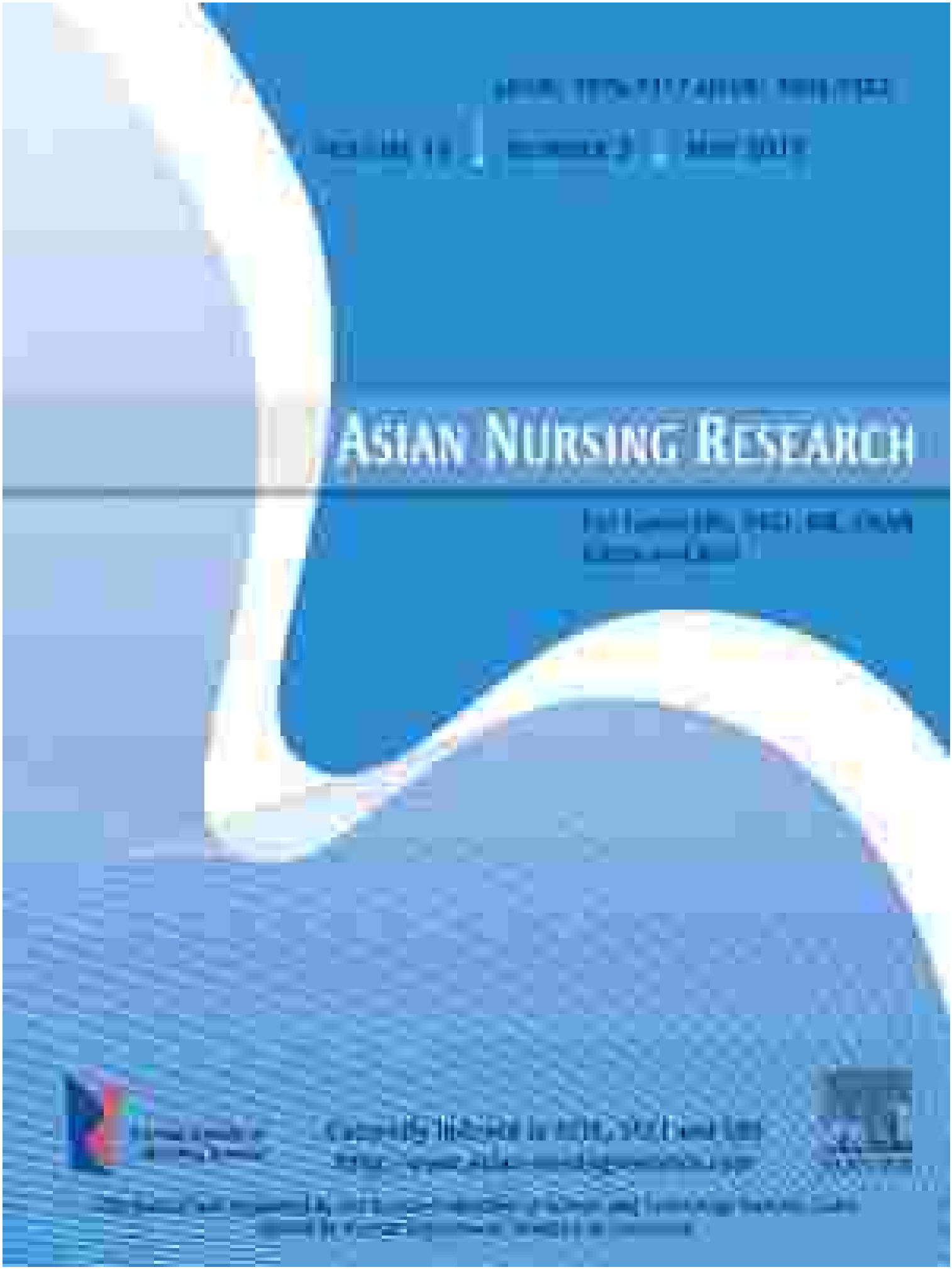
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Review Article

Effects of Nurse Navigators During the Transition from Cancer Screening to the First Treatment Phase: A Systematic Review and Meta-analysis

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ABSTRACT

Purpose: Implementation of nurse navigators during cancer screening to the first treatment visit may facilitate early diagnosis and treatment. This study aims to demonstrate the evidence of the effects of nurse navigators during cancer screening in the first treatment phase.
Methods: Eleven electronic databases were searched, including PubMed, CINAHL, Cochrane Central Register of Controlled Trials (CENTRAL), EMBASE, Web of Science, ScienceDirect, PsycINFO, KoreaMed, KISS, RISS, and DBPIA. The final search was completed in August 2021. Two reviewers independently screened and selected studies, extracted data, and conducted a quality assessment. Data to evaluate the effects of nurse navigators was analyzed through meta-analysis and narrative summary. Subgroup analyses were performed.
Results: A total of 16 studies was included. With low to moderate quality of evidence, nurse navigators had favorable effects on improving the timeliness of care during screening during the first treatment visits (MD = 20.42, 95% CI = 8.74 to 32.10, p = .001). Additionally, 13.0% to 45.0% of nurse navigated patients were more likely to complete cancer care services, although insignificant effects were observed. Study participants from individual studies reported a high satisfaction to the nurse navigators. Subgroup analyses indicated that nurse navigators working as key members in multidisciplinary programs had the greatest effect on reducing waiting times.
Conclusion: Nurse navigators improve cancer patient outcomes by providing more timely care. Additionally, nurse navigators have the substantial potential to increase completion rates to cancer care services and patient satisfaction. For facilitating multidisciplinary care, the use of nurse navigators is highly recommended in the future.

Introduction

Through early screening and treatments, healthcare providers can now prevent and treat cancer significantly [1]. However, delay of treatment initiation and treatment refusals still remain worldwide. In the United States (U.S.), a significantly increased time before cancer treatment initiation was observed between 2004 to 2013, from a median of 21 days to 29 days [2]. Additionally, 8.7% of colorectal cancer patients in Taiwan did not undergo treatments within 4 months of diagnosis, and 28.4% of Korean patients newly diagnosed with lung cancer received no treatments until death [3,4]. Delaying or refusing treatment is counterintuitive, although most cancer patients have a higher survival rate when treated earlier and a greater survival chance upon receiving treatment [2–5]. Yet many cancer patients, voluntarily or involuntarily, choose to postpone or refuse treatments because of various individual barriers, such as unclear information on treatment benefits, fear of side effects, financial problems, or distrust issues/poor communication with healthcare providers [6].

For addressing patient barriers to utilizing healthcare services, a patient navigation program was developed [7]. Patient navigation in cancer care is defined as “specialized assistance for the community, patients, families, and caregivers to assist in overcoming

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barriers to receiving care and facilitating timely access to clinical services and resources" [8, p. 54]. The program implementation has shown promise in facilitating the timely use of cancer care services [9]. Patient navigation services provide personalized and practical assistance to overcome the barriers that each cancer patient faces. This ensures that patients undergo timely care and adhere to treatment plans [8]. For instance, direct counseling was offered to assist anxious patients seeking medical information in understanding the cancer treatment options. Appointments were arranged with reminders to facilitate follow-ups for patients not understanding the importance of timely treatment adherence, and cancer care coordination was provided to reduce the burdens of confusion for patients having difficulties navigating through multidisciplinary care systems [10]. As types and/or complexity of services vary, depending on each patient's needs, patient navigation programs provide individualized care to cancer patients [8]. To achieve high-quality patient-centered care, the Commission on Cancer now requires the incorporation of a patient navigation process into the clinical cancer care system [11].

Within a cancer care continuum, the most essential phases to implement a patient navigation program are from screening, diagnosis, and the transition phase to first treatment. Throughout the movement across the span of the cancer care continuum, or transition, from screening to the first treatment phase, making a prompt decision to receive medical care could greatly increase one's survival rate by early diagnosis and immediate treatments [2]. However, the research conducted at National Cancer Center, Korea, [5] reported 47.6% of untreated cancer patients refused treatments right after a cancer diagnosis. Additionally, 40% of the untreated patients did not involve healthcare providers during their treatment decision-making processes, implying a lack of informed decisions and professional support [5]. In recent studies, researchers discuss the need for having an adequate means of communication between cancer patients and the medical team because sufficient information and the attitudes of health professionals increase the likelihood of cancer patients receiving treatment [12]. For reducing treatment delays and refusal rates, patient navigation programs should be delivered during screening for the first treatment phase by patient navigators who have health professional backgrounds.

While all types of patient navigators are known to be beneficial, nurse navigators during screening for the first treatment phase may be of particular assistance, allowing patients to receive immediate cancer care and direct access to healthcare providers. Individuals with abnormal cancer screening and a new cancer diagnosis are known to become quite motivated to seek information and to be at great risk of psychological issues [13]. With profound clinical knowledge, nurse navigators can provide accurate medical information allowing immediate answers to patient questions and helping with doubts when making treatment decisions [10]. Nurse navigators are also proficient in offering psychosocial support, which can reduce the patients' emotional distress and anxiety [10]. Additionally, nurse navigators have close working relationships with other health professionals, which can facilitate communication between cancer patients and multidisciplinary healthcare providers [14].

In previous literature, a number of systematic reviews evaluated the effects of cancer patient navigation programs [9,15,16]. However, there was no systematic review that specifically focused on evaluating the nurse navigators' effects during cancer screening for the first treatment phase. Only one article systematically reviewed patient navigation programs implemented during screening for the first treatment phase, but the authors did not limit the types of navigators to nurses only [15]. There was another systematic review, which identified the effects of nurse navigators, but this study assessed these effects during the treatment phase only [16]. Therefore, the purpose of this systematic review and meta-analysis is to provide the most current evidence of the effects of nurse navigators on the timeliness of care, completion rates of cancer care services, and patient-reported outcomes during transitions from cancer screening to the first treatment phase within a cancer care continuum.

Methods

Design

A systematic review and meta-analysis of studies reporting the effects of nurse navigators during the transition from cancer screening to the first treatment phase were conducted following the guidelines of the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) [17]. The Synthesis Without Meta-analysis (SWiM) guideline was also used to complement the PRISMA guideline [18].

Search strategy

The initial search was conducted by two reviewers using eleven electronic databases: PubMed, CINAHL, CENTRAL, EMBASE, Web of Science, ScienceDirect, PsycINFO, KoreaMed, KISS, RISS, and DBPIA. The search was finalized in August 2021. This study used a PICOT (population, intervention, comparison, outcome, and time) tool to formulate a research question and guide search strategy. The research question was "In adult clients who were positively screened for cancer or newly diagnosed with cancer (P), what is the effect of nurse navigators (I) on the timeliness of care, completion rates of cancer care services, and any patient-reported outcomes (O) compared to usual care (C) during transitions from cancer screening to the first treatment phase (T)?." The search strategy was built based on a combination of population and intervention from the PICOT question using a Boolean operator of "AND" between P and I. The basic search terms and search strategy used were ("neoplasm*" or "cancer*" or "tum*r*") AND ("patient navigat*" or "nurse navigat*" or "oncology nurse navigat*" or "nurse practitioner navigat*" or "oncology nurse practitioner navigat*" or "pivot nurs*" or "care coordinat*" or "cancer care coordinat*"). Subject headings (e.g., MeSH terms, CINAHL headings, Emtree, PsycINFO Thesaurus) for "Neoplasms" and "Patient Navigation" were also used accordingly. In three Korean databases (KISS, RISS, and DBPIA), corresponding Korean search terms were used. Table S1 shows the details of the search strategy used in each database. An additional manual search was conducted by screening the references in key articles.

Inclusion criteria

The eligibility criteria for this study were as follows:

1. Participants: Adults aged 18 or over who were screened for cancer or newly diagnosed with cancer and who have not undergone any forms of cancer treatments.
2. Intervention: Patient navigation programs implemented solely by any type of nurses (e.g., registered nurses, certified oncology nurses, advanced nurse practitioners, etc.) during cancer screening for the first treatment phase. The programs facilitated in a combination form of nurses with other types of navigators, such as lay workers, community health workers, or social workers, were excluded.
3. Comparisons: Usual or standard care.
4. Outcomes: Studies evaluating the timeliness of care, completion rates of cancer care services, or any patient-reported outcomes

(e.g., satisfaction level and any psychological outcomes) were included. The outcomes of timeliness of care and completion rates of cancer care services were regarded as primary outcomes, and any patient-reported outcomes were regarded as secondary outcomes. Only the outcomes reported during transitions from cancer screening to the first treatment phase or before treatment initiation were included.

Any eligible studies published in English or Korean after the years 1990 to 2021 were included. Randomized controlled trials, quasi-experimental studies, and cohort studies (either prospective or retrospective) were included in this review.

Study selection

Two reviewers independently screened and selected eligible studies. Initially, the reviewers screened the titles and abstracts to narrow down the potential studies that met the inclusion criteria. For the secondary screening, the reviewers obtained the full texts of the relevant studies to evaluate their eligibility. Any disagreements between reviewers were discussed and resolved by involving third parties.

Risk of bias assessment

Two reviewers independently evaluated the risk of bias for the selected studies, and any disagreements were resolved by involving third parties. Tools used for the evaluation were version 2 of the Cochrane Risk of Bias tool (RoB 2) [19] for randomized controlled trials (RCTs) and the Risk of Bias In Non-randomized Studies − of Interventions (ROBINS-I) for the non-RCTs [20].

Data extraction

Study details from the selected studies were independently extracted by reviewers, using the predetermined table developed by the author. The reviewers obtained characteristics of included studies by populations, intervention, comparisons, outcomes, and study designs. The extracted data were then organized, and additional study details were obtained based on a core set of outcomes, which was developed to promote consistency in measuring the impact of patient navigation programs [21–23]. To determine the effects of nurse navigators, the reviewers extracted quantitative data about the timeliness of care (primary outcome), completion rates of cancer care services (primary outcome), satisfaction level (secondary outcome), and psychological outcomes (secondary outcome). The outcome of the timeliness of care was categorized into four transition phases, which were (1) screening to the treatment phase; (2) screening to the diagnosis phase; (3) diagnosis to the treatment phase; and (4) first consultation to the treatment phase. The completion rates of cancer care services were also classified into two groups by cancer care services. They were (1) diagnostic resolution; and (2) treatment initiation. Based on the proposed metrics by Fiscella et al [23], the outcomes of satisfaction level and psychological outcomes were separately grouped as patient-reported outcomes.

Synthesis

Meta-analysis was mainly used as a synthesis method. Quantitative outcomes that were synthesized into a meta-analysis were (1) timeliness of care; (2) completion rates of cancer care services; and (3) psychological outcomes. The data that was not synthesized into a meta-analysis, or satisfaction level, was presented as a narrative summary. Summarizing effect estimates, combining p-values, or vote-counting were not appropriate to synthesize the data of satisfaction level due to the absence of the reported outcomes of historical control groups.

For the meta-analysis, most effect sizes of continuous data were computed with means and standardized deviations (SD) using Comprehensive Meta-Analysis (CMA) software, Version 3. When the SD was not available, means and *p*-values were used. In studies that reported median and interquartile ranges (IQR), the outcomes were converted into mean and SD using a formula from Wan, Wang, Liu, & Tong [24]. Quantitative data from both RCTs and non-RCTs were calculated into unmatched formats to analyze the effect sizes. In a study that reported multiple measures that could be synthesized into one meta-analysis, we used a combined measure of effect for each outcome data. The reason for using this calculation for multiple outcomes within the same study was to avoid counting the same participants in one meta-analysis [25].

The raw difference in means (MD) and 95% confidence interval (CI) were used to measure the differences in the timeliness of care days between the intervention and control groups. MD was calculated because of its use of the same scale (interval days), allowing intuitive interpretation of the results. For any other outcomes reported with continuous data (e.g., psychological outcomes), corrected standardized mean difference with Hedges' *g* and 95% CI were calculated for analyses. The reason for using Hedges' *g* instead of Cohen's *d* was because of the small number of studies included in this meta-analysis [25]. For those outcomes reported with dichotomous data, we used a relative ratio (RR) for calculating effect sizes. A random-effect model was used for all meta-analyses, regardless of the degree of statistical heterogeneity among studies [25]. The reason for using this model was because of its substantial variations in study participants and details of interventions.

Heterogeneity assessment

For evaluating the statistical heterogeneity among studies, we used the Q value and I^2 index. Heterogeneity was considered to be low when the I^2 index was less than 25%, moderate if 50%, and high if greater than 75% [26]. For those meta-analyses of timeliness of care with high statistical heterogeneity, subgroup analyses were performed to further examine the causes of heterogeneity. A random-effect model was used for subgroup analyses. The heterogeneity of outcomes that were presented as a narrative summary was assessed visually using a table.

Publication bias assessment

Funnel plots were used to evaluate publication bias. Funnel plots of meta-analyses, which pooled three or more studies, were presented using CMA software, but the interpretation was not conducted because of the small number of studies included in each meta-analysis [27].

Certainty of evidence assessment

Two reviewers independently evaluated the certainty of the evidence for each outcome based on the GRADE approach, and any disagreements were resolved by involving third parties. Regardless of study designs, we initially rated the evidence as "high" certainty for all evaluated studies because of the use of the ROBINS-I tool for evaluating the risk of bias of non-RCTs [28]. The results were presented in a "summary of findings" table using GRADEpro GDT software.

Results

The reviewers initially identified 11,529 records through electronic database searches and two records by a manual search of key articles. After removing the duplicates, 7,689 studies remained. During the initial screening phase, 7,594 studies were removed, which left a total of 95 articles for a full-text screening to assess for eligibility. In the final meta-analysis, 16 studies were included [29–44]. Figure 1 shows the selection process for this study. The primary reasons for exclusion during full-text article screening were the implementation of intervention during other phases within the cancer care continuum, the use of non-nurse navigators, and the use of study designs that did not meet the inclusion criteria.

Results of risk of bias assessment

All 16 included studies, with three randomized controlled studies [36,38,41] and 13 nonrandomized controlled studies [29–35,37,39,40,42–44], were separately assessed for risk of bias

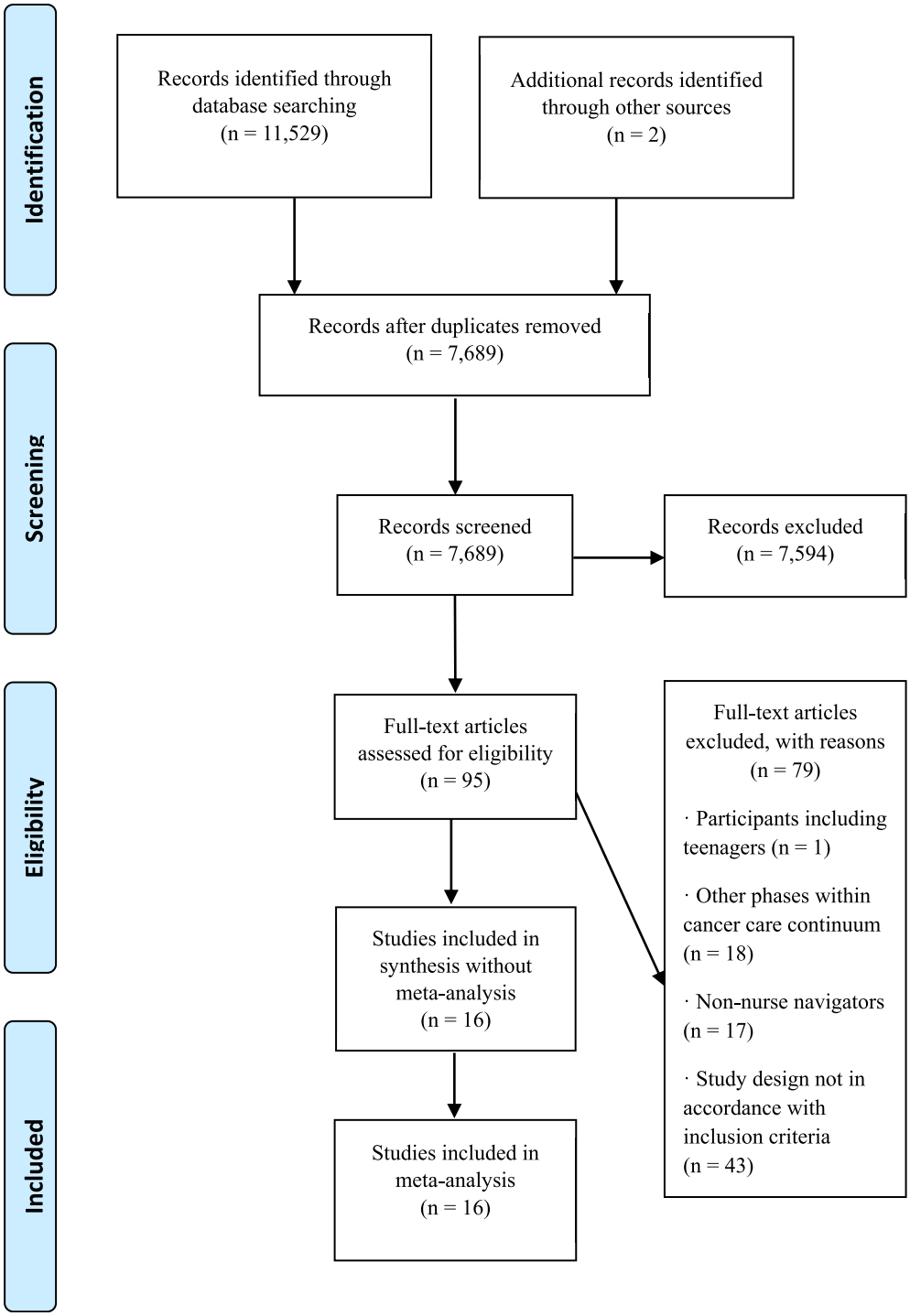


Figure 1. Flow Diagram of the Selection Process.

Table 1 *Summarized Characteristics of Included Studies (N = 16).*

Characteristics	n (%)	Included Studies
Published year		
2011–2012	2 (12.5)	[39,41]
2013–2014	3 (18.7)	[29,30,36]
2015–2016	2 (12.5)	[38,40]
2017–2018	5 (31.3)	[31,35,37,42,44]
2019–2020	3 (18.7)	[32–34]
2021	1 (6.3)	[43]
Countries		
United States	10 (62.5)	[29,32–36,39,40,42,43]
Canada	3 (18.7)	[30,31,44]
Korea	2 (12.5)	[38,41]
Botswana	1 (6.3)	[37]
Study designs		
RCTs	3 (18.7)	[36,38,41]
Retrospective cohort studies	9 (56.3)	[29–31,34,35,37,40,42,44]
Prospective cohort studies	2 (12.5)	[39,43]
Pragmatic QI trials	2 (12.5)	[32,33]
Participants		
Cancer continuum transition phases		
Screening to the first treatment visit	4 (25.0)	[29–31,40]
Screening to diagnosis	3 (18.7)	[36,43,44]
Diagnosis to the first treatment visit	9 (56.3)	[32–35,37–39,41,42]
Types of cancer		
Breast cancer	3 (18.7)	[30,39,44]
Colorectal cancer	2 (12.5)	[36,43]
Lung cancer	4 (25.0)	[29,31,33,40]
Gastric/Gastrointestinal cancer	2 (12.5)	[38,42]
Gynecologic cancer	1 (6.3)	[37]
Pancreatic cancer	1 (6.3)	[34]
Combination of two cancer types	3 (18.7)	breast & lung [32], gynecologic & hematologic [35], gastric & breast [41]
Intervention		
Liaison role of nurse navigators		
MDT (NN)	7 (43.8)	[29,31–33,37,42,43]
NN (MDT)	4 (25.0)	[30,35,40,44]
NN	5 (31.2)	[34,36,38,39,41]
Types of nurses		
Advanced nurse practitioners	1 (6.3)	[29]
Certified oncology nurses	10 (62.5)	[34–36,38–44]
RNs with oncology clinical experiences		
Not specified	5 (31.2)	[30–33,37]
Contact methods		
Face-to-face meetings	2 (12.5)	[30,34]
Phone calls	2 (12.5)	[31,36]
Both	5 (31.2)	[32,35,38,41,44]
Not specified	7 (43.8)	[29,33,37,39,40,42,43]
Clinical settings		
General tertiary hospital	10 (62.5)	[29–31,34,37–39,41–43]
Specialized cancer center	5 (31.2)	[32,33,35,40,44]
Primary care clinics	1 (6.3)	[36]
Use of conceptual models		
Yes	4 (25.0)	[32,36,38,41]
No	12 (75.0)	[29–31,33–35,37,39,40,42–44]
Risk of Bias Assessment (n, tool)	**Overall Results**	**Included Studies (results)**
RCTs (3, RoB2)	Low	[36,38,41] (low)
non-RCTs (13, ROBINS-I)	Serious	[29–35,39,40,42] (low), [37,43,44] (serious)

Note. MDT (NN) = multidisciplinary team programs with nurse navigators working as key members among multidisciplinary professionals; NN (MDT) = nurse navigation programs with nurse navigators actively playing the liaison role among multidisciplinary professionals; NN = nurse navigation programs with nurse navigators inactively playing the liaison role among multidisciplinary professionals; QI = quality improvement; RCTs = randomized controlled trials; RNs = registered nurses; RoB2 = Cochrane Risk of Bias tool, version 2; ROBINS-I = Risk of Bias In Nonrandomized Studies – of Interventions.

using corresponding tools. Table 1 presents the summarized results of risk of bias (Summarized results of risk of bias for each study with reasons are shown in Table S2). The overall risk of bias for the three RCTs was low. Some concerns in risk of bias were found only in the randomization process domain in one study (33.3%) [41] due to unclear statements about allocation sequence concealment. An overall risk of bias for 13 non-RCTs was serious. Moderate risk of bias due to confounding was identified in most studies (76.9%) as potential confounding variables were appropriately controlled for. However, a serious risk of bias due to confounding was given in three studies (23.1%) [37,43,44], as the authors did not consider processing possible confounding variables during the design or analysis phases.

