal engagement was a difficult or vulnerable process. As such, "Understanding the people with dementia who suffer from difficulties in daily and social life" and "Understanding that dementia is only an illness" were necessary. Below are the characteristic subcategories and specific ex-

amples.

(1) Understanding the PWD who Suffer from Difficulties in Daily and Social Life

This subcategory refers to understanding the behavioral context of PWD. Mrs. M was tasked with caring for her mother. In this context, she cohabitated with her mother, husband, and children, which meant she was also responsible for childcare. She expressed that this arrangement was arduous because she did not have an amicable relationship with her mother prior to moving her into the household. Moreover, she did not know how to solve this problem. She did not fully understand how her mother felt about this for a long time:

Looking back on those days, I can see that my mother was having a hard time. She thinks her mother noticed that her abilities were declining, and she felt that her daily life was not going well [Mrs. M, family caregiver].

(2) Understanding that Dementia Is Only an Illness

This subcategory represented the caregivers' understanding of dementia as a common illness. Upon learning that her husband had developed young-onset dementia, Mrs. C was saddened that there was a PWD in her family. When her husband was admitted to psychiatric care, she was shocked to find that the hospital was "really like a prison" and chose to hide the situation from others. With the help of her supporters, she could eventually admit that her husband had dementia:

I could not accept that my family had a dementia case. First, I wondered why this problem happened only in my house. However, after understanding dementia, I started talking frankly about my husband. My husband is not in jail. My husband is not doing anything wrong. Dementia is one of the most common illnesses, [like] cancer [Mrs. C, family caregiver].

Main Category: (c) Working on Long-term Care as a Unified Team Handling Issues Concerning Caregiving for Dementia

This main category—investigated through five subcategories—indicates that the caregiver works to form a team comprising all possible helpers to handle the surrounding issues.

The interviewees took great responsibility in their care duties but experienced difficulty when they were the only ones providing the care. Therefore, "Sharing long-term care life with the whole family," "Acquiring the help of trusted specialists," "Selecting an appropriate consultant according to the content," and "Understanding the benefits of long-term care for your family" were necessary. To effectively utilize the family's power, "Understanding that each family member has different thoughts and perceptions" was necessary. Below are the characteristic subcategories and specific examples.

(1) Sharing Long-term Care Life with the Whole Family

This subcategory refers to sharing caregiving roles regarding

PWD with their families. Mr. L once held a long-term care job but retired and devoted himself to caring for his mother. This was largely due to an assertion made by his father (i.e., "neighbors say that Mr. L does not take care of his family but only takes care of others"). There were also influences from other family members; it may be a characteristic of Japanese culture to decide who will be in charge of long-term care according to the opinions of neighbors.

My younger brother often says, "I want you to live your own life, so you don't have to worry too much about our mom." I wanted to prioritize my mother's care, but I began to think I had to make my own life plan [Mr. L, family caregiver].

(2) Understanding that Each Family Member Has Different Thoughts and Perceptions

This subcategory demonstrates the recognition and affirmative acceptance of the differences in family members' opinions. Mrs. A had numerous experiences abroad and optimally utilized these in her work, but she was called upon by her mother. At the time of the interview, she provided her father with care and helped run his business. She had an older brother and younger sister; however, each had their own families and were rarely involved in long-term care duties. She once asked her brother to take care of her father, but he declined (i.e., "it was hard because I did not know what my father was saying. You should leave it to the experts"). Her siblings often disregarded responsibility:

They just say, "you are doing your best." I want them to help with my father's care. So, I am angry with them. I learned that even within the same family there are different ways of thinking about caregiving [Mrs. A, family caregiver].

Main Category: (d) Promoting an Active Role as a Member of Society

This main category—investigated through five subcategories—demonstrates the establishment of social roles in both work and the community, specifically aimed at improving the circumstances surrounding dementia.

The interviewees had difficulty balancing their work and long-term care duties, thus changing or quitting their jobs. Thus, "Understanding the responsibility of playing an active role as a member of society" and "Establishing one's own life to maintain a balance between work and long-term care" were important. They noticed some existing social problems related to dementia care but could not find workable solutions. Therefore, "Supporting changes in the images of dementia and the long-term care society," "Promoting and disseminating useful information about dementia and long-term care," and "Increasing family involvement to improve the nature of care and the welfare service system" were necessary. -Below are the characteristic subcategories and specific examples.

(1) Establishing One's Own Life to Maintain a Balance Between Work and Long-term Care

This subcategory indicates having a social life with proper management of work and caregiving. After being tasked with caring for his father, Mr. K resigned from his position at a major company, divorced his wife, and returned to his hometown. He took care of his father alone because he had no other family members to help him; it may be a characteristic of male caregivers that Mr. K tried to take care of himself without relying on familiar people such as his wife.

I lost my work and career. No one needs me now, even if I have worked for a big company in the past. This is frustrating and sad...However, since I have gained experience in caregiving, I may be able to work on a new caregiving job while balancing my own caregiving for parents [Mr. K, family caregiver].

(2) Supporting Changes in the Images of Dementia and the Long-term Care Society

This subcategory represents the attempt to address dementia and caregiving issues. Mrs. M majored in sociology while attending college and was therefore highly interested in social issues. She actively exchanged views with her classmates about long-term care:

I think it tends to be reported that there are many problems in long-term care facilities. However, the problem was only with 10%, and the remaining 90% were good. We need to know the truth about the problems in long-term care facilities [Mrs. M, family caregiver].

Discussion

This study examined learning needs in caregiving based on the experiences of individuals in the working generation in Japan who also provided care to community-dwelling PWD. The learning needs derived from the analysis were arranged into four main categories: (a) increasing long-term care literacy, (b) dispelling the negative images associated with dementia and long-term care, (c) working on long-term care as a unified team that handles issues concerning caregiving for dementia, and (d) promoting an active role as a member of society.

Dementia care research has strong cultural characteristics (Samson et al., 2016; Tuomola et al., 2016) and requires culturally related conceptual models and theoretical perspectives (Dilworth-Anderson et al., 2020). This study discusses dementia care based on the perspective of empowerment among family caregivers of community-dwelling PWD in Japan by Sakanashi and Fujita (2020); this is regarded as an excellent practice in dementia care and helps with understanding the essence of dementia care, caring for oneself as well as for the person with dementia, and having peers with shared support activities.

Increasing long-term care literacy extracted in this study

shows that Japanese working generation caregivers can greatly benefit from preparing before engaging in long-term care. While those in the working generation tend to be physically healthier and more active than older caregivers (Chiao et al., 2015), they are also more often confronted with a greater variety of challenges, both in society and at home. Owing to time limitations, they must quickly learn how to obtain useful resources and information, especially by availing flexible services that are easy to use. Some interviewees had actually quit their jobs or divorced their spouses to focus on providing long-term care, which indicates that collecting information once the process has already begun may be too late. In other words, working families who have not yet experienced long-term care must adequately prepare themselves by increasing their long-term care literacy prior to the actual caregiving. While a previous study offered some learning needs of family caregivers of PWD (Yoon & Kim, 2019), these suggestions pertained to a wide variety of caregiver ages and were solely focused on long-term care. "Increasing long-term care literacy" may promote excellent practice in dementia care (Sakanashi & Fujita, 2020) for individuals in the working generation who can prepare themselves prior to caregiving engagement. This also constitutes a new perspective on the issue.

Alzheimer's Disease International (2019) is working to resolve an issue wherein over 35% of family caregivers worldwide hide the presence of dementia in their families. According to a survey of urban communities in Japan, approximately half of the family caregivers were embarrassed to have PWD in their families (Aihara et al., 2016). Younger people's tendency to exhibit negative attitudes toward dementia has also been reported (Chang & Hsu, 2020). This indicates widespread prejudice against people with disabilities in the working generation that must be addressed both in Japan and abroad. "Dispelling the negative images associated with dementia and long-term care" found in this study refers to a biased perception of dementia that family caregivers must work to replace with positive judgments and evaluations. This is similar to Yoon and Kim's (2019) suggestion that caregivers must be "able to talk optimistically." Chang and Hsu (2020) reported a link between negative perceptions of dementia and knowledge. In other words, a poor understanding of dementia precipitates negative emotions. Contrarily, Aihara et al. (2016) suggested that increasing the ability to obtain and use information improves attitudes. The need for educating the younger generation about PWD has also been suggested (Chang & Hsu, 2020). In summary, both this study and the current literature demonstrate the importance of acquiring knowledge and information about caregiving for the working generation. Hence, "increasing long-term care literacy" may lead to "dispelling the negative images associated with dementia and long-term care," which may be related. Furthermore, this may aid empowerment through understanding the essence of dementia care (Sakanashi & Fujita, 2020).

Japanese families are traditionally expected to fulfill caregiving responsibilities in cases when older adult family members require care (Kumagai & Ishii-Kuntz, 2016). However, since kinship networks have recently begun transforming, caregivers may find that gaining help and understanding from other family members is difficult. Indeed, the modern decline in family functions increases the burden placed on caregivers, especially for the adult children of parents that need care (Chiao et al., 2015). For family caregivers to be empowered, long-term care requires active cooperation with one's immediate surroundings and society in general (Sakanashi & Fujita, 2017). Here, "working on long-term care as a unified team that handles issues concerning caregiving for dementia" reflects a situation wherein members of the working generation who also provide care to PWD must take the initiative to form a care team. This may enable caring for oneself as well as for the person with dementia (Sakanashi & Fujita, 2020). Several studies have reported that dementia care exhibits a significant cultural impact (Samson et al., 2016). Therefore, this learning need may be especially important for Japanese caregivers due to the substantial influence of family culture in Japan.

Yoon and Kim (2019) suggested some learning needs that focus on the relationship between PWD and their caregivers or what it means for self-development through caregiving in caregivers from results, including data of older caregivers. However, several Japanese working individuals spend a large amount of time at work, where they also establish social roles and identities (Funashima & Mochizuki, 2017). In other words, they play social roles and find value through their work. This makes caregiving even more difficult for those in the working generation, who must establish a balance between their existing purposes in life and the value of self-development found by providing long-term care. According to Resciniti et al. (2020), providing these individuals with educational materials that describe the cultural relevance of long-term care is important. Here, "promoting an active role as a member of society" will help family caregivers in the working generation understand that their new social roles constitute respectable positions in society. This may lead to care for oneself as well as for the person with dementia (Sakanashi & Fujita, 2020).

Thus, a link may exist between "increasing long-term care literacy" and "dispelling the negative images associated with dementia and long-term care." Hence, "increasing long-term care literacy" may lead to an understanding of the essence of dementia care and, thereby, improve dementia care. Therefore, "increasing long-term care literacy" was hypothesized to influence empowerment among the family caregivers of community-dwelling PWD in Japan.

Implications

The learning needs developed in this study offer a useful perspective for health professionals in Japan, particularly in the context of structured learning support and relevant interventions. This perspective may also be helpful for professionals in countries with similar family cultural values and working conditions. Notably, the task of increasing long-term care literacy prior to beginning caregiving may positively affect other learning needs and should, therefore, receive greater attention in practice. Here, critical support may also be provided to caregivers based on their level of understanding. This should include educational programs provided by healthcare professionals. For example, family caregivers who begin providing assistance during the early stages of long-term care and have lower understanding of the relevant learning needs typically require immediate help, which may prompt health professionals to proactively offer support and strategical advice. Meanwhile, individuals in the working generation may be unable to afford learning programs or may be less interested in their engagement prior to beginning caregiving, especially when they do not fully understand the learning needs. In such cases, health professionals may actively provide support that is focused on increasing their interest in matters related to caregiving.

In summary, these findings have important implications in dementia care research, from both the Japanese cultural perspective and for members of the working generation. However, continued research is needed to construct and verify educational programs that are tailored to fit different levels of understanding regarding the learning needs.

Study Limitations

This study has some limitations. First, the results may have been affected by sampling bias, as participants were limited to family caregivers in one Japanese prefecture. Second, some perspectives may not have been represented in the study sample. Future studies should, therefore, conduct interventions to assess the validity of the learning needs in different environments.

Conclusion

Using a qualitative descriptive design, this study clarified important learning needs of family caregivers in the Japanese working generation who are tasked with providing care for community-dwelling PWD based on data from 18 family caregivers. The components of learning needs were arranged into four main categories as follows: (a) increasing long-term care literacy, (b) dispelling the negative images associated with dementia and long-term care, (c) working on long-term care as a unified team that handles issues concerning caregiving for dementia, and (d) promoting an active role as

a member of society. These findings may also be pertinent in other countries with similar social cultures and working habits. Finally, the structured nature of the learning needs offers a useful perspective for health professionals when conducting assessments and prescribing interventions that reflect specific cultural characteristics and the needs of the working generation.

Author Contributions

S. S. contributed to the study conception and design, data collection, data analysis and interpretation, and manuscript drafting. K. F. contributed to the study conception, data analysis and interpretation, and critical revision of the manuscript for intellectual content. M. N. contributed to the data collection, data analysis, and interpretation processes. S. O. contributed to the data collection process. K. O. contributed to the data analysis and interpretation processes. All authors read and approved of the final manuscript.

Declaration of Conflicting Interests

The authors declare no conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Original Research

Nurse managers' support during organizational change and nurses' organizational commitment: A cross-sectional study using nurses' career stage

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Abstract

Objective: Hospital organizational changes are known to deteriorate nurses' organizational commitment, and the support of frontline nurse managers is crucial in preventing this deterioration. However, the effects of the practical support provided by frontline nurse managers at different subordinate career stages during organizational change are yet to be determined. Thus, in this study, we aim to clarify the associations between nurses' organizational commitment and the two types of frontline nurse manager support (i.e., preparation for organizational change and personal counseling) based on subordinate nurses' years of experience. **Methods:** This cross-sectional study was conducted among nurses using a self-report survey method. Hierarchical multiple regression analyses were conducted, with _organizational commitment_ as the dependent variable. **Results:** Responses from 1,603 nurses at 63 hospitals were analyzed. As per our findings, both types of frontline nurse managers' practical support were found to positively and significantly affect nurses' organizational commitment. The association of these two types of frontline nurse manager support with organizational commitment based on years of nursing experience was deemed insignificant. However, the results of a subgroup analysis per career stage based on years of experience showed that organizational commitment for nurses with more than 20 years of experience was not associated with preparation for organizational change. **Conclusions:** Both types of practical support provided by frontline nurse managers during organizational change are important to retain nurses' organizational commitment. However, the effectiveness of each type of support may differ according to the nurses' career stage. For expert nurses, personal counseling was found to be more important than preparation.

Introduction

Hospital organizational changes have emerged as an issue affecting the healthcare industry globally. Organizational change is defined as the process by which organizations re-

design their structure or culture to increase their effectiveness (Jones, 2013). "Change scale" refers to the degree of change required to reach the desired outcome (Al-Haddad & Kotnour, 2015). Hospital organizational changes often range from hospital level (e.g., mergers) to unit level (e.g., func-

tional, clinical specialty, or number of beds). Various scales of hospital organizational change occur worldwide due to the ever-changing social conditions (Malach & Baumol, 2010), making the phenomenon a global healthcare issue.

The deterioration of affective organizational commitment is one of the effects of such organizational change among nurses (Jensen & Sørensen, 2017; Keane et al., 2016). Some meta-analyses have shown that affective organizational commitment has strong positive correlations with organizational citizenship behavior and negative correlations with stress and turnover (Bowling et al., 2015; Cetin et al., 2015; Guzeller & Celiker, 2019). Nurses with low affective organizational commitment are noted to quit, show poor performance, or fail to implement patient safety measures (Al-Zamel et al., 2020; Baird et al., 2019; Liu et al., 2020). Thus, maintaining nurses' affective organizational commitment via nursing management is essential for hospital organizations as well as for individual nurses.

As per systematic reviews of organizational change, the psychological outcomes of employees, including nurses, are found to be largely related to supervisor support (De Jong et al., 2016; Oreg et al., 2011). Although not organizational change, longitudinal studies of nurses required to adapt to new tasks, for example, during an infection outbreak or entering the workforce, have reported higher affective organizational commitment and lower emotional exhaustion among nurses who have received support in the past (Church & Yarbrough, 2018; Maunder et al., 2006). Thus, supervisor support received by nurses during organizational change may subsequently affect their affective organizational commitment. Notably, frontline nurse managers play a major role in addressing and preventing the decline of nurses' affective organizational commitment (Asiri et al., 2016), as they are in charge of managing the day-to-day activities in work units and providing direct support to subordinates (Sullivan, 2017). The support of supervisors, especially, frontline nurse managers, during organizational change may enhance nurses' affective organizational commitment at the time of the survey. However, how frontline nurse managers' support affect nurses' affective organizational commitment has not been clarified. Moreover, there remains limited research on the types of practical support frontline nurse managers should provide during organizational change.

Effective types of support can be found among the success factors of organizational change, as identified by Kotter (1996). He noted that training is a major success factor that managers should provide, particularly when new technical skills, social skills, or behaviors are needed for new work arrangements (Kotter, 1996). In another study, nurses expressed concerns regarding their insufficient knowledge of caring for new patients and the difficulties of cooperating with new colleagues before a unit merger (Salminen-Tuomaala et al., 2017). Thus, having the opportunity to pre-

pare for organizational change by receiving frontline nurse managers' practical support may be key to nurses continuing to provide quality care. Another type of support that frontline nurse managers can provide during organizational change is personal counseling, which is an aspect of individualized consideration, according to transformational leadership theory (Bass et al., 2003). Individualized consideration describes the leader's provision of personal attention, coaching, and support to followers (Bass, 1999), and it has been found to be associated with nurses' affective organizational commitment (Top et al., 2015; Weng et al., 2010) as they have different skills, techniques, and career plans. Additionally, the roles, skills, and activities required by unit characteristics and clinical specialties differ (Cooper et al., 2019; Kilpatrick et al., 2013; Kramer et al., 2013). Previous studies have reported that during organizational change, nurses commonly perceive role conflicts, role ambiguity, and career stagnation (Blythe et al., 2001; Cummings & Estabrooks, 2003). Nurses' reactions to organizational change can vary; thus, personal counseling, including providing explanations and rationales that consider nurses' individual situations, can help them design resilient career paths while fulfilling their professional aspirations.

Although frontline nurse managers should provide nurses with opportunities for preparation and personal counseling, the relationships between these two types of support as they relate to nurses' affective organizational commitment are yet to be clarified. Intervention requirements may differ depending on nurses' years of experience. Benner (1984) stated that nurses go through stages from novice to expert, depending on their experience, and they require different types of support at each stage. Clarifying the differences in the association between these two types of support and nurses' affective organizational commitment according to their years of experience will enable frontline nurse managers to provide support that is suited to the characteristics of the nurses. These differences will enable frontline nurse managers to support nurses efficiently during organizational change. However, these differences have not been well-investigated.

Thus, this study aims to reveal the associations and the strengths thereof between frontline nurse managers' practical support during organizational change and nurses' affective organizational commitment based on years of experience.

Materials and Methods

Design

A cross-sectional study using anonymous self-report questionnaires was conducted between June and September 2017.

Hypotheses

In this study, we evaluated the following two hypotheses:

H1: Among nurses, frontline nurse managers' practical support (i.e., preparation for organizational change and personal counseling) is positively related to nurses' affective organizational commitment.

H2: Among nurses, years of nursing experience moderates the positive relationship between frontline nurse managers' practical support (i.e., preparation for organizational change and personal counseling) and nurses' affective organizational commitment.

Participants

Although several types of organizational changes may have different effects on nurses' affective organizational commitment, previous studies have used several change types as the selection criteria and analyzed subjects who experienced these changes according to the situation in each country (Bernstrøm & Kjekshus, 2015; Brown et al., 2006; Montour et al., 2009). As an organizational change that occurs due to changes in inpatient characteristics and care practices, in this study, hospital organizational changes were defined as any of the following changes implemented for managerial reasons: change in function (e.g., a unit that changes from being an acute general unit to a long-term care unit); change in clinical field specialty (e.g., a unit that changes from being a gastroenterology unit to a mixed unit with both gastroenterology and gastrointestinal surgeries); or change in the number of beds (e.g., increase or decrease in the number of beds per unit).

The targeted hospitals were those in Japan with more than 200 beds and units that had changed in the year before the survey date. Specialized psychiatric hospitals and facilities for disabled persons were excluded.

Inclusion/Exclusion Criteria

The participant inclusion criteria were as follows: nurses, midwives, and licensed practical nurses who had experienced organizational change, apart from frontline nursing managers.