Characteristics of included studies

Table 1 presents the summarized characteristics of all 16 included studies (Full details of characteristics for each study are

shown in Table S2). The studies were published between 2011 to 2021. Most researchers conducted their studies in North America, with ten studies in the United States [29,32–36,39,40,42,43], and three in Canada [30,31,44]. Studies from other countries included Korea (n = 2) [38,41] and Botswana (n = 1) [37]. Study designs varied by each study. There were three randomized controlled studies [36,38,41], nine retrospective cohort studies [29–31, 34,35,37,40,42,44], two prospective cohort studies [39,43], and two pragmatic quality improvement trials [32,33].

Participants

Participants were grouped into three different transition phases within the cancer care continuum of screening for the first treatment visit. Four studies [29–31,40] included individuals at the screening to diagnosis and to the first treatment visit, which consisted of all transition phases that this study has targeted. Three other studies [36,43,44] focused on individuals at screening for the diagnosis phase. The remaining nine studies [32–35,37–39,41,42] included participants at diagnosis to the first treatment visit (Table 1).

Participants' cancer types also varied by each study. Types of cancer from included studies were as follows: breast cancer (n = 3) [30,39,44], colorectal cancer (n = 2) [36,43], lung cancer (n = 4) [29,31,33,40], gastric/gastrointestinal cancer (n = 2) [38,42], gynecologic cancer (n = 1) [37], and pancreatic cancer (n = 1) [34]. While most studies recruited individuals from a single cancer group, the remaining three studies [32,35,41] included participants from two different cancer groups in their research (Table 1).

Intervention

Most nurse navigators were implemented to streamline cancer care and to facilitate timely access to cancer diagnostic or treatment services. Most nurse navigators carried out similar tasks. Those tasks were (1) coordinating and managing cancer care flow (n = 10) [29–31,34,36–40,42]; (2) serving as a primary contact person (n = 10) [29,31–37,39,41]; (3) following up on patients to ensure the completion of appropriate cancer care (n = 4) [33,35,36,39]; (4) obtaining patient records and ensuring test results were available (n = 4) [30,36,37,43]; (5) assessing and resolving individualized barriers to receiving care (e.g., financial issues, lack of transportation, mistrust and/or miscommunication, beliefs, fear, etc.) (n = 8) [32–36,39–41]; (6) providing educational information and psychosocial support (n = 8) [30,34–36,38,40,41,44], and 7) referring to or providing information about available resources (n = 2) [35,44].

One significant variation among the tasks of nurse navigators was the liaison role within multidisciplinary team members. In seven studies [29,31–33,37,42,43], the authors evaluated multidisciplinary team programs but identified nurse navigators as being the key members within the team who mainly worked to facilitate interprofessional communications [MDT (NN)]. In four other studies [30,35,40,44], the effects of nurse navigation programs were assessed, but the authors explicitly stated their navigators worked in collaboration with multidisciplinary healthcare providers [NN (MDT)]. In the remaining five studies [34,36,38,39,41], the authors solely analyzed the effects of nurse navigators, and the liaison role with other healthcare providers was not clearly stated (NN) (Table 1).

Other variations among nurse navigators depended on the type of nurses, the means of contacting study participants, clinical settings where the programs were carried out, and conceptual models that were based upon a few developed programs (Table 1).

Results of nurse navigators' effects

Table 2 shows the summary of findings for the primary (timeliness of care, completion rates of cancer care services) and secondary outcomes (patient-reported outcomes) of this study.

Timeliness of care (primary outcome)

Eleven studies [29–31,34–37,39,40,42,43] reported the timeliness of care as their major outcome. Individual data was measured by the number of days that participants took to access one care service to the next care service. Most studies reported two or more transition phases in one research. The interval days used to calculate the timeliness of care were retrieved from electronic health records or computerized databases.

Timeliness of care: from screening to the first treatment visit. Data from four studies [29–31,40] was combined in this meta-analysis. Nurse navigators improved the timeliness of care by reducing an average of 20.42 (95% CI = 8.74 to 32.10, $p = .001$) days between the date of receiving abnormal screening results to the first treatment visit, compared to the usual care. An evidence of a fairly high statistical heterogeneity was identified (I^2 index = 70.0%, $p = .020$) (Figure 2). There was low quality of evidence for this outcome due to the serious risk of confounding risk of bias and inconsistency (Table 2).

Timeliness of care: from screening to diagnosis. Six studies [29–31,36,40,43] were synthesized for this outcome category. The mean differences showed nurse navigated groups waited 30.15 days (95% CI = 11.97 to 48.32, $p = .001$) fewer than did the usual care groups during the screening to diagnosis phase. The I^2 index value indicated high statistical heterogeneity (I^2 index = 93.8%, $p < .001$) (Figure 2). There was low quality of evidence for this outcome due to the serious risk of confounding risk of bias and inconsistency (Table 2).

Timeliness of care: from diagnosis to the first treatment visit. Six studies [29–31,37,39,42] were included in this meta-analysis. The difference in means indicated that nurse navigators reduced the number of interval days to 17.54 between the date of diagnosis to the first treatment visit (95% CI = 2.45 to 32.63, $p = .023$). A high I^2 index value was identified (I^2 index = 96.0%, $p < .001$) (Figure 2). There was low quality of evidence for this outcome due to the serious risk of confounding risk of bias and inconsistency (Table 2).

Timeliness of care: from the first consultation to the first treatment visit. Data from two studies [34,35] with three different population groups were utilized in this meta-analysis. Among study participants who had their first consultation with healthcare providers in a tertiary referral cancer center, participants in the nurse navigated group waited fewer than 11.41 days until the time of their first cancer treatment visit compared to those in the control group (95% CI = 6.02 to 16.80, $p < .001$). A low statistical heterogeneity was identified (I^2 index = 8.0%, $p = .337$) (Figure 2). There was a moderate quality of evidence for this outcome due to the serious risk of confounding risk of bias (Table 2).

Completion rates of cancer care services (primary outcome)

Six studies [32–34,36,40,43] reported participant completion rates of cancer care services. Individual data was measured as being the number of individuals or the proportion rates of participants who completed diagnostic testing or treatments. The researchers obtained the data from medical records.

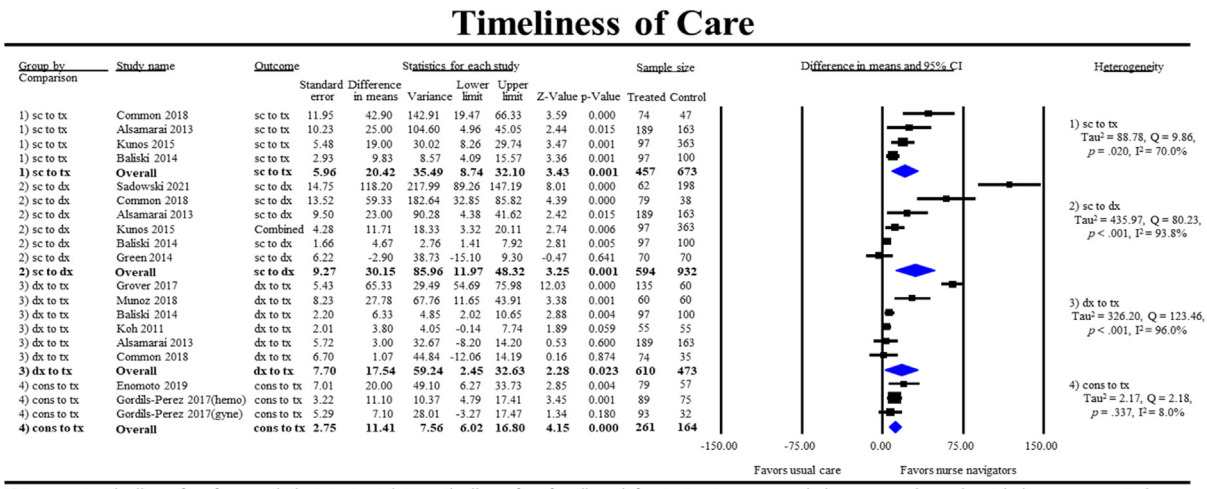
Table 2 *Summary of Findings: Timeliness of Care, Completion Rates of Cancer Care Services, and Patient-Reported Outcomes.*

Nurse Navigators for Individuals Transitioning from Cancer Screening to the First Treatment Phase

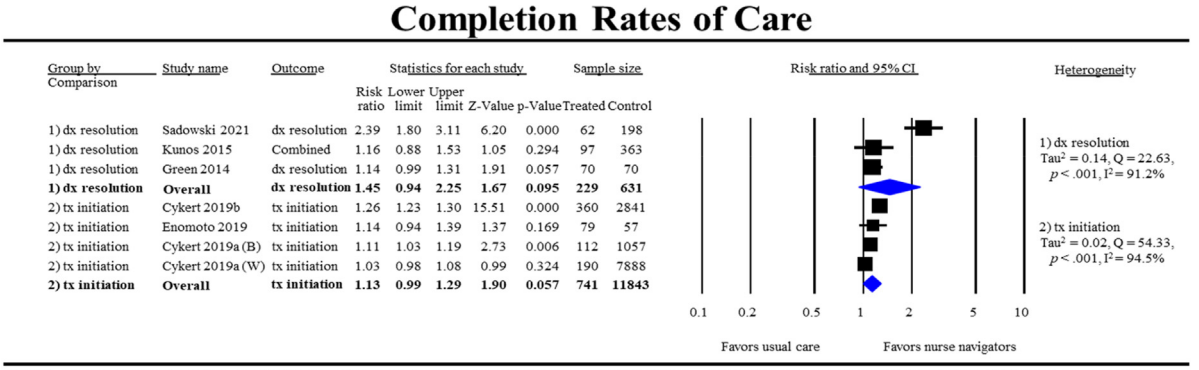
Patient or population: Individuals transitioning from cancer screening to the first treatment phase
Settings: Any healthcare settings
Intervention: Nurse navigators
Comparison: Usual care

Outcomes	Anticipated absolute effects (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)
	Risk with usual care	Risk with nurse navigators			
Timeliness of care: screening to treatment	The mean timeliness of care: screening to reatment ranged from 59.83 to 126.00 days	MD20.42 days more (8.74 more to 32.10 more)	-	1130 (4 observational studies)	⊕⊕○○ LOW[a,b]
Timeliness of care: screening to diagnosis	The mean timeliness of care: screening to diagnosis ranged from 11.00 to 140.10 days	MD30.15 days more (11.97 more to 48.32 more)	-	1526 (1 RCT, 5 observational studies)	⊕⊕○○ LOW[a,b]
Timeliness of care: diagnosis to treatment	The mean timeliness of care: diagnosis to treatment ranged from 30.00 to 108.67 days	MD 17.54 days more (2.45 more to 32.63 more)	-	1083 (6 observational studies)	⊕⊕○○ LOW[a,b]
Timeliness of care: consultation to treatment	The mean timeliness of care: consultation to treatment ranged from 27.10 to 47.80 days	MD 11.41 days more (6.02 more to 16.80 more)	-	425 (2 observational studies)	⊕⊕⊕○ MODERATE[a]
Completion rates: diagnostic resolution	444 per 1,000	643 per 1,000 (417 to 998)	RR 1.45 (0.94 to 2.25)	860 (1 RCT, 2 observational studies)	⊕⊕○○ LOW[a,b]
Completion rates: treatment initiation	838 per 1,000	947 per 1,000 (830 to 1,000)	RR 1.13 (0.99 to 1.29)	12584 (3 observational studies)	⊕○○○ VERY LOW[a,b,c]
Satisfaction level PROs	One study had a small but insignificant effect on improving satisfaction level (Hedges' $g = 0.07$, 95% CI = −0.24 to 0.37). In the other two studies, the intervention group participants from both studies reported high satisfaction levels to the overall cancer care received.			296 (1 RCT, 2 observational studies)	⊕○○○ VERY LOW[a,d,e]
Psychological outcomes		Hedges' g 0.12 lower (0.33 lower to 0.09 higher)	-	357 (2 RCTs, 1 observational study)	⊕⊕○○ LOW[a,d]

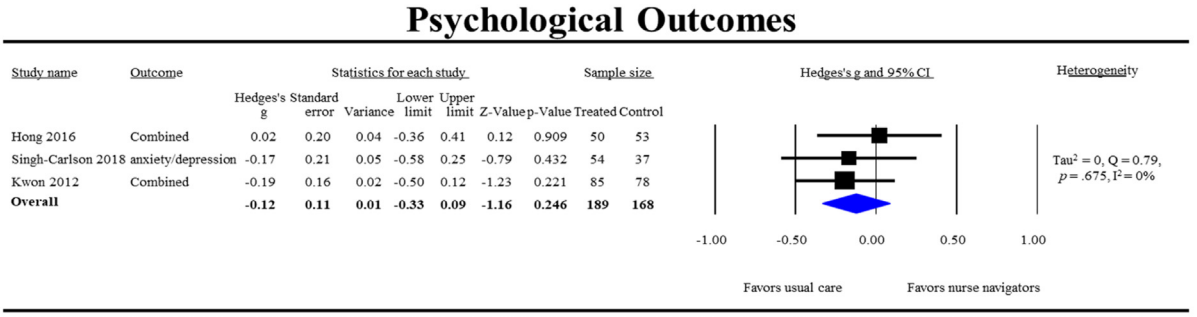
GRADE Working Group grades of evidence.
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect. **Moderate certainty:** We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. **Low certainty**: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect. **Very low certainty**: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.
Note. a. Evidence downgraded by one level for serious risk of bias. Included observational studies have the risk of bias due to confounding; b. Evidence downgraded by one level for serious risk of inconsistency. The I^2 index value for the meta-analysis demonstrated high statistical heterogeneity; c. Evidence is downgraded by one level for serious risk of imprecision. Confidence interval (CI) included both null effect and appreciable benefit; d. Evidence downgraded by one level for the serious risk of imprecision. The number of study participants was small (less than 400); e. Evidence downgraded by one level for the serious risk of imprecision. Only one study was able to evaluate the effects of nurse navigators by comparing the intervention and control groups, while the other two studies were unable to measure the satisfaction level of their historical control groups; CI = confidence interval; MD = mean difference; PROs = patient-reported outcomes; RR = risk ratio.



Note: cons to tx = timeliness of care from consultation to treatment; dx to tx = timeliness of care from diagnosis from treatment; gyne = gynecologic cancer group; hemo = hematologic cancer group; sc to dx = timeliness of care from screening to diagnosis; sc to dx, Kunos 2015, Combined = combined the outcomes of days from abnormal chest X-ray to seven different lung cancer diagnostic services (chest CT scan, abdominopelvic CT scan, whole-body bone scan, MRI scan of brain, whole-body PET-CT scan, bronchoscopy, tissue diagnosis) reported in Kunos 2015, assuming the outcomes were not independent to each other; sc to tx = timeliness of care from screening to treatment



Note: B = black patients; dx resolution = completion rates of diagnostic resolution; dx resolution, Kunos 2015, Combined = combined the outcomes of completion rates of six different lung cancer diagnostic medical services (chest CT scan, abdominopelvic CT scan, whole-body bone scan, MRI scan of brain, whole-body PET-CT scan, bronchoscopy) reported in Kunos 2015, assuming the outcomes were not independent to each other; tx initation = completion rates of treatment initiation; W = White patients



Note: Hong 2016, Combined = combined the outcomes of resilience, uncertainty, and anxiety reported in Hong 2016, assuming the outcomes were not independent to each other; Kwon 2012, Combined = combined the outcomes of anxiety, depression, and distress reported in Kwon 2012, assuming the outcomes were not independent to each other

Figure 2. Forest plots: Effects of Nurse Navigators.

Completion rates: diagnostic resolution. Three studies [36,40,43] were synthesized for this meta-analysis. The effect size of the risk ratio showed that 45.0% of individuals from the navigated group were more likely to complete diagnostic resolution as compared to the participants from the nonnavigated group. However, the effect size was statistically insignificant (95% CI = 0.94 to 2.25, $p = .095$). A high statistical heterogeneity had been observed (I^2 index = 91.2%, $p < .001$) (Figure 2). There was low quality of evidence for this outcome due to the serious risk of confounding risk of bias and inconsistency (Table 2).

Completion rates: treatment initiation. In this meta-analysis, three studies [32–34] with four different population groups were included. The effect size of the risk ratio showed that 13.0% of the participants in the nurse navigated group was more likely to initiate cancer treatment as compared to those in the control group, but the effect size was not statistically significant (95% CI = 0.99 to 1.29, $p = .057$). The I^2 index value indicated high statistical heterogeneity (I^2 index = 94.5%, $p < .001$) (Figure 2). There was very low quality of evidence for this outcome due to the serious risk of confounding risk of bias, inconsistency, and imprecision (Table 2).

Patient-reported outcomes (secondary outcome)

Satisfaction level. Three studies measured patients' satisfaction level with the overall cancer care experience [35,39,41]. The results of the included studies were not pooled for meta-analysis as two of

the studies [35,39] were not able to measure the satisfaction level of historical control groups. Only Kwon et al. [41] compared the patient survey outcomes between navigation and control groups, which reported a favorable outcome to the nurse navigators (Hedges' $g = 0.07$, 95% CI = −0.24 to 0.37, $p = .669$, 163 participants, RCT). Although the comparisons between intervention and control groups were not possible in the other two studies, the intervention group participants reported high mean scores in both studies of Koh et al. (4.52 ± 0.51, 32 participants) [39], and Gordils-Perez *et al.* (4.78 ± 0.38, 54 gynecologic cancer participants; 4.87 ± 0.32, 47 hematologic cancer participants) [35]. A total possible score was five in both studies. There was very low quality of evidence for this outcome due to the serious risk of confounding risk of bias and very serious risk of imprecision (Table 2).

Psychological outcomes. Three studies [38,41,44] evaluated psychological outcomes of resilience [38], uncertainty [38], anxiety [38,41,44], depression [41,44], and distress [41]. The effect size showed nurse navigators did not have a positive impact on patients' overall psychological outcomes, but the effect size was not statistically significant (Hedges' $g = -0.12$, 95% CI = −0.33 to 0.09, $p = .246$). A low statistical heterogeneity was observed (I^2 index = 0%, $p = .675$) (Figure 2). There was low quality of evidence for this overall psychological outcome due to the serious risk of confounding risk of bias and imprecision (Table 2).

Additional meta-analysis was performed to evaluate the differences between effect sizes for each psychological outcome by assuming the independence among study variables (Table S3). Each psychological outcome was reported in one study, except anxiety that was reported in two studies [38,41]. Only resilience (Hedges' $g = 0.07$, 95% CI = −0.31 to 0.46, $p = .714$) and uncertainty (Hedges' $g = 0.06$, 95% CI = −0.33 to 0.44, $p = .775$) favored nurse navigators, but the effect sizes were statistically insignificant.

Results of subgroup analysis by the cancer types and liaison role of nurse navigators

To find out the sources of heterogeneity among studies reporting three phases of timeliness of care (screening to the first treatment visit, screening to diagnosis, diagnosis to the first treatment visit), we conducted subgroup analyses by the cancer types of participants and three different levels of nurse navigators' liaison role within multidisciplinary team members [MDT (NN), NN (MDT), NN]. Table 3 presents the results of the subgroup analyses. The cancer types were effective during the phases of screening to the first treatment visit ($Q_B = 4.98$, $p = .026$), and diagnosis to the first treatment visit ($Q_B = 122.69$, $p < .001$). The level of nurse navigators' liaison role was also effective during the phases of screening to the first treatment visit ($Q_B = 3.91$, $p = .048$) and screening to diagnosis ($Q_B = 6.81$, $p = .033$).

Although the level of nurse navigators' liaison role was not effective during the one remaining phase (diagnosis to the first treatment visit), a consistent pattern in size effects was observed by the level of nurse navigators' liaison role in all three evaluated phases. The greatest effect sizes were observed in the MDT (NN) groups during all three phases of screening to the first treatment visit (MD = 32.88, 95% CI = 15.46 to 50.30, $p < .001$), screening to diagnosis (MD = 65.99, 95% CI = 11.66 to 120.32, $p = .017$), and diagnosis to the first treatment visit (MD = 24.36, 95% CI = −8.40 to 57.12, $p = .145$), compared to the other two subgroups [NN (MDT), and NN]. Greater effect sizes were also found in the NN (MDT) groups during all evaluated phases of screening to diagnosis (MD = 7.09, 95% CI = 0.53 to 13.64, $p = .034$), and diagnosis to the first treatment visit (MD = 6.33, 95% CI = 2.02 to 10.65, $p = .004$), compared to the NN groups (Table 3).

Discussion

Our findings showed that nurse navigators successfully improved the timeliness of care between screening to the first treatment visit, screening to diagnosis, diagnosis to the first treatment visit, and first consultation to the first treatment visit. Nurse navigators also increased the completion rates of diagnostic and treatment cancer care services, but the effects were insignificant. In respect to patient-reported outcomes, cancer patients were highly satisfied with the overall cancer care they received with nurse navigators, although their psychological outcomes did not improve.

Similar findings were demonstrated in a recent systematic review [45] in respect to improved timeliness of care from diagnosis to treatment and completion rates of treatment initiation. Although Wu et al. (2021) [45] examined the effects of nurse-led case management, their search terms and included studies involved nurse

Table 3 *Results of Subgroup Analysis: by Cancer Types, and Liaison Role of Nurse Navigators.*

Timeliness of care	Subgroups		No. of studies	MD (95% CI), *P*-value	Heterogeneity	Q_B, *df*, *P*-value
From screening to the first treatment visit	Cancer types	Lung	3	25.83 (13.01, 38.65), <.001	$Tau^2 = 53.61$, Q = 3.33, $p = .189$, $I^2 = 39.9\%$	4.98, 1, .026
		Breast	1	9.83 (4.09, 15.57), .001	$Tau^2 = 0$, Q = 0, $p = 1.000$, $I^2 = 0\%$	
	Liaison role	MDT (NN)	2	32.88 (15.46, 50.30), <.001	$Tau^2 = 36.45$, Q = 1.30, $p = .255$, $I^2 = 22.8\%$	3.91, 1, .048
		NN (MDT)	2	13.25 (4.56, 21.93), .003	$Tau^2 = 22.75$, Q = 2.18, $p = .140$, $I^2 = 54.1\%$	
From screening to diagnosis	Cancer types	Colorectal	2	56.91 (−61.76, 175.58), .347	$Tau^2 = 7204.24$, Q = 57.12, $p < .001$, $I^2 = 98.2\%$	4.49, 2, .106
		Lung	3	28.53 (4.62, 52.44), .019	$Tau^2 = 359.13$, Q = 11.73, $p = .003$, $I^2 = 83.0\%$	
		Breast	1	4.67 (1.41, 7.92), .005	$Tau^2 = 0$, Q = 0, $p = 1.000$, $I^2 = 0\%$	
	Liaison role	MDT (NN)	3	65.99 (11.66, 120.32), .017	$Tau^2 = 2142.90$, Q = 29.69, $p < .001$, $I^2 = 93.3\%$	6.81, 2, .033
		NN (MDT)	2	7.09 (0.53, 13.64), .034	$Tau^2 = 14.29$, Q = 2.36, $p = .125$, $I^2 = 58\%$	
		NN	1	−2.90 (−15.10, 9.30), .641	$Tau^2 = 0$, Q = 0, $p = 1.000$, $I^2 = 0\%$	
From diagnosis to the first treatment visit	Cancer types	Gyne	1	65.33 (54.69, 75.98), <.001	$Tau^2 = 0$, Q = 0, $p = 1.000$, $I^2 = 0\%$	122.69, 3, <.001
		GI	1	27.78 (11.65, 43.91), .001	$Tau^2 = 0$, Q = 0, $p = 1.000$, $I^2 = 0\%$	
		Breast	2	4.95 (2.04, 7.86), .001	$Tau^2 = 0$, Q = .72, $p = .396$, $I^2 = 0\%$	
		Lung	2	2.19 (−6.34, 10.71), .615	$Tau^2 = 0$, Q = .05, $p = .826$, $I^2 = 0\%$	
	Liaison role	MDT (NN)	4	24.36, (−8.40, 57.12), .145	$Tau^2 = 1073.94$, Q = 82.47, $p < .001$, $I^2 = 96.4\%$	2.06, 2, .357
		NN (MDT)	1	6.33 (2.02, 10.65), .004	$Tau^2 = 0$, Q = 0, $p = 1.000$, $I^2 = 0\%$	
		NN	1	3.80 (−0.14, 7.74), .059	$Tau^2 = 0$, Q = 0, $p = 1.000$, $I^2 = 0\%$	

Note. CI = confidence interval; GI = gastrointestinal cancer; Gyne = gynecologic cancer; MD = raw difference in means; MDT (NN) = multidisciplinary team programs with nurse navigators working as key members among multidisciplinary professionals; NN (MDT) = nurse navigation programs with nurse navigators actively playing the liaison role among multidisciplinary professionals; NN = nurse navigation programs with nurse navigators inactively playing the liaison role among multidisciplinary professionals; Q_B = between-groups heterogeneity.

navigators, as well, and stated *navigators* and *case managers* were often used interchangeably. As the nurse navigators in our study also performed the role of care coordination, patient education and follow-ups, and collaboration with multidisciplinary healthcare providers, which were the defined role of nurse case managers by Wu et al. (2021) [45], our study outcomes could be compared to the results of Wu et al. (2021) [45]. However, unlike the recent systematic review [45] that also included programs led by a combination of multiple providers (e.g., a care-management-model-based patient navigation program facilitated by a registered nurse, a dental hygienist, a social worker, a business administrator, and a promotora), our study outcomes were based on patient navigation programs facilitated by the nurses only, which add stronger evidence to the positive effects of nurses on cancer patients. In addition, Wu et al. (2021) [45] indicated limited types of cancer, mostly breast cancer, were included in their study, which might cause bias in intervention effectiveness. With six or more cancer types included in our systematic review and a demonstration of different size effects by cancer types using subgroup analysis, our study outcomes reinforce the evidence of nurse navigators' beneficial effects with more precise findings.

Whereas most of the included studies dealt with nurse navigators for facilitating timely access to cancer care services, our findings of low to moderate quality evidence showed that improved timeliness of care was clinically meaningful during all four phases of screening to the first treatment visit. In the United Kingdom, the National Health Services (NHS) England [46] is setting the target waiting time to be 62 days (2 months) between the time of a referral for suspected cancer until the first treatment visit, 28 days between the time of a referral for abnormal screening to diagnostic testing visit, and 31 days between the time of the decision to treat until the first treatment visit. Reflecting on these NHS England waiting time targets, our study results of 20.42 days' reduction between screening to the first treatment visit, 30.15 days' reduction between screening to diagnosis, and 17.54 days reduction between diagnosis to the first treatment visit demonstrate that nurse navigators have a clinically significant potential to reduce about one third to full days of the nationally defined waiting times. The use of nurse navigators may be one of the key interventions to improve cancer outcomes by facilitating timely access.

Along with improved timeliness of care, our study findings demonstrated 13.0% to 45.0% increased completion rates of cancer diagnostic and treatment services in the nurse navigated group with very low to low quality of evidence. However, the effect sizes of both completion rates were statistically insignificant. Thus, the results can be interpreted as nurse navigators potentially having the ability to increase completion rates of cancer care services. Our study outcomes of increased completion rates, as well as the outcomes of shorter waiting times, suggest that nurse navigators can facilitate a higher proportion of individuals receiving early diagnosis and treatments if diagnosed with cancer. A possible explanation for the positive impact of nurse navigators may be explained by improved communication between healthcare providers and patients. In actual clinical practice, cancer treatment refusal rates were lower (48.5%) among untreated patients who had involved healthcare providers when making the decision to treat, compared to those who had made their own (69.0%) without healthcare providers [5]. Additionally, the researchers who identified treatment refusals in countries with universal health insurance strongly emphasize the need for adequate communication between healthcare providers and patients [3,4]. Sufficient communication will increase the likelihood of building trust between providers and patients and providing enough education about diagnosis and treatment options. Nurse navigators may play an important role in facilitating communication between cancer care providers and patients, thereby assisting in decision making to treat during the transition from screening to the first treatment phase.

Despite finding no remarkable effects on improved psychological outcomes, our included studies suggested a very low quality of evidence that study participants were highly satisfied with the nurse navigators. Our study findings were consistent with the results of previous meta-analyses in which cancer patients also expressed high satisfaction with the nurse navigators [16]. These results can be explained by the patient-centeredness characteristic of the service, which is to deliver individualized care for each cancer patient. Patient-centered care has been recognized as an essential feature of high-quality care since the Institute of Medicine reported *Crossing the Quality Chasm* in 2001 [47]. However, we are still at an early stage of integrating patient-centered care in the healthcare system for quality improvement. For example, the study conducted at Korea Institute for Health and Social Affairs reported that awareness of patient-centered care was increasing among Korean healthcare providers, but whether the value has been realized in clinical sites is not yet clear [48]. As the services provided by nurse navigators require the incorporation of patient-centered care, the spread of this program could mark a step forward towards fulfilling the value in real clinical settings, improving the quality of the cancer care system.

Our subgroup analysis results demonstrated that nurse navigators who worked as primary members in multidisciplinary team programs had the greatest effect on improving the timeliness of care during screening to the first treatment phase. These outstanding MDT (NN) size effects might be the consequence of nurse navigators working in multidisciplinary team programs in a more structured way with cooperative multidisciplinary healthcare providers, thus allowing efficient integration of interdisciplinary professionals. Additionally, nurse navigators who actively played a liaison role showed greater size effects than did the navigators who inactively played a liaison role during all evaluated phases. The greater effect of nurse navigators with an active liaison role suggests the importance of nurse navigators' role in facilitating multidisciplinary teamwork. The central role of nurse navigators among multidisciplinary healthcare professionals has been well identified in a previous study [14]. The significance of the multidisciplinary cancer care model has been recognized by many healthcare providers, and the Commission on Cancer has recently announced new 2020 standards that incorporate multidisciplinary participation in cancer care [11]. Nurse navigators will be a valuable resource in upcoming multidisciplinary cancer care settings.

Limitations

A limitation in this study was that included studies lacked a rigorous design. Out of 16 included studies, 81.3% (13 studies) were non-RCTs, including eight before and after studies without control groups. According to Cuijpers, Weitz, Cristea, & Twisk [49], combining the results of prestudies and poststudies for meta-analysis might result in biased outcomes. However, the role of nurse navigators was newly emerging in the current healthcare system, and before studies and after studies constituted the main current literature about nurse navigators. Conducting this study was meaningful as the results suggest the potential and actual value of nurse navigators in the current cancer care system. In the future, additional meta-analysis should be performed with primary studies, including control groups.

Another limitation was the exclusion of the term *case management* within the search strategy. Despite the interchangeable use of *navigators* and *case managers* [45], the reason for not including *case management* in this study was because of the presence of distinct

differentiation in the use of terms between patient navigation and case management [50]. Both concepts focused on providing needs-based care, although the historical context and some functions differed [50]. With the more recent introduction of patient navigation in the 1990s, compared to case management, which emerged from the early 1900s, this study attempted to explore the effects of nurse navigators by assuming the role of nurse navigators and case managers were dissimilar. However, as delineated in the results section, many of the tasks performed by nurse navigators overlapped with the role of nurse case managers. Thus, future studies may consider applying the term or concept of *case management* led by nurses when conducting a systematic review or other types of studies relevant to nurse navigators.

Last, despite the presence of nurse navigators' studies conducted in Europe or Asia [50], most included studies in this review were conducted in the United States and Canada. However, similar findings were also identified in relevant review articles. In a systematic review by Wu et al. (2021) [45], eight out of 11 included studies (72.7%) were conducted in the United States. Also, in a scoping review by Kelly et al. (2019) [50], 120 U.S. studies (75%) and 26 Canadian studies (16.3%) were included out of a total of 160 studies. The reasons might have been caused by the variations in patient navigation definitions and use of terms across countries due to different governing healthcare systems (e.g., US Medicare, universal healthcare), various ways of integrating patient navigation within each individual healthcare facility, and the original emergence of patient navigation in the US cancer care setting [50]. Further studies are recommended to devise a broad search strategy to include studies from more diverse countries.

Implications for nursing research and practice

This study provides baseline data on the effects of nurse navigators during the transitions from screening to the first treatment visit phase within the multidisciplinary cancer care system. Our study findings suggest the need for conducting primary research, with an additional focus on providing stronger evidence for the nurse navigators' role in resolving psychological distress. At the same time, this study offers an idea of how the role of nurse navigators should develop in a future multidisciplinary cancer care system. For practitioners, our results recommend the use of nurse navigators during the transition phase of cancer screening in the course of the first treatment visit to improve timeliness of care and to increase completion rates to care services. In addition, our subgroup analyses findings encourage clinicians to use nurse navigators in multidisciplinary cancer care settings. In a cancer care setting where implementing multidisciplinary team programs might yet be difficult, a beneficial effect could still be obtained by fostering nurse navigators to liaise actively with clinical nurses.

Conclusion

In short, very low to moderate quality evidence suggested nurse navigators were effective in reducing waiting times and in facilitating the utilization of cancer care services from the time of the screening phase to the first treatment visits. Moreover, very low quality of evidence demonstrated that nurse navigators might enhance the satisfaction level with cancer care services, which may lead to improved quality of cancer care. However, current nurse navigators have limitations in relieving psychological distress. Nurse navigators will play a significant role in multidisciplinary cancer care systems that link interdisciplinary professionals to derive the best patient outcomes. The involvement of nurse navigators may improve overall cancer outcomes and the quality of care by bridging the gaps currently caused by cancer care fragmentations. Further, rigorously designed studies are needed to evaluate the accurate and precise impact of nurse navigators.

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Ethical approval statement

Exemption was granted from ethics review (IRB No. 201711-SB-071-01).

Declaration of competing interest

No conflict of interest has been declared by the authors.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.anr.2021.10.001.

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Research Article

Male Nurses' Experiences of Workplace Gender Discrimination and Sexual Harassment in South Korea: A Qualitative Study

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ABSTRACT

Purpose: The purpose of this study was to explore male nurses' experiences of workplace gender discrimination and sexual harassment in South Korea.
Methods: Phenomenological qualitative methodology exploring male nurses' experiences was employed to collect data, and thematic analysis of the data was conducted. Research subjects were recruited by convenience and snowball sampling. Ten male nurses participated in individual in-depth interviews via mobile phone. Data were collected from June 15 to July 24, 2020.
Findings: Two themes were extracted that described male nurses' experiences of workplace gender discrimination and sexual harassment. In the first theme, "facing gender discrimination from various dimensions," nurses' thoughts and feelings regarding gender discrimination from various sources were expressed. The second theme, "experiencing sexual harassment at work as a man," presented experiences of sexual harassment as a male nurse and difficulties in being recognized as a victim.
Conclusion: Gender discrimination and sexual harassment experienced by male nurses stem from a wide range of socio-cultural factors, ranging from individuals to organizations, and institutions. Therefore, this problem requires a correspondingly broad approach for improvement, such as making efforts to avoid classifying certain roles according to gender, developing new standards considering the specific experiences of men as victims of sexual discrimination and sexual harassment, and continuing training to increase social sensitivity and interest in the harm suffered by minorities in society.

Introduction

As the number of male nurses continues to increase worldwide [1–3], it can be predicted that male nurses will play a more important role in the healthcare field. According to the statistics of the Korean Nurses Association [4], the number of male nurses in South Korea (hereafter, Korea) increased by 6.5 times between 2009 and 2019. The proportion of male nurses among those who were newly licensed in 2019 was 13.8% [4], which is higher than the ratio of male nurses (9.4%) reported in the United States in 2020 [5]. Despite the steady increase in the number of male nurses, nursing is still a profession where women constitute the majority, and male nurses are still perceived as men who have chosen a nontraditional career [6]. As such, it has been reported that male nurses experience several stereotypes at work [7–9].

Previous studies on male nurses' work experiences found that male nurses experienced difficulty in establishing comfortable relationships with female nurses, felt alienated [8], and experienced different expectations from those of female nurses [8,9]. Differences in work content, work environment, or job-related opportunities according to gender in healthcare institutions can lead to discrimination, and male nurses have also reported experiencing gender discrimination in the workplace [7,9,10]. Social expectations and prejudices toward male nurses can lead to negative results. In fact, some male nurses reported that they themselves were unclear about their future as hospital nurses [11], experienced gender role conflict in their workplace [12], and therefore considered job turnover [13].

Another issue that should be noted is male nurses' experiences of sexual harassment in the workplace. Most previous studies related to sexual harassment in the workplace have defined women

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as victims and men as perpetrators [14–19], and sexual harassment in the workplace has been defined as being perpetrated by a person with social power in a higher position [19]. Even based on the traditional definition of workplace sexual harassment, nursing is a women-dominated profession with more women leaders in power than men [8]. Therefore, the sexual harassment experiences of men as minorities in the nursing profession should be studied, and this issue should be managed as an important problem in the workplace. According to a previous study that was conducted in Korea, approximately 20% of nurses reported experiencing sexual harassment in the workplace [20]. The perpetrators of sexual harassment were mainly patients, and it should be noted that the proportion of male nurses who reported experiences of sexual harassment was about 38%, which was higher than that of female nurses [20]. In a study conducted in Australia, 34% of male nurses reported that they had experienced at least one type of sexual harassment in the workplace [21]. The number of male nurses who participated in both of those studies was small to generalize the research results [20,21], but the fact that this phenomenon continues to be relatively unnoticed because of the small number of male nurses creates a vicious circle that lowers the likelihood of these problems improving in the future. However, unfortunately, it was difficult to find a study examining sexual harassment experiences at work only among male nurses, although a previous study explored experiences of sexual harassment among male physicians in the United States and reported that experiences of sexual harassment were not uncommon among men, especially those working in healthcare [22]. Therefore, studies on reverse gender discrimination and sexual harassment experienced by men in female-dominant groups, especially in the healthcare field, should be dealt with in more depth.

Previous studies have provided valuable insights into the clinical experiences and barriers faced by male nurses in a female-dominated profession [6–8]. However, less research in the field of nursing has addressed workplace gender issues in depth, including sexual harassment within the socio-cultural context of masculinity and femininity. Therefore, this study explored various cases of gender discrimination and sexual harassment experienced by male nurses in the workplace through qualitative research and also explored male nurses' attitudes and possible ways to improve their work environment.

Research question

What is the nature of male nurses' experiences of workplace gender discrimination and sexual harassment?

Methods

This study was conducted using phenomenological qualitative methodology [23] and thematic analysis [24], which is a simple and flexible method, to understand the essence of the participants' experiences of workplace gender discrimination and sexual harassment as male nurses. In-depth interviews with semi-structured questions were used to guide the interviews. The reporting of this study complies with the consolidated criteria for reporting qualitative research (COREQ) recommendations [25].

Participants

The study participants were male nurses working at hospitals with more than 6 months of career experience. Ten individuals, who were able to voluntarily share their experiences after hearing about the aims of the study and the interview method, participated in the interviews (Table 1).

The sampling of male nurses was conducted based on convenience and snowball sampling method. Because the interviews were conducted by mobile phone (according to the quarantine guidelines of social distancing principles due to the coronavirus disease 2019 pandemic) [26], the researchers provided the research explanations and consent form prior to the interview via email to the subjects who had stated their intention to participate in the study, and they were asked to fill out the consent form. After it was confirmed that a subject had submitted a written consent form for research participation, the researchers sent a concise questionnaire, which the subject was instructed to fill out and submit. The questionnaire contained questions eliciting information on the general characteristics of the research subjects and allowed the subject to select the desired time for an interview and to choose an online interview method (mobile phone or video call). All 10 nurses who participated in the study chose to be interviewed via mobile phone, with no video component.

Qualifications of the research team

One author is a woman, and the other is a man. Both the authors are PhD-level scientists and were working as professors at universities located in two different cities at the time of the study. Both authors who participated in this study are familiar and experienced with qualitative research methods. The authors attended a course on qualitative research methods during their graduate degree program. All of the interviews were conducted by the female author for neutrality in the interview process. The interviews were transcribed by two research assistants.

Data collection

For data collection, recruitment advertisements for research participants were posted on online communities and social media frequently accessed by nurses. In addition, male nurses were introduced through nurses known to the researchers, and snowball sampling was used in the next step. Data collection took place from June 15 to July 24, 2020. The study subjects did not have any prior personal relationship with the researcher. Therefore, the study subjects first contacted the researcher voluntarily through the researcher's mobile phone number presented in the recruitment notice, and the subjects who expressed their intention to participate were sent informed consent forms in the order that they replied. During this prepreparation process, the researcher who planned to conduct the interviews was able to judge the suitability of the research subjects and established a relationship with them through text messages and e-mails. Five male nurses expressed their intention to participate after seeing the recruitment notice, and 10 nurses expressed their intention to participate in the study through introductions from male nurses who had completed participation using the snowball sampling method. Consequently, a total of 15 male nurses expressed their intention to participate, of whom three answered that they had no experience of workplace gender discrimination or sexual harassment; therefore, they were excluded from the study. Subsequently, two nurses who expressed their intention to participate in the study did not proceed with the interviews because the research team decided that data saturation had been reached. As data collection and data analysis for each subject were conducted simultaneously, data saturation was confirmed based on a daily debriefing between the authors, and data collection was finished when no new information was generated from the interviews. Thus, data from 10 participants were finally included.

Information was collected on age, marital status, educational level, hospital location and nursing unit, position, career years, and

Table 1 *General Characteristics of the Study Participants (N=10).*

Participant ID	Age (years)	Marital status	Education level	Hospital location	Number of beds	Nursing unit	Total clinical career	Shift type
1	28	Unmarried	Bachelor's degree	Capital region	>1,000	Surgical ward	2 years 11 months	3 shifts
2	31	Married	Bachelor's degree	Capital region	>1,000	Medical ward	7 years 1 months	3 shifts
3	26	Unmarried	Bachelor's degree	Capital region	>1,000	ICU†	9 months	3 shifts
4	32	Unmarried	Bachelor's degree	Capital region	>1,000	Surgical ICU†	7 years 2 months	3 shifts
5	31	Unmarried	Bachelor's degree	Capital region	>1,000	Medical ward	5 years	3 shifts
6	25	Unmarried	Bachelor's degree	Capital region	>1,000	ICU†	1 year	3 shifts
7	33	Unmarried	Bachelor's degree	Capital region	>1,000	Pediatric ICU†	8 years 6 months	3 shifts
8	35	Married	Bachelor's degree	Capital region	>1,000	Medical ward	11 years 1 months	3 shifts
9	26	Unmarried	Associate degree	Non-capital region	800–999	Medical ward	1 year 3 months	3 shifts
10	42	Unmarried	Associate degree	Non-capital region	100–249	ICU†	10 years 2 months	Night fixed

Note. † ICU = Intensive care unit.

type of shift through a simple questionnaire to investigate the sociodemographic characteristics of the subjects.

In-depth interviews were conducted by a researcher one-on-one at a time that participants preferred using mobile phones. The interviews lasted from 60 minutes to 120 minutes, and each participant was interviewed once. Since the interviews were conducted using mobile phones, nonverbal expressions could not be included. For compensating this, open-ended questions were used to encourage subjects to continue expressing the emotions related to their experiences, and the interviewer used active listening, paraphrasing, and reflecting skills during the interview process. Therefore, for some participants, the interviews took more time than would have been likely for face-to-face interviews. Field notes were taken by the researcher during the interviews. After the interviews, the subjects were informed of the possible need for an additional interview, and verbal consent was obtained. However, based on the interviews with 10 subjects, the authors did not find any new research questions related to the research topic that had to be added. All of the interviews were audio-recorded using a digital recorder. The questions for the participants' interviews used a semi-structured interview guide that was constructed through discussion among researchers and a literature review [3,6,8–10,13,27]. Before starting the interview, the definitions of workplace gender discrimination and sexual harassment used in this study were explained to the study subjects, and they were asked if they had experience with this phenomenon and could speak frankly about their experiences. Subsequently, the participants were notified of the research topic and research questions before the interview, giving them sufficient time to consider the research topic. The main questions for the interview were: "Tell us about your experiences of gender discrimination and sexual harassment while working as a nurse," "What are your feelings and thoughts about the experiences?" and "How have you been dealing with gender discrimination or sexual harassment at work?"

At the end of the interview, the researchers checked once again whether the participants felt uncomfortable about participating in the study and whether they consented to data analysis and utilization. All 10 participants expressed their voluntary consent; therefore, there was no drop-out.

Data analysis

In this study, the subjects' statements collected through in-depth interviews were analyzed through the thematic analysis method suggested by Braun and Clarke [24]. First, the transcribed data were read multiple times by the researchers to familiarize themselves with the content of the interviews. Second, initial codes were generated by finding 497 meaningful and interesting statements in the data. Third, 32 subthemes and 11 themes were formed by collating codes into potential themes. Fourth, the subthemes and themes were reviewed to check whether they worked in relation to the entire data set. Fifth, an ongoing analysis was conducted to refine the themes, which were finally named and defined. Finally, the report presented in the Findings section was produced. The data analysis process was conducted by two researchers at the same time, and the selected sentences, phrases, the classification process, and findings according to the categorization were reviewed. This process was continued until the researchers reached an agreement.

For ensuring the qualitative rigor of this study, the four criteria established by Lincoln and Guba [28] were used. For enhancing credibility, the analyzed data were returned to three participants, and their feedback was applied to the findings to confirm the reliability and accuracy of the analysis. Participants who had experienced workplace gender discrimination and sexual harassment were selected using snowball sampling to ensure transferability, and detailed descriptions with quotations were provided in the manuscript. Dependability was ensured by describing the study design and data collection process in detail. Before conducting each interview, the researchers conducted a reflective analysis to confirm that the process was proceeding as intended. All authors participated in the data analysis simultaneously and debriefed daily with each other to ensure confirmability.

Ethical considerations

This study was approved by the Institutional Review Board (IRB) of the institution where the first author was affiliated before data collection(Approval no. KYU-2020-053-01). This study was conducted in accordance with the principles of the Declaration of Helsinki and the guidelines provided by the IRB. Before starting each interview, the researcher informed the participant about the purpose of the study, the interview process, and plans for using the collected data. Written informed consent was submitted by e-mail or mobile phone, and the participant was informed that the interview would be recorded. Careful attention was paid to the collection of mobile phone numbers and e-mail addresses, as the survey and interview were conducted online. Additional consent was obtained for the collection of the above-mentioned personal information, and it was used only for conducting the interview and sending a gift as a reward for participation. In addition, participants' contact information was kept in a separate file that only two researchers could check and was discarded after the reward coupon for participation was delivered to participants' mobile phones. The interview content and transcripts were coded in a way that the subjects could not be identified.

Findings

This study analyzed male nurses' experiences using the methods proposed by Braun and Clarke [24]. Based on meaningful statements, 12 codes, five subthemes, and two themes were identified (Table 2).

Theme 1: Facing gender discrimination from various dimensions

This theme contains three subthemes: "experiencing unfair treatment from nursing colleagues," "burden of standing out as a 'man' rather than a 'nurse'" and "institutional discrimination that makes male nurses think they cannot stay longer."