The participant exclusion criteria were as follows: nurses who had endured a long-term absence and had joined the hospital after the organizational change.

Data Collection

Randomly selected hospitals throughout Japan were sent a written request to participate in this study, as there is no available list that enumerates hospitals that have underwent organizational changes. Directors of nursing in the selected hospitals were notified of the study's criteria, and if their hospital met these criteria, they were asked to pledge a commitment to participate. Prior to conducting this study, the sample size was estimated using G*Power 3.1 (Faul et al., 2007). We used *a priori* power analysis for multiple regression with a moderate effect size of .15, a power of .95, and α =.05, which yielded a minimum total sample size requirement of 153. We then divided the nurses into four groups (i.e., advanced beginner, competent, proficient, and expert) according to their years of experience, which refers to the stages of nurse proficiency excluding nursing students, as proposed by Benner (1984). Therefore, our total sample size was 612 (4 groups × 153 nurses). In some countries, career-ladder systems for nurses have been created based on Benner's theory (Pertiwi & Hariyati, 2019). As the approximate number of years separating career stages varies from study to study, we referred to prior studies to reconcile the differences (Chatchumni et al., 2016; Farčić et al., 2020; Lee et al., 2021; Mortensen et al., 2019); we were able to determine that the thresholds of the nursing experience year should be 3, 8, and 20 years. A follow-on discussion with experts has confirmed this structure. To ensure the required sample size, 1,000 hospitals with 200 or more beds were randomly selected from a database of all Japanese hospitals developed by Wellness Co. Ltd. (2011). Then, the directors of nursing who agreed to participate in this study distributed the questionnaire to the participants who met the inclusion criteria through their frontline nurse managers. The participants were given approximately 2 weeks to complete the questionnaire, seal it in the provided envelope, and drop it in a collection box. The collection box was then returned to the authors unopened.

Instruments

Information on affective organizational commitment, frontline nurse manager support, and demographic data was collected from the nurse participants. Organizational information was collected from frontline nurse managers.

Affective organizational commitment was measured using a 7-point Likert-type scale ranging from 1 ("strongly disagree") to 7 ("strongly agree"). The total scores ranged from 6 to 42. In this current study, the alpha coefficient was .87. The measurement applied a subscale of the Japanese version of the Three-Dimensional Organizational Commitment Scale (Takahashi, 1997), which was originally developed by Allen and Meyer (1990). The Japanese version is valid, reliable, and satisfactory. Organizational commitment consists of affective, continuance, and normative commitments, which are conceptually separate ideas. The use of the subscale was authorized by Allen and Meyer (1990). The subscale has been commonly used with nurses. Participants were asked about their affective organizational commitment at the time of the survey.

Frontline nurse managers' support during organizational change was assessed using two subscales, namely, preparation for organizational change and personal counseling. The

authors explored items based on themes from practice reports and interviews with directors of nursing regarding the organizational change process. To assess preparation for organizational change, the questionnaire sought information from nurses on whether they had received sufficient opportunity to prepare. This subscale consisted of six items as follows: (1) sharing of emotions, (2) learning specific medical knowledge, (3) practicing new medical skills, (4) a tour of the other units inside or outside the hospital, (5) the opportunity to discuss operations with nurses, and (6) the opportunity to discuss operations with other medical professionals. Regarding the sharing of emotions in the above subscale, a recent study reported that shared emotions among staff during restructuring efforts affected their change implementation behavior (Kanitz et al., 2022). Therefore, shared emotions were regarded as the first step in preparing for organizational change. A sample item read as follows: "Were you given the opportunity to practice the nursing care required after the organizational change?" Each item was rated using a 6-point Likert-type scale, ranging from 0 ("no preparation") to 5 ("sufficient preparation"). The total scores ranged from 0 to 30. A subscale consisting of five items was used to assess personal counseling: (1) explanation of organizational change, (2) answering questions about organizational change, (3) role change, (4) expectation, and (5) career meaningfulness. One sample item read "Did you receive an explanation about what the organizational change means for your career?" Each item was rated using a 6-point Likert-type scale, ranging from 0 ("no explanation") to 5 ("sufficient explanation"). The total scores ranged from 0 to 25. The face validity of the two subscales was confirmed via cognitive interviews with four graduate students and two hospital nurses who had experienced organizational change. A single factor with a loading of 0.6 or greater was confirmed for all questions from each scale using factor analysis. Reliability was affirmed by alpha coefficients: .92 for preparation for organizational change and .91 for personal counseling.

Organizational information included hospital size, hospital founder (public or private), type of organizational change, and the date when the organizational change was conducted. The demographic variables of the nurses included age, sex, qualification (i.e., registered nurse, midwife, or licensed assistant nurse), years of nursing experience, employment status (full- or part-time), educational background (i.e., nursing school, junior college, university, or graduate school), and position (i.e., staff, chief nurse, or assistant frontline nurse manager).

Ethical Considerations

This study was approved by the Research Ethics Committee of the Graduate School of Medicine at the University of Tokyo (No.11583). The authors requested that the frontline

nurse managers ensure that nurses participated on their own volition and return the collection box to the authors without opening it.

Statistical Analysis

Descriptive analyses of all variables were first conducted; thereafter, the authors conducted hierarchical multiple regression from Steps 1 to 3 using the forced-entry method to verify Hypothesis 1. The authors entered the control variables (those with $p < .2$ in the bivariate analyses for sex, marital status, years of nursing experience, qualification, educational background, position, hospital founder, hospital size, and change in clinical field specialty) in Step 1. Frontline nurse managers' support was handled in Step 2.

To verify Hypothesis 2, the authors entered the interaction term of frontline nurse manager support and years of nursing experience in Step 3.

Moreover, we conducted subgroup analyses using hierarchical multiple regression using the forced-entry method by career stage, with reference to Benner's theory (1984). The processes in Steps 1 and 2 were then repeated. Group 1 (advanced beginner) included nurses with less than 3 years of experience, and Group 2 (competent) included nurses with between 3 and 8 years of experience. Group 3 (proficient) nurses had between 8 and 20 years of experience. Lastly, Group 4 (expert) had nurses with more than 20 years of experience. To avoid multicollinearity, correlations between all variables and variance inflation factors were checked. As age was strongly correlated with experience ($r = .91$), the authors selected *years of nursing experience* as the control variable. The statistical significance was set to $p < .05$. To analyze the data, the authors used IBM SPSS Statistics ver.24.0 for Windows.

Results

In total, 199 out of 1,000 hospitals have restructured units in the previous 2 years. Directors of nursing from 80 of these hospitals accepted our request to participate in this study. The number of questionnaires distributed to nurses was 3,998, of which 2,622 from 80 hospitals (176 units) were returned. Ultimately, 1,603 responses (120 units) were analyzed. Those with blank answers ($n = 58$), no organizational information from frontline nurse managers ($n = 175$), exclusion criteria ($n = 606$), or missing data for any analyzed variables ($n = 180$) were excluded.

Characteristics of Nurses

The characteristics of the nurses are shown in Table 1. The nurses' mean age ± standard deviation was 34.4 ± 9.9 years, and the mean for years of nursing experience was 11.4 ± 9.2 years. Most nurses were female (91.6%), registered nurses (95.1%), and full-time workers (96.9%). Most partici-

pants were full-time, licensed nursing staff. The nurses' average affective organizational commitment score was 21.5 ± 6.5.

Associations of Frontline Nurse Managers' Support and Affective Organizational Commitment

Model 2 in Table 2 show the associations between frontline

nurse managers' support and affective organizational commitment. In Step 2, the two types of frontline nurse managers' support (i.e., preparation for organizational change and personal counseling) were found to be positively and significantly related to affective organizational commitment (β = .150, p < .001; β = .180, p < .001). Thus, Hypothesis 1 was supported.

Differences in Associations by Nurses' Years of Experience

Model 3 in Table 2 presents the interaction term of each frontline nurse managers' support (i.e., preparation for organizational change and personal counseling), and years of nursing experience was deemed insignificant (β = −.036, p = .186; β = .017, p = .539). Thus, Hypothesis 2 was not supported.

Moreover, Table 3 presents the results of the subgroup analyses. For Group 1 (advanced beginners) in Step 2, both types of frontline nurse managers' support were positively and significantly related to affective organizational commitment. Preparation for organizational change (β = .225, p = .001) showed a sharper slope than that of personal counseling (β = .162, p = .015). Meanwhile, in Group 2 (competent nurses) in Step 2, both types of frontline nurse managers' support were found to be positively and significantly related to affective organizational commitment. Personal counseling (β = .173, p = .001) showed a slightly sharper slope than that of preparation for organizational change (β = .158, p = .004). Regarding Group 3 (proficient nurses) in Step 2, both types of frontline nurse managers' support were found to be positively and significantly related to affective organizational

Table 1. Characteristics of nurses.

Participants (N = 1,603)	n (%) Mean ± SD	
Age (years)	34.4 ± 9.9	
Sex		
Female	1,468	(91.6)
Qualification		
Registered nurse	1,524	(95.1)
Midwife	53	(3.3)
Licensed assistant nurse	26	(1.6)
Nursing experience		
Years of nursing experience	11.4 ± 9.2	
Employment status		
Full-time	1,553	(96.9)
Educational background		
Nursing school and junior college	1,267	(79.0)
University and beyond	336	(21.0)
Position		
Staff	1,431	(89.3)
Chief nurse or assistant frontline nurse manager	172	(10.7)

Note. SD : standard deviation.

Table 2. Hierarchical multiple regression analysis for affective organizational commitment.

		Model 2		Model 3	
	Mean ± SD	β	p	β	p
Step 2: Frontline nurse managers' support					
Preparation for organizational change	13.2 ± 6.8	.150	<.001	.148	<.001
Personal counseling	13.3 ± 5.3	.180	<.001	.181	<.001
Step 3: Interaction effects					
Preparation [a] × Years of experience [b]				−.036	.186
Personal counseling × Years of experience [b]				.017	.539
R^2		.167		.168	
Adjusted R^2		.160		.160	
ΔR^2		.083		.001	

Note.

[a] Preparation for organizational change; [b] Years of nursing experience

SD : standard deviation; β: standardized partial regression coefficient.

R^2: determined coefficient.

Although each β is not shown in the table, sex, marital status, years of nursing experience, qualification, education background, position, hospital founder, hospital size, and change of clinical field specialty were entered as control variables in Step 1.

ΔR^2 represents the amount of change from R^2 when only the control variables were entered.

Table 3. Subgroup analyses using hierarchical multiple regression analysis by career stage.

	Career stage (Years of nursing experience)							
	Group 1 Advanced beginners <3 years ($n = 287$)		Group 2 Competent nurses 3 years ≤, <8 years ($n = 465$)		Group 3 Proficient nurses 8 years ≤, <20 years ($n = 530$)		Group 4 Expert nurses 20 years ≤ ($n = 321$)	
	β	p	β	p	β	p	β	p
Step2: Frontline nurse managers' support								
Preparation for organizational change	.225	.001	.158	.004	.119	.015	.062	.332
Personal counseling	.162	.015	.173	.001	.178	< .001	.243	< .001
R^2	.177		.103		.157		.177	
Adjusted R^2	.141		.077		.135		.142	
ΔR^2	.111		.082		.067		.074	

Note.

β: standardized partial regression coefficient.

R^2: determined coefficient.

Although each β is not shown in the table, sex, marital status, years of nursing experience, qualification, education background, position, hospital founder, hospital size, and change of clinical field specialty were entered as control variables in Step 1.

ΔR^2 represents the amount of change from R^2 when only the control variables were entered.

commitment. Personal counseling (β = .178, p < .001) showed a sharper slope than that of preparation for organizational change (β = .119, p = .015). Regarding Group 4 (expert nurses) in Step 2, only personal counseling was found to be significantly and positively related to affective organizational commitment (β = .243, p < .001).

Discussion

The nurses' average affective organizational commitment score in this study was 21.5. Previous studies of hospital nurses reported scores ranging from 24.1 to 30.1 (including studies that converted mean scores to total scores; e.g., Asiri et al., 2016; Neves et al., 2016; Santos et al., 2016). In this study, the affective organizational commitment of nurses who experienced organizational change is noted to be lower than that reported in the studies mentioned above. This indicates that the organizational change has caused deterioration of nurses' affective organizational commitment.

Associations of Frontline Nurse Managers' Support and Affective Organizational Commitment

This study showed significant positive associations between the two types of frontline nurse managers' practical support (i.e., preparation for organizational change and personal counseling) and nurses' affective organizational commitment. A previous review indicated that the perception of training related to organizational change can influence employees' well-being (De Jong et al., 2016). This finding aligns with the results of the current study for nurses who experienced organizational change; however, preparation for organizational change included not only skill acquisition but

also discussion of operations. The current study showed that comprehensive preparation, which includes clinical skills training and discussions of unit operations provided by frontline nurse managers, may be related to higher levels of affective organizational commitment among hospital nurses.

Regarding personal counseling, a previous review showed that a supportive process of manager communication was related to employee outcomes (Oreg et al., 2011); however, the effect of explanations on the individual-level impact of organizational change was not verified. In this current study, it was shown that personal counseling provided by frontline nurse managers may be related to higher levels of affective organizational commitment in nurses. Previous studies reported that individualized considerations were related to nurses' affective organizational commitment (Top et al., 2015; Weng et al., 2010). On the other hand, previous studies have also reported that this association was not present (Kodama et al., 2016). One possible reason for these inconsistent results is that the effect of individualized considerations on affective organizational commitment may differ depending on nurse attributes and hospital organizational contexts. In the context of hospital organizational change, personal counseling may be important for nurses' affective organizational commitment. As discussed, frontline nurse managers who provide both types of support will likely enable nurses to strengthen their affective organizational commitment.

Differences in Associations by Nurses' Years of Experience

The interaction effect showed that the two types of frontline nurse managers' practical support on nurses' affective organizational commitment did not vary by nurses' years of expe-

rience. Therefore, preparation for organizational change and personal counseling provided by frontline nurse managers may be vital to enhancing nurses' affective organizational commitment at all levels of experience.

Although preparation for organizational change was deemed insignificant, there was a reversal of the coefficients. Moreover, according to the results of the subgroup analysis, for Group 4 (expert nurses), preparation for organizational change was not significant for nurses' affective organizational commitment, unlike the other groups. In previous studies, late-career nurses expressed that they wanted to contribute to a better work environment in their unit or to patient care by taking advantage of their own roles, careers, and experiences (Price et al., 2018). Based on these findings, the results of this current study can be interpreted as follows: For Group 4 (expert nurses), personal counseling may be more important than preparation for organizational change as they have already mastered general nursing skills and played important roles in their organization.

These results demonstrate that frontline nurse managers during organizational change should provide opportunities for preparation and personal counseling to nurses. All nurses require these two types of practical support from nurse managers. Notably, expert nurses benefit more from personal counseling than from preparation.

Strengths and Limitations

This study has two major strengths. First, two types of practical support (i.e., preparation for organizational change and personal counseling) provided by frontline nurse managers during organizational change were shown to be significant in maintaining nurses' affective organizational commitment. Preparation for organizational change added opportunities to discuss the new operations, and personal counseling included explanations that considered nurses' career paths. This study was able to identify the specific types of practical support that frontline nurse managers should provide to nurses during organizational change. Second, the effectiveness of each instance of support may depend on a nurse's career stage. The results demonstrate the importance of considering differences in career stage while providing support to nurses during organizational change.

This study also has several limitations. First, it used a cross-sectional design; thus, the observed associations among the variables might not be causal. Second, there was a common method bias, as this study used self-reported data and targeted units that had been changed between 1 month and 1 year prior to this study. Therefore, the study results were not completely controlled for post-organizational change effects. Third, this study targeted medium-sized or larger hospitals. Therefore, further examinations in small hospitals may be necessary. Fourth, the number of participants was larger than the required sample size, which could

result in overinterpretation. Fifth, there might be a bias toward favorable responses as only the nurses who had received information from frontline nurse managers could complete the questions with all analyzed variables. Sixth, the number of organizational changes experienced by all nurses was not controlled. Seventh, 20 years of nursing experience is not a clear delimiter for "expertise," although an expert nurse was defined as having 20 years of experience in this study. Further research is thus needed to determine whether there is an interaction between years of nursing experience and frontline nurse managers' support. For example, because a nurse's career is not limited to years of experience, additional indicators should be considered in future studies.

Implications for Practice

In this study, we were able to identify two important types of practical support from frontline nurse managers to strengthen nurses' affective organizational commitment. That is, frontline nurse managers should provide preparation for organizational change and personal counseling to nurses. All nurses require these types of practical support from frontline nurse managers. Moreover, expert nurses are found to benefit more from personal counseling.

Conclusions

Two types of practical support, preparation for organizational change and personal counseling, provided by frontline nurse managers during organizational change were found to be positively related to nurses' affective organizational commitment. Furthermore, there may be differences in the strengths of these associations based on the nurses' career stages. Frontline nurse managers should provide support to unit nurses by prioritizing different types of intervention depending on nurses' career stages.

Author Contributions

C.F, K.K, Y.T, and K.T contributed to the conception and design of this study. C.F and K.K performed the statistical analysis. C.F, K.K, and Y.T drafted the manuscript. C.F, K.K, Y.T, K.T, and N.I contributed to the data interpretation. K.K, Y.T, K.T, and N.I 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 no conflicts of interest.

Ethical Approval
This study was approved by the Research Ethics Committee of the Graduate School of Medicine, the University of Tokyo (no. 11583).

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Original Research

Development of a medication-adherence assessment tool to assess and support medication self-management by older adults

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Abstract

Objective: To develop a medication-adherence assessment tool for nurses to acquire greater understanding of autonomous medication self-management by older adults. **Methods:** This study was based on an exploratory sequential study design using a qualitative inductive study and pretest results from which we created a draft medication-adherence assessment tool containing 74 items. Then, to verify reliability and validity, questionnaires were sent to nurses with three or more years of clinical experience in randomly selected acute care hospitals or in home-visit nursing stations. The research was conducted with the approval of the Shimane University Nursing Research Ethics Review Committee. **Results:** From a total of 747 responses and following an item analysis, 40 items were selected and exploratory factor analysis was performed. From this, we prepared a "medication-adherence assessment tool for older adults" consisting of 40 items and 6 factors. The six factors were the following: 1) active participation in their treatment, 2) stable medication compliance, 3) medication behavior and stable lifestyle, 4) health control ability with continuous medication, 5) inhibitors of medication self-management, and 6) capability of medication record management. This assessment tool was proven to show internal consistency based on Cronbach's α coefficient, criterion-related validity, and constructive concept validity. **Conclusions:** The "medication-adherence assessment tool for older adults" allows nurses to systematically assess the status of autonomous self-management of medication by older adults from a medication-adherence perspective.

Introduction

Noncommunicable diseases (NCDs), also known as chronic diseases, have a long duration and are the result of a combination of genetic, physiological, environmental, and behavioral factors (WHO, 2021). NCDs are the number-one cause of death and are a common health issue worldwide. Continuous medication therapy plays an important role in controlling the pathology of such NCDs, and older adults tend to suffer from multiple diseases, including NCDs, as they age (Salive, 2013). There is a strong correlation between the number of diagnosed diseases and the number of medications prescribed (Suzuki et al., 2006), with a mean number of 6.9 ± 4.7 medications used by patients at admission and 6.8 ± 4.3 at discharge (Tomita et al., 2018). Thus, older adults are particularly likely to be prescribed multiple medications for treatment.

The greater the number of prescription medications is, the

greater is the challenge to the patient for self-management of such medications. When multiple episodes of forgetfulness or intentional avoidance accumulate, the amounts of unused prescription medication increase. The reported average compliance rates for self-managing patients are 26.4% for ages 65 to 74 years and 23.7% for ages 75 years and over, and the average numbers of days of unused medication are 8.5 days for the former group and 8.7 days for the latter (Omotani et al., 2020). The older the patient is, the greater is the difficulty self-managing medications for timing and appropriate dosage.

The degree of compliance with prescription medications is associated with the risk of developing cardiovascular disease (Krousel-Wood et al., 2015), risk of death from asthma (Suissa et al., 2003), and worsening of Parkinson's disease symptoms (Kulkarni et al., 2008). Furthermore, noncompliance by self-managing patients is reportedly related with readmission events (Tuppin et al., 2010) and health-related quality of life (Holt et al., 2010). Thus, prolonged improper medication self-management by older adults not only has a negative effect on pathological control of target diseases but also hinders smooth continuity of daily life.