This theme presents various types and dimensions of gender discrimination experienced by male nurses at their workplace. It was found that gender discrimination in the workplace occurred both from nursing colleagues and from patients and patients' families, who are the subjects of nursing. In addition, discrimination at the level of the organization and institution of the workplace to which male nurses belonged was confirmed.

Experiencing unfair treatment from nursing colleagues

This subtheme deals with unfair treatment and discrimination committed by nursing colleagues. Many nurses described being called upon when physical labor was needed for nursing tasks because their colleagues thought they would be strong due to being "men." A participant also described a situation wherein a female nurse was unable to work night shifts due to pregnancy or childbirth, and a male nurse was forced to work additional shifts rather than supplementing the workforce. Some of the participants stated that a bias was already present among nursing colleagues or nursing managers who expressed worries about whether male nurses would be able to adapt well. In other words, the nursing colleagues or nursing managers spoke as if they would give male nurses a fair chance, but their statements reflected their underlying perception that male nurses would not be able to adapt well.

> *"There seems to be a sense of masculinity. A sense that men should do the physical work?"* (Nurse 9)

> *"Because you are a man, you have good stamina. […] There was a time when there were multiple pregnancies (among nurses) in one ward, so we only had 6 days off during the month. […] There was almost no replacement personnel. […] I think I was on the night shift for 10 nights in a row."* (Nurse 8)

> *"In my opinion, people who have the wrong idea, those who basically think nursing is a female-majority field, those who are concerned about men. I think that concern itself is an undervaluation."* (Nurse 1)

Burden of standing out as a "man" rather than a "nurse"

The subtheme presents negative attitudes toward male nurses from patients or their families, who are the subjects of nursing care. In particular, male nurses were disappointed and frustrated when their patients refused to let them perform nursing care and asked to change to another nurse. Since male nurses are a minority compared to female nurses, they talked about the inconvenience of receiving unwanted attention due to their noticeable status. Additionally, the prejudice that men are generally slower, blunter, and less sensitive than women led to the idea that they would not be suitable as nurses.

> *"The patient was uncomfortable about being assigned a male nurse from the beginning and requested a switch …"* (Nurse 3)

> *"Just because I am male? I get noticed. Huh, a man? People looking at me like that, I feel a bit uncomfortable. I also thought, 'Am I doing something I shouldn't be doing?'"* (Nurse 1)

> *"People think men have slower hands. That they can be a bit blunt. They thought male nurses might not have good relationships with patients. They also think men cannot multitask well."* (Nurse 1)

Institutional discrimination that makes male nurses think they cannot stay longer

This subtheme addresses various types of discrimination that exist even within the institutions to which male nurses are affiliated. Many complained of the inconvenience of having to travel long distances to use the toilet or changing room due to the lack of facilities for male nurses. Male nurses also experienced limitations in providing nursing care to female patients. In addition, they stated that they were discriminated against in terms of vacation and welfare benefits in comparison with female employees. Female

Table 2 *Themes, Subthemes, and Codes of Male Nurses' Experiences of Workplace Gender Discrimination and Sexual Harassment.*

Themes	Subthemes	Codes
Facing gender discrimination from various dimensions	Experiencing unfair treatment from nursing colleagues	Feeling of being used mainly for physical work
		Unpleasantness of hearing worries about male nurses' adaptability
	Burden of standing out as a "man" rather than a "nurse"	Frustration from patients' refusal to allow them to provide care
		Facing prejudices about men at work
		Unpleasant interest from patients and patients' families
	Institutional discrimination that makes male nurses think they cannot stay longer	Discomfort at work due to a lack of facilities
		Feeling of not being regarded as a professional when internal regulations limit their work
		Disappointment with unfair welfare and vacation regulations
Experiencing sexual harassment at work as a man	Too subtle to say "this is harassment"	Difficult to distinguish between intimacy and harassment
		Regretting not having recognized harassment immediately
	Finding it hard to be recognized as a victim	Hard to understand ambiguous definitions of sexual harassment between men and women
		Facing a lack of social empathy and interest in male victimization

nurses receive menstrual leave, but male nurses find it even difficult to receive official leave for military duties.

> *"The structure of the ward and such facilities are built mainly for women because there have been more women in the past. For example, even bathrooms, mostly there aren't any male bathrooms for employees. So men, if they want to go to the bathroom, they have to go to the public bathroom outside of the ward. Changing rooms too, because there are few men, changing rooms for female nurses are all close to the ward, but the changing rooms for male nurses are isolated further away from the ward. This environment is not great."* (Nurse 5)

> *"For example, I know it differs across hospitals, but in this hospital, doctors put in the Foley for male patients. Same with CIC (clean intermittent catheterization). For female patients, nurses do it. It's not documented in the guidelines or regulations. But the work is distributed that way. This is a remnant of very long-held gender stereotypes."* (Nurse 4)

> *"At first, when I first started working, I don't know which ward, but there was a ward that explicitly said we don't need male nurses. […] For male nurses, it's a bit limited when putting a Foley in. Male nurses don't do it for female patients, but female nurses can do it for male patients. I think it's because of that. I heard other hospitals prefer female nurses for those reasons."* (Nurse 9)

> *"When they make the work schedule, most women have menstrual cycle days protected by law. […] I first felt this was an issue. I need some scheduling accommodation for reserve forces training. It's not like I'm going on a personal trip. But the training schedules are not notified a month in advance. […] The schedule is notified two, three weeks in advance. I need to attend the reserve forces training because I was in the military where I served our country. But they got really angry and didn't understand this."* (Nurse 8)

Theme 2: Experiencing sexual harassment at work as a man

This theme contains two subthemes: "too subtle to say 'this is harassment'" and "finding it hard to be recognized as a victim."

This theme deals with subtle sexual harassment experienced by male nurses. Male nurses stated that it was an embarrassing and unpleasant experience but that it was too subtle to take issue with overtly.

Too subtle to say "this is harassment"

In this subtheme, the male nurses stated that after getting somewhat close with nurse colleagues, sometimes physical contact and sexually harassing remarks were made; however, it was difficult to recognize such behavior as sexual harassment at the moment, and it was even more difficult to take issue with it after a period of time. There was an additional explanation that it was difficult to distinguish whether or not the female nurses who made these sexually harassing behaviors and remarks had negative intentions. The harassment appeared in the form of intimate jokes, so male nurses had a hard time figuring out how to deal with it.

> *"Because we are somewhat close, they say it like a joke. They say it like that. Like a joke? But it's subtle …"* (Nurse 1)

> *"One of the nurses, she was female, asked me how tall I was. […] I answered without thinking twice, but later I realized [the actual intent of the question] because other people told me. That's also sexual harassment. 'How did you meet your girlfriend?' Like that."* (Nurse 6).

> *"I'm not sure if there are people who intentionally make harassing comments. So in that situation, when I hear those comments, when I start to think 'this feels a bit weird,' I was not able to say, 'don't do this.' I think it's a bit awkward."* (Nurse 1)

Finding it hard to be recognized as a victim

This subtheme addresses the lack of awareness that men can also be victims of sexual harassment. The participants reported that there were many cases where words and actions perceived as sexist or sexual harassment were not perceived to be a problem when they were done by a female to a male. They also stated that due to the low overall awareness that men can be sexually harassed by women, even male nurses were often unaware of this possibility. It was pointed out that sexual harassment was permitted as an extension of gender discrimination because the perceptions and standards of sexual harassment differ between men and women and are ambiguous.

> *"For example, a patient putting a piece of fruit in my mouth. But even that, for example, when an older man says 'open up, I'll feed you a strawberry' to a young female nurse, some might be okay with that. I just went 'ah- ', but later when I thought about it, I had experienced sexual harassment."* (Nurse 8)

> *"For example, physical touch. Male nurses don't touch female nurses. This is just a social given. But it's very common for female nurses to pat male nurses on the shoulder or the back or the stomach. Because society does not define it as such, most of the time they don't recognize it as being sexually harassed."* (Nurse 2)

Discussion

This qualitative study explored gender discrimination and sexual harassment experienced by male nurses in the female-dominated nursing field. The phenomenological qualitative method enabled researchers to reveal the essential content and structure of male nurses' perceptions through in-depth interviews with 10 participants in Korea.

Male nurses' gender discrimination was revealed to be primarily affected by three stakeholders: nursing colleagues, patients, and institutions. There were cases of receiving requests for help from nursing colleagues when they needed physical strength or being asked to work additional night shifts. Male nurses also stated that they felt prejudices inherent against male nurses, although nursing colleagues disguised those prejudices in comforting and concerned words. Gedzyk-Nieman and Svoboda [29] conducted a study to discover attitudes of acceptance of male nurses using a survey on sexist attitudes and reported that female nurses had a lower acceptance toward male nurses than male nurses did [30]. Male nurses made efforts to work harmoniously with female nurses as colleagues, as has also been discussed in previous studies [7,8,31]. However, male nurses' feelings of not being accepted by female nurses seem to have continued for a long time [30]. In the findings of this study, male nurses felt that they were recognized as support personnel when there was a need for physical strength rather than being recognized as nursing colleagues by female nurses, which aligns with the results of those previous studies.

Furthermore, male nurses faced rejection by the patients they were taking care of simply because they were male and because the patients preferred female nurses. Choi and colleagues [32] likewise reported that male nurses experienced being rejected when attempting to provide nursing care, and other studies have also reported similar experiences in other countries [7,33]. Earlier studies have reported that patients preferred female nurses [34] or nurses of the same gender as themselves [35]. In connection with these findings, it should be noted that patients want to receive nursing care in a comfortable environment, and healthcare institutions are pursuing patient-centered care worldwide [36].

The phenomenon of female patients refusing to receive care from male nurses is linked to the findings found in this study that male nurses were occasionally regarded as "men" rather than as "nurses." This aligns with the other findings of this study regarding stereotypes about men and the stereotypical perception that nursing is a female job. Korea has been strongly influenced by Confucianism, in which the patriarchal system is deeply rooted, and men who choose jobs perceived as "females' jobs" tend to be stigmatized, and doing so is seen as taboo [37]. This social prejudice has also been reported as an issue in other Asian countries [38,39]. This cultural and social atmosphere can cause discomfort when female patients receive nursing care from male nurses. Conversely, when caring for female patients, male nurses may feel uncomfortable when they make contact with sensitive body parts, and this anxiety may interfere with the mindset of providing professional nursing care as a nurse. A previous study found that male nurses had been misunderstood as inappropriately touching female patients when unavoidable physical contact took place during the nursing process [32]. It is also possible that some patients may have legitimate reasons for preferring a same-gender nurse, including previous experiences of gender violence or sexual assault. In light of this atmosphere, the social perception that patients can choose the gender of their nurses raises doubts about nurses' professionalism and may cause role conflict for male nurses. This conflict can be further amplified when hospitals randomly divide the duties of doctors and nurses according to patients' gender. In fact, some of the subjects had been limited in the scope of work that they could perform, and there were also departments that male nurses could not be assigned to. This coping method can damage the social status and professionalism of nurses by arbitrarily limiting the role of nurses and may also constitute institutional gender discrimination. In addition, healthcare institutions should also handle this issue with great caution, as it may affect male nurses' opportunities for employment or promotion in the future.

Sexual harassment in the workplace has been defined as a hostile work environment involving threats to make employment-related decisions (e.g., hiring, promotion, or termination) on the basis of target compliance with requests for sexual favors or sex-related conduct that unreasonably interferes with an individual's work performance or creates an intimidating, hostile, or offensive working environment [16]. Sexual harassment has mainly been perpetrated by men toward female employees [15], and research has focused on female victims under this premise [14]. Workplace sexual harassment also has the characteristics of using position and power [17], and in the case of service workers, it includes cases where the customer engages in sexual harassment from a position of power [16]. In recent years, sexual harassment has been psychologically defined based on whether an individual feels harassed [16]. In this respect, it can be said that the social position of male nurses makes them highly likely to be victims of sexual harassment.

In traditionally male-centered societies, people may consider that women are victims of sexual harassment, and men may be perceived as potential perpetrators. In this study, the participants stated they perceived low levels of sensitivity regarding male victimization. According to Raj, Johns, and Jose [40], men employed in male-dominated occupations were less likely to have experienced workplace sexual harassment and less likely to report harassment or assault by a supervisor. This means that male nurses, who belong to the female-led nursing profession, may be at an increased risk of sexual harassment. In fact, sexual harassment from nurse colleagues frequently involved taking advantage of close relationships and was done in a subtle and ambiguous manner that made it hard to avoid. The perception that men cannot be victims of sexual harassment may also explain the low level of sensitivity that male nurses reported regarding the sexual harassment they had experienced, to the point it can be said that they are in a vulnerable position to identify themselves as victims. These findings show that the characteristics of sexual harassment that men can experience may be different from those of sexual harassment against women. Therefore, it is necessary to elucidate the characteristics of sexual harassment directed toward male nurses through continuing research on their experiences, considering the specificity of the healthcare field, and preparing measures to deal with these issues appropriately.

There are several important lessons and suggestions that can be made based on this study. First, there should be various ways for male nurses to expand their voice as a way to prevent workplace gender discrimination and sexual harassment. This is in line with proposals for the influx and development of male nurses in existing studies [41,42]. To promote the influx of men into the nursing profession, Kane and colleagues [41] recommended the implementation of cognitive programs for gender bias within medical institutions, avoiding the use of gender terminology and stereotypes, and protocols for reporting gender inequality incidents. Brady and Sherrod [43] also recommended strategies to retain male nursing students in educational programs and proposed changes to programs traditionally designed for women. Efforts should be made to avoid classifying certain roles according to gender. Second, newly developed standards considering the specific experiences of men as victims of sexual discrimination and sexual harassment must be established through in-depth studies. A universal standard for both men and women in defining gender discrimination and sexual harassment should be established. Finally, continuing efforts and training should be made to increase social sensitivity and interest in the harm suffered by minorities in society. Both male and female nurses should be aware that they can become perpetrators or victims, even unintentionally.

Limitations

The study had several limitations. First, the geographical range of the study was confined to some districts of one country (South Korea), and most of the participants worked at tertiary hospitals located in the capital region. Therefore, it is necessary to conduct an extended study targeting male nurses working in a wider variety of environments and countries. Second, we did not include nonverbal messages from participants because all interviews were non-face-to-face due to the coronavirus disease 2019 pandemic.

Conclusion

This qualitative study explored experiences of gender discrimination and sexual harassment among male nurses currently working at hospitals in Korea. Male nurses experienced various stereotypes as members of a minority in a female-led profession and experienced gender discrimination by patients, nursing colleagues, and institutions. Sexual harassment in the workplace experienced by male nurses was attributed to a low level of sensitivity to the fact that men could be victims of sexual harassment. Sexual harassment of male nurses was mainly carried out by female nursing colleagues and patients.

In addition to efforts to recognize and understand the different experiences of men and women, increasing the number of male nurses and improving the overall development and treatment of nurses are expected to lead to improvements in the problems of gender discrimination and sexual harassment faced by male nurses.

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Conflict of interest

The authors have no conflict of interest to declare.

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Introduction to the Special Issue: "Nursing Education and Research in the Remote Era"

The spread of severe acute respiratory syndrome coronavirus 2, which started in 2019, reached a pandemic declaration by the WHO on March 11, 2020 [1], and has now penetrated every corner of our lives. As of June 3, 2021, more than 170 million people worldwide have been infected with the coronavirus disease 2019 (COVID-19), and more than 3.7 million have died [2]. The quantitative scale of the number of infected and dead from COVID-19 and related health and medical problems are enormous, and all aspects of society, including the economy, industry, education, research, culture, art, and daily life, have changed since the pandemic. As the importance of social distancing as a strategy to prevent the spread of COVID-19 has been emphasized, the use of online education, electronic payment, and kiosks has skyrocketed along with the words "non-face-to-face" or a newly coined word, "untact."

Education, like other sectors of society, has changed dramatically since the COVID-19 outbreak. Compared to before, interest in online, non-face-to-face, untact, or remote education has increased overwhelmingly. The COVID-19 pandemic has limited classroom learning and clinical practice, two main components of nursing education. Many nursing schools around the world have closed their campuses and maintain only online classes. The increased workload for nurses due to the spread of COVID-19 has pushed back the priority of clinical training for nursing students. Moreover, nursing students have been removed from clinical practice in some countries where the spread of COVID-19 infection has been severe [3]. A virtual classroom education that enables real-time interaction between students and educators has been proposed to replace training in field practice [4]. In addition, a pedagogical caring framework to humanize virtual classrooms and remote or online teaching have also been offered [5].

The differences in infrastructure for digital access between individuals and institutions have created a new issue of educational disparities. Nursing students experienced a number of difficulties with the abrupt transition from traditional learning to remote learning, especially among students with limited electronic resources [6]. Issues such as teaching and learning gaps, inability to conduct proper clinical assessments and standard operating procedures, and disruption towards professional development have been revealed with respect to clinical practice during the COVID-19 period [7]. These issues will inevitably affect nursing students' access to learning opportunities and the establishment of a professional identity and nursing roles, eventually threatening the sustainability of the nursing workforce.

Due to the sudden outbreak of the COVID-19 pandemic, many nursing schools were not sufficiently prepared for education and teaching in remote environments. Limited IT infrastructure, digital illiteracy, and lack of human interaction are some of the challenges facing nursing schools and students. However, an advantage of remote learning is the ability to provide equitable learning opportunities across geographic areas and time. In order to reorganize and promote nursing education in this pandemic era of crisis, we need successful innovation and transformation of on-campus learning and clinical site training so that nursing education can fully progress. Specifically, it requires the joint participation of schools and healthcare providers in governance [8] and the pooling of digital and hands-on education resources such as virtual learning environments [9]. In addition, in order to guide changes in the future, there must be a consideration of the principles, philosophy, and theories of remote education.

The COVID-19 pandemic is also having a profound impact on nursing research. Research into the nursing workforce is on the rise, as medical resources and staff redeployment to support COVID-19 critical care is a global phenomenon. Nursing research to improve understanding of new phenomena, including effective treatment and management of diseases, is also being actively conducted [10,11]. Research in the context of the COVID-19 pandemic has many challenges. First of all, it is essential to establish a good relationship with the clinical team because meeting with patients and their families has become more limited when conducting clinical research [11]. This limitation of access to the field has triggered a digital transformation in nursing research. Researchers are considering non-face-to-face methods such as online or telephone surveys as an alternative to the face-to-face approach. The latest digital technologies, including big data extraction and processing, virtual reality, wearable medical devices, artificial intelligence, and blockchain, have been introduced into the field of nursing research. Their applications in nursing care include hospital information systems, electronic health records, computerized decision support systems, telecare, general communication support, systems to support process planning and/or data exchange, specific applications, and target group-specific interfaces [12]. Digital nursing technologies affect the health, satisfaction, and quality of life of formal and informal caregivers, as well as those in need of care, while influencing the care process, access to care, and communication, and social interaction within healthcare institutions [13]. There are various types of digital technology used in nursing practice, and research and most of them report positive effects, but the level of evidence is relatively weak, or the study sample size is small. Therefore, higher quality studies that can show the effects of digital procedures on nursing care are needed. Meanwhile, a nursing journal club as a means to narrow the gap between research evidence and clinical practice can be implemented virtually, in line with the recent non-face-to-face trend [14].

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Since the onset of the COVID-19 pandemic, the basis of nursing education and research has been changing, and not all of these changes are negative. Even after the end of COVID-19, education is more likely to maintain blended learning and education rather than returning to the predominantly face-to-face system of education and learning. Nursing practice and research have begun to embrace new technologies more actively and are expanding their scope and applicability. The framework of nursing research has also been shifting towards collaborative research teams rather than individual research [15]. As nursing educators and researchers, we must lead a successful transition to a new normal, beyond overcoming the crisis, by collecting and sharing the changes accelerated by the pandemic.

Asian Nursing Research journal has planned a special issue to prepare for changes in nursing education and research after the pandemic and to guide schedules and timelines of transition. The theme of this special issue is "Nursing Education and Research in the Remote Era." We would like to share with our readers the needs, interests, new knowledge, experiences, and perspectives on the following topics: education technology and electronic platforms to support non-face-to-face education, systems and technologies to support nursing care during the COVID-19 crisis, development, and application of nursing interventions to support non-face-to-face nursing care, and mobile or smartphone applications to manage COVID-19-related situations.

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Research Article

Effects of a Thermoelectric Element Band on Venipuncture-associated Pain and Anxiety: A Randomized Controlled Trial

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SUMMARY

Purpose: Venipuncture is an invasive procedure for diagnosis and treatment, which is often attributed to pain and anxiety. In this study, a thermoelectric element (TEE) band was developed to apply heat therapy (40~45°C), cold therapy (0~10°C), or thermal grill illusion (TGI) therapy (40~45°C, 0~10°C) to cause an illusion of pain by simultaneously applying heat and cold. This band was subsequently used to investigate its effect on patient pain, anxiety, and satisfaction.
Methods: This was a randomized controlled study. Participants, who were to undergo venipuncture, were randomly assigned to the heat therapy, cold therapy, TGI therapy, or control groups. Each group had 30 participants. The interventions were employed for 10 seconds during venipuncture, and the pain, anxiety, and satisfaction were measured before and after the procedure.
Results: Subjective pain, anxiety, and physiological responses after TEE band intervention were not significantly different between the four groups. However, there was a significant difference in satisfaction ($F = 4.21$, $p = .007$) between the four groups, and the cold therapy group showed the highest satisfaction.
Conclusion: In this study, when heat, cold, and TGI therapy were applied with a TEE band, pain and anxiety relief effects were not confirmed, but satisfaction was high. TEE band is a newly developed product that can easily apply hot and cold treatments without using ice packs or hot water packs. Further studies with various individual characteristics of chronic pain or repeated venipuncture are warranted to evaluate the effect of TEE.

Introduction

Venipuncture is an essential process in the examination and treatment of individuals in various healthcare settings. It involves the access of a vein for obtaining blood samples and intravenous medication administration for a quick onset of action. Venipuncture is, however, often also a source of anxiety and pain [1,2]. Attempting this procedure on hard-to-find veins has been associated with increased psychological pressure and workload on the staff [2]. Consequently, the novel job position of the "intravenous (IV) nurse," whose work scope includes IV care (including peripheral IV injections and blood draws), was created to alleviate the patients' pain and anxiety associated with venipuncture and to boost the nurses' job satisfaction [3]. Therefore, pain relief associated with venipuncture is an important topic of interest, requiring simple and effective methods to relieve both the psychological (fear, anxiety) and physical aspects of this procedure.

Pain serves as both a warning for potential danger as well as an index of recovery. Despite these positive aspects, pain itself is an unpleasant experience, which coupled with psychological torment, such as anxiety and fear, is further aggravated. Nursing interventions are, therefore, mostly focused on pain and anxiety relief, since the two are closely related to each other [4]. The gate control theory can explain the relationship between pain and anxiety. This posits that a pain sensation can increase or decrease during the process in which the pain stimulus travels up the nerve fibers along the pain pathway. At this point, psychological factors, such as cognition, motivation, and emotional state, affect the stimulation of the large fibers (A-beta fibers) of the spinal cord and alter the experience of the pain stimulus [5].

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Based on this understanding, many studies have explored nursing interventions, which are effective at alleviating the pain and anxiety associated with punctures and injections. Previous studies have included children vulnerable to pain [6–8], patients undergoing hemodialysis requiring punctures regularly [9–13], and patients with diabetes mellitus who undergo regular insulin therapy [14]. Nursing interventions that have been studied include heat and cold therapy [15,16], topical anesthetic cream [6,7,12], distraction therapy [8], aromatherapy [9], and vibration therapy [17,18], all of which have been reported to be effective in pain relief. However, topical anesthetics and aromatherapy are limited in terms of systemic absorption through the skin and the onset of action. Additionally, few studies have attempted to reduce the pain and anxiety associated with venipuncture in adults [17,18], since venipuncture is considered a simple procedure that causes only temporary pain. However, nurses who perform venipuncture are responsible for the patients' sense of wellbeing. Therefore, it is important to continuously strive to identify effective methods of pain and anxiety relief in patient care.

Among the various simple, independent, nursing interventions conducted to relieve pain and anxiety, heat and cold therapies are effective [10]. Heat therapy effectively relaxes the muscles and lowers the pain by increasing the rate of blood flow [15], while cold therapy reduces pain by decreasing the rate of nerve conduction and increasing the pain threshold [19]. Healthcare facilities may have different techniques for heat and cold therapies, which use gel packs, ice cubes, and heat pads [15,19]. Nurses, while remaining within their specialty of patient care, need to expand the scope of independent nursing interventions, as well as to keep abreast of medical technological advances to utilize effective devices for patient care.