Polypharmacy, cognitive decline, and health literacy are associated with the medication self-management capabilities of older adults (Yap et al., 2016), as are various physical factors such as decreased visual acuity, deafness, decreased swallowing function, and trembling of fingers. Inherent emotions of older adults (Nakamura et al., 2016), such as distrust of medication and different perceptions of medication compared to those of healthcare professionals, may also prevent older adults from proper self-management. To effectively support medication self-administration by older adults, healthcare professionals must evaluate medication self-management programs from various angles.

Compliance with a healthcare professional's directive has traditionally been used as a factor when evaluating medication self-management. However, there has recently been a shift from medical-staff-centered medical care to patient-centered medical care, and the concept of adherence has been adopted. Adherence includes the patient's consent to a healthcare professional's recommendations, collaboration and partnership between the healthcare professional and the patient, and the patient making autonomous decisions. It is a concept of a collaborative model for the patient and medical staff.

The measurement index of medication-adherence for older adults established in previous studies is the eight-item Morisky Medication-Adherence Scale (MMAS-8) (Morisky et al., 2008; Krousel-Wood et al., 2009). In addition, the Medication Possession Ratio and the proportion of days covered are used. These metrics are limited to the evaluation of forgetting and self-interrupting of medication, suggesting that they are used synonymously with compliance (Sakane,

2019).

A tool with which to objectively evaluate medication-adherence by an older adult from the viewpoint of collaboration with and autonomy from healthcare professionals is still lacking. Thus, the results of the current support efforts for medication self-management may not effectively lead to helpful or positive patient outcomes. The aim of this study is to develop such a medication-adherence assessment tool for nurses, who play a central role in supporting medication self-management, to assess the autonomous medication self-management status of older adults.

Definitions of Terms

1. Medication-adherence
On the basis of the definition presented by the WHO (2003), supplemented by the results of a conceptual analysis of adherence by Cohen (2009), Medication-adherence is defined as "Patients build partnership-based collaborative relationships with healthcare professionals, actively participate in treatment policy decisions, agree to the treatment policies and support recommended by healthcare professionals, and apply desirable medication and health behaviors."
2. Medication Self-management
Medication self-management in this study is defined as "The activity in which older adults who require continuous medication therapy continue to take medication based on the prescribed usage of medications and manage their effects."

Materials and Methods

1. Research Design

This study was an exploratory sequential study design for the development of metrics by mixed methods research (Creswell & Creswell, 2018). The study was conducted from May 2018 to July 2020.

2. Preparation of the Draft of the Medication-adherence Assessment Tool for Older Adults

We first conducted a qualitative inductive study to explore the content of medication-adherence for older adults. Eighteen people participated in the study, including six nurses, six pharmacists, four doctors, and two patients who had been hospitalized and had been taking medication. The nurses, pharmacists, and doctors were selected from both acute care hospitals and community healthcare institutions. To supplement the nurses' assessment perspectives, we sought input from pharmacologists for a pharmacological perspective as to what was necessary for maintaining and improving medication-adherence (Sakane, 2020). From this, adherence by older adults was classified into 88 items and 6 categories. Finally, the content was further supplemented from literature on medication-induced older adults' syndrome. Ultimately, we prepared a draft of 91 items for the

medication-adherence assessment tool.

3. Pilot Study

To confirm the structure of the draft assessment tool and establish the validity of its content, a pilot study was conducted on nurses with more than 3 years of clinical experience at acute care hospitals and home-visit nursing stations. Responses covering 38 active patient cases were obtained and included opinions on the items regarding their difficulty for use in evaluations, difficulty of answering, and possible overlapping of items. Following the discussions and examination of the opinions of the doctors, pharmacists, and nurses, 19 items were deleted, wording and expressions were appropriately adjusted, and a reordering of the questions was conducted to facilitate answering. With the structure and content validity of the assessment tool confirmed, a final draft questionnaire composed of 74 items for the medication-adherence assessment tool for older adults was prepared.

4. Questionnaire Survey and Path Analysis

Participants

We requested research cooperation from 500 randomly selected acute care hospitals with more than 200 beds and 500 randomly selected home-visit nursing stations nationwide in Japan. Acute care hospitals diagnose and treat older patients, initiate medication self-management, and change prescriptions. Therefore, it is necessary to provide individualized and timely support by nurses for medication self-management by older patients. In addition, home-visit nursing stations must provide ongoing nursing support, and therefore, they were selected as study sites. Questionnaires were sent to 3,377 nurses who had more than 3 years of clinical experience and who were working in the medical institutions that had agreed to participate in this study.

Extraction of Sample Size

Our sample size was based on the generally accepted concept that approximately 5 to 10 times as many respondents as the number of samples are necessary (Burns & Grove, 2007). In addition, the number of hospital nurses and home-visiting nurses was calculated and stratified by the ratio of the age composition of nurses in Japan. To minimize any bias in the scale of regions and hospitals, the number of facilities approached for research cooperation was stratified according to the scale of regions and hospitals.

Data Collection

A request document for cooperation in the survey was sent to the nursing managers of the randomly selected acute care hospitals and home-visit nursing stations. Request documents and questionnaires were distributed to the nurses working at each institution with the consent of the nursing manager. Collection was by individual mailing.

Survey Contents

The questionnaire asked the participants to answer question items regarding one case of an older adult for which the nurse was currently providing some type of self-management support, including monitoring self-management of medication, checking the remaining number of dosages, setting prescription medications, and providing guidance for self-management. Of these reported cases, those of older adults (65 years old and over) diagnosed with dementia and those with obvious problems in daily life due to cognitive decline were excluded.

The items in the questionnaire covered the individual attributes of the participant as well as those of older adult patients as recalled by the participant, the characteristics of particular medication self-management, the 12 revised medication-adherence scales used for chronic disease patients in Japan (Ueno, 2018), and the 74 prepared medication-adherence assessment tool draft items. In the explanation portion of the questionnaire, we also asked for participant opinions as to the feasibility of the use of the assessment tool relative to the current medication status of the older adult.

The assessment tool questionnaire answer format was a five-step rating scale as well as "not applicable" and "unknown."

Data Analysis

Statistical software SPSS ver. 22 and covariance structure analysis software Amos ver. 19 were used for data analysis.

1) Descriptive statistics were calculated for all items, and the average score and standard deviation of each item were calculated.

2) Selection of question items: As item analysis, (1) the calculation of the change in the α coefficient when each question item is excluded, (2) the confirmation of the ceiling effect/floor effect, (3) item-overall (I-T) correlation analysis, (4) G-P analysis, (5) the calculation of the interitem correlation coefficient, and (6) exploratory factor analysis.

3) Examination of reliability: Cronbach's α coefficient was calculated to confirm the internal consistency of this assessment tool.

4) Examination of criterion-related validity: As coexistence validity, the correlation with this assessment tool was calculated using the revised medication-adherence scale of Ueno (2018) as an external criterion.

5) Examination of construct validity: A confirmatory factor analysis was performed on the assumption that the factors extracted by the exploratory factor analysis were influenced by higher-order factors (dose adherence for the older adults).

Ethical Considerations

The research was conducted with the approval from the Shimane University Nursing Research Ethics Review Commit-

tee (Notification No. 344). All nurses who met the conditions at the medical institution from which research permission had been obtained were considered potential participants, and the participants were asked to read the information provided regarding the research purpose, method, benefits/disadvantages associated with research cooperation, the means or protection of privacy, and the publication of the results. The participants were also asked to acknowledge that they freely agreed to cooperate and to provide certain personal information. The completion and submission of the questionnaire by the responder/participant was considered as consent for the study.

Results

General research cooperation permission was obtained from 40 randomly selected acute care hospitals and 36 home-visit nursing stations nationwide, and a total of 737 questionnaires (recovery rate of 21.8%) were returned with responses.

1. Participant Demographics

The average number of years of nursing experience of the participants was 15.0 ± 9.3 years, and 85.3% worked for acute care hospitals and 13.4% for home-visit nursing stations.

2. Demographics of the Older Adults in Participants' Responses

Table 1 shows the demographics of the older adults who were the subjects of the participants' responses. The older adults' age ranges were 65-75 years (28.0%), 75-85 years (44.6%), and 85+ years (22.3%). Their main current illnesses were digestive illnesses, followed by cardiovascular disease. Ninety percent had medical histories, with cardiovascular disease being the most common, followed by gastrointestinal disease. The average number of medications taken daily was 6.8 ± 3.6, each taken at an average of 3.1 ± 1.0 times/day. Of the reported cases, 37.7% fully self-managed their prescription medications and 40.7% self-managed with the support from others.

3. Selection of Question Items by Item Analysis

Examination of Changes in α Coefficient when Each Question Item was Excluded
The α coefficient of the entire assessment tool composed of 74 items was .976. We confirmed the α coefficient when each question item was excluded. There was no item that threatened the internal integrity of the assessment tool.
Confirmation of Ceiling Effect and Floor Effect
There were no items that had a floor effect. There was one item that caused a ceiling effect, but this bias may have been influenced by the response results of acute care hospi-

Table 1. Demographics of the older adults reported by the survey participants (n = 737).

Demographics		n	%
Sex	Male	271	57.8%
	Female	449	60.9%
	Unknown	17	2.3%
Age (years)	65-74	206	28.0%
	75-84	329	44.6%
	≥85	164	22.3%
	Unknown	38	5.2%
Main disease	Digestive disease	140	19.0%
	Cardiovascular disease	115	15.6%
	Musculoskeletal disorder	107	14.5%
	Cancer	71	9.6%
	Respiratory disease	68	9.2%
	Cranial nerve disease	61	8.3%
	Endocrine disease	35	4.7%
	Others	107	14.5%
	Unknown	33	4.5%
Medical history	Yes	663	90.0%
	No	68	9.2%
	Unknown	6	0.8%
Previous disease[2]	Cardiovascular disease	310	42.1%
	Digestive disease	176	23.9%
	Endocrine disease	124	16.8%
	Musculoskeletal disorder	122	16.6%
	Respiratory disease	101	13.7%
Number of medications taken[1]			6.8 ± 3.6
Number of doses per day[1]			3.1 ± 1.0
Medication self-management status	Self-management	278	37.7%
	Self-management with support from others	300	40.7%
	Management by others	142	19.3%
	Unknown	17	2.3%

Note.
1) Mean ± SD
2) Disease prevalence

tal nurses, who accounted for more than 80% of all respondents. Therefore, the Mann-Whitney U test was performed on the response results from both the hospital nurses and home-visiting nurses for this item, and as a significant difference was found in the response results, the item was included.
Calculation of the Ratio of Not Applicable/No Answer
Percentages were calculated for each item having a "not applicable" response or no answer, and items having 10% or more of such responses were deleted.
I-T Correlation Analysis
The correlation coefficient between each question item and the total score of the assessment tool ranged from −.103 to .760. There were six question items showing a correlation

coefficient of .3 or less. These were removed because of lack of consistency.

G-P Analysis

The average of the total score of the assessment tool was 220.6 points, which was divided into an upper group and a lower group, and the t-test was performed based on the score of each question item. As a result, the significance probability was .05 or more for three items, indicating that these three should be deleted. However, they had already been removed following the I-T correlation analysis.

Calculation of Correlation Coefficient between Items

The interitem correlation coefficient for 74 items ranged from −.178 to .891. Principal component analysis was performed for each of the six categories determined at the qualitative research stage. For a combination of question items with an interitem correlation coefficient of .7 or more, the item with a higher factor loading was adopted and the other was excluded. As a result, 21 items were deleted, and of these, 3 had a high percentage of nonapplicable and nonanswered items and had already been targeted for deletion.

Exploratory Factor Analysis

As a result of the item analysis, 40 items were ultimately selected. Of the 737 returned questionnaires, 545 subjects answered all 40 items. We next tested whether the data from the 545 questionnaires were suitable for factor analysis. The sample validity of Kaiser-Meyer-Olkin was .959 and the sphericity test of Bartlett was $p < .01$, confirming that the data were in fact suitable. Factor analysis was then performed using the pro max rotation by the generalized least squares method. Factors were extracted with an eigenvalue of 1 or more and a factor loading of .3 or more as setting criteria. As a result, the 40 items and 6 factors were extracted. The cumulative contribution rate was 55.45%, the commonality was .436 to .822, and the interfactor correlation coefficient was .204 to .693.

The six factors were interpreted and labeled as follows. The first factor (18 items) was interpreted as showing an attitude of actively participating in treatment through collaboration with healthcare professionals and in autonomous medication self-management and was defined as "active participation in their treatment." The second factor (five items) was interpreted as indicating that medication can be taken according to prescribed dosages and the administration instructions of the prescription medications and was defined as "stable medication compliance." The third factor (six items) was interpreted as indicating that the actions in basic daily life associated with the physical taking of the medications are stable, defined as "medication behavior and stable lifestyle." The fourth factor (four items) indicated that symptoms and distress can be controlled by continuous medication self-management and was defined as "health control ability with continuous medication." The fifth factor (four

items) indicated whether the patient has cognitive, physical, and sensory functions necessary to continue medication self-management and was labeled "inhibitors of medication self-management." The sixth factor (three items) was interpreted as indicating records generally and records related to medication can be managed and was defined as "capability of medication record management." The assessment tool using the selected 40 items and 6 factors was named "medication-adherence assessment tool for older adults" (Table 2).

Score Status of the Medication-adherence Assessment Tool for Older Adults

The total scores of this assessment tool ranged from 49 to 198 points, with an average of 123.8 ± 31.6 points (Figure 1). In the Kolmogorov-Smirnov test, the significance probability was .042. In the response distribution, the number and percentage of respondents for each option were calculated for each question item. As a result, all question items were answered using all of the options.

4. Reliability and Validity of the Assessment Tool

Reliability

Cronbach's alpha, which represents the internal consistency of the scale, was .960 for the entire assessment tool. The Cronbach's alpha coefficient for each factor ranged from .725 to .950.

Criteria-related Validity

Using the revised medication-adherence scale (Ueno, 2018) for patients with chronic diseases as an external standard, the total score of the assessment tool and the correlation coefficient with each factor were calculated. The correlation coefficients were all significant, ranging from .126 to .605.

Construct Validity

A confirmatory factor analysis was performed using the medication-adherence of the older adults as a secondary factor and the six factors extracted by exploratory factor analysis as primary factors (Figure 2). As a result, all path coefficients were significant. The path coefficient from the secondary factor, medication-adherence to the primary factor, was .53 to .91, and the path coefficient from the primary factor to the observed variable was .49 to .88. The goodness of fit between the model and the data was GFI = .825, AGFI = .805, CFI = .887, and RMSEA = .060.

Discussion

1. Data Adequacy

The normality of the total score of the assessment tool was slightly less than .05 in the Kolmogorov-Smirnov test, but the histogram generally had a bell shape (Figure 1), and as the number of data is large, we elected to treat it as a normal distribution. When there is a large quantity of data, overdetection is likely to occur and tends to be significant (Orikasa, 2017). It is possible that overdetection occurred

Table 2. Exploratory factor analysis of the medication-adherence assessment tool for older adults (n = 545).

Factor/item	Factor loading					
	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5	Factor 6
Factor 1: active participation in their treatment						
q50 Asks medical staff about the effects of their medication	.875	−.035	−.016	.031	−.027	−.087
q47 Actively talks to medical staff about their physical condition and the effects of the prescribed medicine	.856	−.102	.087	−.063	−.011	−.069
q63 Stays aware of medical examination values and symptoms of the disease	.830	−.157	.106	.019	−.056	−.018
q48 Searches for diseases and medicine on their own	.828	−.033	−.232	−.063	.066	.030
q59 Ability to talk about their prescribed medicine when consulting another hospital	.743	−.098	−.058	.053	−.055	.104
q37 Knowledge of the effect of forgetting to take a medicine	.742	−.140	−.028	.008	.131	.026
q46 Ability to explain the details of ordinary self-medication	.720	.081	.153	−.082	−.005	−.006
q66 Feeling the effectiveness of the medicine	.715	.032	−.085	.162	−.049	−.091
q45 Try to listen to the medical staff's explanation carefully	.710	.138	.106	.007	−.084	−.151
q44 Read and understood the instructions regarding the appropriate dose	.705	.079	−.129	−.032	−.033	.092
q57 Ability to consult about the disease and medicine	.694	−.026	.139	.117	−.038	−.083
q42 Aware of medicines running out or of insufficiency before the next prescription day	.668	−.009	−.043	.062	.059	.080
q33 Knowledge of the side effects of the prescribed medicine	.641	−.014	.039	−.196	.182	.128
q65 Having the will to appropriately take medicines by themselves	.635	.032	.099	.101	−.012	−.057
q32 Knowledge of the effects of the prescribed medicine	.594	.101	.071	−.078	.103	.023
q29 Ability to contrive methods for continuing medication on their own	.554	.185	−.040	−.041	−.043	.161
q61 Understand the explanation by medical staff	.541	.202	.144	.143	−.156	−.081
q69 Aware of healthy habits such as diet and exercise	.351	.042	−.144	.251	.116	.080
Factor 2: stable medication compliance						
q13 No self-judgment or no self-adjustment of prescribed medicine	−.094	1.011	−.100	−.099	−.005	.000
q12 At minimum, medicine was taken in the morning and evening.	−.041	.797	−.009	.017	−.018	.005
q14 Ability to manage medicines for a day	.143	.654	.046	.014	.027	−.011
q18 The numbers of prescribed days and remaining medicines are almost in accord	−.043	.585	.061	.093	−.095	.111
q11 Capable of following instructions and advice for lifestyle	.120	.538	.185	−.052	.104	−.048
Factor 3: medication behavior and stable lifestyle						
q22 No problems swallowing medicine	−.079	−.022	.899	−.054	−.018	.005
q21 No spillage of medicine	−.003	.021	.826	−.038	.005	.041
q20 No problems opening and taking out the medicine	.134	−.066	.708	−.059	.049	.106
q7 Eats meals 3 times every day	−.170	.101	.354	.152	.087	.075
q8 Has financially stable life	−.022	−.067	.338	.077	.259	.102
q9 Properly dressed when consulting the hospital or visited by medical staff	.034	.200	.313	.089	.090	.032
Factor 4: health control ability with continuous medication						
q71 Pain is well-controlled in daily life	−.044	−.097	−.075	.882	.095	.006
q70 Stability in biochemical values and condition related to the disease	.020	−.064	.043	.658	.063	.037
q72 Medication management method and patient's ability match	.126	.157	−.030	.590	−.031	.027
q73 Daily-life schedule and medication schedule match	.085	.040	.023	.575	−.036	.058
Factor 5: inhibitors of medication self-management						
q5 No decline in ADL or cognition ability compared with that in the past	−.014	−.012	.059	.047	.801	−.049
q6 No problems for transportation and ADL to consult hospitals/clinics	.089	−.096	−.015	.039	.702	.036
q2 No problems for medication management because of cognitive decline	.042	.342	−.039	.018	.617	−.082
q3 No problems for medication management due to visual impairment	−.085	−.009	.302	.053	.527	−.124
Factor 6: capability of medication record management						
q26 No problem storing or bringing a medicine notebook	−.025	.025	.155	.033	.012	.772
q27 Attaches printed prescription lists to medicine notebook	−.021	.008	.095	.117	−.136	.724
q28 Regularly records physical condition and administered medicines in a medical record book or a medicine notebook	.421	.035	−.204	−.140	.093	.435
Cronbach's α coefficient	.950	.862	.824	.809	.825	.725
Cumulative contribution ratio	39.49%	45.84%	48.69%	51.47%	53.61%	55.45%

Note. Shading for factor loading of .30 or more

here as there were large amounts of data used in this analysis. In the reaction distribution, there were no items with low discriminating power, and it was confirmed that the scores of the items of the assessment tool ranged from low to high.

Therefore, we believe that the data of this study are generally appropriate data for use in the examination of reliability and validity.

2. Reliability and Validity of the Assessment Tool

Generally, for the internal consistency of the measurement tools, Cronbach's alpha of >.7 is appropriate and >.80 is extremely desirable (Polit & Beck, 2010). Here, the Cronbach's alpha of the entire assessment tool was .960, indicating internal consistency of the assessment tool. The correlation coefficient between the medication-adherence scale by Ueno (2018), an external criterion in the criterion-related validity examination, and the total score of the assessment tools, and the score of each factor were all calculated. A moderately significant correlation between the total score of the assessment tool and the total score of the external standard scale was confirmed with a correlation coefficient of .605 ($p < .01$). A significant correlation was confirmed between this assessment tool and the total score of the external criteria, each factor of the assessment tool, and the corresponding subscale of the external criteria, indicating criteria-related validity.