A thermoelectric element (TEE) is a module that converts heat energy into electric energy or vice versa. TEEs can be easily used for heating and cooling and are currently utilized in a wide range of appliances and products used in daily life, including cold water dispensers, cooling car seats, and heating and cooling beauty products. Owing to the recent development of a flexible TEE, the range of potential applications has expanded. In this study, we developed a TEE band for the easy application of heat and cold therapy during nursing interventions. This TEE band contains a flexible TEE plate inside the band, and heat and cold can be applied by pressing a button on the power unit. Further, we applied thermal grill illusion (TGI), which simultaneously applies warm and cool stimuli to trigger a sensory illusion of pain relief.

In 1896, Torsten Thunberg first described TGI as the sensation resulting from the simultaneous application of warm and cool stimuli to the skin [20]. The TGI device causes an illusory sensation of pain at a temperature that does not actually cause warm or cool injuries to the body [21], and paradoxically has been reported to be effective in reducing pain [22], particularly neuropathic and chronic pain [23,24]. We decided to investigate whether TGI application would be effective in reducing the level of acute pain experienced during venipuncture.

This study, therefore, aimed to examine the pain and anxiety-relief effects of a flexible TEE band generating instant heat, cold, or TGI therapy during venipuncture, and to determine the patients' satisfaction with it to explore the device applications in various healthcare settings.

Methods

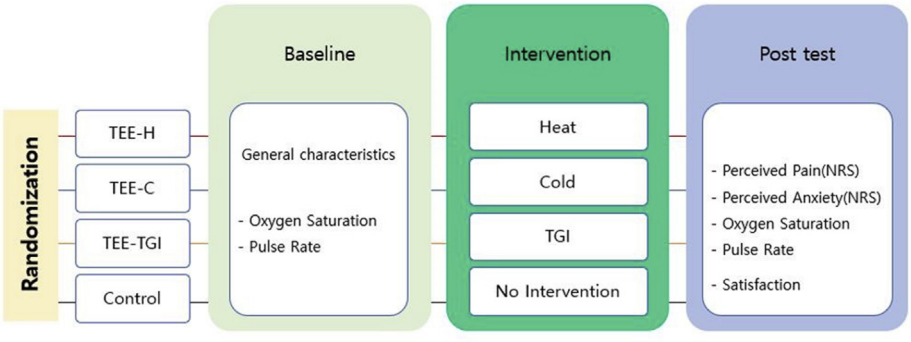
Study design

This study was a randomized controlled trial, designed to evaluate the effects of a TEE band applied during venipuncture for a blood test at a healthcare center. The participants were divided into either a control group, who wore a TEE band without any intervention, or into one of the following intervention groups: the heat, cold, or TGI therapy (simultaneous heat and cold stimuli) groups (Figure 1).

Participants

The participants were recruited from among adults requiring venipuncture for blood tests. The inclusion criteria were 1) aged 20–75 years, 2) history of venipuncture in the past 6 months; a study comparing recalls of pain experiences found that recalling a previous pain experience within 6 months accurately remembered pain and emotions with no difference [25], and 3) no wound present at the venipuncture site. Individuals who were consuming drugs that could have influenced the pain and/or anxiety measures, and those who were incapable of effective communication were excluded.

The sample size was determined using the G-power 3.1.9 program. The calculation parameters were four groups, an effect size of 0.3 [17], an α value of 0.05 and power of 0.80, which resulted in a sample size estimate of 111. Consideration a potential withdrawal rate of 10%, we recruited 120 participants for this study. In order to



TEE-H:Thermoelectric element band-Heat group; TEE-C:Thermoelectric element band-Cold group;
TEE-TGI:Thermoelectric element band-Thermal Grill Illusion group; Control: Control group;
TGI:Thermal Grill Illusion; NRS:Numeric Rating Scale

Figure 1. Study design.

prevent allocation bias, random numbers were generated using Excel's random number generation function before recruitment, and information on each allocation group was placed in a clear envelope and arranged in an orderly manner. Participants were recruited using a recruitment poster as per the recruitment list, the author (HC) opened the envelope and assigned each person accordingly to the TEE-H, TEE-C, TEE-TGI, and control groups. Either heat, cold, or TGI was applied to the participants by means of the TEE band. In the control group, the TEE band was applied without operating the machine. In the course of the research, the author (HC) operated the machine, while the phlebotomist was unaware of the participant's allocation group; the study participant was not aware of the temperature stimulus until the machine was operated. Thirty participants were assigned to each group, and there were no dropouts; therefore, a total of 120 participants completed the study (Figure 2).

Measurements and instruments

1) *TEE band*

The TEE band refers to a wristband developed for this study (Tegway, Daejeon, South Korea). A flexible TEE plate patented in Korea (10-1989908, 10-1829709, 10-1689308) was inserted in the band (5.5 × 3.5 cm), through which heat and/or cold stimuli could be applied using electric energy by pressing the HOT/COLD button on the power unit.

2) *Subjective pain*

Subjective pain was measured using the Numeric Rating Scale (NRS). The NRS is valid, reliable, and appropriate for pain measurement in clinical practice. It has good sensitivity and generates

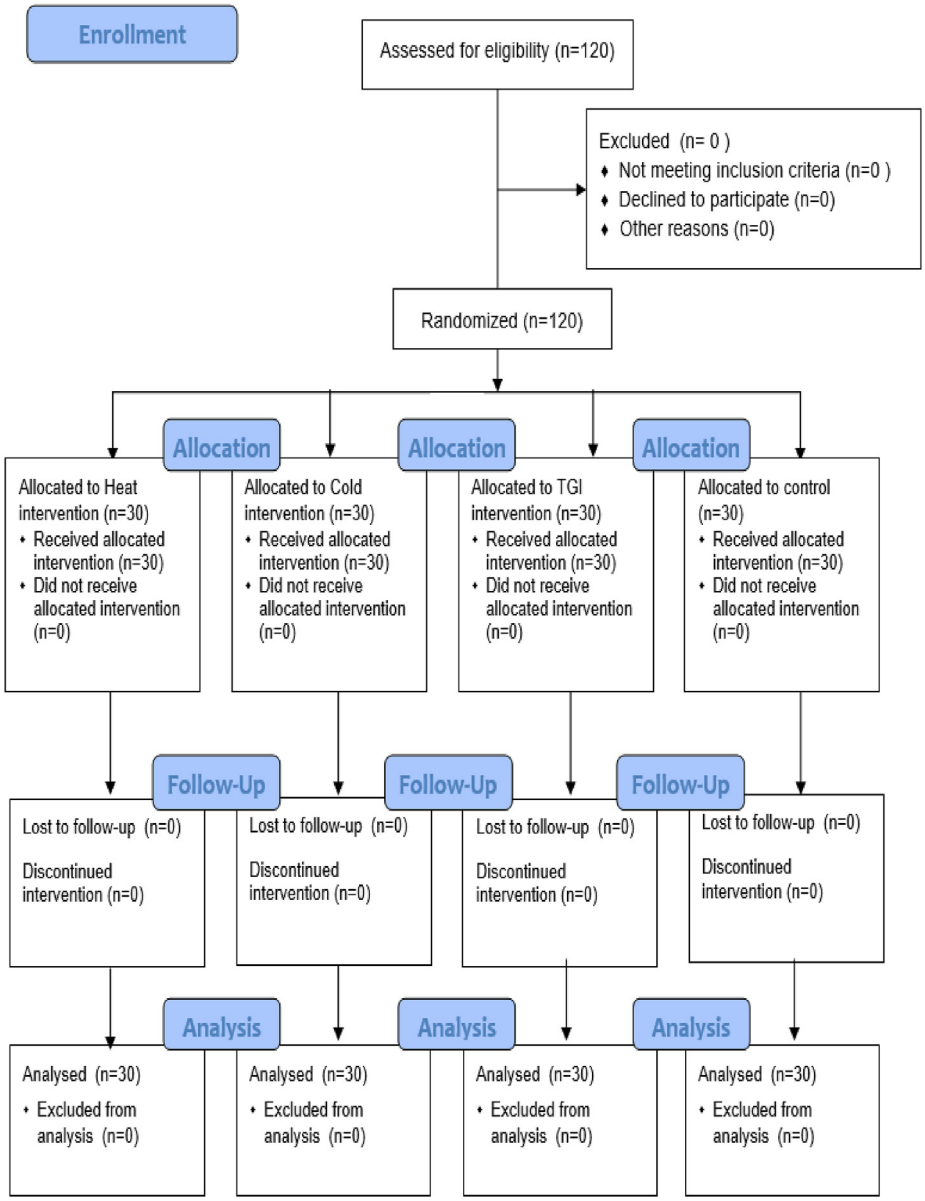


Figure 2. Flow diagram.

data that can be analyzed for audit purposes [26]. Pain was measured in centimeters from 0 “no pain at all” to 10 “very severe pain”.

3) *Anxiety*

Anxiety was measured using the NRS. The NRS is also effective in evaluating anxiety because it is validated and self-evaluated by the subjects [27]. In this study, anxiety was measured in centimeters from 0 “no anxiety at all” to 10 “very severe anxiety.”

4) *Physiological response*

Pain induces alterations in the autonomic nervous system. Physiological responses include biological and behavioral reactions to pain. Physiological changes are parameters that support the measurement and evaluation of pain [28]. Among the physiological parameters, pulse rate and oxygen saturation are used as indicators of pain in various studies due to their objectivity, and changes can be quickly and easily measured through pulse oximeter [6,28–30]. These were determined using the peripheral oxygen saturation rate and the pulse rate, which were measured using a pulse oximeter (MD300 C22, ChoiceMMed).

5) *Satisfaction*

To measure the participants' satisfaction with the TEE band, we developed six preliminary items based on a questionnaire used in a previous study assessing satisfaction [31], and a literature review. The preliminary items were reviewed by an expert panel comprising two nursing professors and three nurses with a minimum of 10 years of clinical phlebotomy experience. After some modifications and improvements, the final version of the questionnaire had 10 items. The content validity of these 10 items was evaluated by an expert panel comprising two Fundamentals of Nursing professors and four nurses with a minimum of 10 years of clinical phlebotomy experience. The content validity index (CVI) for each item ranged from 0.8 to 1.0, with a mean CVI of 0.98. The 10 items used to assess satisfaction were rated on a five-point Likert scale, with a higher score indicating greater satisfaction. The reliability (Cronbach's α) of the tool was .87 in this study.

Interventions

Thermoelectric band development

A TEE is a module that converts heat energy into electric energy and vice versa. TEE is effectively used to produce electricity with heating and cooling features, especially in thermoelectric cooling equipment and parts [32]. While TEE has been utilized in healthcare for heat and cold therapies, the firm and flat structure of the device hinders the immediate expression of cool and warm sensations. A flexible TEE was therefore developed with small pieces of thermoelectric chips to address these shortcomings. This flexible TEE is lighter than a firm TEE and features a rapid temperature response, making it convenient for application on curved body parts, such as a wrist, to provide warmth, cold, and simultaneous warm and cold stimuli instantly.

We utilized this flexible TEE to administer heat and cold therapy to patients since these are independent nursing interventions used in venipuncture. We developed the TEE band through several rounds of discussions with venipuncture experts and flexible TEE developers, focusing on the shape of the band, application method, temperature settings, and patient convenience (Tegway, Daejeon, South Korea) (Figure 3). The TEE band, which was designed to be wrapped around the skin, contains a 5.5 $\times$ 3.5 cm flexible TEE plate within.

The appropriate temperature for thermotherapy for pain-control is based on the contents presented at an average of 41.22 $\pm$ 9.77°C according to the literature review [10,17]. To identify the most effective and safe temperature for cold therapy based on previous randomized controlled trial studies, ice packs of −4 to 4°C and cooling gel packs of 0 to 10°C were recommended [19,33]. This study also aimed to induce TGI in terms of the most suitable degree of temperature difference between the simultaneous cold and warm temperatures. Smaller differences (e.g., 10–15°C) are sufficient for illusory heat, while larger differences (e.g., $\geq$20°C) are required for illusory pain sensations [34]. To summarize, the TEE band set the temperature for heat and cold therapy at 40~45°C and 0~10°C, respectively, to prevent skin burns or other injuries.

Data collection and procedures

Participants were recruited, using a recruitment poster, from a population of adults who were required to undergo a blood test with venipuncture during a health examination from March to April 2021. The volunteers were explained that they would have to wear a wristband during the venipuncture and that the stimulation received would not cause skin damage. All the participants signed an informed consent form prior to participating in the study. The participants completed a questionnaire to gather information on the general characteristics and perceived pain and anxiety experience during their previous venipuncture. Additionally, their peripheral oxygen saturation and pulse rate were measured using a pulse oximeter.

Venipuncture was performed with the participants sitting comfortably in an environment maintained at 23~25°C. A consistent treatment stimulus was maintained to minimize the error in the experiment, and the puncture site was set to the antecubital fossa for all the participants; syringes with the same needle size (5 cc, 22-gauge) and identical serum separator tubes were prepared. A single nurse with more than 5 years of clinical experience was designated the phlebotomist in order to prevent any variability in the characteristics of the experimenter and puncture skills; the phlebotomist was blinded to participant allocation.

We placed the allocation number results, which were generated using the randomization function of Excel and created by the investigator, in a sealed envelope stored in a drawer. Prior to the experiment, each participant was given an allocation envelope to open, at which point we checked the participant's group allocation.

Figure 3. Thermoelectric element (TEE) band.

Group allocation was written in numbers; thus, both the participant and the phlebotomist were blinded to the assigned number and could not anticipate group assignment. When the phlebotomist was ready for venipuncture, we wrapped the TEE band around the wrist of the patient's arm such that the plate was in close contact with the skin, 10 s of the corresponding stimulus was provided: heat (40~45°C), cold (0~10°C), or TGI (simultaneous administration of 40~45°C and 0~10°C). The participants of the control group wore the TEE band but did not receive any stimulation. We turned on the power unit and 10-s timer as soon as the phlebotomist had pulled the skin tautly below the needle injection site such that the corresponding stimuli would be generated. The phlebotomist inserted the needle, collected the 5-cc blood sample, and then removed the needle. The entire process took approximately 10 s. We turned off the power unit of the TEE band following the completion of the 10-s timer. Immediately after needle removal and stimuli elimination through the TEE band, we measured the participants' peripheral oxygen saturation and pulse rate using the connected pulse oximeter and removed the TEE band. The participants were subsequently asked to complete the questionnaires regarding their perceived pain and anxiety following the venipuncture, and their satisfaction with the TEE band.

Data analysis

Data were statistically analyzed using the IBM SPSS Statistics 26.0 software. The participants' general characteristics and dependent variables were analyzed as the frequency, absolute number, percentage, and mean with standard deviation; homogeneity was tested using the χ^2 test and one-way ANOVA. The effects of the TEE band were analyzed using ANOVA. Significant results ($p < .05$) were tested using the Bonferroni post-hoc test.

Ethical considerations

This study was approved by Institutional Review Board at Eulji University (Approval No. EU21-001), and the protocol was registered with a clinical trials registry (KCT0006176) before any data were collected. We explained the purpose of the study and informed the participants that the collected data would only be used for research purposes and that they were free to withdraw from the study at any time. All the participants signed the written informed consent form. Participants were provided approximately $10 as a token of appreciation for their participation.

Results

Baseline homogeneity

A total of 120 participants who were divided into four groups of 30 as heat therapy, cold therapy, TGI therapy, and control groups. The baseline homogeneity of the four groups was no statistically significant differences in sex, age, height, weight, exercise, baseline pain, anxiety, peripheral oxygen saturation, or pulse rate (Table 1).

Effects of the TEE band on variables with venipuncture

1) *Subjective pain*

There were no significant differences in subjective pain among the four groups (F = 1.69, $p = .173$) (Table 2).

Table 1 *Homogeneity Test for General Characteristics and Dependent Variables between Groups (N = 120).*

Variables	Category	TEE-H ($n = 30$)	TEE-C ($n = 30$)	TEE-TGI ($n = 30$)	Control ($n = 30$)	χ^2/F	*p*
		Mean ± D or *N* (%)	Mean ± SD or *N* (%)	Mean ± SD or *N* (%)	Mean ± SD or *N* (%)		
Gender	Female	23 (76.7)	24 (80.0)	22 (73.3)	26 (86.7)	1.77	.622
	Male	7 (23.3)	6 (20.0)	8 (26.7)	4 (13.3)		
Age (yr)		28.40 ± 12.28	26.10 ± 10.59	24.43 ± 8.44	27.83 ± 11.94	0.81	.490
Height (cm)		163.67 ± 6.16	163.10 ± 5.96	164.21 ± 6.81	161.33 ± 7.18	1.09	.356
Weight (kg)		61.77 ± 11.44	60.10 ± 10.90	60.92 ± 12.15	57.38 ± 9.80	0.88	.456
Exercise	None	9 (30.0)	13 (43.3)	9 (30.0)	12 (40.0)	4.19	.652
	Often	18 (60.0)	15 (50.0)	15 (50.0)	15 (50.0)		
	Daily	3 (10.0)	2 (6.7)	6 (20.0)	3 (10.0)		
Pain[a] (NRS)		4.07 ± 1.98	4.43 ± 1.77	4.14 ± 2.00	3.82 ± 1.81	0.54	.656
Anxiety[a] (NRS)		3.09 ± 2.55	3.70 ± 2.63	3.12 ± 2.53	3.35 ± 2.42	0.32	.814
SpO_2 (%)		98.20 ± 1.28	98.30 ± 1.21	98.10 ± 1.35	98.60 ± 1.19	0.88	.455
Pulse Rate (bpm)		92.43 ± 13.86	85.80 ± 13.90	90.33 ± 15.88	84.03 ± 16.65	1.99	.119

Note. TEE-H = Thermoelectric element band-Heat group; TEE-H = Thermoelectric element band-Cold group; TEE-TGI = Thermoelectric element band-Thermal Grill Illusion group; Control = Control group; Mean ± SD = Mean ± Standard Deviation; NRS = Numeral rating scale.
[a] Previous venipuncture experience.

Table 2 *Effects of TEE Band on Pain, Anxiety, Oxygen Saturation, Pulse Rate, and Satisfaction between Groups after Intervention (N = 120).*

Variables	TEE-H[a]($n = 30$)	TEE-C[b] ($n = 30$)	TEE-TGI[c] ($n = 30$)	Control[d] ($n = 30$)	F	*p*
	Mean ± D	Mean ± SD	Mean ± SD	Mean ± SD		
Pain (NRS)	3.30 ± 2.28	2.71 ± 2.10	3.96 ± 2.27	3.57 ± 2.14	1.69	.173
Anxiety (NRS)	1.87 ± 1.63	2.03 ± 1.92	2.63 ± 2.52	1.73 ± 1.82	1.16	.327
SpO_2(%)	98.20 ± 1.19	98.03 ± 1.00	97.93 ± 1.36	98.43 ± 1.17	1.05	.375
Pulse Rate (bpm)	85.70 ± 11.67	80.23 ± 13.31	86.43 ± 14.27	83.33 ± 16.85	1.17	.324
Satisfaction	32.90 ± 8.09	35.30 ± 9.83	32.53 ± 7.13	28.20 ± 6.03	4.21	.007 b > d[†]

Note. TEE-H = Thermoelectric element band-Heat group; TEE-H = Thermoelectric element band-Cold group; TEE-TGI = Thermoelectric element band-Thermal Grill Illusion group; Control = Control group; Mean ± SD = Mean ± Standard Deviation; NRS = Numeral rating scale.
[†] Bonferroni.

2) *Anxiety*

There were no significant differences in anxiety among the four groups (F = 1.16, $p = .327$) (Table 2).

3) *Peripheral oxygen saturation*

There were no significant differences in peripheral oxygen saturation among the four groups (F = 1.05, $p = .375$) (Table 2).

4) *Pulse rate*

There were no significant changes in pulse rate among the four groups (F = 1.17, $p = .324$) (Table 2).

Effects of the TEE Band on satisfaction with venipuncture

Satisfaction significantly differed among the four groups (F = 4.21, $p = .007$), with the TEE-C group expressing the highest satisfaction compared to the control group, as confirmed by the post-hoc test (Table 2).

Discussion

This study aimed to investigate whether a TEE band developed with flexible thermoelectric modules generating heat, cold, and simultaneous heat and cold stimulation would improve the pain, anxiety, and satisfaction in adults undergoing venipuncture. Our study results demonstrated that providing cold therapy with the TEE band during venipuncture resulted in the highest satisfaction, and greatest intention to reuse the device. Previous studies have reported that cold therapy reduced pain during injections and was associated with the highest satisfaction [17,31]. Although previous studies applied cold therapy for 1–13 min for a puncture [11,17], our results confirmed that even a short application of 10 s resulted in satisfaction, a finding which could help enhance the efficiency of cold therapy in clinical practice.

We examined the pain-relief effects of TGI generated using the TEE band during venipuncture. In a previous study, TGI has been confirmed to reduce the pain in patients with persistent pain [23,24]. However, no previous study has examined the effects of TGI on pain during venipuncture. We hypothesized that TGI would be effective in reducing acute pain such as that associated with venipuncture. This was based on the findings that electric stimulation produced by devices, such as an electromyogram, effectively reduced pain by increasing the pain threshold and reducing the pain awareness [35], and that massaging the injection site using pressure following an intramuscular injection also effectively reduced pain [36]. Furthermore, as described by the gate control theory, pain can be controlled by activating the large fiber that will close the gate of the spinal cord and inhibiting the transmission of pain information through small fibers. We, therefore, hypothesized that heat and cold sensations would stimulate the muscle fibers and thus relieve pain. Thus, we designed the TGI by simultaneously generating heat and cold stimuli using the TEE band and we developed a prototype of the TEE band. However, TGI did not reduce pain and anxiety during venipuncture in this study. We speculate that pain was not controlled since the simultaneous heat and cold sensation is a novel sensation, and hence, the body may fail to distinguish between the heat and cold stimuli and therefore fail to close the gate that inhibits pain. Another possibility may be that the intended sensation was not delivered to the participants owing to the differences in skin thickness and sensory processing. Hence, further research is needed to identify the optimal TEE band temperature settings to produce the ideal TGI for each sex and age group.

Also, the post-intervention reduction in pain and anxiety was not significant. This is consistent with previous findings [16,17] and can be attributed to the different properties of anxiety across individuals. In addition, the participants of this study were healthy adults aged 20-75 years, the age range was too wide, and the baseline for pain and anxiety were relatively low, so it seems that the appropriate effect could not be confirmed. Furthermore, the TEE band developed in this study is only a prototype with a focus on the functional aspect rather than the esthetical quality. Therefore, the application of an emotional design to relieve anxiety could help alleviate the participants' psychological anxiety during invasive procedures and facilitate the treatment process [37]. Hence, attractive and emotionally appealing design components would also be essential when developing devices for use in patients in healthcare facilities.

Generally, the sympathetic nervous system is stimulated in the early phase of acute pain, which in turn increases the pulse rate and oxygen demand; these parameters are widely used as markers of pain and anxiety owing to their objectivity [28]. In our study, there was no significant difference in the post-intervention period concerning peripheral oxygen saturation between the four groups, since 10 s was not sufficient for appearance of changes in the peripheral oxygen saturation. In addition, the other physiological response variable, pulse rate, did not show a significant difference, as in a previous study [7,9,30]. These results show that an insignificant physiological response may be insufficient to indicate pain. We, therefore, need to assess more than the physiological response variables.

Heat, cold, and TGI stimuli application with a TEE band is a novel intervention; hence, we interviewed some participants following the experimental treatment. A participant who received cold therapy stated that "It felt cold, and I didn't know that a needle was being inserted." A participant who received heat therapy commented that "I felt the needle coming in and it hurt, but I felt relaxed." While heat and cold stimuli were familiar sensations, participants who received TGI stated that simultaneously feeling heat and cold was an unfamiliar sensation: "It was weird and unpleasant, where it suddenly felt cold and suddenly felt hot" and "I was startled because I had never felt this before." As shown here, most participants felt the intended sensation after 10 s of TGI generated by the TEE band.

Through the interview, both heat and cold therapies applied with the TEE band were effective in reducing pain, and the warmth from heat therapy tended to be more effective than the coolness from cold therapy in promoting psychological relaxation. In this study, heat therapy did not show a statistically significant difference in the reduction of pain and anxiety; however, it was the most effective intervention method experienced by participants during the interview. Moreover, the unfamiliar sensation from the TGI resulted in some individuals experiencing an unpleasant sensation, and thus the pain was not masked at all. Nevertheless, this was the first attempt at using this device in clinical practice and follow-up research is required to further evaluate this method.