Regarding the validity of the construct, higher-order factor
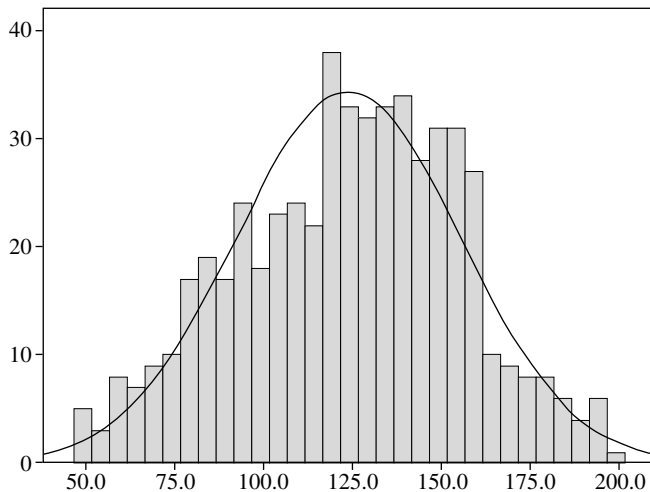
Figure 1. Total score of the assessment tool (n = 545).
Note. The horizontal axis indicates the total score, and the vertical axis indicates the number of subjects.

All path coefficients are $p<.01$
X^2 = 2162.14 ($p<.001$)
GFI = 0.825, AGFI = 0.805, CFI = 0.887
RMSEA = 0.060
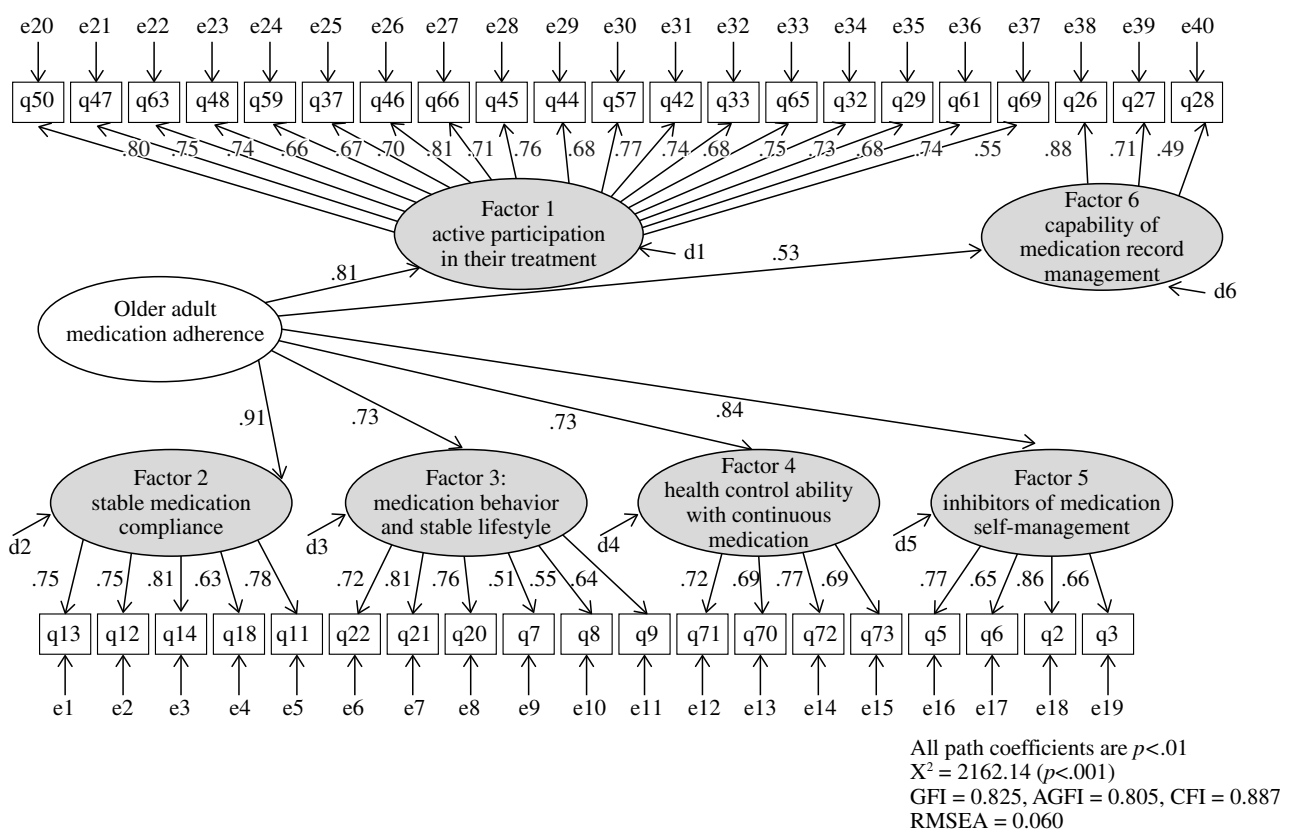
Figure 2. Confirmatory factor analysis results of the assessment tool.
Note. White circle = secondary factors; gray circles = six factors extracted by exploratory factor analysis, primary factor; (q) = observed variable; (d, e) = error variable; arrows = causal relationship, path coefficients are shown next to the arrows.

analysis was performed with the medication-adherence of the older adults as the secondary factor and the six factors extracted by exploratory factor analysis as the primary factor. The results indicated permissible conformance (GFI: .923; AGFI: .893; CFI: .927; and RMSEA: .066), and the tool displayed great construct validity. Therefore, it was confirmed that the medication-adherence of older adults in this study explained the six factors obtained by the exploratory factor analysis, and the validity of the construct was confirmed.

The above analyses established the content validity, reliability, criteria-related validity, and construct validity of the "medication-adherence assessment tool."

3. Clinical Applicability of the Assessment Tool

This assessment tool may be used to evaluate the attitude of older adults toward autonomously maintaining medication self-management while continuing their disease control and daily life through medication and to provide an assessment from a viewpoint based on the definition of medication-adherence.

High assessment scores for older adults are an indication of the presence of the necessary judgment, execution ability, and attitude for continued medication self-management, and thus, self-management and support may be continued as it is. The event of low scores indicates a need for adjustments in the support for self-management. Until now, it has been difficult to predict medication-adherence by older adults, and evaluation for self-management ability was left to nurses' experiences (Sakane, 2020). With this newly developed assessment tool, it is possible to identify changes in an older adult's medication self-management abilities and to provide the support determined necessary for maintaining and improving medication-adherence.

Further, the items of this assessment tool include evaluations of collaboration with healthcare professionals, autonomous attitude to participate in medication and treatment, and the status of continuous medication control, so the score will not change significantly from day to day. Assessments may be conducted at regularly scheduled times (for example, during an initial interview), as well as when prescriptions change or the condition of the patient changes, among others. Rather than comparisons between patients, an individual patient's situation may be assessed, compared to prior assessments over intervals of time, and adjustments to support may be made accordingly.

The assessment tool may also serve as a tool for sharing of useful patient data and may contribute to the promotion of multidisciplinary collaboration and collaboration in the comprehensive community care system.

4. Study Limitation

The assessment tool developed in this study assesses medication-adherence, focusing on autonomy in medication self-management. Therefore, it is difficult to use this tool for older adults who have been diagnosed with dementia or who need support in all aspects of their lives due to cognitive decline.

Conclusion

To verify the reliability and validity of a medication-adherence assessment tool for older adults, we conducted a survey on nurses at acute care hospitals and home-visit nursing stations nationwide and received 747 responses. Item and exploratory factor analysis showed that a reliable and valid "medication-adherence assessment tool for older adults" incorporating 40 items and 6 subfactors could be constructed.

Our results indicated that this medication-adherence assessment tool may be used by home-care and hospital acute care nurses for evaluating the autonomous self-management status of older adult patients and may aid in the implementation of appropriate support.

Author Contributions
Kanako Sakane, Yuko Tsumoto, Yuta Kobayashi, and Hiromi Uchida contributed to the study design. Kanako Sakane was responsible for data collection, data analysis, and interpretation of the results. Yuko Tsumoto, Yuta Kobayashi, and Miki Fukuma contributed to critically revising the methods and statistics section of the manuscript. Kanako Sakane, Yuko Tsumoto, Miki Fukuma, and Mayumi Miyamoto contributed to drafting and critically revising the entire study. All authors read and approved the final version of the manuscript.

Declaration of Conflicting Interests
There are no conflicts of interest in this study.

Ethical Approval
Study number: 344
    The Shimane University Institutional Committee on Ethics

Note
A portion of this research was presented at ICN Congress

2021. This research is a partial addition of a doctoral dissertation from Shimane University Graduate School.

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Original Research

Association between family functioning, resilience, and psychosocial burden among family members of patients in the intensive care unit: A cross-sectional study

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Abstract

Objective: Families of patients in the intensive care unit (ICU) often experience severe stress, and understanding their experience is important for maintaining family functioning. This study aimed to determine the characteristics and factors associated with family functioning in families of patients admitted to the ICU. **Methods:** This cross-sectional study recruited all family members ($N = 144$) of patients admitted to the ICU at two teaching and advanced treatment hospitals, 77 (53.5%) of whom completed a questionnaire. Family members provided the demographic and clinical characteristics of the patients and completed the Family Relation Index (FRI), the Impact of Event Scale-Revised, the Center for Epidemiologic Studies Depression Scale, the State-Trait Anxiety Inventory (STAI) Form X, the Connor-Davidson Resilience Scale (CD-RISC), and the Social Support Questionnaire. **Results:** Ten (13.0%) and 37 (48.1%) family members had the "hostile" and "sullen" family functioning type, respectively. Multiple regression analysis revealed the presence of a significant negative relationship between the FRI and the STAI-state ($B = -0.057$, $\beta = -0.36$; $p = .001$) that the participants had experienced a stressful event within the previous month ($B = -1.201$, $\beta = -0.276$, $p = .009$), and that the participants' CD-RISC scores were correlated with family functioning ($B = 0.021$, $\beta = 0.176$, $p = .049$). Moreover, this model explained 23.9% of the variance in total FRI scores with regard to family functioning. **Conclusions:** In total, 61% of the family members had poor family functioning and required support. Among the family members of patients in the ICU, anxiety was associated with poor family functioning, whereas resilience was associated with good family functioning.

Keywords

family functioning, intensive care unit, post-intensive care syndrome-family

Introduction

Most patients admitted to the intensive care unit (ICU) are unable to communicate for a variety of reasons, including heavy sedation, a state of delirium, and connection to a ventilator (McAdam & Puntillo, 2009). Therefore, families of such patients often experience severe stress due to having to make decisions on behalf of the patient when the risk to the patient's life is high (White et al., 2007). To act as proxy decision-makers for the patient, family members must listen to explanations about the patient's therapeutic options and prognosis from healthcare providers. Some family members may also experience a degree of mental shock after witnessing a loved one in the ICU in a severe condition and/or connected to medical apparatuses, especially in comparison with the patient's usual condition (White et al., 2007). Experienc-

ing severe mental stress in the initial period after a patient's admission to the ICU has been reported to be among the most predictive factors for the development of posttraumatic stress disorder (PTSD) among family members (Harvey & Bryant, 1999).

Given this background, family members of patients in the ICU may be prone to developing a type of psychological stress called post-intensive care syndrome-family (PICS-F) (Davidson, Jones, & Bienvenu, 2012). PICS-F comprises a set of symptoms such as anxiety, depression, PTSD, and posttraumatic stress symptoms (PTSSs).

Since PICS-F was named, it has been widely accepted in the research community for describing the psychiatric symptoms that occur in family members after a patient is admitted to the ICU (Hoo et al., 2022; Inoue et al., 2019). Regarding the prevalence of PICS-F in patients' spouses or cohabitants, exploratory studies for investigating the factors that affect PICS-F have been performed, as have intervention studies to reduce PICS-F (Cairns et al., 2019; Naaktgeboren et al., 2022; Shirasaki et al., 2022). Nevertheless, those studies have involved only spouses or cohabitants. Since PICS-F can affect the functioning of entire families, factors that ease the burden should also be identified.

Studies that aim to gain an understanding of the functioning of the entire family and elucidate the relationship between family functioning and psychological symptoms have been conducted in Europe, the United States, Australia, and Taiwan since the 1990s. Among such efforts, we identified six quantitative studies that used family functioning scales in the ICU, including the Feetham Family Functioning Survey; versions II, III, and IV of the Family Adaptability and Cohesion Evaluation Scale; the Family Assessment Device; and the Family Environment Scale (FES) (Ballantyne, Benzies, & Trute, 2013; Finello, Dellemos, & Chan, 1998; Klassen et al., 2004; Vance, Pan, Malcolm, & Brandon, 2020; Youngbult & Lauzon, 1995; Youngbult & Shiao, 1993). All of the participants in those studies were family members of children admitted to the neonatal intensive care unit (NICU) or pediatric intensive care unit (PICU). Four of the studies were cross-sectional, and two were longitudinal.

One of the two longitudinal studies elucidated the relationship between family functioning and negative psychological symptoms, and the other examined the relationship between family functioning and psychological states, including positive ones, with self-efficacy as the independent variable (Vance, Pan, Malcolm, & Brandon, 2020; Youngbult & Shiao, 1993). Vance et al. (2020) examined the relationships between family functioning, psychological symptoms, and self-efficacy. The study participants were 67 mothers of infants who had a severe medical condition and were admitted to the PICU or intensive care nursery. Measurements were performed at three time points. The relationships between family functioning, psychological well-being, and parenting

self-efficacy were examined, with the results showing that maternal self-efficacy increased significantly over time. If family functioning was poor at the first time point, maternal self-efficacy was low at all time points.

Few previous studies of families of patients admitted to an adult ICU that used these family functioning scales have examined the direct relationship between family functioning and positive psychological states among family members of a patient admitted to an adult ICU. Moreover, few previous studies have elucidated the characteristics of family functioning using family functioning scales. Komachi and Kamibeppu (2018) previously conducted a cross-sectional study focused on the resilience of families with severe stress such as PTSSs in early ICU admission. The results indicated that high PTSSs were associated with low resilience, and thus, early support concentrating on resilience during admission to the ICU was believed to reduce the psychological symptoms of family members. To maintain a good psychiatric condition among family members, the functioning of the whole family should also be understood. Consequently, to clarify the relationship between the functioning and psychiatric condition of the entire family, in the present study, a secondary analysis was carried out using data from the previous study regarding family functioning, psychiatric conditions, social support, and demographic characteristics (Komachi & Kamibeppu, 2018).

Therefore, the present study aimed to examine the characteristics of family functioning among families of patients after admission to an adult ICU, as well as positive psychological states and other psychosocial factors in family members that affect family functioning.

Materials and Methods

Study Design and Participants

This cross-sectional study was conducted in an urban area of Japan at two teaching and advanced treatment hospitals with medical/surgical (35 beds) and emergency ICUs (eight beds: four each in the emergency ICU and coronary care unit). The inclusion criteria for patients were as follows: 1) planned admission to the ICU after surgery; 2) unplanned immediate admission to the ICU after a flare-up in the patient's condition while in the general ward; and 3) unplanned admission to the ICU after treatment in the emergency room. The exclusion criterion was living alone. The inclusion criteria for family members were as follows: 1) being a close relative to the patient (e.g., spouse, child, parent, or sibling), 2) provision of consent to be surveyed by a physician or member of the ICU staff, 3) age over 20 years, and 4) ability to communicate in Japanese. The exclusion criterion was being a caregiver for multiple family members.

We recruited potential participants from November 2010 to March 2011 and collected data from electronic medical

records through April 2011. We then conducted a secondary analysis of the present study in 2020. Consent to collect patient information from electronic medical records and a family questionnaire survey was obtained from the physicians, managing nurses, and nursing staff who were treating and caring for patients who had been admitted to medical/surgical ICUs within each facility. After explaining the study aims and methods to the staff, we requested a list of patients and family members who met the inclusion criteria and then visited each family member in the medical/surgical ICU. We asked all family members to complete and return the questionnaire by mail within 24 h to protect their anonymity and alleviate any pressure associated with completing the questionnaire in front of us. After obtaining consent from the participants, information regarding the patients was collected from electronic medical records by the investigators.

Data Collection

Data were collected as described previously (Komachi & Kamibeppu, 2018). The Family Relationship Index (FRI), Impact Event Scale-Revised (IES-R), State-Trait Anxiety Inventory (STAI), Center for Epidemiologic Studies Depression Scale (CES-D), Connor-Davidson Resilience Scale (CD-RISC), Social Support Questionnaire (SSQ), and items on the participants' demographics were used to estimate family functioning, psychiatric symptoms, resilience, social support, and the characteristics of the participants in the present study. The previous study used participants' demographics, IES-R, and CD-RISC data (Komachi & Kamibeppu, 2018).

Family Relationship Index (FRI)

The FRI is a scale derived from the short form of the FES (Moos & Moos, 1975) that measures the perceptions of family members regarding family functioning. The FRI has been used for members of families such as those of patients with advanced cancer, head injuries, and somatization disorder and those of patients with cancer receiving palliative care (Kissane & Blosh, 2002; Laratta et al., 2021; Nissen et al., 2016; Obimakinde, Ladipo, & Irabor, 2015). It is composed of 12 dichotomous (true/false) items categorized into the following three subscales (four items per subscale): cohesion, which captures the overall sense of family togetherness and the willingness toward family time; expressiveness, which measures the capacity of family members to express their feelings to each other; and conflict resolution, which measures the ability of the family to resolve disagreements among one another. The score for each subscale ranges from 0 to 4, with higher scores indicating better family functioning. Additionally, the FRI can be used for screening to identify families at risk of family dysfunction and categorize families according to the type of family functioning.

The present study adopted the classification of Kissane and Blosh (2002) to determine the characteristics of the family functioning of the study participants. For categorizing families by type, a scoring system has been established in which families are classified according to five types of functioning and designated depending on the main characteristics of each type. Two of the five types indicate that a family exhibits good family functioning: the "cooperative type" and "conflict resolution type." Cooperative families have the characteristics of high cohesiveness, good expressiveness, and absence of conflict. The conflict resolution type has the characteristics of moderate conflict, as well as high cohesiveness and above-average expressiveness. Two other types represent dysfunctional families. The first is the "hostile type," and the second is the "sullen type." The hostile family is the most dysfunctional, characterized by high conflict and low cohesiveness, but low expressiveness. The sullen type is characterized by muted anger and high rates of depression among members. Sullen families are characterized by reduced cohesiveness, mild-to-moderate conflict, and poor expressiveness. The final type is an intermediate type between dysfunctional families and families that function well; it is therefore referred to as the "intermediate type." This type is characterized by moderate cohesiveness, as well as high rates of psychosocial morbidity.

The FRI score for each type is as follows: 12 points for the cooperative type, 10-11 points for the conflict resolution type, 0-4 points for the hostile type, 5-7 points for the sullen type, and 8-9 points for the intermediate type, respectively. Cronbach's α coefficients in this study were 0.67 for expressiveness and cohesion and 0.73 for conflict resolution.

Impact of Event Scale-Revised (IES-R)

We used the Impact of Event Scale-Revised (IES-R) to assess PTSS in the families of patients admitted to the ICU (Weiss, 1997; Asukai et al., 2002). The IES-R has been used in numerous studies and is considered a reliable measure of PTSD in Japanese subjects (Asukai et al., 2002). To categorize PTSS, the items on the IES-R comprise three dimensions (eight intrusion items, eight avoidance items, and six hyperarousal items), as described in the DSM-IV (Weiss, 1997), that consist of 22 statements rated on a five-point scale (0-4) in terms of the response to a specific stressful life event in the past week. All PTSS and total scores on the IES-R were calculated. Cronbach's α coefficient for the IES-R in the present study was 0.96. Cronbach's α coefficients were 0.94, 0.76, and 0.87 for the three IES-R subscales of intrusion, avoidance, and hyperarousal, respectively.

State-Trait Anxiety Inventory (STAI)

We used the State-Trait Anxiety Inventory (STAI) Form X to measure the anxiety in the family members of patients admitted to the ICU. The original STAI was developed by

Spielberger et al. (1970), and the Japanese version by Nakazato and Mizuguchi (1982). The reliability and validity of these scales have been confirmed. The STAI is a self-rated tool composed of two scales that measure state and trait anxiety symptoms using 20 items rated on a scale from 1 to 4 (1 = "almost never" to 4 = "almost always"). The total score ranges from 20 to 80, and a score ≥40 is considered to indicate "high anxiety." In the present study, the total score was measured. Cronbach's α coefficients for state and trait anxiety were 0.89 and 0.91, respectively.

Center for Epidemiologic Studies Depression Scale (CES-D)

We used the Center for Epidemiologic Studies Depression Scale (CES-D) to measure depression in the families of patients admitted to the ICU. The CES-D is a self-rated scale composed of 20 items that was developed to assess depression symptoms based on a four-point scale. The original CES-D was developed by Radloff (1977), and the Japanese version by Shima et al. (1985). The total score ranges from 0 to 60, with a cutoff value of 15/16. The higher the score, the worse the depression symptoms. Cronbach's α coefficient for the CES-D is 0.89.

Connor-Davidson Resilience Scale (CD-RISC)

To assess resilience, we used the CD-RISC, for which the responder rates the question on a five-point scale (0-4) and the scores range from 0 to 100, with higher scores indicating a higher level of resilience (Connor & Davidson, 2003). For the purposes of the present study, we measured the total score. The CD-RISC has demonstrated excellent reliability and validity in clinical trials and various settings, including medical facilities (Sottile, Mealer, & Moss, 2016). Cronbach's α coefficient for the CD-RISC in the present study was 0.87.

Social Support Questionnaire (SSQ)

We used the SSQ to measure satisfaction among families of patients admitted to the ICU. The SSQ is a reliable, valid, and convenient index of social support that was developed by Sarason et al. (1983). Two versions of the SSQ, a 27-item version and an abbreviated six-item version, have been found to have high internal consistency, validity, and test-retest reliability (Sarason et al., 1983). In the present study, the six-item instrument developed by Furukara et al. (1999) was used to measure satisfaction with social networks. The SSQ asks about the number of people in the respondent's support network and his or her satisfaction with it. The satisfaction score is calculated based on a six-point Likert-type scale (from 0 = very dissatisfied to 5 = very satisfied). The internal consistency value for the satisfaction score in the present study was 0.94.

Statistical Analysis

To determine the characteristics of family functioning, the type classifications of Kissane and Blosh (2002) were used to classify the families into five types according to functioning. For each type, means and standard deviations (SDs) were calculated for the following measures of psychosocial factors, and a one-way analysis of variance was performed: IES-R, CES-D, STAI-state, STAI-trait, CD-RISC, and SSQ (satisfaction). Multiple comparisons were adjusted using the Bonferroni method.

To examine the relationship between the FRI score and each variable, the correlation with the FRI score was examined when the independent variable was a continuous variable, and the mean FRI scores for the individual responses were compared when the independent variable was not a continuous variable. An exploratory analysis of the related factors for the FRI score and each variable was then performed. With the FRI score as the dependent variable, variables for which a correlation ($r \geq .2$) or difference ($p < .1$) was seen were checked for multicollinearity and selected as explanatory variables. Moreover, a multiple regression analysis was performed using the forced entry method.

We also calculated variance inflation factors (VIFs) for the final models to examine multicollinearity. The VIFs of all variables in the final models ranged from 1.02 to 1.18. After constructing a multiple regression model, we performed a residual analysis, and the residuals were found to be normally distributed. All statistical analyses were conducted using SPSS 25.0 (SPSS, Chicago, IL, USA), with statistical significance set at $p < .05$.

Ethical Considerations

This study was approved by all relevant ethics committees. Written informed consent was obtained from all participants after they received written and oral explanations of the study aims and were assured that their anonymity would be preserved and their condition and treatment would be prioritized. They were also informed that their participation in the study was voluntary and that withdrawing at any time would not affect their care.

Results

Overview of the Participants

The characteristics of the participants, shown in Figure 1, were the same as those in a previous study (Komachi & Kamibeppu, 2018). Table 1 shows the demographic characteristics of the family members of the patients in the ICU (family members = 68% female, mean age of 54.6 years; patients = 32.5% female, mean age of 64.1 years). Three of the participants had a history of mental disorders. Acute ischemic heart disease was the most common causative dis-
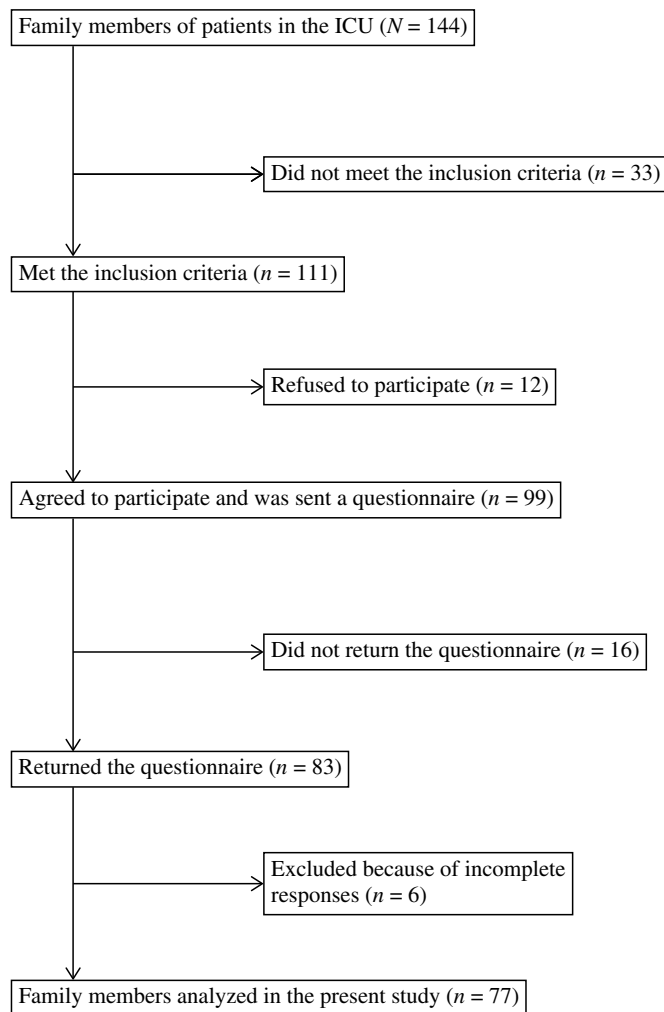
Figure 1. Flowchart summarizing the recruitment of participants in the present study. ICU, intensive care unit.

ease among the patients in the ICU (Table 1). Table 2 shows the findings regarding the prevalence of family functioning based on the FRI.

Relationship between Family Functioning Type and Psychosocial Factors

Family functioning was classified into three types. Ten (13.0%) family members had the hostile family functioning type, and 37 (48.1%) had the sullen type (Table 3). The remaining 29 family members (37.7%) had the intermediate type. There were no cooperative or conflict resolution types. The examination of differences in the mean scores for the scales related to psychosocial factors according to the type of family functioning showed that the CD-RISC score was significantly associated with family functioning type (F (2, 73) = 2.99, *p* < .0). Significant differences were found between the hostile and sullen types and between the hostile and intermediate types.

Multiple Regression Analysis of Major Factors Associated with Family Functioning

Four variables for which significant trends were seen in the univariate analysis were used as independent variables in the multiple regression analysis (Table 4). The STAI-state scores (B = −0.057, β = −0.36; *p* = .001), experience of a stressful event within the previous month (B = −1.201, β = −0.276, *p* = .009), and CD-RISC scores (B = 0.021, β = 0.176, *p* = .049) were significantly correlated with the FRI scores. The results of the multiple regression analysis showed that family functioning explained 23.9% of the variance in the total FRI scores in this model. No associations were found between family functioning and experiencing the loss of a family member.

Discussion

Status of Family Functioning

The family functioning of the families of patients admitted to the ICU was measured in this study using the FRI. The mean score was 6.8 (SD = 1.2). By contrast, the mean FRI score in a previous study on the family functioning of outpatients with somatic symptom disorder was 5.92 (SD = 2.85), which was lower than that observed in the present study (Obimakinde, Ladipo, & Irabor, 2015). Patients with somatic symptom disorder often experience abuse or a lack of affection from caregivers during childhood (Stuart & Noyes, 1999). Families with such experiences have a high likelihood of chronic family dysfunction. For the participants in the present study, the illnesses that resulted in admission to the ICU, such as myocardial infarction, were unlikely to be related to the factors that worsened family functioning. Consequently, the difference in mean scores was attributed to differences in the family backgrounds of the patients affected by illness. Conversely, the mean FRI score ranged from 7.97 to 10.3 points for patients with advanced cancer and was 9.4 (SD = 2.4) for patients with a head injury (Laratta et al., 2021; Nissen et al., 2016), which were both higher than the result of 6.8 (SD = 1.2) in the present study. The patients with advanced cancer were receiving outpatient treatment, and the patients with a head injury were undergoing rehabilitation. Therefore, the condition of the patients was relatively stable. By contrast, the patients in the present study had only recently been admitted to the ICU, and their condition was therefore unstable. The differences in the mean FRI scores were therefore linked to differences in the conditions of the patients.

Scores of the Family Functioning Types

To determine the characteristics of family functioning among the participants, the type classifications of Kissane and Blosh (2002) were adopted, and the families were clas-

Table 1. Characteristics of the patients and their family members ($n = 77$).

Characteristics of the participants		n	%	Mean	SD	Median	Range	p value
Age (years)	≤45	16	20.78	54.61	11.93	57.1	20–72	.718[b]
	46–55	24	31.17					
	56–65	23	29.87					
	≥66	14	18.18					
Number of household members, including patients in the ICU	≤2	30	38.96	2.86	1.09	3.94	1–7	.418[b]
	3	30	38.96					
	≤4	17	22.08					
Sex								.53[a]
	Female	53	68.83					
	Male	24	31.17					
Education level								.544[c]
	Junior high school	9	11.69					
	High school	49	63.64					
	Technical school	4	5.19					
	Junior college	5	6.49					
	University	10	12.99					
Marital status								.444[a]
	Married							
	Not married							
Relationship to patient								.994[c]
	Spouse	39	50.65					
	Child	23	29.87					
	parent	6	7.79					
	Sibling/Other	9	11.69					
Household income (million JPY)								.224[c]
	<3	20	25.97					
	3.01–5	21	27.27					
	5.01–7	26	33.77					
	7.01–15	7	9.09					
Participants with a history of mental disorders	Yes	3	3.9					.422[a]
	No	74	96.1					
Family has a member with a history of mental illness	Yes	2	2.6					.311[a]
	No	75	97.4					
Experienced a loss of a family member	Yes	69	89.6					.048[a]
	No	8	10.39					
Experienced a loss of a close relative	Yes	43	55.84					.763[a]
	No	34	44.16					
Experienced a stressful event within the previous month	Yes	25	32.47					.011[a]
	No	52	67.53					
Encountered a traumatic event in the past	Yes	4	5.19					.208[a]
	No	73	94.8					

sified according to family functioning type. Thirteen percent of the families (10 people) in this study were classified as the hostile type. In a previous study that classified the functioning of families of patients with cancer, 6% of the families were classified as the hostile type during the palliative care period, and this proportion increased to approximately 12% early in the period after the patient's death, which was comparable to the proportion seen in the present study (Kissane & Blosh, 2002). The timing the survey in the present study was soon after the patient had been admitted to the ICU, which is a period of rapid changes in the patient's condition and invasive treatments, all of which place a heavy mental and physical burden on the family. The mental and physical burden is also believed to be heavy during the period immediately after a patient dies, and stressful events related to the patient that the family encounters during this period explain the comparable proportions of families classified as the hostile type.

The results of this study showed that the family functioning type of 48% of the families was the sullen type. Kissane

Table 1. Characteristics of the patients and their family members (*n* = 77) (continued).

Patient characteristics		*n*	%	Mean	SD	Median	Range	*p* value
Age (years)	≤55	14	18.18	64.06	13.78	67.0	20–86	.351[b]
	56–65	23	29.87					
	66–75	28	36.36					
	≥76	12	15.58					
APACHE II score	1–10	28	36.36	14.4	8.83	13.0	1–40	.07[b]
	11–20	29	37.66					
	≥21	20	25.97					
Duration of ICU stay (h)	≤24	18	23.38	84.56	84.95	48.0	12–491	.197[b]
	25–48	25	32.47					
	49–96	12	15.58					
	≥97	22	28.57					
Duration of mechanical ventilation (h)	0	48	62.34	59.14	76.62	37.5	3–360	.188[b]
	1–24	11	14.29					
	25–48	8	10.39					
	≥49	10	12.99					
Sex	Female	25	32.5					.386[a]
	Male	52	67.5					
Use of cardiac stimulants or vasopressors	Yes	25	32.47					.937[a]
Use of sedatives	Yes	23	29.87					.386[a]
Use of mechanical ventilator support	Yes	29	53.7					.302[a]
Use of artificial heart-lung machine	Yes	4	7.0					.199[a]
Use of blood transfusion	Yes	17	31.5					.487[a]
Use of hemodialysis	Yes	2	4.0					.82[a]
Number with complications		25	46.3					.976[a]
Admitted to ICU in the past		12	22.2					.775[a]
Primary causative diseases among patients in the ICU		*n*						
Hepato-biliary-pancreatic cancers		8						
Esophageal cancer or other alimentary canal cancer		9						
Lung cancer		6						
Other underlying causes of cancer		6						
Cancer recurrence		9						
Acute ischemic heart disease		10						
Valvular heart disease		5						
Arterial and peripheral arterial occlusive disease		9						
Heart failure		5						
Irregular heartbeat		1						
Septic shock		3						
Hemorrhagic shock		2						
High-energy trauma injuries		1						
Cardiac arrest caused by respiratory failure		1						
Other		2						
Total		77						

APACHE II, Acute Physiology and Chronic Health Evaluation II; ICU, intensive care unit; SD, standard deviation.

[a]paired *t* test, [b]Pearson's correlation coefficient, [c]one-way analysis of variance.

and Blosh (2002) found that this type of family functioning was exhibited by 9% of the families of patients with cancer receiving palliative care and approximately 18% of families soon after the death of the patient. Additionally, the proportion was higher than that immediately after the death of a patient with cancer. Sullen-type families have been described as guardedly expressing candid emotions and exhibiting rigid attitudes. In the period immediately after the death of a patient with cancer, many families report having foreseen the patient's death since the palliative care stage and have accepted changes in the patient's condition with time. Conversely, families at the stage early after admission to the

Table 2. Psychosocial characteristics of the respondents ($n = 77$).

	n	Mean	SD	Median	Range	Pearson's correlation coefficient
FRI	75	8.0	1.8	8.0	4–12	-
IES-R	-	-	-	-	-	-
Total score	77	18.1	17.1	11	0–56	0.771[a]
Re-experience	77	7.7	7.3	6	0–32	-
Avoidance	77	6	5.7	4	0–21	-
Arousal	77	4.4	4.9	3	0–20	-
STAI-trait	77	44.4	10.8	42	23–75	0.496[a]
STAI-state	77	47.9	12.6	48	22–77	0.002[a]
CES-D	77	15.9	11.2	13.0	0–54	0.759[a]
CD-RISC	76	57.6	17.8	58.0	17–100	0.038[a]
SSQ (satisfaction)	73	4.0	1.8	4.7	0–6.0	0.24[a]

FRI, Family Relationship Index; IES-R, Impact Event Scale-Revised; STAI, Spielberger's State–Trait Anxiety Inventory; CES-D, Center for Epidemiological Studies Depression Scale; CD-RISC, Connor–Davidson Resilience Scale; FRI, Family Relationship Index; SSQ, Social Support Questionnaire; SD, standard deviation.

Table 3. Relationship between family functioning type and psychosocial factors ($n = 77$).

	Hostile type $n = 10$ (13.0%)		Sullen type $n = 37$ (48.0%)		Intermediate type $n = 30$ (38.9%)		F (2, 73)	p
	Mean	SD	Mean	SD	Mean	SD		
IES-R	24.4	18.2	15.0	15.0	18.6	18.9	1.2	.2
CES-D	16.8	8.1	11.9	10.7	15.0	9.5	1.2	.2
STAI-state	53.5	21.6	58.3	11.2	55.6	12.3	0.6	.5
STAI-trait	54.1	9.8	53.2	12.9	54.6	10.4	0.1	.8
CD-RISC	45.7	17.0	59.4	19.7	60.4	13.4	2.9	.0
SSQ (satisfaction)	3.8	1.6	4.0	1.5	4.0	2.0	0.1	.9

IES-R, Impact Event Scale-Revised; CES-D, Center for Epidemiological Studies Depression Scale; STAI, Spielberger's State–Trait Anxiety Inventory; CD-RISC, Connor–Davidson Resilience Scale; SSQ, Social Support Questionnaire; *p* < .05; SD, standard deviation.

ICU are psychologically traumatized immediately after encountering the appearance and condition of a patient who has drastically changed from before admission and cannot accept the patient's condition (White et al., 2007). The differences in the proportions of families with sullen-type family functioning were therefore related to differences in the events leading to the patient's condition at the time of the survey.

Factors Associated with the Functioning (FRI) of Families of Patients Admitted to the ICU

An examination of the factors associated with family functioning showed a relation between severe anxiety in the family and poor family functioning. In a comparative investigation of the psychological symptoms and family functioning

of immigrant mothers of premature infants admitted to the NICU and mothers who were born and raised in that region, Ballantyne et al. (2013) found that negative psychological symptoms such as maternal stress and depression became more pronounced as family functioning worsened. Although this finding is similar to that of the present study, the negative psychological symptom in the study by Ballantyne et al. (2013) was depression, whereas it was anxiety in the present study; therefore, the types of psychological symptoms differed, as did the patients. The participants in the study by Ballantyne et al. (2013) were mothers of premature infants, whereas those in the present study were the family members of patients admitted to the ICU. Although the patients were in similar environments, the types of psychological symptoms associated with family functioning may also have dif-

Table 4. Results of multiple regression analysis of major factors associated with family functioning ($n = 77$).

	B	β	t	*p* value
STAI-state score	−0.057	−0.36	−3.534	.001
CD-RISC score	0.021	0.176	1.694	.049
Participant experienced a loss of a family member[a]	−1.014	−0.145	−1.412	.162
Participant experienced a stressful event within the previous month[b]	−1.201	−0.276	−2.677	.009
R^2		0.28		
Adjusted R^2		0.239*		

*$p < .05$

[a]Experiencing the loss of a family member was categorized into two groups for analysis: yes = 1 or no = 0.

[b]Participants experiencing a stressful event within the previous month were categorized into two groups for analysis: yes = 1 or no = 0.

STAI, Spielberger's State–Trait Anxiety Inventory; CD-RISC, Connor–Davidson Resilience Scale.

fered if the backgrounds and attributes of the patients and subjects had differed. Consequently, it will be necessary in the future to accumulate further findings related to patients admitted to the ICU and their families.

The results of the multiple regression analysis revealed that resilience was associated with stable family functioning. In a study that examined the causal relationship between self-efficacy and family functioning in mothers of infants who received medical treatment in the NICU, Vance et al. (2020) found that if family functioning was poor when the patient was admitted to the NICU, the mother's self-confidence was continuously low through 3 months after NICU discharge. Because a healthy family environment fosters a positive psychological state in mothers, the investigators emphasized the importance of family support. The results of the study by Vance et al. (2020) were similar to those of the present study; however, the present study determined only the correlations between family functioning and positive psychological states, and the results therefore suggest only the possibility that family resilience is associated with family functioning. It will be necessary in the future to elucidate the causal relationship between family resilience and family functioning.

It has been shown that family functioning may be poor if families of patients admitted to the ICU have encountered a stressful life event in the previous month. Baseline data in a cohort study of medical university students who responded to the spread of infection of the 2019 novel coronavirus showed that those who had encountered a stressful life event during the previous year tended to experience severe psychological distress, but the psychological distress tended to be mild if the student's family functioning was good (Li et al., 2021). Although the causal relationship between encountering a stressful life event within the previous year and family functioning was not examined in the present study, the results were similar to those of the previous study. To clarify the association between family functioning and stressful life events, further longitudinal studies are needed.