Our study has some limitations. First, we compared the pain level during venipuncture by selecting healthy adults without disease who had venipuncture experience within 6 months. Considering that there are individual variations in pain, the pain and anxiety of venipuncture within 6 months were measured by memory of the previous venipuncture experience. In addition, since the TEE band was first created to relieve the pain of venipuncture, it was not possible to reflect individual characteristics by setting the temperature in advance as a pilot study. In addition, there was no study applying TGI to venipuncture; hence, it was difficult to compare the pain relief effect of TGI to venipuncture. Considering the individual variations in pain, a

follow-up study is warranted to target patients who are repeatedly punctured, and it is necessary to investigate the effects on pain and anxiety after applying a TEE band that reflects the individual characteristics.

Conclusion

This study showed that heat, cold, and TGI stimuli application with a TEE band is a novel intervention. It is important to apply nursing interventions to reduce venipuncture-associated pain and anxiety, and efforts are warranted for convenient application. Since pain and anxiety are subjective measures, they differ across individuals. Hence, heat, cold and TGI therapy to relieve pain and anxiety should be tailored to individual characteristics and preferences.

The TEE band composed of TEEs, which have been commonly used in daily life, was developed as a novel TEE band that can be used in healthcare. The TEE band developed in this study is safe because the electric energy delivers a consistent temperature to the user, and the hot and cold settings can be switched easily using the hot and cold buttons, allowing users to choose their preferred setting. Since TEE band is a newly developed product that can easily apply hot and cold treatments without using ice packs or hot water packs, it is necessary to conduct research to devise more application methods for effective use in patient care.

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Conflict of interest

The authors have no conflicts of interest to declare.

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Review Article

Effects of Lavender on Anxiety, Depression, and Physiological Parameters: Systematic Review and Meta-Analysis

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SUMMARY

Purpose: The recent evidence suggested substantial anxiolytic efficacy of lavender. The aim of this study was to examine the efficacy of lavender for anxiety, depression, and physiological parameters and to elucidate the differential effects of lavender on anxiety and depression by study characteristics.

Methods: A systematic review and meta-analysis was performed following the PRISMA guidelines. We searched PubMed, Embase, Cochrane Library, Web of Science, and Cumulative Index of Nursing and Allied Health Literature databases for randomized controlled trials investigating the efficacy of lavender on anxiety, depression, or physiological parameters in humans. We assessed the risk of bias within studies with the revised Cochrane risk of bias tool for randomized trials. We used random effect model to estimate the average effect and computed bias-corrected standardized mean difference as effect size metric, Hedges' $\hat{g}$ for all outcomes.

Results: Lavender was superior to placebo or no treatment in reducing anxiety (Hedges' $\hat{g} = -0.72$, 95% confidence interval [CI] −0.90 to −0.55, p value <.001), depression (Hedges' $\hat{g} = -0.43$, 95% CI, −0.59 to −0.27, p value <.001), and systolic blood pressure (Hedges' $\hat{g} = -0.23$, 95% CI, −0.41to −0.05, p value = .01). The moderator analysis by meta-regression indicated that route of administration accounted 6.5% (p value = .187) for the heterogeneity in anxiolytic effects, sessions of treatment accounted 13.2% (p value = .055), and participants' health state accounted 8.9% (p value = .131) for the variance in anxiolytic effects.

Conclusion: Lavender aromatherapy showed substantial effect in reducing anxiety and depression, and sessions of administration increased the anxiolytic effects. The effects on physiological parameters showed small with inconsistent significances and randomized controlled trials on the effect of lavender on depression were scarce. Future trials on depression and physiological parameters are recommended, and increasing the sessions of administration is recommended.

Introduction

Anxiety disorders are the most prevalent mental disorders around the world and are associated with significant comorbidity and morbidity [1]. Anxiety is a characteristic feature of modern times, and the prevalence of anxiety disorders has increased in response to political, societal, economical, and environmental changes [2]. The result of meta-regression adjusted for methodological difference indicated the global prevalence of anxiety disorders as 7.3% [3].

The etiology of anxiety disorders includes an interaction of psychosocial factors, for example, childhood adversity, stress, or trauma, and a genetic vulnerability, which manifests in neurobiological and neuropsychological dysfunctions [4]. Anxiety disorders are often comorbid with other anxiety disorders, major depression, or substance abuse [5]. Current anxiolytic treatment options have limited efficacy, such as delayed onset (e.g., selective serotonin reuptake inhibitors, serotonin–norepinephrine reuptake inhibitors, and buspirone) as well as the potential for habituation, tolerance, and abuse (e.g., benzodiazepines and pregabalin) [6]. In addition, anxiolytic agents may cause side effects, such as sedation, impaired concentration, amnesia, depression, delirium, dependency, and, not least, withdrawal syndrome [7]. Therefore, there is a demand for efficacious, safe, and acceptable anxiolytics that are also applicable in subthreshold conditions [8].

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Lavender oil administered by different routes has been recognized for centuries for promoting "well-being" and for reduction of distress [9]. Lavender, a plant from the Lamiaceae family, comes in many species with different chemical characteristics. The lavandula genus has approximately 30 species grown around the world that share similar major chemical constituents and properties [10]. Lavender oil is the essential oil extracted from flowers and stalks of the lavender plant by steam distillation. It is a colorless or pale-yellow liquid with a sweet, floral, herbaceous aroma [11]. Lavender oil is a multi-ingredient mixture that contains more than 160 substances. The major components of lavender oil are linalool, linalyl acetate, 1,8-cineole, b-ocimene, terpinen-4-ol, and camphor [12].

Silexan, a proprietary essential oil from *Lavandula angustifolia* flowers, has been approved in Germany and several other countries for the oral treatment of anxiety [9]. Silexan® showed pronounced anxiolytic effects in patients with subthreshold anxiety disorders [13,14] at a daily oral dose of 80 mg (1 capsule) as well as in anxiety-related restlessness and agitation [15] and generalized anxiety disorder for daily single doses of 80 mg and 160 mg [16–18]. Moreover, evidence for antidepressant-like properties of Silexan has been observed in anxious patients suffering from comorbid depressive symptoms and in patients with mixed anxiety–depression disorder [19], which may indicate intrinsic antidepressant-like properties independent of its anxiolytic activity [20].

The neuroendocrine response to the stressors involves the activation of the hypothalamic–pituitary–adrenocortical axis, resulting in the release of the glucocorticoid hormone cortisol from the adrenal cortex into blood, and the autonomic response is the activation of the sympathetic-adrenergic system, culminating in the release of adrenaline and noradrenaline from adrenal medulla into the blood circulation [21]. Cortisol is produced in the adrenal cortex and is the main glucocorticoid hormone in humans. It is released in response to various psychosocial stimuli, such as anxiety and stress via hypothalamus–pituitary–adrenal axis. Endocrinological stress markers such as cortisol are useful for objectively evaluating psychosocial distress, including stress or anxiety. In addition to self-reporting anxiety measure, physiological parameters including blood pressures, heart rate, or salivary cortisol level are useful for evaluating anxiety objectively.

The existing evidence has suggested anxiolytic and antidepressant properties of lavender based on clinical trials. However, the evidence based on systematic review and meta-analysis has concentrated on anxiolytic effects exclusively [22–24]. And the reviews have presented the overall anxiolytic effects with substantial heterogeneity, but the potent source of variations in effects, such as study design, sample characteristics, or intervention characteristics, has not yet been identified adequately.

The first aim of the present review is to identify the overall effects of lavender for anxiety and its physiological referents and depression. The second aim is to investigate moderating factors for substantial variations in effect on anxiety and depression. Specifically, we assumed that the effects of lavender might vary with the study characteristics comprising the routes of administration, sessions of intervention, and health conditions of populations. The results of this review could provide a scientific evidence for applying lavender for the amelioration of anxiety and depression levels.

Methods

Study design

A systematic review and meta-analysis was performed to examine the effects of lavender on anxiety, depression, and physiological parameters following the PRISMA guidelines.

Eligibility criteria

Study characteristics used as criteria for eligibility are as follows: (1) population: clinical trials with human subjects of any age, sex, and with or without diseases were included; (2) intervention: lavender administration with any route of administration, any type of preparation, and any species of lavender; (3) comparator: no intervention, standard or routine care, or placebo; (4) outcomes: primary outcomes were anxiety and depression measured by validated or standardized measures; secondary outcomes were physiological parameters of anxiety, that is, blood pressures, heart rate, or salivary cortisol; and (5) study design: randomized controlled trials (RCTs). We excluded RCT studies that compared different types of lavender preparations without a control group or used combined lavender treatments. Trials with missing essential data were excluded from qualitative and quantitative synthesis. Trials with animal subjects were excluded.

Report characteristics used as eligibility criteria are all studies written in English and published from 2010 to 2019. Since recent systematic reviews and meta-analyses on assessing the effect of lavender in the treatment of anxiety screened up to November 2018 [22–24], we limited publication year from 2010 to 2019 for up-to-date evidence and avoiding duplication of results. Trials regardless of publication status were all included except for those published in abstract form only.

Information sources

The title/abstract/keywords fields of Cochrane Library, MEDLINE and PubMed Central via PubMed, Embase, Cumulative Index of Nursing and Allied Health Literature, and Web of Science databases were systematically searched for eligible articles. We checked out references of articles retrieved from database searches to locate additional relevant articles.

Search

We searched databases and references from located articles from May 15, 2019, to June 15, 2019. We used Boolean operators to search for the following terms: (*lavender OR lavandula OR silexan)* AND (*anxiety OR anxious OR anxiolytic OR stress* OR *depression OR depressive*) and derivatives of those terms, including MeSH thesaurus terms. We set additional filters to publication years: "from 2010 to 2019," article type: "randomized controlled trial," language: "English," and species: "humans" in the database searches. The full electronic search strategy for MEDLINE and PubMed Central was presented in supplementary material (Appendix E).

Study selection and data collection process

Two reviewers (E.N. and Y.L.) performed eligibility assessment individually. In case of disagreement, the items were discussed and resolved by consensus between the two reviewers. We then established a coding structure for data extraction and pilot-coded it on five randomly selected included trials and revised it accordingly. Two of the authors (M.K. and H.K.) independently coded the data, and the other two authors (E.N. and Y.L.) checked the coded data. Disagreements were resolved through discussion among all reviewers.

Data items

The authors extracted the following descriptive and numerical data from the included studies: (1) settings and characteristics of participants; (2) intervention (such as a method of application, dose, frequency, and duration of lavender aromatherapy); (3)

measured outcomes of anxiety, depression, and physiological parameters of anxiety; (4) comparator interventions; (5) adverse effects of the intervention; (6) numerical data for meta-analysis: mean, standard deviation, randomized, and analyzed sample sizes of treatment groups, sessions and doses of interventions, and length of follow-up.

Risk of bias in individual studies

Bias assessment was performed by two independent assessors (M.K. and H.K.) based on the primary outcome (self-rated anxiety and depression) level using the revised Cochrane risk-of-bias tool for randomized trials (RoB 2) [25]. Disagreements were resolved by discussion between reviewers (E.N. and Y.L.) until consensus was made. As we planned to estimate the effect of starting and adhering to lavender intervention, we assessed the risk of bias based on per-protocol analysis.

The RoB 2.0 for individually randomized trials has five domains, including bias (1) from the randomization process, (2) due to deviations from intended interventions, (3) from missing outcome data, (4) in measurement of the outcome, and (5) in selection of the reported result. Each risk of bias domain has three response options, comprising low, some concerns, and high risk of bias. One of the key innovations of the RoB 2.0 is automatic judgement of overall risk of bias via algorithm by the risk of bias judgments of the individual domains in each study.

Summary measures and synthesis of results

In the meta-analysis of all outcomes, including anxiety, depression, and physiological parameters, the bias-corrected standardized mean difference (Hedges' $\hat{g}$) was calculated as the effect size metric. Standardized mean differences are upwardly biased when samples are small, especially less than 20 participants, and Hedges suggested a correction for small sample bias, known as Hedges' $\hat{g}$ [26].

We assessed the heterogeneity in effects using I^2 statistics and Cochran's Q based on Chi-squared statistics. If an I^2 value was greater than 50% and the p value of Chi-squared was below 0.1, we concluded that there was substantial heterogeneity.

We used the inverse variance weighting for pooling the results of individual studies. Based on the assumption that the true effect might vary across samples and populations, depending on the health conditions of populations, type or sessions of interventions, and study design artifacts, we estimated the mean effects using the random effect model.

Meta-analyses were calculated in R software version 4.0.2 [27] using packages meta and metafor. We also performed meta-analyses in Review Manager 5.4 (Version: 5.4.1) [28] using non-Cochrane mode.

Risk of bias across studies

Publication bias across studies was assessed with funnel plot followed by linear regression of intervention effect estimate against its standard error (Egger's regression) as tests for funnel plot asymmetry. Publication bias was assessed only when at least 10 studies were included in the meta-analysis because when there are fewer studies, the power of the tests is too low to distinguish chance from real asymmetry [29]. We assessed publication bias in each meta-analysis on the primary outcomes anxiety and depression.

Additional analyses

When substantial heterogeneity in effects in any meta-analysis was identified, moderator analysis by meta-analysis of variance (ANOVA) and/or meta-regression was performed to examine factors creating variations in effect sizes across studies.

In each meta-analysis, subgroup analysis and/or moderator analysis was performed to see whether lavender intervention might have differential effects for different subgroups by study characteristics. Moderator analysis can be performed by two main statistical methods including meta-ANOVA and meta-regression; both approaches require at least 10 studies for every moderator in the analysis. In the meta-analysis on anxiety, we performed three moderator analyses by the route of administration, health state of participants, and sessions of treatment. Meta-regression was used to identify the amount of heterogeneity accounted for by each moderator.

In the meta-analysis on depression, as the number of included studies was 10, we performed a moderator analysis by the route of administration of lavender.

To identify the effect of the risk of bias assessments for the variation of mean effect, we performed a sensitivity analysis to examine whether inclusion of the studies at high overall bias influences the mean effect. And we performed a subgroup analysis by assessment of risk to examine the difference between studies at high, some concerns, and low risk.

Results

Study selection

A total of 562 citations were retrieved through database searches, and additional 12 trials were identified by reviewing the references of the selected articles. After duplicates were excluded, 378 studies remained. Then we evaluated the titles and abstracts and excluded 298 articles. The remaining 80 full-text articles were screened for eligibility, and 42 articles were excluded. Finally, 38 articles were included in qualitative analysis, and 37 articles were included in quantitative synthesis. Details of the process of screening and selection of the studies were presented in Figure 1. The final included articles are listed in the supplementary material (Appendix A).

Study characteristics

Characteristics of all included studies were summarized in the supplementary materials (Appendix B). Methods and overview of the studies are as follows: 38 RCTs published in English from 2010 to 2019 were included in qualitative synthesis, and 37 of 38 studies were included in quantitative synthesis. Geographic origins of the studies are Iran (17 trials), Turkey (8), Germany (4), Greece (1), India (1), South Korea (2), Taiwan (3), the United States (1), and Thailand (1).

Across all studies included in quantitative analyses, a total of 4316 participants were randomized to either lavender (2165) or control treatment (2151). In the meta-analysis on anxiety, a total of 3906 participants (lavender 1955 and control 1951) were randomized, and 3825 (lavender 1917 and control 1908) were analyzed. In depression, a total of 1312 participants (lavender 657 and control 655) were randomized, and 1282 (lavender 644 and control 638) participants were analyzed. Studies included in meta-analysis on cortisol a total of 206 participants were randomized to either lavender (102) or control treatment (104), and 180 (lavender 96, control 94) were analyzed. Pooled premature withdrawal rates were 1.94% for lavender and 2.2% for control group in analysis for anxiety, 1.98% for lavender and 2.60% for control group in analysis for depression, and 5.9% for lavender and 9.6% for control in analysis for salivary or serum cortisol.

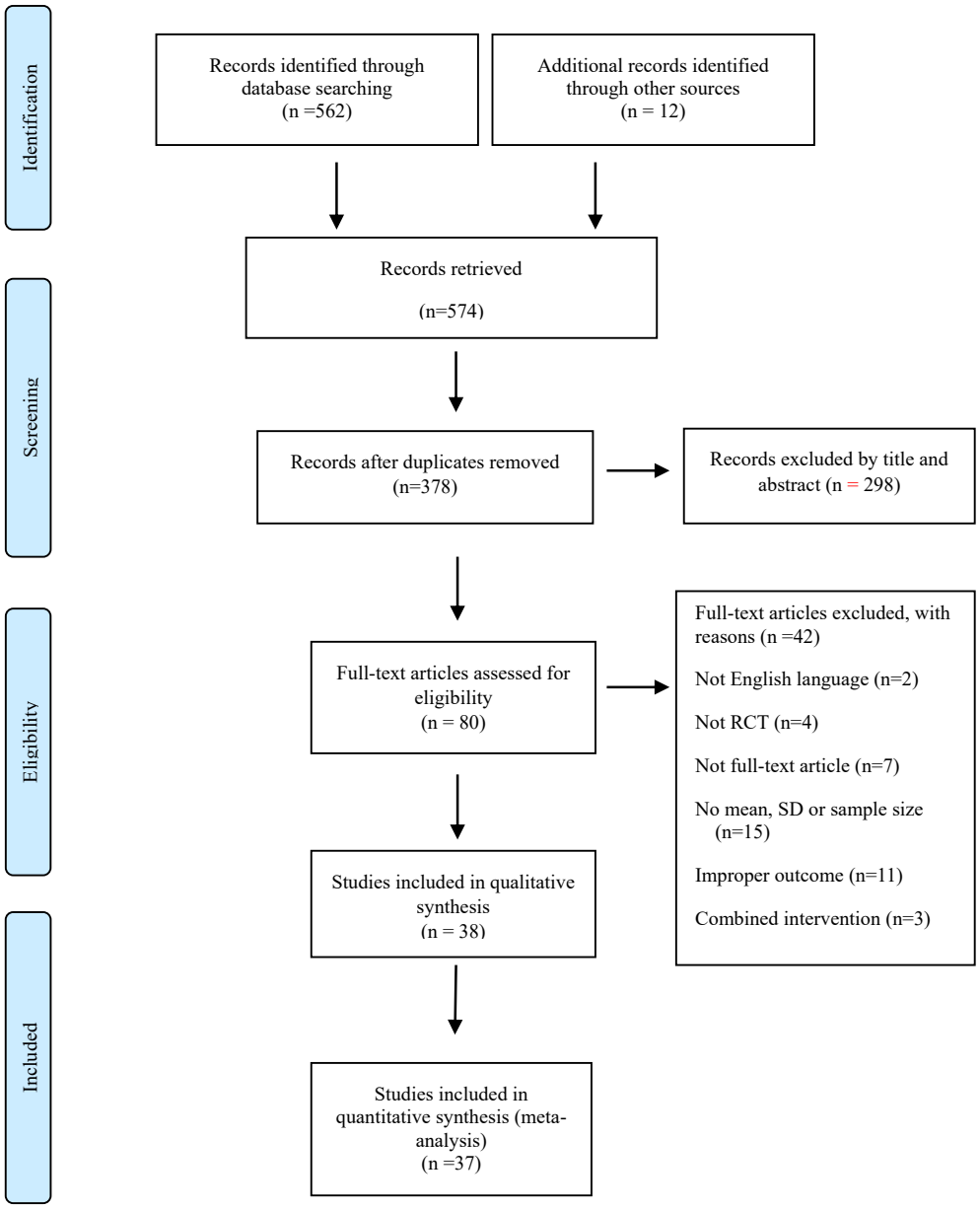


Figure 1. Flow diagram of the study selection process.
Note. RCT = randomized controlled trial; SD = standard deviation.

The populations of the studies included in the analysis for anxiety consisted of patients undergoing surgery or invasive procedure, critically ill patients with cardiac diseases or in intensive care units, healthy students under stressful conditions, pregnant or postpartum women, and patients in anxiety and/or depressive disorders. The participants of studies on depression were composed of patients undergoing hemodialysis, women in pregnancy, postpartum, or menopause, patients in anxiety and/or depression or dementia, or healthy students with premenstrual syndrome.

The participants in the experimental group received one of four routes of administration of lavender: inhalation, massage, tea, or oral preparation (silexan). The participants in the control group received standard or routine care, placebo, or no treatment. The details of dose, duration, and sessions of experimental and control treatments are presented in supplementary material (Appendix B).

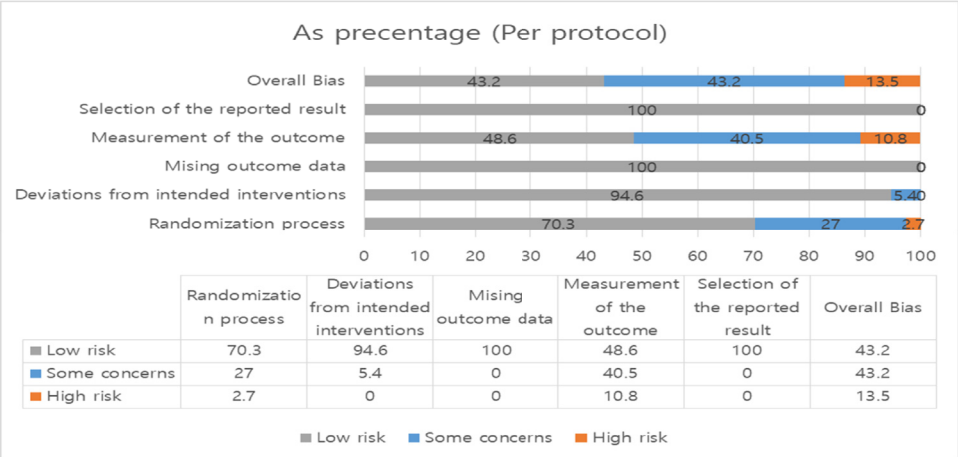
The primary outcomes measured were anxiety and depression, and the secondary outcomes measured were physiological indicators of anxiety. Of all 38 included studies, self-rated anxiety was assessed in 30 studies, and depression was evaluated in 10 studies. Anxiety was measured by standardized measure (visual analog scale) or validated measures (Beck Anxiety Inventory, Depression Anxiety Stress Scale, Hospital Anxiety and Depression Scale, Hamilton Anxiety Scale, Modified Dental Anxiety Scale, State-Trait Anxiety Inventory, or Zung Self-Rating Scale). Depression was measured by validated measures including Beck Depression Inventory, Cornell Scale for Depression in Dementia—Chinese version, Edinburgh Postnatal Depression Scale, Premenstrual syndrome (depressive affect subscale), Hospital Anxiety and Depression Scale, Hamilton Rating Scale for Depression, and Montgomery Åsberg Depression Rating Scale.

A

Study	D1	D2	D3	D4	D5	Overall
Alemdar 2019	+	+	+	+	+	+
Ayik 2018	?	+	+	?	+	!
Bagheri-nesami 2017	?	+	+	+	+	!
Bahrami 2017	+	+	+	?	+	!
Bakhsha 2014	+	+	+	+	+	+
Chen 2015	+	+	+	?	+	!
Cruz 2011	+	+	+	?	+	!
Effati 2015	+	+	+	+	+	+
Eslami 2018	?	+	+	?	+	!
Kamalifard 2017	+	+	+	+	+	+
Hasanzadeh 2016	+	+	+	?	+	!
Kalayasiri 2018	+	+	+	?	+	!
Karadag 2015	?	+	+	?	+	!
Karaman 2016	+	?	+	?	+	!
Kasper 2015	+	+	+	+	+	+
Kasper 2010	+	+	+	+	+	+
Kasper 2014	+	+	+	+	+	+
Kasper 2016	+	+	+	+	+	+
Kritsidima 2010	?	+	+	+	+	!
Lee 2017	+	+	+	?	+	!
Mirbastegan 2016	?	+	+	?	+	!
Nikfarjam 2013	?	+	+	?	+	!
Senturk 2018	?	?	+	?	+	?
Yayla 2017	?	+	+	?	+	?
Najafi 2014	+	+	+	?	+	!
Seyyed-Rasooli 2016	+	+	+	+	+	+
Seol 2012	+	+	+	+	+	+
Tugut 2017	+	+	+	+	+	+
Uzuncakmak 2018	+	+	+	+	+	+
Yang 2016	+	+	+	+	+	+
Zabirunnisa 2014	?	+	+	?	+	?
Ziyaeifard 2017	+	+	+	+	+	+
Seifi 2014	+	+	+	+	+	+
Kianpour 2016	+	+	+	+	+	+
Rajai 2016	?	+	+	?	+	!
Bekhradi 2016	+	+	+	?	+	?
Hosseini 2016	+	+	+	?	+	?

Low risk
Some concern
High risk

B



	Randomization process	Deviations from intended interventions	Mising outcome data	Measurement of the outcome	Selection of the reported result	Overall Bias
Low risk	70.3	94.6	100	48.6	100	43.2
Some concerns	27	5.4	0	40.5	0	43.2
High risk	2.7	0	0	10.8	0	13.5

Figure 2. A. Risk of bias summary according to the revised Cochrane risk-of-bias tool for randomized trials (R0B 2). D1: Randomization process; D2: Deviations from intended interventions; D3: Missing outcome data; D4: Measurement of the outcome; D5: Selection of the reported result. B. Risk of bias graph according to the revised Cochrane risk-of-bias tool for randomized trials (R0B 2).

Blood pressures were assessed in seven studies and heart rate was assessed in six studies, salivary cortisol was assessed in two studies, and serum cortisol was assessed in one study.

Risk of bias within studies

Figure 2A shows the risk of bias summary presenting the assessment in each domain and overall risk of bias. The overall risk of bias was evaluated as low in 16 trials, as some concern in 16 trials and as high risk of bias in five trials.

The risk of bias from the randomization process was rated as high in only one study, some concern in 10 studies, and low in the remaining 26 studies. Bias in measurement of the outcome was assessed as high in four trials, some concern in 15, and low in 18 trials. Bias due to deviations from intended interventions was rated as some concern risk in only two trials and low risk in the remaining 35 trials. Figure 2B presents the risk of bias graph of included studies according to the revised Cochrane risk-of-bias tool for randomized trials (ROB 2).

Results of individual studies and synthesis of results

We first conducted basic meta-analyses for each outcome: anxiety levels, physiological parameters (systolic blood pressure, diastolic blood pressure, heart rate, and cortisol levels), and depression levels.

As treatment effects are inconsistent across study characteristics of populations, sessions, durations, and types of intervention,

comparison conditions, and methodological features, we hypothesized that the route of administration, sessions of treatment, and health state of population might moderate variations in effect sizes across studies. Subgroup and moderator analysis may be used to explore possible sources of variability in combined effects. According to *Cochrane Handbook for Systematic Reviews of Interventions* version 6.1 [29], subgroup and moderator analysis require at least 10 studies for each moderator. The reason is the statistical power of moderator analysis is affected by the number of included studies and moderators. As our meta-analysis on anxiety included 30 studies, we conducted three subgroup and moderator analyses by route of administration, health state of population, and sessions of treatment using meta-analysis of variance or meta-regression whether the moderator variable is continuous or categorical. Also, the analysis on depression included 10 studies; only one moderator analysis by the route of administration was conducted.

Finally, we performed a sensitivity analysis to determine the effect of study quality on the mean effect. Specifically to examine the inclusion of studies at high risk of bias affects the overall effect on anxiety levels, sensitivity analysis deleting each study was done.

The meta-analysis for self-rated anxiety included 30 studies to evaluate the overall effects of lavender intervention (Figure 3A). Lavender was significantly superior to comparators (standard care, placebo, or no treatment). The mean effect (Hedges' $\hat{g}$) was −0.72 (95% confidence interval [CI] −0.90 to −0.55), and the direction of the mean effect favored lavender. The analysis also showed that lavender intervention was significantly superior to comparator in 21 of 30 trials, with the largest effect of −2.56 (95% CI −3.25 to −1.86). The heterogeneity statistics were $I^2 = 84\%$, $p > .001$, indicating substantial heterogeneity.

The results for the physiological parameters are presented in Figure 3B. The efficacy on the self-rated anxiety was not supported by the physiological parameters except for systolic blood pressure (SBP). Each meta-analysis for SBP and diastolic blood pressure (DBP) included seven studies, and six studies for heart rate, and three studies were included in the analysis for cortisol. The effect size on the SBP was −0.23 (95% CI −0.41 to −0.05). The effect of lavender on DBP was −0.15, the effect on heart rate was −0.2, and the effect on salivary/serum cortisol was −1.4. However, the effects of DBP, heart rate, and cortisol showed no significance.

The meta-analysis on the antidepressive effect included 10 studies. The meta-analysis showed that lavender was superior to placebo or no treatment comparators with the mean effect of −0.43 (95% CI −0.59 to −0.27; Figure 3C). The meta-analysis showed that lavender was superior to control treatment significantly in 7 of 10 RCTs, with the treatment effects ranging −0.18 to −1.2. The statistics of heterogeneity showed a significant medium size heterogeneity ($I^2 = 47\%$, $p = .05$).

Risk of bias across studies

To evaluate potential publication bias, funnel plots were drawn, and then Egger's regression test was performed for self-rated anxiety and depression (see Funnel plots in Supplementary material, Appendices C and D). The funnel plot for standard error and effect sizes on anxiety seemed somewhat asymmetrical, seemingly empty in the lower-right area. However, Egger's regression showed no evidence of significant publication bias ($t = -1.04$, $df = 28$, $p = .308$). Egger's regression on depression also showed no evidence of publication bias ($t = -1.61$, $df = 8$, $p = .146$).

Because the publication biases for both anxiety and depression showed no significant evidence of biases, the results of our meta-analyses on anxiety and depression could be regarded as representative of the population of all published studies.

Additional analysis

Although the overall effect of the lavender treatment on self-rated anxiety levels showed significant medium to large size ($\hat{g} = -0.72$, 95% CI: −0.90 to −0.55), the effect sizes of individual studies around the mean effect showed substantial variability. The heterogeneity statistics showed $I^2 = 84\%$, Chi-squared = 104.75, $df = 29$, and $p > 0.001$. Intervention effects are often heterogenous across study characteristics, including populations, interventions, comparisons, measures of outcomes, and methodological features. These study factors can moderate the effects of interventions and be sources of heterogeneity in combined effects.

Subgroup and moderator analyses can be done for the purpose of investigating heterogeneous results or to explore specific questions about particular patient populations, methods of intervention, or quality of study [29]. In subgroup analysis, the test of significance indicates whether effects were significant within subgroups not whether differences in effects were significant between subgroups. Moderator analysis provides tests of the differences in effects between subgroups and influences of moderators on the overall effect. The two statistical methods for moderator analysis are meta-analysis of variance (ANOVA) and meta-regression, both approaches require at least 10 studies for each moderator to ensure statistical power of the analysis.

We hypothesized in the protocol that the effects of lavender could vary with study characteristics, including routes and sessions of administration of lavender, health conditions of populations, and methodological quality, but the number of included studies in the meta-analysis for anxiety levels was 30; we conducted three moderator analyses, including (1) the routes and (2) sessions of administration and (3) health conditions of populations. The results of subgroup/moderator analysis for the anxiolytic effect are presented in Table 1.

The subgroup analysis by the route of administration showed that the application of lavender using massage, inhalation, and oral administration (silexan) was significantly superior to standard care, placebo, or no treatment comparators. The mean effect of lavender inhalation was −0.83, and the effect of lavender using massage was −0.60, and silexan showed the smallest effect of −0.41.

The moderator analysis using meta-ANOVA to test statistical significance for different mean effects between routes of lavender indicated no statistical significance ($Q_b(df) = 3.35(2)$, $p_b = .187$). To examine the possible impact of the route of administration for the heterogeneity of the overall effect of lavender on anxiety, we conducted additional moderator analysis using meta-regression. Meta-regression can be used to assess the potential impact of one or more continuous or categorical moderators. Categorical variable of the route of administration was expressed as a set of dummy variables with one omitted category in the meta-regression. Therefore, our meta-regression showed that routes of administration accounted for 6.5% for the heterogeneity of the mean effect; the result showed no significance just the same as the statistical result of meta-ANOVA.

As the statistical power of moderator analysis is affected by the number of studies and the number of moderators, we should be cautious to interpret the results. The moderator analyses displayed meaningful results that meta-ANOVA showed that treatment effects according to the routes of administration were clearly different, and the meta-regression indicated the route of administration accounted 6.5% for the variance of mean effect. But both moderator analyses showed no statistical significance; we can consider the possibility of the lack of statistical power by insufficient number of studies in the analyses.

The subgroup analysis for the effect of lavender on anxiety by health conditions of populations showed that the mean effect

was −0.79 (95%CI: −1.05 to −0.53) for populations undergoing surgery or invasive treatment, −1.00 (−1.35, −0.64) for the populations with coronary diseases or patients in intensive care unit (ICU) group, −0.53 (−0.90, −0.15) for healthy population and −0.41 (−0.83, 0.02) for populations in anxiety and/or depression conditions. Lavender aromatherapy showed the largest efficacy in population with coronary diseases and/or patients in ICU and the efficacy for population with anxiety and/or depression showed the smallest and no statistical significance.

We performed both meta-ANOVA and meta-regression to explore possible influence of health conditions of populations on the variation of the mean effect. The meta-ANOVA indicated that different mean effects between health conditions of population were not statistically significant (Qb(df) = 5.63(3), p_b = .131). The mean effects of subgroups of health condition of population were considerably different and the meta-regression showed that health conditions of population accounted 8.9% for the heterogeneity in mean effect (QM(df = 3) = 5.63, p = .131), but both moderator analyses showed no statistical significance. This might be ascribable to possible lack of power because of insufficient number of studies.

The meta-regression to test moderating effect of sessions of treatment showed that sessions of intervention accounted 13.18% for variations of mean effects significantly (QM = 3.68, df = 1, p = .05). Regression coefficient of sessions was b = 0.0057, and the regression equation can be suggested as Y = 0.0057*sessions − 0.82. This result means that the more sessions of treatment make the larger effect sizes on anxiety.

Consequently, we could explain the moderators such as previously mentioned route of administration of lavender and health states of population and sessions of administration can reasonably influence the variability of the mean effect; only the test of statistical significance failed because of possible insufficient statistical power. Random effect model easily concludes nonsignificance.

We performed a subgroup and moderator analysis to test the different means of antidepressive effects by routes of administration (Table 2). The subgroup analysis showed the mean effect of inhalation on depression was −0.43 (95% CI −0.77 to −0.08), the mean effect of massage was −0.63 (95% CI −1.08 to −0.17), the mean effect of silexan was −0.42 (95% CI −0.72 to −0.12). Lavender tea showed no significant effect, and effect size was the smallest (−0.32).

The moderator analysis by meta-ANOVA indicated that the different mean effects between inhalation, massage, tea, and silexan was not significant (Q = 0.95, df = 3, p_b = .814). And also, the meta-regression indicated that the route of administration did not account for heterogeneity in mean effect (0%).

Finally, we performed a sensitivity analysis to examine whether the risk of within-study bias influence the mean effect of lavender on anxiety (Figure 4). Specifically, to examine the

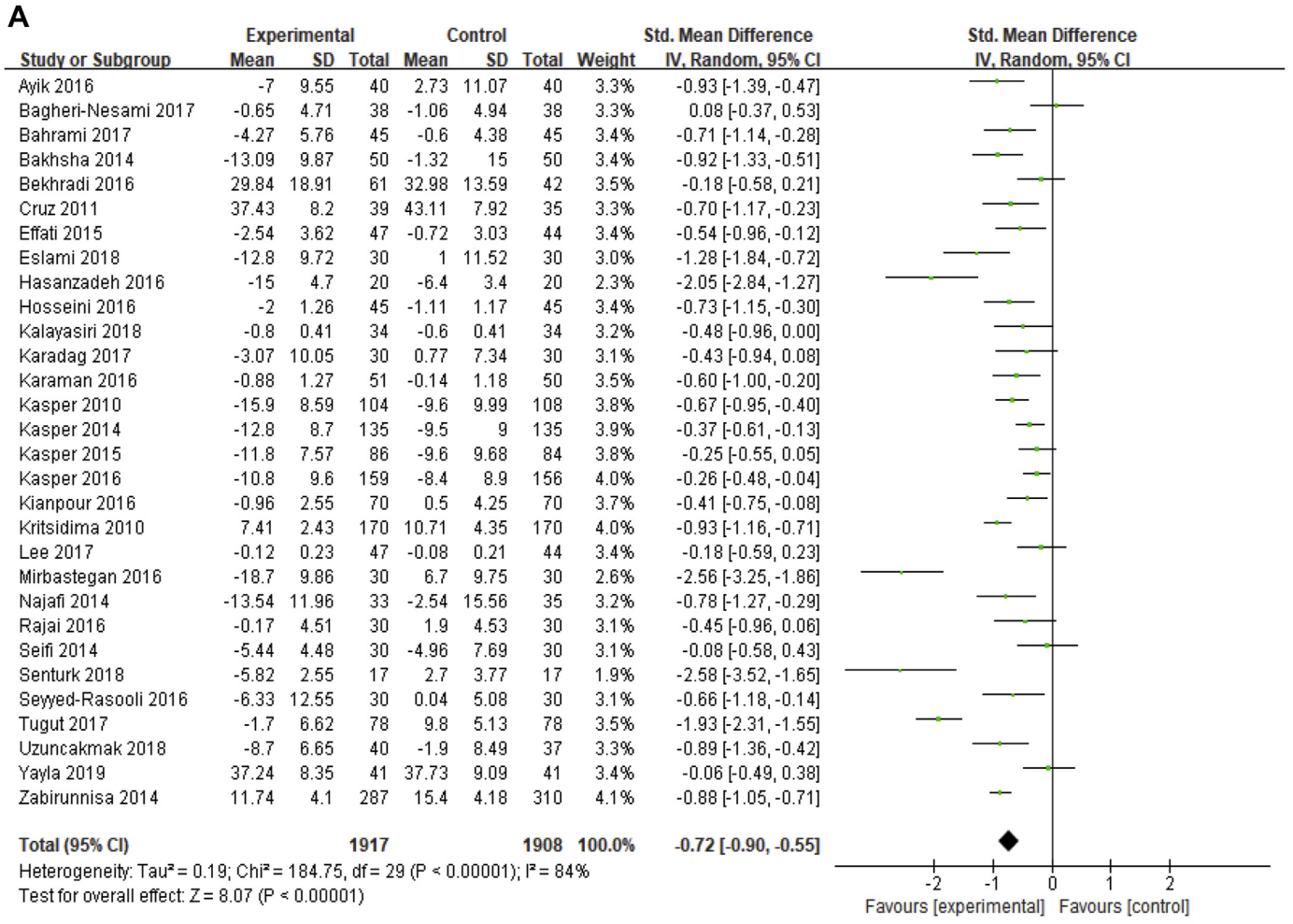


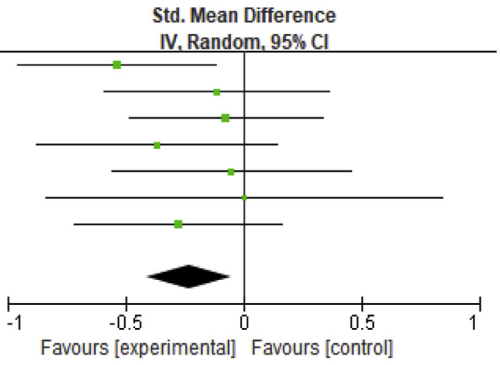
Figure 3. A. Forest plot on the efficacy of lavender on self-rated anxiety levels. B. The effect of lavender on physiological parameters C. The effect of lavender on depression levels. *Note. CI = confidence interval; SMD = standardized mean difference; df = degrees of freedom; IV = inverse variance; SD = standard deviation; SBP = systolic blood pressure; DBP = diastolic blood pressure; HR = heart rate.*

B

SBP

Study or Subgroup	Experimental Mean	SD	Total	Control Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
Bahrami 2017	-11.2	12.62	45	-1.53	21.98	45	18.6%	-0.53 [-0.96, -0.11]
Kalayasiri 2018	-3	2.45	34	-2.7	2.78	34	14.6%	-0.11 [-0.59, 0.36]
Lee 2017	1.21	15	47	2.41	17.17	44	19.5%	-0.07 [-0.49, 0.34]
Mirbastegan 2016	-4.86	19.47	30	2.33	19.46	30	12.7%	-0.36 [-0.88, 0.15]
Rajai 2016	0.23	19.67	30	1.3	21.84	30	12.9%	-0.05 [-0.56, 0.46]
Seol 2012	5.1	18.82	12	5	20.68	10	4.7%	0.00 [-0.83, 0.84]
Ziyaeifard 2017	-5.75	21.4	40	-0.4	17.06	40	17.0%	-0.27 [-0.71, 0.17]
Total (95% CI)			**238**			**233**	**100.0%**	**-0.23 [-0.41, -0.05]**

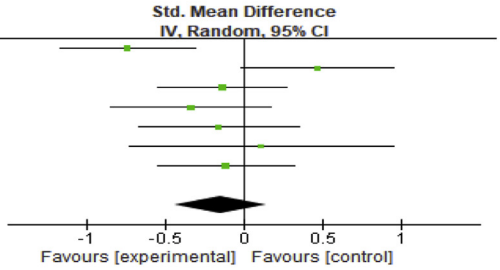
Heterogeneity: Tau² = 0.00; Chi² = 3.89, df = 6 (P = 0.69); I² = 0%
Test for overall effect: Z = 2.48 (P = 0.01)



DBP

Study or Subgroup	Experimental Mean	SD	Total	Control Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
Bahrami 2017	-9.12	9.74	45	0.07	14.52	45	16.2%	-0.74 [-1.16, -0.31]
Kalayasiri 2018	-0.8	1.81	34	-1.7	1.97	34	14.8%	0.47 [-0.01, 0.95]
Lee 2017	-1.46	8.75	47	-0.25	9.49	44	16.7%	-0.13 [-0.54, 0.28]
Mirbastegan 2016	-3.7	15.54	30	1.13	13.1	30	14.1%	-0.33 [-0.84, 0.18]
Rajai 2016	-1.37	9.19	30	0.24	11.2	30	14.2%	-0.16 [-0.66, 0.35]
Seol 2012	3.7	12.95	12	2.1	14.28	10	8.1%	0.11 [-0.73, 0.95]
Ziyaeifard 2017	0.87	15.22	40	2.43	12.78	40	15.9%	-0.11 [-0.55, 0.33]
Total (95% CI)			**238**			**233**	**100.0%**	**-0.15 [-0.44, 0.14]**

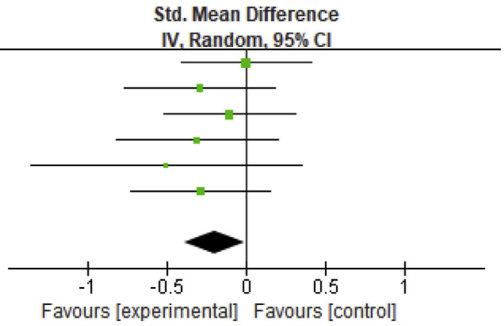
Heterogeneity: Tau² = 0.09; Chi² = 14.46, df = 6 (P = 0.02); I² = 59%
Test for overall effect: Z = 1.01 (P = 0.31)



HR

Study or Subgroup	Experimental Mean	SD	Total	Control Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
Bahrami 2017	-1.71	13.28	45	-1.77	12.33	45	22.1%	0.00 [-0.41, 0.42]
Kalayasiri 2018	-1	2.03	34	-0.4	2.08	34	16.5%	-0.29 [-0.77, 0.19]
Lee 2017	-0.46	7.04	47	0.37	9.15	44	22.3%	-0.10 [-0.51, 0.31]
Rajai 2016	-2.43	10.23	30	1.17	12.72	30	14.5%	-0.31 [-0.82, 0.20]
Seol 2012	-4.5	10.23	12	0.7	9.66	10	5.2%	-0.50 [-1.36, 0.35]
Ziyaeifard 2017	-5.2	16.23	40	-0.1	19.11	40	19.4%	-0.28 [-0.73, 0.16]
Total (95% CI)			**208**			**203**	**100.0%**	**-0.20 [-0.39, -0.00]**

Heterogeneity: Tau² = 0.00; Chi² = 2.09, df = 5 (P = 0.84); I² = 0%
Test for overall effect: Z = 1.97 (P = 0.05)



Serum/salivary cortisol

Study or Subgroup	Experimental Mean	SD	Total	Control Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
Alemdar 2019	1.69	1.68	39	1.83	1.72	39	34.2%	-0.08 [-0.53, 0.36]
Hosseini 2016	-1.88	0.56	45	-0.42	0.45	45	33.7%	-2.85 [-3.44, -2.26]
Seol 2012	0.17	0.2	12	0.68	0.52	10	32.1%	-1.29 [-2.23, -0.35]
Total (95% CI)			**96**			**94**	**100.0%**	**-1.40 [-3.27, 0.47]**

Heterogeneity: Tau² = 2.61; Chi² = 53.78, df = 2 (P < 0.00001); I² = 96%
Test for overall effect: Z = 1.47 (P = 0.14)

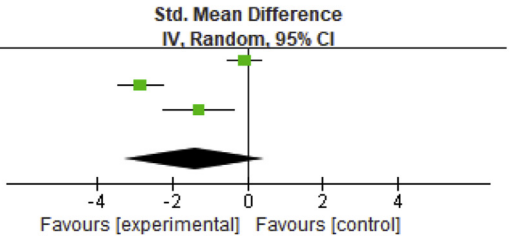


Figure 3. (*continued*).

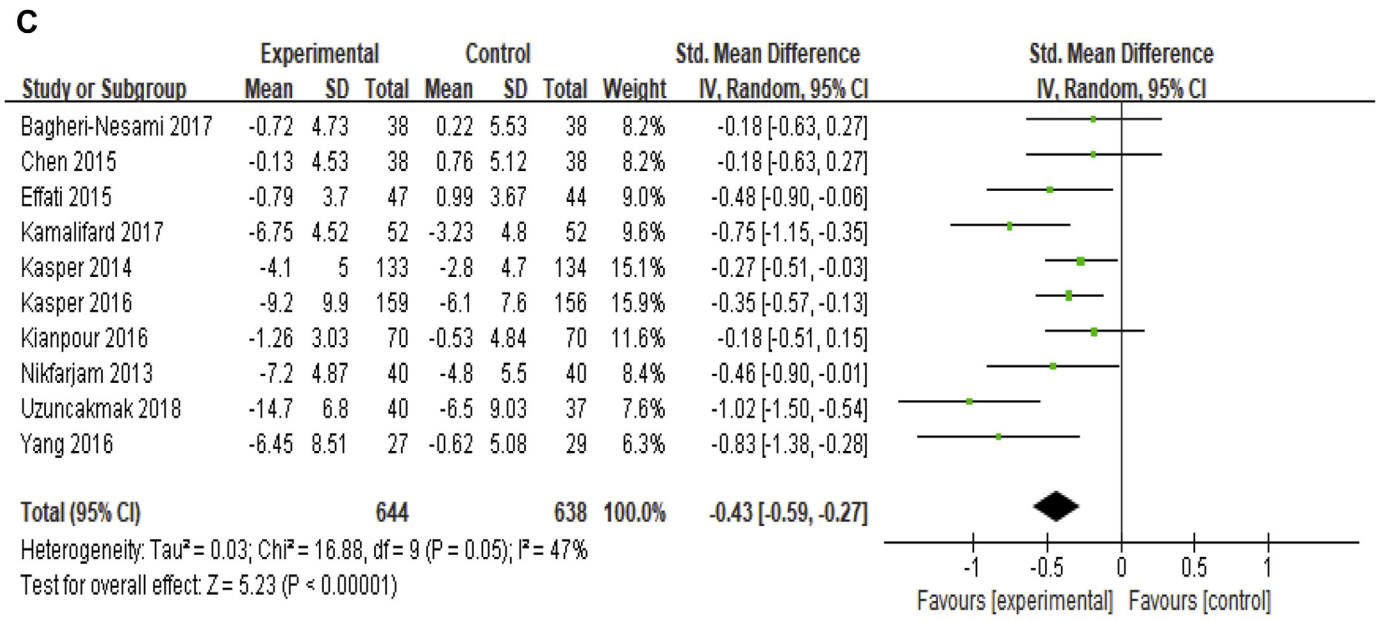


Figure 3. (*continued*).

inclusion of studies at high overall risk impact the mean effect, we estimated the mean effect after deleting each study at high overall risk.