Finally, as a clinical implementation of the current study, the results of this study will serve as basic data for building support for the families of patients admitted to the ICU. The family function status, risk factors, and recovery factors of patients admitted to the ICU were clarified based on scientific evidence. This information will be useful information for ICU staff to support families.

Limitations

This study had several limitations. First, we targeted family members of patients who had been admitted or transferred to a medical/surgical or emergency ICU in only two teaching and advanced treatment hospitals, so many of the participating family members may have done so because of the location, thereby leading to the possibility of a selection bias regarding family status. Hence, the findings may not necessarily apply to family members of patients admitted to the ICU after being transferred from another hospital. Second, as a self-administered questionnaire was used in the present study, the findings could be underestimated or overestimated. Third, the self-administered questionnaire used in this study was developed to evaluate family functioning, resilience, and psychosocial burden. Therefore, although the participants were asked to complete the questionnaire within 24 h of their family member being admitted to the ICU, we cannot rule out the possibility of recall bias because the family members were likely under a great deal of stress when completing the questionnaire. Finally, the changes recently proposed regarding the diagnosis of PTSD in the DSM-5 were not considered (American Psychiatric Association, 2013). The three symptom clusters in the DSM-IV-TR were expanded to four symptom clusters in DSM-5 and should be considered when interpreting the results of the present study.

Conclusion

None of the types of family functioning seen in the partici-

pants in this study were types that would give the impression that the family members were happy. Sixty percent of the families had poor family functioning and required support. The patient's admission to the ICU was a psychologically severe event for the family members. Anxiety was high in this period, and family functioning was vulnerable if the family encountered stressful events within the past month. Conversely, family members with high resilience had good family functioning. These findings indicate that support for the family as a whole is needed, so interventions that specifically focus on the resilience of family members may be effective.

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Technical Report

A comparison of the fine particulate protection rate of face masks reused after washing

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Abstract

Objective: At the start of the coronavirus disease 2019 (COVID-19) pandemic, the Centers for Disease Control and Prevention and the World Health Organization recommended the use of face masks in public places to prevent the spread of COVID-19. Several mask types flooded the market with little information regarding their effectiveness. This study aimed to clarify the change in the fine particle protection rate (FPPR) of face masks reused after washing in an experimental study and to propose a method for reusing face masks that is suitable for non-medical personnel. **Technical Report:** The FPPR was measured using a mask-fitting tester after one participant wore the new masks and after 5, 10, 15, 20, 25, and 30 washes. The dimensions of the masks were measured to determine whether shrinkage occurred after washing. The surgical mask had the highest FPPR, followed by the cloth, gauze, polyester, and polyurethane masks. Furthermore, all five mask types maintained the same FPPRs as those of new masks, even after washing 30 times. An interesting observation was that the FPPR of the surgical mask was higher even after the 30th wash, and therefore, it was more effective than the FPPRs of the other four face masks when they were new. **Conclusions:** Surgical masks were the most effective, even though all five types could be reused after 30 washes. The FPPR of the surgical masks showed better performance after 30 washes than the FPPRs of the other four types when they were new. These findings may start the discussion for the possibility to reuse face masks.

Keywords
COVID-19, droplet infection, face mask, fine particles, reuse

Introduction

To prevent infectious diseases, it is important to block their transmission routes. In particular, respiratory infections for which no cure has been established must be prevented by wearing a face mask. Recently, wearing a face mask has been recommended by the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) guidelines as an effective measure to block the droplet route of transmission of the coronavirus disease 2019 (COVID-19) that has caused a pandemic (CDC, 2021; WHO, 2021).

Various types of face masks, including N95 and surgical masks, prevent the spread of infectious droplets/viral aerosols, thereby blocking the route of infection (Li et al., 2020). If infected persons wear cotton or surgical masks, the spread of the virus can be reduced by 60%-80%. Even if only noninfected persons wear masks, cotton masks reduce viral inhalation by 20%-40%, whereas surgical masks reduce inhalation by approximately 50% (Ueki et al., 2020).

During the 2009 influenza pandemic and in 2020, at the start of the COVID-19 pandemic, the demand for surgical masks exceeded the supply, creating a worldwide situation in which it was difficult to obtain surgical masks. Gauze masks are highly permeable to bacteria as they let moist air pass through, and wearing gauze masks in medical settings has not been recommended for infection control. Even so, in Japan, gauze masks were distributed to Japanese people as a countermeasure when there was a shortage of surgical masks. Concurrently, the demand for face masks made of materials such as polyester and polyurethane increased, but their ability to prevent infection remains unknown. Consequently, the reuse of face masks has been proposed as a crisis management response during the pandemic (CDC, 2020). In fact, 34.5%-48.7% of people reportedly reuse surgical masks, whereas 48.4% dispose of them immediately after use. This clearly shows that face masks are being reused (Lee et al., 2021; Machida et al., 2020). However, although there are reports focusing on the reuse of N95 masks, few reports have assessed the reuse of surgical masks (Zorko et al., 2020), which are generally considered disposable.

This study aimed to clarify the change in the fine particle protection rate (FPPR) of face masks reused after washing and to propose a method for reusing face masks that is suitable for people other than medical personnel. If a reuse method can be proposed, it may contribute to solving the shortage of face masks in the medical field during a pandemic.

Technical Report

Mask Types

In this study, five types of masks were used: surgical masks, gauze masks, pleated cloth masks (cloth mask), polyester masks, and polyurethane masks. Regarding the surgical mask (Company K), the material of the mask body and filter was polypropylene nonwoven fabric, and the size was approximately 145 × 95 mm. The material of the gauze mask (Company S) consisted of a 12-layer structure made of 100% cotton, and the size was approximately 135 × 95 mm. The cloth mask (Company S) was made of 100% cotton, and the size was approximately 195 × 100 mm. The sizes of the masks were approximately 160 × 120 mm for the polyester mask (Company C) and 140 × 120 mm for the polyurethane mask (Company A). Ten of each type of mask were used for the experiment.

Research Period

The research period was from October 2020 to December 2021.

Washing Method

The face mask was worn by one participant once a day and then washed using tap water at room temperature in a Panasonic (Osaka, Japan) household washing machine, which was set to the normal course (9 min/wash, rinse twice, 6 min/dehydration). We added approximately 28 mL of surfactant-based liquid laundry detergent (Attack®: Company K), approximately 20 mL of hydrogen peroxide-based liquid oxygen bleach (Widehaiter®: Company K), and approximately 30 mL of surfactant-based fabric softener (Humming®: Company K) in 33 L of tap water. Masks were placed in a laundry net and washed with other items, and then, they were hung to dry. Washing was performed 30 times for each mask.

Fine Particle Measurement Method

One participant wore a face mask before and after washing 5, 10, 15, 20, 25, and 30 times. The number of fine particles inside and outside the face mask, as well as the leakage rate, was measured using the Labor Research Institute mask-fitting tester MT-05 U (SIBATA, Saitama, Japan). The target particle size was ≥0.3 μm, including microdroplets (Lee et al., 2008). Measurements were made using sodium chloride aerosol particles. After the participant confirmed that the N95 masks could collect more than 95% of particles sized ≥0.3 μm, measurements were taken for each mask. Before testing, the researchers and the participant visually checked each mask for damage and contamination. The experiments were repeated three times.

Data Analysis

The performance of the face mask was evaluated by calculating the leakage rate as the FPPR. The Kruskal-Wallis test and multiple comparisons were used to compare the FPPRs for each type of brand-new face mask, and the Friedman test was used to compare the FPPRs for the number of washes. The Wilcoxon signed rank test was used to compare the facemask sizes. Descriptive data were expressed as median (first quartile, third quartile) for continuous variables. In this study, a two-tailed p-value ($p = .05$) was considered statistically significant. Statistical analyses were performed using Bell Curve for Excel (SSRI, Tokyo, Japan).

FPPR % was calculated as follows: 100 − Number of particles inside the mask/Number of particles outside the mask × 100.

Ethical Considerations

This study was conducted according to the principles of the Declaration of Helsinki. The protocol was approved by the Ethical Committee of the Tottori College of Nursing (No. 2020-9). Written informed consent was obtained from one participant.

Results

Figure 1 shows a comparison of the FPPRs of the five types of new face masks. When the FPPR of the surgical masks (79.3% [67.3, 83.5]) was compared with the FPPRs of the other masks, significantly lower rates were observed with the cloth, gauze, polyester, and polyurethane masks. Further, the FPPR of the cloth masks was similar to that of the gauze masks, and that of the polyester masks was similar to that of the polyurethane masks. The FPPR of the polyurethane mask was the lowest relative to the other four masks.

Figure 2 shows the FPPRs of the five types of face masks according to the number of washes.

Surgical mask: The FPPR of the surgical mask showed a decline from 79.3% (67.3, 83.5) for new products to 61.9% (60.8, 65.1) after 30 washes. There was no significant difference across washes.

Cloth mask: Although the FPPR of the cloth mask was lower after the 30th wash (44.4% [42.9, 51.0]) than that of the new product (58.6% [43.5, 61.5]) with FPPRs of 51.3% (49.2, 53.6) and 55.3% (53.8, 59.4) for the 10th and 20th washes, respectively, there was no significant trend observed across washes.

Gauze mask: The FPPR of the gauze mask also showed no particular trend nor significance when the new product and different washing stages were compared.

Polyester mask: The FPPR of the polyester mask decreased when the new product and each stage of the subsequent washings were compared: 36.3% (18.2, 38.0) for new products and 35.7% (34.6, 38.7), 34.6% (34.3, 36.0), and 32.2% (27.4, 34.4) for the 10th, 20th, and 30th washes, respectively. These differences were not significant across washes.

Polyurethane mask: The FPPR of the polyurethane mask also showed no particular trend nor significance when the new product and different washing stages were compared, revealing values of 34.3% (32.1, 36.8) for new products and 33.1% (32.3, 37.5), 36.0% (33.1, 36.8), and 33.7% (31.7, 34.1) for the 10th, 20th, and 30th washes, respectively.

Table 1 shows the morphological changes in the five types of face masks following washing. Regarding the size of the surgical masks before washing and after 30 washes, the vertical length was shortened. The width and vertical length of the cloth masks were both shortened. The widths of the gauze and polyurethane masks were reduced. However, there was no change in the size or shape of the polyester mask.

Discussion

In this study, we determined the FPPRs of five types of face masks reused through a specific washing method. The surgical, cloth, gauze, polyester, and polyurethane masks main-
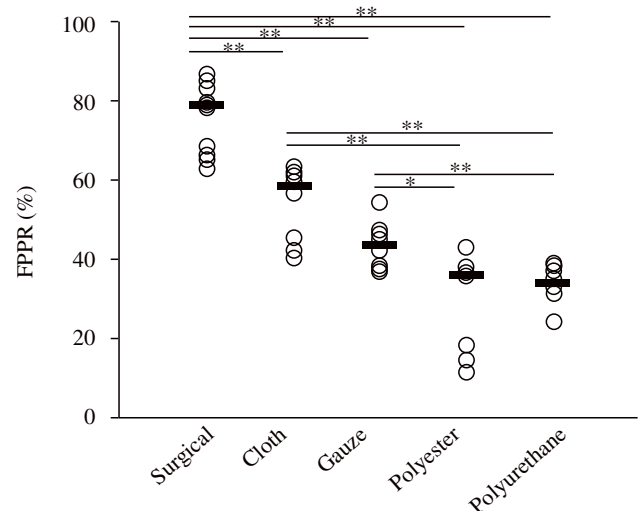

Figure 1. A comparison of the fine particle protection rates of the five types of new face masks.
FPPR indicates the fine particle protection rate. Data are presented as FPPRs (○) and medians (▬). Ten of each type of mask were used for the experiment ($n = 10$). * $p < .05$, ** $p < .01$.

tained the same FPPRs as those of new masks, even after washing 30 times. Furthermore, we compared the FPPRs of the five types of face masks when they were brand new. The surgical mask had the highest FPPR, followed by the cloth, gauze, polyester, and polyurethane masks. An interesting observation was that the FPPR of the surgical mask, even after the 30th wash, was higher and, therefore, more effective than the FPPRs of the other four face masks when new. Although it was reported that the filtration efficiency of surgical masks decreased to 41.9%-66.4% after the 10th wash in a washing machine (Everts et al., 2022), the washing method using the laundry net was expected to maintain the FPPR at a similar level to that of new masks after the 30th wash. The target particle size of this study was ≥0.3 μm, which was smaller than that of droplet particles. Therefore, the FPPRs can be presumed to be higher if the particle size is ≥5 μm (Shakya et al., 2017). The FPPRs of the new surgical and cloth masks used in this study were higher than those identified in a previous report (Ueki et al., 2020), which indicated that these masks protected against virus inhalation by 47% and 17%, respectively. This may be due to the differences in the experimental methods (i.e., in this experiment, a participant actually wore the mask and tested it) and in the efficacy of the masks themselves. Although the surgical mask had the highest FPPR, this rate tended to decrease as the number of washings increased. Considering that friction during washing and wearing affects the expansion of the pore size and decreases the density of the fibers, it may be necessary to consider using surgical masks from other manufacturers for comparison (Wibisono et al., 2020). The washing method used in this study is effective for laun-
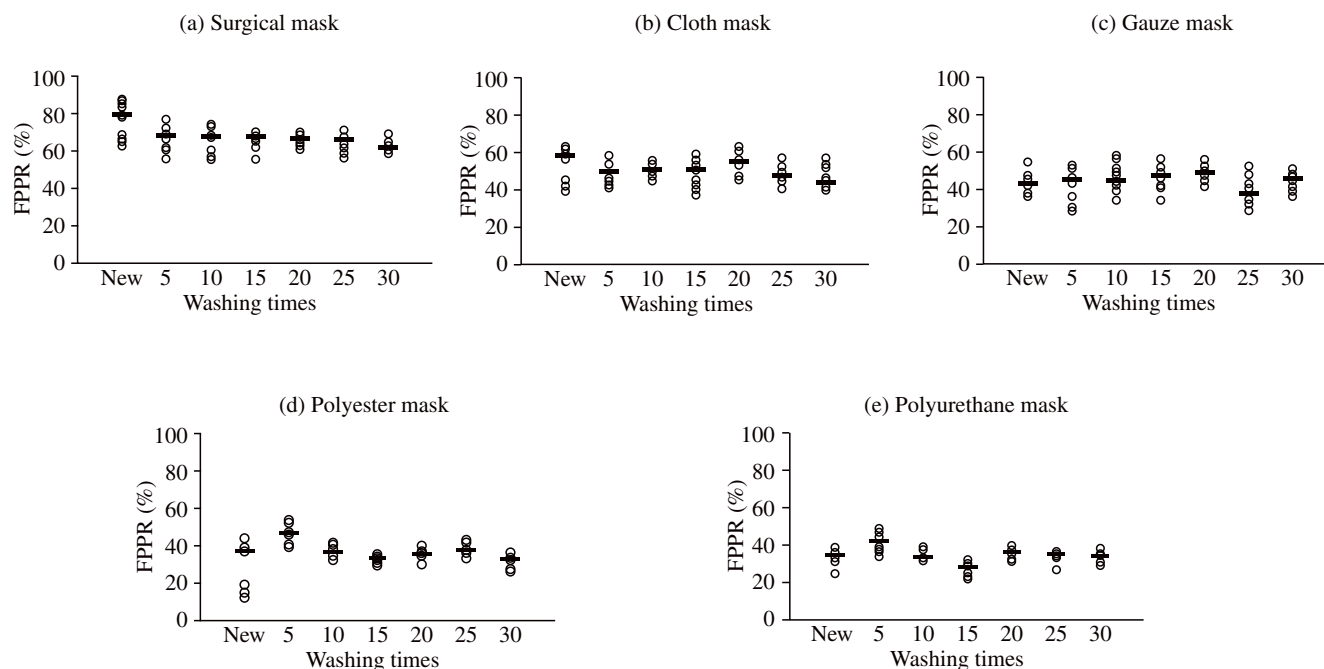
Figure 2. Fine particle protection rates of the five types of face masks according to the number of washes.
FPPR indicates the fine particle protection rate. Data are presented as FPPRs (○) and medians (▬). Ten of each type of mask were used for the experiment (*n* = 10).

Table 1. Morphological changes in five types of face masks following washing.

Face mask		Size of the mask after 30 washes (mm) Median (first quartile, third quartile)	Difference from a new face mask (mm)	*p* -value
Surgical (*n* = 10)	width	146.0 (145.0, 146.0)	0	.950
	vertical	93.0 (93.0, 94.0)	−2.0	.006*
Cloth (*n* = 10)	width	178.5 (176.0, 189.8)	−14.5	.015*
	vertical	95.5 (94.0, 99.0)	−8.5	.009*
Gauze (*n* = 10)	width	123.5 (122.0, 124.0)	−10.5	.002*
	vertical	94.0 (93.0, 95.0)	−1.0	.160
Polyester (*n* = 10)	width	167.0 (166.0, 167.0)	+1.0	.580
	vertical	119.0 (118.0, 119.0)	+1.0	.110
Polyurethane (*n* = 10)	width	154.0 (153.0, 154.8)	−1.0	.025*
	vertical	119.0 (119.0, 119.0)	0	N/A[†]

* *p* < .05. [†]: N/A denotes not available.

dering dirty textiles and fabrics in medical facilities and is safe for the skin (Christian et al., 1983). In the former research regarding hospital healthcare workers, the risk of infection was reduced following the use of masks washed in the hospital laundry in an automatic washing machine compared to following their self-washing (MacIntyre et al., 2020). In the same way, our results suggest that the machine washing of masks may be effective.

Until now, the general view was that surgical masks are disposable. Even in the remaining four types of face masks, very few reports have discussed changes in their FPPR or

morphology when reused. Our results suggest that surgical masks are the most effective for infection control, although all five types of face masks can be reused up to 30 times during pandemics of emerging and re-emerging infectious diseases. Moreover, because the cloth and gauze masks shrink significantly with an increasing number of washings, their reuse must be avoided once they can no longer cover both the nose and mouth.

Surgical masks were the most effective, even though all five types could be reused after 30 washes. The FPPR of the surgical masks showed better performance after 30 washes

than the FPPRs of the other four types when new. Our findings may refute the notion that masks are not reusable and propose a method for reusing face masks that is suitable for nonmedical personnel. Face masks for surgeons were introduced in the 1960s as disposable face masks, and their use spread across the world (Matuschek et al., 2020). As such, the history of face masks is surprisingly recent, and scientific discussions regarding their efficacy are still ongoing. In the future, it will be necessary to consider the FPPR when different types of face masks (with different three-dimensional structures) are considered for reuse and to know the actual amount of droplet dispersion of reused face masks.

Author Contributions

Kanna Okayama and Mitsue Arakawa contributed to the conception, design, and perform of this study; Kanna Okayama drafted the manuscript and supervised the whole study process; and Mitsue Arakawa critically reviewed the manuscript. 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 research was approved by the Ethical Committee of the Tottori College of Nursing (No. 2020-9).

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Brief Report

Feasibility of two guidebooks for parents with mental illness and their children: Healthcare professionals' perspectives

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Abstract
In this study, we aim to examine the feasibility of two guidebooks in Japanese healthcare services, which aimed to support parenting and child well-being in families with parental mental health illness. We sought and explored professionals' perspectives on the translated versions of the Finnish guidebooks, one for parents with mental illness and the other for children. 55 professionals providing support to parents and/or their dependent children were included in this study. Participants were asked to read the guidebooks and completed a self-report questionnaire as regards the necessity/helpfulness and utilization of the guidebooks. Berelson's content analysis method was utilized to analyze the participants' free description responses. As per our findings, around 70%-85% of the participants see the guidebooks necessary and helpful for family members and professionals. These guidebooks were assessed to provide parents and children emotional support, helping them to understand each other, and guide parents in finding ways to address their children's issues. Similarly, the guidebooks were seen to help professionals understand these families, in terms of how to support them and explain parental illnesses to children. Approximately 90%-95% of the participants shared that they would use these guidebooks, but half of them said that they would use them only to a certain extent. Many had worries about how and with whom to utilize them. Guidebooks are recommended for use in clinical training. In conclusion, this study suggests that guidebooks are feasible in Japan as resources in clinical practice and for training professionals to support families. They are likely to promote awareness of families and children with parental mental illness among professionals and within families.

Introduction

Approximately 10% to 45% of clients using adult mental health services are parents of children aged under 18 years old (Maybery & Reupert, 2018). While intergenerational transfer of mental illness is a well-documented phenomenon (Rasic, Hajek, Alda, & Uher, 2014), prevention of child problems is also found to be productive (Siegenthaler, Munder, & Egger, 2012). It is evident that giving support to families and children is both possible and crucial.

All parents are known to face difficulties on a day-to-day basis in terms of raising their children; however, parents who suffer from mental illness have to endure more as they must also cope with their own symptoms (Solantaus, Reu-

pert, & Maybery, 2015). Mothers who suffer from mental illness have emphasized how important their children are in their lives, but they often experience difficulties caring for them (Ueno & Kamibeppu, 2008; Ueno & Kamibeppu, 2012; Wahl et al., 2017). The most common issues facing children of parents with mental illness are as follows: "the need for knowledge/understanding," "worries about parents' well-being/wish for relief," and "the need for normality/stigma reduction" (Wahl et al., 2017). Thus, it is essential for professionals to understand the situation of both parents and children to be able to support families in living as good a life as possible.

However, lacking appropriate knowledge and skills have remained to be the barriers that impede professionals from helping clients with parenting and child-related issues in adult mental health and other services (Maybery & Reupert, 2006; Leonard, Linden, & Grant, 2020). Similarly, in Japan, many professionals have found it difficult to support parents because their practice is often limited to their personal experiences in their careers (Ueno & Osada, 2018).

Despite evidence-based preventative interventions (Solantaus & Toikka, 2006) for parents and their families, these interventions often require extensive training and resources; hence, it is often a challenge to provide them to all clients who are parents. It is thus evident that developing various resources to support parents and their families is urgent.

Finland has been active in developing resources to help support parents and their families; in fact, the country has launched a nationwide program (the Effective Child & Family Programme) in 2001 (Solantaus & Toikka, 2006). Solantaus wrote guidebooks for parents with mental illnesses and for their children (Solantaus & Ringbom, 2002, 2005). They have been utilized in various services in Finland; additionally, they have been translated into 12 languages (Solantaus & Ueno, 2016a; Solantaus & Ueno, 2016b) and used in these respective countries. These guidebooks are commonly utilized, as professionals find them useful to support parents who suffer from any mental illness and their families; however, the feasibility of the guidebooks has never been examined in any country.

As such guidebooks have not been used in Japan for parents with mental illness, it was considered necessary to shed light on professionals' experiences and willingness to accept the guidebooks in their clinical work, i.e., before using them with their clients. Thus, in this study, we examined professionals' perspectives concerning the necessity, helpfulness, and utilization of the translated versions of Solantaus's two guidebooks: one for parents ("parent guidebook" hereafter) and the other for older children and adolescents ("youth guidebook" hereafter). Furthermore, in this study, we have laid down some suggestions on how to promote the use of such guidebooks in order to develop an effective practical approach for parents and/or children.

Methods

The Two Guidebooks

How Can I Help my Children? A Guide to Parents Who Have Mental Health Problems

This guidebook is known to not only provide information and understanding for family members and professionals on how children might experience their parents' symptomatic behaviors but also answer questions that parents often have. A very important topic discussed in this guidebook is what parents can do for their children in relation to their symptoms. This illustrated guidebook contains 21 pages (Solantaus & Ringbom, 2002).

What's Up with Our Parents? A Handbook for Older Children and Adolescents Whose Mother or Father Has Mental Health Problems

This guidebook explains, in an age-appropriate way, what mental disorders and their symptoms and treatment. Children's possible experiences of emotions which can range from worry, anxiety, and being scared to anger and shame are discussed in this guidebook. Youth are encouraged to initiate a discussion with the parents on issues that trouble them. The importance of a trusted adult and the meaning of one's own social life are emphasized. This illustrated guidebook contains 34 pages (Solantaus & Ringbom, 2005).

The Japanese Versions of the Two Guidebooks

The first author has obtained permission from Solantaus to translate and publish the two guidebooks in Japan. The first author has carefully translated the guidebooks into Japanese and then requested comments from the third author, a child psychiatrist, and an academic manager from The Finnish Institute in Japan. As agreed with Solantaus, some adaptations were made due to differences between the healthcare services and customs of Japan and Finland. Ringbom, the illustrator, and Sandman, the graphic designer, of the original guidebooks were involved in producing the Japanese guidebooks in the same style as the originals (Solantaus & Ueno, 2016a; Solantaus & Ueno, 2016b).

Participants

This study was approved by the ethics committees of the first author's university at the time of the study. Informed consent was obtained from all participants by returning the completed questionnaire. We recruited the participants through the managers of the six institutions in the Kanto area in 2014: children and family support centers (29.1%), psychiatric hospitals (25.4%), community health centers (14.6%), public health centers (14.6%), mental health and welfare centers (12.7%), and child consultation centers (3.6%). We mailed explanatory statements regarding this study to 206 institutional managers with the Japanese versions of the guidebooks, an anonymous self-report questionnaire, and a return envelope. We asked the institutional man-

Table 1. Perceived necessity, helpfulness, and utilization of the guidebooks (*n* = 55).

Answers / Questions	Yes		Not very much		No	
	Parent*	Youth**	Parent*	Youth**	Parent*	Youth**
Do you think that the guidebook is necessary?	44 (81.5%)	46 (83.6%)	10 (18.5%)	9 (16.4%)	0 (0%)	0 (0%)
Do you think that the guidebook is helpful?	38 (70.4%)	42 (76.4%)	16 (29.5%)	12 (21.8%)	0 (0%)	1 (1.9%)
Do you think that you would utilize the guidebook in your facility?	25 (47.2%)	26 (50.0%)	25 (47.2%)	21 (40.4%)	3 (5.7%)	5 (9.6%)

Note.

Because some participants did not respond to all questions, the total number of participants (*n*) varied.

*A guidebook for parents: "How can I help my children? A guide to parents who have mental health problems"

**A guidebook for youth: "What's up with our parents? A handbook for older children and adolescents whose mother or father has mental health problems"

agers to select one professional from their institutions to participate in this study. The collection rate was 27.7% (57/206), with one respondent from each facility. Two responses were excluded because fewer than half of the questions were answered. Finally, 55 participants were included in the data analyses.

Data Collection

Participants read the two guidebooks, completed a self-report questionnaire anonymously, and then sent it to the first author. This study used a cross-sectional research design.

Questionnaire

We asked the following three questions: "Do you think that the parent/youth version of the guidebook is necessary?," "Do you think that the parent/youth version of the guidebook is helpful?," and "Do you think that you would utilize the parent/youth version of the guidebook in your facility?" In each question, the participants were asked to choose from "Yes," "Not very much," and "No," followed by an open-ended question ("Why do you think so?") that will be answered in a free-response space. Additionally, we asked the participants about their profession and workplace.

Data Analyses

Berelson's content analysis method was utilized to analyze the participants' free description feedback in response to each question regarding the guidebooks (Berelson, 1957). As per the content analysis, the first author read the entire description and regarded one sentence with a specific type of content as a unit for analysis. The first author classified each unit of analysis based on similarities and then grouped them into categories. Then, the first author and the third author, who is also a mental health professional/researcher, discussed all the data, including the raw data, units of analysis, and categories, several times before reaching an agreement, which ensured the reliability of the results.

Results

Participants' Professions

Approximately half of the participants (49.1%) were public health nurses, 16.4% were clinical psychologists, 14.5% were social workers, 10.9% were psychiatric nurses, and 9.1% were doctors.

Perceived necessity, helpfulness, and utilization of the guidebooks

For each guidebook, over 80% of the participants have answered that the guidebook was necessary. Almost three-quarters of the participants (70.4% for the parent, 76.4% for the youth) have answered that the guidebook was deemed helpful. Approximately half of the participants (47.2%/50%) answered "Yes," indicating that they would utilize the parent/youth guidebook, whereas 47.2%/40.4% answered "Not very much" (Table 1).

Healthcare Professionals' Free Description of the Necessity/Helpfulness and Utilization of the Guidebooks

Due to the similar free responses to the necessity and helpfulness questions, we have opted to analyze the data by combining them.

Reasons the guidebook is necessary/helpful

In total, 33 of the 44 participants who answered that the parent guidebook was necessary provided valid data. Moreover, 27 of the 38 who answered that the guidebook was helpful provided valid data. Only valid data were included in this analysis (the same hereinafter). The participants' feedback was divided into 61 units of analysis; then, these were grouped into 13 categories according to their similarities.

In total, 32 of the 46 participants who answered that the youth guidebook is necessary provided valid data. Meanwhile, 27 of the 42 participants who answered that the youth guidebook was helpful were able to provide valid data. The participants' feedback was divided into 59 units of analysis and thereafter grouped into 13 categories (Table 2).

Table 2. Reasons the guidebook is necessary/helpful.

	Parent guidebook ($n = 60$)			
Category number	Category	Example of units of analysis		Units of analysis
1	Providing specific and helpful content for parents in the context of parenting and mental illness	•Parents can understand what is necessary for their children, what the children struggle with, and how they should engage with their children. •The guidebook describes what parents should consider and can do when they are parenting.	14	23%
2	Providing parents with emotional support	•The guidebook encourages parents to adopt self-acceptance. •It is important for parents to know that there are parents who have the same difficulties and worries, and parents can think about what they can do.	10	16.4%
3	Rich in content	•The guidebook is rich in content. •The guidebook answers many questions.	5	8.2%
4	Concrete content	•The guidebook contains concrete content, such as what parents can do for their children. •The guidebook is helpful because it describes to the point of parents' and children's feelings.	5	8.2%
5	Allows parents to understand their mental illness and behaviors	•Parents can understand their mental illness and treatment well. •It is needed for parents to understand and accept their mental illness.	5	8.2%
6	Need for something like this guidebook	•The guidebook is needed.	4	6.6%
7	Necessary to consider parents' conditions and needs	•It would be necessary to assess parents using the guidebook because some parents might experience anxiety, of which they are unaware.	4	6.6%
8	Easy to understand	•The guidebook is easy to understand.	3	4.9%
9	Few or no similar guidebooks available	•There are few similar guidebooks available.	3	4.9%
10	Makes it easy for professionals to discuss parenting with the parents	•The guidebook makes it easier for professionals to discuss the topics covered with parents.	3	4.9%
11	Learning about parent care resources for professionals	•The guidebook can be a resource for professionals to understand parents and support them.	2	3.3%
12	Parent care resources for professionals	•It could be utilized for professionals who support parenting, such as public health nurses, psychologists, and child and family supporters, depending on the situation.	2	3.3%
13	Giving children relief	•Children will be relieved to know that there is a guidebook containing general information about mental illness that helps them understand their parents' situation.	1	1.6%
	Youth guidebook ($n = 59$)			
Category number	Category	Example of units of analysis		Units of analysis
1	Acquiring knowledge and learning how to cope with their concerns and difficulties	•Children can come to know whom to consult and how to acquire knowledge of their parents' mental illness. •The guidebook explains what children can do and what they cannot/should not do.	12	20.3%
2	Helps professionals to explain their parents' illness/situation to children	•The guidebook itself can provide a chance to have a conversation what covered in the guidebook. •(The guidebook is necessary) Because it is difficult to tell their parents' illness/situation to children in words.	9	15.3%
3	Helps children to understand their parents' illness/situation and their relationships with their parents	•Children can understand their parents' mental illness/situation. •Children can understand their relationships with their parents.	9	15.3%
4	Providing children with emotional support	•Children can positively accept their feelings by reading the guidebook. •Children can keep on living without blaming themselves.	6	10.2%
5	Necessary to consider children's age and situation	•It would be necessary to consider the children's age.	4	6.8%
6	Learning about parent/child care resources for professionals	•I will utilize the guidebook to help professionals to understand parents and as a learning resource for professionals.	3	5.1%
7	Concrete content	•It is easy to understand because the explanations are concrete.	3	5.1%
8	Focus on children's needs and perspectives	•The guidebook is written from children's perspectives and considers their feelings. •The guidebook explains what children want to know.	3	5.1%
9	Need for something like this guidebook	•The guidebook is needed.	3	5.1%
10	Rich in content	•The guidebook is rich in content.	2	3.4%
11	Supports children when direct help is unavailable	•Children can read the guidebook repeatedly when professionals often cannot directly support them.	2	3.4%
12	Necessary to follow-up with children after reading it	•Follow-up might be necessary after children have read the guidebook.	2	3.4%
13	Few similar guidebooks available	•There are few opportunities for children to acquire necessary knowledge like this; there are few similar guidebooks or websites in Japan.	1	1.7%

Table 3. Reasons the guidebook is necessary/helpful "not very much".

		Parent guidebook (*n* = 22)		
Category number	Category	Example of units of analysis	Units of	analysis
1	Long text	•The content is good; however, the text seems to be too long for parents.	7	25.9%
2	Small print	•The print is small for parents.	6	22.2%
3	Necessary to consider parents' condition	•The guidebook can be utilized according to the condition of the parents (degree of stability of illness). •There may be many parents who cannot read (or will not try to read) the guidebook.	6	22.2%
4	Translation/explanation is difficult to understand	•The translation/explanation seem to be difficult to understand.	4	14.8%
5	Unfamiliar illustrations for Japan	•The illustrations are unfamiliar in Japan.	2	7.4%
6	Not concrete in some of its advice for children	•It would have been better had the guidebook adopted more specific advice for the children because it has several abstract parts.	1	3.7%
7	Content seems unsuitable	•The purpose of the guidebook is good; however, the content does not seem to be very suitable.	1	3.7%
		Youth guidebook (*n* = 17)		
Category number	Category	Example of units of analysis	Units of	analysis
1	Necessary to consider children's age and situation	•It cannot be utilized by children in lower elementary school.	6	24%
2	Long text	•The text is long.	5	20%
3	Small print	•The print is small.	4	16%
4	Explanation is difficult for children	•The explanation is difficult for children.	4	16%
5	Unfamiliar illustrations for Japan	•The illustrations are unfamiliar in Japan.	3	12%
6	Unfriendly font	•The font is unfriendly.	1	4%
7	No phonetic guides on Kanji*	•There are no phonetic guides on *Kanji**.	1	4%
8	Content seems unsuitable	•The purpose of the guidebook is good; however, the content does not seem to be very suitable.	1	4%

*Note.
The Japanese language uses three different types of characters: Hira-kana, Kata-kana, and Kanji. Hira-kana and Kata-kana are syllables, while each Kanji has specific phonetics and meanings. It is sometimes difficult for (young) Japanese children to read Kanji without phonetic guides.

Reasons the guidebook is necessary/helpful "not very much"

Eight of the ten participants who answered that the parent guidebook was not necessary have provided valid data. Meanwhile, 14 of the 16 participants who answered that the guidebook was not helpful very much provided valid data. The participant' feedback was divided into 27 units of analysis and then grouped into 7 categories.

Eight of the nine participants who answered that the youth guidebook is not necessary provided valid answers. Moreover, 9 of the 12 participants who responded that the youth guidebook was not very helpful provided valid data. The participant' feedback was divided into 25 units of analysis and then grouped into 8 categories (Table 3).

Reasons the youth guidebook is not necessary/helpful

While no participant answered that the parent guidebook is not necessary/helpful, one participant responded that the youth guidebook is not necessary/helpful because "It is possible that children might be more anxious if the guidebook is utilized with unsuitable children."

Reasons participants would utilize the guidebook

As per our findings, 21 of the 25 participants who answered that they would utilize the parent guidebook were able to provide valid data. The participants' feedback was divided into 24 units of analysis and then grouped into 9 categories.

Also, 21 of the 26 participants who answered that they would utilize the youth guidebook provided valid data. The participants' feedback was divided into 22 units of analysis and then grouped into 11 categories (Table 4).

Table 4. Reasons participants would utilize the guidebook.

Category number	Category	Example of units of analysis	Units of analysis	
Parent guidebook (*n* = 21)				
1	Learning about parent care resources for professionals	•The guidebook could be utilized for professional workshops to better understand parents and methods of supporting them. •It is necessary to share the guidebook with coworkers.	8	33.3%
2	Parent care resources for professionals	•It would be possible to share with parents' situation and concerns by reading the guidebook with them.	4	16.7%
3	Discussing the time required to utilize and how to utilize the guidebook	•It would be necessary to discuss how to utilize the guidebook.	3	12.5%
4	Necessary to consider parents' situation	•I would like to utilize the guidebook to consider parents' situations, relationships with their children, and individual situations.	3	12.5%
5	Distributing the guidebook to parents	•I would like to distribute the guidebook to parents.	2	8.3%
6	For parents' families	•Some parents who participate in return-to-work rehabilitation programs are worried about how to explain their mental illness to their families.	1	4.2%
7	Keeping guidebook in the outpatient area	•I would like to keep the guidebook in the outpatient area, where the parents can freely read it.	1	4.2%
8	Mental health awareness	•To raise awareness in people around persons with mental illness or those without knowledge of mental illness.	1	4.2%
9	Concrete content	•The guidebook is helpful because it describes the parents' and children's feelings.	1	4.2%
Youth guidebook (*n* = 21)				
Category number	Category	Example of units of analysis	Units of analysis	
1	Discussing the time required and how to utilize the guidebook	•I would like to utilize the guidebook if I have an opportunity.	5	22.7%
2	Learning resource for professionals	•The guidebook could be utilized as a learning resource for professionals.	3	13.6%
3	Necessary to consider children's age and situation	•I would like to utilize the guidebook in the consultation setting for children after considering their age and situation.	3	13.6%
4	Distributing guidebook to children and/or parents	•I would like to distribute it to children because consultations with children are rare.	2	9.1%
5	Concrete/important content	•The content of the guidebook is important and is what we want to tell the children.	2	9.1%
6	For understanding themselves/ their parents and family situation	•Children can understand themselves and what is happening in their families.	2	9.1%
7	Keeping the guidebook in the outpatient area	•I would like to keep the guidebook in the outpatient area, where the parents can freely read it.	1	4.5%
8	Mental health awareness	•I would like to utilize the guidebook to help those people without knowledge of mental illness learn about mental illness.	1	4.5%
9	Short versions are better	•It would be better were there a short version of the guidebook.	1	4.5%
10	Tips for utilization are better	•It would better if there were tips for utilization depending on children's age.	1	4.5%
11	Helps professionals to explain their parents' illness/situation to children	•It could be utilized for professionals to have conversations with children because the guidebook covers necessary content and the illustrations describe the text.	1	4.5%

Reasons participants would utilize the guidebook "not very much"

In total, 23 of the 25 participants, who answered that they would not utilize the parent guidebook very much, provided valid data. The participants' feedback was divided into 32 units of analysis and then grouped into 15 categories.

Moreover, 18 of the 21 participants who responded that

Table 5. Reasons participants would utilize the guidebook "not very much".

Parent guidebook (*n* = 23)

Category number	Category	Example of units of analysis	Units of analysis	
1	Translation/explanation is difficult to understand	•The explanation is difficult to understand.	4	12.5%
2	Long text	•The content is good; however, the text is somewhat long.	3	9.4%
3	Few or no opportunities to utilize the guidebook	•There are few opportunities to utilize this guidebook when interacting with parents.	3	9.4%
4	Unfamiliar illustrations for Japan	•The illustrations are unfamiliar in Japan.	2	6.3%
5	Necessary for parents to be aware of their illness	The content of this guidebook requires that parents be aware of their illnesses.	2	6.3%
6	Small print	•The print is small.	2	6.3%
7	Difficult for professionals to read it with parents	•It is difficult for professionals to read the guidebook with parents.	2	6.3%
8	Necessary to discuss how to utilize the guidebook	•I do not understand how to utilize the guidebook, at what time to introduce it, or what form of meeting to adopt.	2	6.3%
9	Seems better utilized by other institutions	•It would be easy to utilize at educational institutions.	2	6.3%
10	Short versions are better	•It would be better if there is a short version of the guidebook.	2	6.3%
11	Partial utilization	•If partially utilized, the guidebook can be utilized more frequently.	2	6.3%
12	Necessary to consider parents' condition	•Reading the guidebook would make persons with mental illness be tired and confront their illness too directly, although it may be helpful for professionals.	2	6.3%
13	Learning about parent care resources for professionals	•I will share the guidebook with coworkers.	2	6.3%
14	Difficult for professionals to address the topic	•Currently, it is difficult to address the topics of this guidebook in the treatment of parents.	1	3.1%
15	Unsuitable for Japanese culture	•I would love to utilize the guidebook if it were more suitable for Japanese culture.	1	3.1%

Youth guidebook (*n* = 18)

Category number	Category	Example of units of analysis	Units of analysis	
1	No opportunities to utilize the guidebook	•There seem to be no opportunities to utilize the guidebook.	4	18.2%
2	Necessary to consider children's age and characteristics	•It would be necessary to consider the children's age.	3	13.6%
3	Necessary to discuss how to utilize the guidebook	•I do not know how to utilize the guidebook.	3	13.6%
4	Long text	•The text is long.	2	9.1%
5	Difficult content	•The content is difficult.	2	9.1%
6	Necessary to have a relationship with the children	•I feel that maintaining a continuous relationship with the children is necessary.	2	9.1%
7	Seems better utilized by other institutions	•The guidebook is appropriate at medical institutions. •The guidebook would be easy to utilize at educational institutions.	2	9.1%
8	Unfamiliar illustrations for Japan	•The illustrations are unfamiliar in Japan.	1	4.5%
9	Necessary to carefully consider whether approach is appropriate for children at institutions supporting parents	•I think that medical institutions treating parents with mental illnesses should carefully consider whether a direct approach with children is suitable.	1	4.5%
10	Unsuitable for Japanese children	•I would love to utilize the guidebook if it were more acceptable for Japanese children.	1	4.5%
11	Partial utilization	•I would like to utilize the guidebook, quoting it in part.	1	4.5%

they would not utilize the youth guidebook very much provided valid data. The participant' feedback was divided into 22 units of analysis and then grouped into 11 categories (Table 5).

Reasons participants would not utilize the guidebook

Three participants who answered that they would not utilize the parent guidebook provided valid data, which were included in this analysis. Their feedback was divided into five units of analysis and thereafter grouped into four categories: "Translation/explanation is difficult to understand" (two participants), "Small print," "Long text," and "Seems better utilized by other institutions" (i.e., "It would be appropriate to utilize at medical institutions").

Five participants answered that they would not utilize the youth guidebook. Only the valid data were included in this analysis, and their feedback was divided into seven units of analysis and then grouped into four categories: "No opportunities to utilize the guidebook" (two participants), "Necessary to consider children's age and situation" (two participants), "Explanation is difficult to understand," and "Unfamiliar illustrations for Japan."

Discussion

As per our findings, it was determined that both guidebooks were considered necessary and helpful for parents, children, and professionals; in fact, most participants would use them in their work (70%-95% of the participants), although it should be noted that the participants had not used the guidebooks with their clients. These results are consistent with Solantaus's intention (Solantaus & Ueno, 2016a) for guidebooks to serve both families and professionals.

These two guidebooks were also reported to provide specific and helpful content for family members. They were seen to provide emotional support for parents and children, to help them understand each other, and to help parents find ways to deal with their children's struggles. In line with this, the guidebooks were assessed to have the potential to empower parents to overcome their helplessness when it comes to parenting, which has been reported by Ueno and Kamibeppu (2008).

As practically all participants perceived the guidebooks as both helpful and necessary for families and professionals, nearly half of them were hesitant to use them with their clients. This was deemed a very important and informative finding.

Such hesitation to use these guidebooks with clients seemed to come from little experience using them. Additionally, there were concerns regarding therapeutic relationship (Strand & Rudolfsson, 2018) and suitable clients. These are valid concerns, as it reveals reveal that responsible professionals are not prepared to use tools they are not skilled

with. Furthermore, discussing sensitive issues, such as parents' mental illnesses, children and parenting (Solantaus, Reupert, & Maybery, 2015), without a sense of mastery of the method, can only do more harm than good, e.g., increased worries and anxieties in the client and the child and self-blame in the parent.

Biebel et al. (2015) have indicated that it is necessary for professionals to understand families with parental mental illness to be able to work constructively with them. As per our results, it demonstrates that guidebooks are likely to be helpful learning resources for professionals to gain a deeper sense and understanding of parents' and children's experiences and issues. Therefore, the respondents' suggestions to use these guidebooks as educational materials for professionals should be heeded. This was a novel type of use of the guidebooks. To the best of our knowledge, guidebooks have not previously been seen as educational materials for professionals.

Following the participants' suggestions, it is thus recommended that workshops, including lectures and groupwork based on the guidebooks, be organized. In particular, role-play may be effective in obtaining experiential understanding and practical knowledge and skills (van Ments, 1999). Moreover, encouraging professionals to have discussions with parents, children, and other professionals might help them find their own ways of using the guidebooks based on their clinical settings and clients' features, including the clients' needs and recovery stages. Such discussions could lead to better and more effective practical approaches to support both parents and children and provide valuable learning resources for professionals.

Limitations

As a first step, we have sought and analyzed professionals' experiences as regards this topic. Then, we included those of parents and children. We used a self-report questionnaire, which might be limited in capturing the participants' detailed thoughts. This was a selective sample, and the response rate was relatively low. However, we consider the findings informative and useful in advancing ways to increase support for parents and children in families with parental mental illness.

Conclusions

Solantaus's two guidebooks written for parents with mental illness and for their children are found to be valuable and thus appreciated; in fact, their content is regarded as highly beneficial for families and professionals. This study suggests that guidebooks are thus feasible resources in Japan for clinical practice and professional training, provided the clinicians receive training on how to use them. In this study, we were able to capture real and significant issues one should

be aware of when supporting professionals and promoting effective practices for parents and children. Thus, we recommend more systematic research on different support materials used in clinical work.

Author Contributions

R.U. obtained permission from Solantaus to translate the two guidebooks from English to Japanese, translated the two guidebooks to Japanese, designed the study, collected and analyzed the data, and drafted the manuscript. T.S. gave permission for R.U. to translate the two guidebooks from English to Japanese and contributed to the writing and revisions for the intellectual context of the manuscript. H.O. made comments on the translations of the two guidebooks, designed the study, provided data interpretation, edited the manuscript, and made intellectual contributions to the writing of the manuscript. All authors have read and approved the final manuscript.

Declaration of Conflicting Interests

The authors declare no conflicts of interests.

Ethical Approval

This study was approved by the ethical committees of Tokyo Medical University, Institutional Review Board for Nursing Studies (approval number 6).

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Informed Consent

Informed consent was obtained from all participants by returning the completed questionnaire.

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Education

Current status of the *JINR*: From the editor-in-chief

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The Japan Society of Nursing Research (JSNR), whose forerunner was founded in 1970, is the oldest academic society in the Japanese nursing community. To meet the demands of the era of globalization in nursing science, in February 2022 JSNR launched the *Journal of International Nursing Research* (*JINR*) as its international English journal. In February 2023, an online seminar being planned for *JINR* exceeded the limit of 500 registrations, indicating that *JINR* is attracting attention among people in the nursing field. In light of this, we have decided to include the essentials of the four speakers' seminars here. At first, the contents of my presentation are as follows.

Launched in February 2022, Volume 1, Number 1 of *JINR* contained five papers. Its web version is publicly available on J-STAGE. *JINR* is open to nursing researchers from all over the world, and of course contributions by non-members of JSNR are also welcome. *JINR*'s scope of research extends to a wide range of areas related to nursing science.

For a newly launched publication *JINR* attracted considerably more submissions than anticipated. We began accepting submissions on May 23, 2021, and as of February 9, 2023, we have received a total of 77 submissions. Since many of the papers have been published in advance publication on J-STAGE, we decided to publish two issues per year (February and August) to expedite the publication process. Volume 2, Number 1 was published in February 2023, and the next issue, Volume 2, Number 2, is scheduled to be published in August 2023. A printed version of the issue is also available and has been carried by the National Diet Library of Japan and other institutions. The pdf file is available on the *JINR* website. The printed version incorporates a table of contents, a list of reviewers, the recipients of Outstanding Reviewer Awards and other information.

Currently, selection of reviewers has posed a challenge, due in part to the Coronavirus pandemic, and this has resulted in drawing out the time required for reviews. We would like to request your cooperation in terms of both submissions and peer reviews. Through various measures taken to address this problem, the period needed for reviews has been successively reduced. One way we achieved this was by increasing the number of associate editors outside Japan, which has brought with it the benefit of expanding *JINR*'s international horizons. *JINR* also established Outstanding Reviewer Awards, in which outstanding reviewers receive recognition. This hopefully will also serve as an incentive for reviewers to undertake their tasks with the aim of winning an award. We are, moreover, making efforts to reduce the duration between acceptance of manuscripts and advance publication.

At present *JINR* does not pose a high threshold and is receptive to submissions, even from the uninitiated. We do hope you will join with us in helping *JINR* to grow and thrive. In the very near future, we aim to publish *JINR* in PMC and PubMed, thereby attaining an impact factor (IF) among international English journals. I am confident you will be seeing us develop in the future.

Disclaimer

Naohiro Hohashi serves as Editor-in-Chief of *Journal of International Nursing Research* as well as on the journal's Editorial Committee. He was not involved in the process of editorial evaluation or the decision to accept this article for publication.

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Education

Boosting the chances of getting your paper accepted in the *Journal of International Nursing Research*: Understanding common reasons for paper rejection in international nursing journals

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Nursing research is essential to expand the body of knowledge needed to guide evidence-based nursing practice, education, and policy that modern healthcare requires. Publishing research papers is a responsibility of nursing researchers because it promotes scholarship and the sharing of scientific knowledge, among other reasons. If you wish to publish high-quality papers and/or have been discouraged by rejections from international nursing journals, this article will help you understand what factors could lead to rejections, thereby enabling you to rectify deficiencies before submitting your work to the *Journal of International Nursing Research* (*JINR*). Let us examine some of the common reasons for rejection proposed in an Editorial of the International Journal of Nursing Studies (Griffiths & Norman, 2016).

"Failure to set the study clearly in the context of what is already known"—Insufficient description of the novelty and significance of your work is one of the most common reasons for quick rejection. Authors must perform a comprehensive search and review of existing literature in the early stages of their research to explore what is known about a topic and what the paper adds. It varies depending on the journal, but authors are often required to address what the paper contributes to the advancement of nursing knowledge and/or its clinical relevance. Some leading nursing journals request that the authors include a clear statement on the novelty and clinical relevance of the paper in the abstract or at the beginning of the paper.

"Out of scope" and *"First study in Country X"*—The International Journal of Nursing Studies and our journal (*JINR*) are INTERNATIONAL journals, and a paper that does not match the aim and scope of the journal is likely to get rejected. The aims and scope of *JINR* are reproduced here: *"The purpose of this Journal is to publish advanced, evidence-based original research findings and clinical information on clinical practice, nurse education, and management in the field of nursing to broaden the knowledge of nursing professionals across the world."* Moreover, Japanese authors sometimes emphasize the originality/novelty of their paper by saying something like "this is the first study in Japan". The fact that a research topic has not been studied in a particular country does not necessarily underscore its originality/novelty; this makes your paper less interesting to readers in other countries. Certainly, journal editors and reviewers recognize that some research focusing on a particular location or group is valuable, but authors should explain how, from a broader international perspective, their research contributes to nursing knowledge/practice, and why it is necessary to study the topic in terms of a novel location/group.

"Not (clearly) reporting essential details of the research"—If your research is lacking in certain essential details, your paper is more likely to be rejected. *JINR* encourages authors to follow the relevant reporting guidelines (https://www.equator-network.org/) when writing up research; this will help you provide essential details of your research and help reviewers and readers understand what was done and what was found in a study, so that they can judge whether such findings are likely to be reliable. By following reporting guidelines, nursing researchers will further ensure that their research papers are robust, reliable, and usable, leading to advancement of knowledge in nursing science and better patient care.

Avoiding these common mistakes and addressing the reporting guidelines in your document will greatly boost the chances of your research being accepted by the *JINR*.

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

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Education

Tips for papers' acceptance from a peer review perspective

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To turn research into "shareable knowledge," a paper must be submitted to and accepted by a journal. The following prerequisites must be met for journal acceptance: submission rules, manuscript-writing guidelines, ethical considerations, and correct referencing. Papers must pass muster with peer reviewers, who judge whether a paper is worthy of being published. Papers should be written in a reader-friendly manner. For example, most readers read the title, abstract, results, and conclusion to gain an overview of the content to decide whether to read the whole paper. Papers should therefore describe the necessary content through the following components: title, introduction, purpose, methods, results, discussion, and conclusions. This type of logical sequence is called technical writing, which enhances the paper's structure, consistency, understandability, and completeness.

Peer reviewers partly base their decision on whether a submitted paper is suitable for publication based on this "logic." Reviewers also apply the following criteria during their adjudication: "legitimacy (appropriateness, reproducibility and reliability of research methods)," "ethics" (human rights), "originality and novelty," and "importance of research" (the academic value and usefulness of research). "Legitimacy" is the lifeline of research, meaning that the paper's hypotheses are presented and argued with reliable data that are not fabricated. Authors should describe the "originality and novelty" of their study, including a logical presentation and discussion of not only unpublished facts about the paper but also new findings and differences from previous research. This study describes a research method that other researchers can emulate to meet the aforementioned requirements.

Regarding the structure of the paper, the introduction is an important part that conveys the "originality and novelty" of the research generated from the literature review, based on the research question or problem. Research should be based on "problems to be solved," related to the "importance of the research." It is therefore essential to provide a description of the research question or problem at the beginning of the introduction. The introduction must also include the research findings required to address the problem, which must be stated logically by citing relevant literature. Authors must briefly present the findings of previous, related research, and succinctly explain the difference between their papers and the results of previous research. This is an important part of the "originality and novelty" of one's research. The introduction should also highlight the purpose of the research to acquaint the reader with what can be expected in the rest of the paper.

A clearly stated purpose, supported by a sound research design and the employment of appropriate research methods, will enhance the quality of the paper and facilitate readers' understanding and reproduction of the research. The results should be presented graphically for ease of comprehension, with text descriptions highlighting new and important findings. The results should be germane to the research question/problem, and the discussion section should be used to interpret the results, compare the findings with those of previous research, and logically convey the conclusions drawn from the results. It is important to provide consistent and logical explanations throughout the text.

The conclusion summarizes the results, interpretations, and conclusions. All studies have limitations. To avoid distorting the interpretation of the research results, and as a point of caution when drawing conclusions from them, it is necessary to describe the limitations of one's study, and to state the scope for future research.

Peer reviews serve to maintain high-quality papers. The authors should understand that peer reviewers are collaborators on an equal footing with the authors, working together to improve the quality of the manuscript through scientific discussion.

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Education

Some tips for writing a paper in English

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Welcome to the Japan Society of Nursing Research (JSNR) ! Fifty years have passed since the JSNR was founded. JSNR was established as Japan's first comprehensive academic organization for nursing science. I would like to describe some tips for writing a paper in English to young nursing scientists.

The Mission of JSNR

Nursing research aims to find clues to solve the problems that material science has not been able to deal with, such as the pain and conflicts of people in their daily lives. Nursing is a human science that is always close to people. Therefore, the mission of JSNR is to bring out into the world meaningful studies that contribute to nursing practice.

A Message from the Seniors to the Young Nursing Scientists

The ultimate goal of nursing science is human health and well-being. Show respect for the truth and good scientific decency. Please check the global standard reporting guidelines (i.e., ICMJE, equator network) frequently and follow them when writing a manuscript. The meaningful new knowledge you discover will surely contribute to academics and society.

Things to Keep in Mind When Starting Your Research

The research method section is a description of how to convert the nursing phenomena you want to know into data using just enough existing knowledge (90% of the mental work in research). Please brush up the research method through the ethical review of the research protocol. If the research results are meaningful new knowledge, the possibility of the paper being accepted is very high.

What Should be Learned from the Literature Review?

It is a scientist's duty to collect papers from around the world in their specialized field. Get into the habit of regularly browsing literature in relevant areas to keep yourself up-to-date. Researchers should know what has been clarified so far in a related research field. Are you able to name excellent papers and their authors in your field of research? It is preferable that your name is in it. If you find an excellent English paper (both the content and English), read it carefully as an important reference. Besides, have another copy of it and use it as a language text (technical terms, grammar, English expressions with markers, etc.).

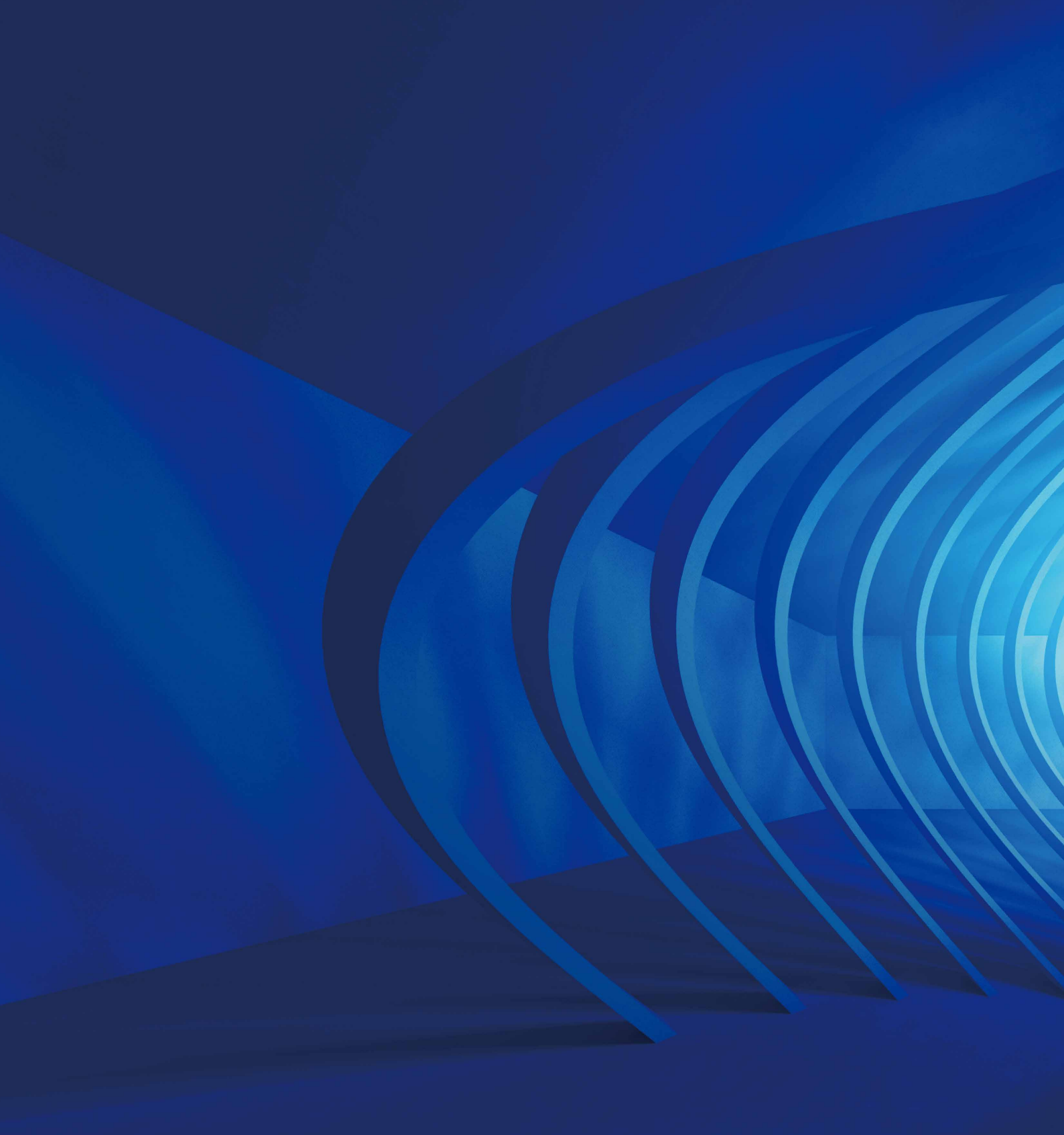## Why is it Necessary to Write Academic Papers in English?

It is said that "scholars must write their papers in English" because science is a culture that originated in the West and spread throughout the world. However, it is not easy for non-native people.

Scientific papers are required to be described objectively and concisely, and to develop a coherent argument. However, as scientific papers are not novels, easy and understandable writing for readers (nursing scientists) is encouraged. To do this, you need to use proper technical terms and use correct English grammar (but at most high school English level).

I hope that young nursing researchers (scholars, teachers, practitioners, and students) will engage in research with courage and hope. People all over the world look forward to the important results of your research.

Disclaimer
Kiyoko Fukai is an Editorial Advisor 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.

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