According to sensitivity analysis, the mean effect changed to −0.68 from −0.66 after deleting the study of Bekhradi [30], −0.66 after deleting Hosseini [31], −0.65 after deleting Senturk [32], −0.68 after deleting Yayla [33], and −0.62 after deleting Zabirunnisa [34]. Consequently, deleting each study at high overall risk did not change the mean effect significantly. So the mean anxiolytic effect of lavender demonstrated relatively robust and does not seem to be sensitive to the inclusion of the studies at high risk.

Discussion

Summary of evidence

The use of lavender essential oil has become popular in aromatherapy, and its therapeutic efficacy has been assessed in a large number of clinical trials. Aromatherapy with lavender essential oil was found to be effective in decreasing anxiety and its comorbid depression in various settings. Physiological parameters did not demonstrate consistent effects among parameters. Lavender showed significant decrease in systolic blood pressure but did not affect DBP, heart rate, and salivary or serum cortisol significantly.

Our meta-analysis demonstrated that lavender is superior to controls, including standard care, placebo, or no treatment in decreasing self-rated anxiety in diverse populations. The overall risk of bias in the primary studies assessed with revised ROB tool displayed that 5 of 37 studies were rated as high risk. But judging from the sensitivity analysis, deleting each high-risk study did not change the mean effect distinctly, implying the effect sizes of high-risk studies might not be overestimated. Consequently, the overall effects demonstrated relatively robust and do not seem to be influenced by the study quality of the included studies.

Our meta-analysis confirmed the results of Kang et al [22] and Donelli et al [24] in the efficacy for a significant decrease in anxiety, although the magnitude of the effect varied slightly. The mean effect on anxiety levels of −0.72 can be interpreted as medium to large [35]. This effect is larger than the evidence (−0.65) of the review of Kang et al [22], which synthesized 19 studies published 2000 to 2019. As the present review included 30 studies published from 2010 to 2019, the change of effect sizes between the reviews is noteworthy.

As our meta-analysis included studies administering routes of inhalation, massage, and oral silexan and also included studies comprising participants in diverse health states, the analysis demonstrated substantial heterogeneity in effects.

According to subgroup analysis by the route of administration, the effect size of inhalation was the largest other than massage and silexan. Our meta-analysis confirmed the results of Kang et al [22] and Donelli et al [24] in the efficacy of inhalation for a significant decrease in anxiety, although the magnitude of the effect varied slightly. The effect estimate of inhalation (−0.83) is slightly larger than other evidence −0.71 [22] and −0.73 [24]). The result of our review and previous reviews suggest that inhalation of lavender oil is effective in decreasing anxiety levels in high anxiety inducing situations considerably. The inhalation of lavender essential oil can be recommended as efficacious intervention to decreasing anxiety in people in diverse situations of anxiety.

The massage with lavender oil showed medium to large anxiolytic effect (−0.60). This effect estimate is similar to other evidence (−0.61 [22], −0.66 [24]). Therefore, combined with the previous evidence, the massage with lavender oil can be interpreted to have substantial effect of relieving anxiety for populations in anxiety conditions.

The oral lavender silexan also confirmed a significant anxiolytic effect. The included studies in meta-analysis for silexan showed high study quality of all low risk in overall risk of bias. The result confirms the evidence of Kang et al [22], Donelli et al [24], and Möller et al [23], although the magnitude of the effect is different slightly and the effect measures are different (Hedges' $\hat{g}$ vs. weighted mean difference).

The analysis for publication bias by funnel plot and Egger's regression showed no evidence of publication bias, which signifies our sample of meta-analysis may be representative of the population of published studies on this topic. Consequently, the evidence of the anxiolytic effect of lavender can be interpreted as fairly robust considering the quality of research designs, no evidence of publication bias, and CIs that do not cross the line of no effects.

Table 1 *Subgroup/Moderator Analyses for the Impact of Study Characteristics on Anxiolytic Effect of Lavender.*

Moderators/subgroups	k	Hedges' ĝ	95% CI	Q_b (df)	p_b
Route of administration					
Massage	5	−0.60	−1.02, −0.18	3.35(2)	.187
Inhalation	21	−0.83	−1.03, −0.62		
Silexan 80 mg	4	−0.41	−0.84, 0.03		
Meta-regression	QM(df = 2) = 3.35, p = .187				
	R^2 (amount of heterogeneity accounted for): 6.5%				
Health condition of populations					
Patients undergoing surgery or invasive	13	−0.79	−1.05, −0.53	5.63(3)	.131
Patients with coronary disease or in ICU	7	−1.00	−1.35, −0.64		
Healthy population	6	−0.53	−0.90, −0.15		
Anxiety or depression	4	−0.41	−0.83, 0.02		
Meta-regression	QM (df = 3) = 5.63, p = .131				
	R^2 (amount of heterogeneity accounted for): 8.9%				
Overall risk of within-study bias					
Some concern	14	−0.81	−1.08, −0.53	0.68(2)	.713
Low	11	−0.64	−0.93, −0.34		
High	5	−0.74	−1.20, −0.28		
Meta-regression	QM (df = 2) = 0.68, p = .713				
	R^2 (amount of heterogeneity accounted for): 0.0%				
Sessions of intervention					
Meta-regression	QM(df = 1) = 3.68, p = .055				
	R^2 (amount of heterogeneity accounted for): 13.2%				

Overall effect	k	Hedges' ĝ	95% CI	Q (df)	p	I^2
	30	−0.72	−0.90, −0.55	184.75(29)	<.001	84.3%

Note. CI = confidence interval; df = degree of freedom; ICU = intensive care unit; Q_b = Q between groups; QM = Q moderator; p_b = p between groups.

Vital signs and salivary cortisol are recognized as important physiological measures that indirectly indicate anxiety. Our results indicated that lavender has a decreasing effect on SBP. The effect size is small, but it can be interpreted as meaningful change because systolic blood pressure may be difficult to change. The risk of bias of included studies on physiological measures was low, as the effects of these outcomes would not be affected by participants' awareness of intervention. Therefore, study quality might not influence treatment effects. In conclusion, the effect of lavender on blood pressure is small but not weak based on consistent effect sizes, significant effect, and strong study quality.

The efficacy of lavender on diastolic pressure and heart rate showed small effect sizes of −0.15 and −0.20 and no significant effects. The effect of cortisol was −1.4 with no statistical significance. We can interpret that there is no evidence that the mean effect is statistically different from no effect. However, no evidence of an effect is not the same as evidence of no effect, that is to say, no significant effects do not prove that there is no effect. An alternative explanation may be because of too small sample size or too much heterogeneity. The results of DBP, heart rate, and cortisol can be attributed to insufficient statistical power due to overly few studies because statistical power is affected by the number of studies in the meta-analysis. Therefore, we recommend future studies of RCTs investigating the anxiolytic efficacy of lavender on physiological or endocrinological stress markers such as vital signs or cortisol.

Depression has been recognized as a major comorbidity symptom of anxiety. Our results demonstrate that lavender has a favorable relieving effect on depression levels. The mean effect was medium effect size according to Cohen's standard [35]. Subgroup analysis indicated that route of lavender application tea, massage, and silexan showed significant antidepressive effects, and massage with lavender demonstrated the largest effect size. Only inhalation showed no significant effect. The evaluation of the risk of bias across studies indicated that there is no evidence of publication bias. This evidence on antidepressive effect of lavender is not able to be compared with other evidence because published evidence on this topic could not be located.

In conclusion, lavender aromatherapy by means of massage, silexan, or tea significantly decreases depression in people with various health conditions. There is some evidence of the efficacy of lavender on depression levels on the grounds that there was no evidence of publication bias, and the quality of studies showed no evidence of impact on the observed effect.

Limitations

To ensure study quality, we synthesized only RCTs on the effect of lavender on anxiety and depression; however, the risk of bias assessment showed that of all 37 studies included in quantitative analysis, 16 were rated as some concern of risk, and five studies were evaluated as high risk of overall risk of bias. Only 16 of 37 studies were at low risk of bias. Outcomes such as self-rated anxiety or depression can be influenced by outcome assessor's knowledge

Table 2 *Subgroup/Moderator Analysis on the Impact of the Route of Administration on Antidepressive Effects of Lavender.*

Moderator/subgroup	k	Hedges' ĝ	95% CI	Q_b (df)	p_b
Route of administration					
Inhalation	3	−0.42	−0.77, −0.08	0.95(3)	.814
Tea	2	−0.32	−0.76, 0.12		
Massage	2	−0.63	−1.08, −0.17		
Silexan 80 mg	3	−0.42	−0.72, −0.12		
Meta-regression	QM(df = 3) = 0.95, p = .814				
	R^2 (amount of heterogeneity accounted for): 0.0%				

Overall effect	k	Hedges' ĝ	95% CI	Q (df)	p	I^2
	10	−0.43	−0.59, −0.27	16.88 (9)	.051	46.7%

Note. CI = confidence interval; df = degree of freedom; Q_b = Q between groups; QM = Q moderator; p_b =p between groups.

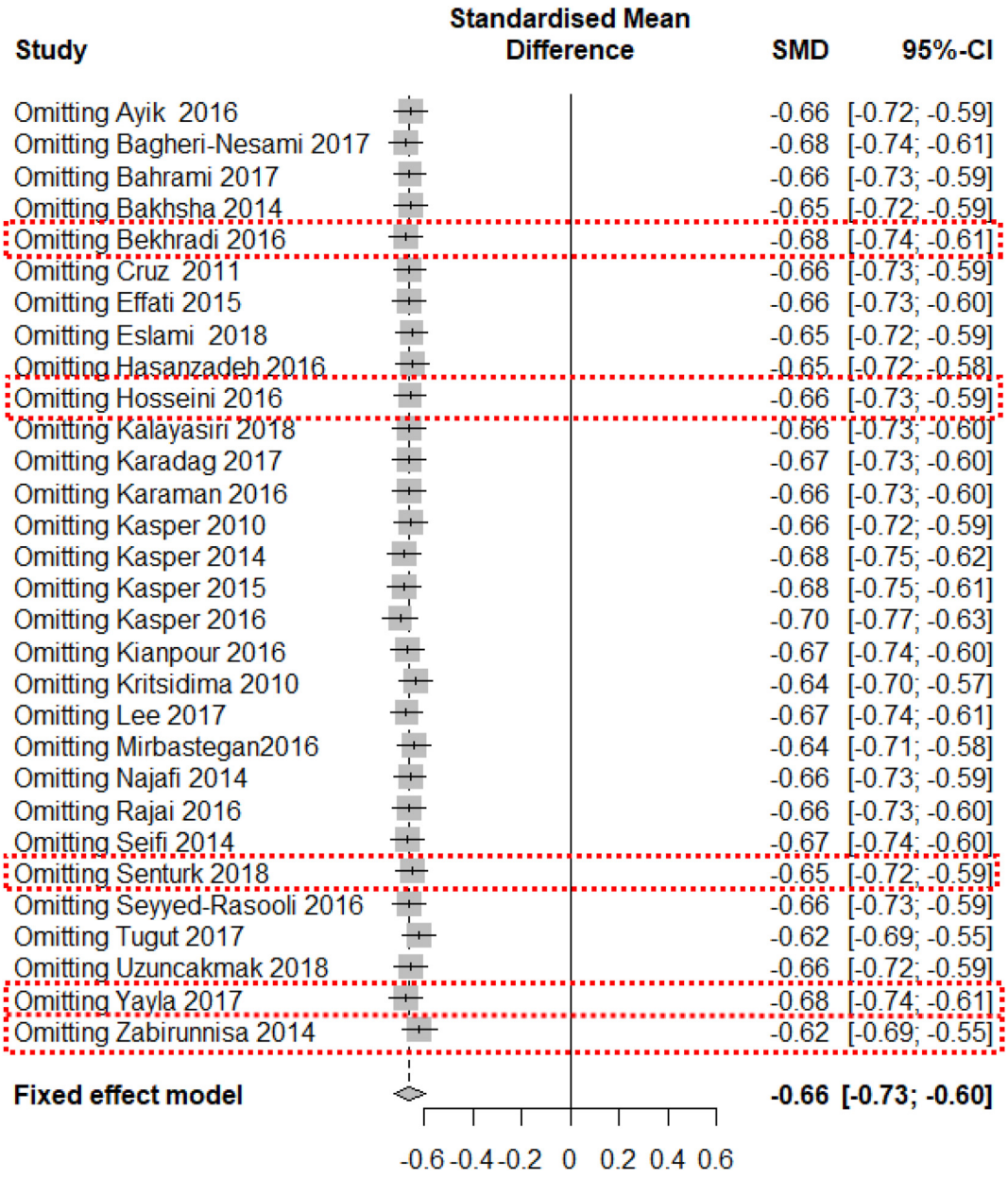


Figure 4. Sensitivity analysis: the mean effect after dropping each study at high overall bias for anxiety levels; studies enclosed by square dotted line are at high overall bias.
Note. CI = confidence interval; SMD = standardized mean difference.

of intervention received. Therefore, our results on anxiety and depression could have been influenced by participants' knowledge of the intervention received, for example, inhalation of lavender or massage using lavender oil.

Although the evaluation of publication bias in our quantitative analysis showed no evidence of risk of bias across studies, in our review process, we included only studies written in English, published reports, and accessible reports based on preset inclusion criteria. These limits in the locating and screening process might have introduced sampling bias.

Conclusions

Our meta-analysis confirmed the results of existing reviews on the effect of inhalation and massage applicating lavender essential oil for a significant decrease in anxiety levels, although the magnitude of the effect varied slightly. The effect of silexan also confirmed a significant anxiolytic effect of previous evidence.

The effects on physiological parameters, including DBP, heart rate, and salivary or serum cortisol, showed small in effect sizes and no evidence of significant effects. Only systolic blood pressure displayed significant small effect size. The statistical power of the analyses on physiological parameters might be weak because of overly small samples, and the magnitude of effects was small. Therefore, more and larger randomized trials testing the effect of lavender aromatherapy for anxiety measured with physiological measures including vital signs or cortisol are recommended.

Our analysis on the effect of the application of lavender for the treatment of depression demonstrated a beneficial effect on decreasing depression. The effect size on depression cannot be compared with the literature because published data on this topic could hardly be located. Our review included any type of

participant, method of intervention, or outcome measure in primary studies investigating the efficacy of lavender aromatherapy. We recommend future reviews focusing on populations in specific health conditions and routes of application of lavender.

Conflict of interest

No potential or any existing conflict of interest relevant to this article was reported.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.anr.2021.11.001.

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Research Article

Factors Associated with Behaviors Toward End-of-life Care Among Chinese Oncology Nurses: *A Cross-Sectional Study*

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SUMMARY

Purpose: The goal of this study was to describe the current status of oncology nurses' behaviors toward end of life (EOL) care in China and to explore the factors associated with oncology nurses' behaviors toward EOL care.

Methods: A cross-sectional design was applied and a convenience sample of 1038 oncology nurses from 22 grade A hospitals were recruited into this study. A general social demographic data questionnaire was administered, and the Chinese version of Nurses' Behaviors of Caring for Dying Patients Scale was used to assess nurse behavior toward EOL care. The total score ranges from 40 to 200 points. Data were analyzed with SPSS 26.0 software.

Results: Chinese oncology nurses' average score of holistic EOL care behaviors was 2.97 ± 0.59. Oncology nurses provide physical care most (3.81 ± 0.76), followed by family care (3.02 ± 0.86), and spiritual care (2.37 ± 0.67). Multiple regression analysis showed that a higher frequency of sharing EOL care experience with colleagues, in-service palliative care education, higher level of head nurse support for EOL patient care, more cases of EOL care, higher working position, and nurse's perceived high level of support were positively associated with behavior toward EOL care. These six factors explained 16.2% of the total variance.

Conclusions: The results may help provide a basis for converting behavior for EOL care among oncology nurses and design interventions to better improve quality of life for EOL patients with cancer in China.

Introduction

Cancer is a serious threat to human health and a major public health problem in China and globally, which impairs social and economic development [1]. According to 2018 cancer statistics [2], there are estimated 18.19 million new cancer cases annually and 9.6 million cancer deaths worldwide. About 10,000 people are diagnosed with cancer every day in China, equivalent to 7 diagnoses every minute. The rapid rises in cancer rates and deaths must be accompanied by a dramatic increase in palliative care, hospice care, and end-of-life (EOL) care. The World Health Organization indicated that nowadays 19.92 million people worldwide require palliative care at the end of their lives, of whom 34.0% were cancer patients [3]. These data reveal that a large number of cancer patients die or receive EOL care in hospitals. As a result, oncology nurses play a vital role in caring for these patients during this critical time [4].

EOL cancer patients often face physical, psychosocial, and spiritual pain in the process of disease progression. They may experience pain, dyspnea, anorexia/cachexia, nausea, vomiting, constipation, malignant bowel obstruction, fatigue, sleep disorders, and mental disorders/delirium [5]. When families and patients have to face the decision to shift the focus of care from active life-prolonging treatment toward comfort-oriented care, there will be also significant psychological consequences [6]. Spiritually, they may find hope and find the meaning of life [7]. When the disease enters the final stage and the focus of treatment shifts from curative to palliative treatment, nurses need to provide care and support with more empathy for patients and their families [8]. A 2013

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statement by the American Association of Pain Management Care [9] pointed out that comprehensive and empathetic end-of-life care is the responsibility of nurses. The core purpose of hospice care is to help patients attain a good death, which requires oncology nurses to systematically assess the patient, communicate with empathy, identify and manage symptoms, recognize and deal with dying and death, and understand the holistic elements of dying [10]. Therefore, it is very important for oncology nurses to be confident in providing care to dying cancer patients, discussing goals of care with the patient and family, and possess enough knowledge and skills to provide EOL care.

Although cancer is a leading cause of death, little is known about cancer-related EOL care in China until recent years, when it gradually gained attention [11,12]. Because of cultural factors, there is no universal regulation on EOL care. In China, Zheng and colleagues [13] reported that the nursing behaviors of oncology nurses in China include physical and mental care, family care, maintaining patient dignity, facilitating communication between patients and their families, providing education on life and death, and coping with negative emotions during the care process. A growing body of evidence has confirmed the benefits of EOL care on both cost and quality of care [14,15]. Several studies have revealed that a high level of EOL care has significant effects on physical and psychological symptoms, quality of life, and patient satisfaction with care and provider communication [16,17].

The behavior of oncology nurses toward EOL care is closely related to the patient's quality of EOL. However, there are no consistent conclusions on the factors associated to behaviors toward EOL care among oncology nurses, and there is a lack of theoretical framework. A study from Taiwan used Green's model as a theoretical framework to explore the influencing factors of nurses' care behavior for dying patients [18]. Based on precede model, promoting the change of human behavior includes predisposing factors, reinforcing factors and enabling factors [19].A study from Australia found that emotional support for nurses, knowledge are influential factors affecting nurses' EOL care behaviors, The findings highlight the importance of future training and practice development opportunities [20]. Others also reported that knowledge and courses in caring for EOL patients are related to the behavior of oncology nurses toward EOL care [18,21]. A study from Korea found that factors that significantly influencednurses' performance of EOL were EOL care stress, obstacles and EOL care attitudes [22]. In addition, some study pointed that the experiences of caring for EOL patients helped nurses to reflect on the meaning of death and life, and positively influenced their behaviors toward caring for the dying [13]. What's special is that death is a taboo in traditional Chinese culture, This increases the difficulty of effective communication between nurses, patients and families [13]. Nurses will face discomfort and experience various setbacks in the process of caring for EOL patients, this will affect nurse physical and mental health and reduce the quality of the EOL care they provide [13,23].

At present, there are few domestic studies on the nursing behavior of oncology nurses for EOL patients, and most research tools are self-designed, indicating a lack of systematic and comprehensive evaluation criteria and methods. However, despite marked development in other countries, EOL care is still in its infancy in China; only a few quantitative studies have examined Chinese nurses' behaviors toward caring for terminal cancer patients [24]. The purpose of this study was to describe the current status of oncology nurses' behaviors toward EOL care in China and to explore the factors associated with oncology nurses' behaviors toward EOL care. The findings of this study may provide a basis for promoting behavior for EOL care among oncology nurses that will lead to the design of interventions to improve the quality of life of cancer patients at the EOL stage in China.

Methods

Study design

This study used a cross-sectional design and convenience sampling.

Setting and sample

This cross-sectional survey was conducted with a convenience sample of nurses from 19 tertiary hospital oncology departments and 3 specialist oncology hospitals in China's Guangdong province between October 2017 and March 2018. Nurses who satisfied the following criteria were included: (1) registered nurses, (2) have at least 1 year of clinical nursing experience, and (3) have experience caring for EOL patients. Manager level nurses who do not deliver bedside care were excluded. A total of 1266 oncology nurses were recruited. Of these oncology nurses, 148 were were excluded because they did not deliver bedside care fo now. Eventually, 1118 participants were included, and 80 oncology nurses refused to participate in the study (participation rate: 92.8%).

Ethical considerations

The guidelines of the Declaration of Helsinki were followed. The study was approved by Institutional Review Board (IRB) of the Anthropology Department at Sun Yat-sen University (Approval no. 20170618). All participants were informed about the study and the voluntary nature of participation. All collected data were kept confidential and anonymous.

Variables and instruments

Two instruments were used to assess the demographics, work-related information, and EOL care information of participants and investigate behaviors toward EOL care among nurses.

Demographic, work-related information, and EOL care information questionnaire

Participants' demographic (age, gender, marital status, educational background , religious beliefs) and work-related information (years of nursing experience, professional title, personal monthly income, working position, type of work unit) were collected. Based on precede model, promoting the change of human behavior includes predisposing factors (such as knowledge, attitude, skills, etc.), reinforcing factors (such as encouragement from colleagues) and enabling factors (policy support, social support) [19]. Therefore, this study chose 13 items for collecting EOL care information.The questionnaire also asked about EOL care information (loss of an important family member or a friend, number of EOL patient care cases, frequency of sharing EOL care experience with colleagues, level of hospital support for EOL patient care, level of head nurse support for EOL patient care, nurse's perceived support in care of EOL patients, nurse's perceived difficulty in care of EOL patients, training status in palliative care as a nursing student, training status in EOL care as a nursing student, training status in communication as a nursing student, in-service training status in palliative care, in-service training status in EOL care courses, and in-service training status in communication).

Nursing behavior scale of nurses facing dying patients

The Nurses' Behaviors of Caring for Dying Patients Scale was adopted to evaluate behaviors toward EOL care among Chinese nurses. The scale was designed by Gu [18] and contained 38 items and 3 dimensions (physical care behavior; spiritual care behavior;

and family care behavior.). It uses a five-point Likert scale that ranges from 1 (never) to 5 (always).The official Cronbach's α was 0.9742. Due to linguistic and cultural differences between mainland China and Taiwan, the researchers re-evaluated the content validity consistency of the scale. In addition to retranslation of the professional terms, two items were added to the source scale: "To provide privacy and a quiet environment" and "to respect the customs and requirements of the patient and his/her family." After re-evaluating, the scale was submitted to the expert committee to evaluate the content validity, and the item-content validity index (I-CVI) was 0.99. After the expert evaluation, a pre-test was carried out and yielded a Cronbach's α of 0.888.The total score ranges from 40 to 200 points and mean score for this instrument was obtained by dividing the total score by the number of items, with a higher score indicating a higher frequency of caring behavior.

Data collection

The researchers conducted the study after obtaining permission from the hospitals. Uniform instructions were used to explain the project aims and significance. Nurses were asked to fill in the questionnaire independently using unified instruction language. If there were any questions, researchers provided guidance and explanations. Each participant needed 10–15 min to finish questionnaires.The investigators collected the questionnaires immediately, and responses with obvious errors and missing information were discarded or corrected.

Data analysis

Data were analyzed using the IBM Statistical Package for Social Sciences (SPSS) version 26.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics are used to present participants' demographic and work-related factors and the prevalence of behaviors toward EOL care. Independent sample *t*-tests and one-way analyses of variance (ANOVAs) with LSD test were used to assess homogeneity of variance, and Pearson's or Spearman's correlation analyses were used to compare differences and examine relationships between participants' demographic and work-related variables and behaviors toward EOL care. Finally, four multiple linear regression models were used to identify salient variables associated with behaviors toward EOL care among demographic and work-related factors. An alpha-level of $p < .05$ was considered significant in all analyses.

Results

General characteristics

A descriptive analysis of the general demographic and work-related characteristics of participants is shown in Table 1. A total of 1038 nurses were included; 1018 participants (98.1%) were female and 627 (60.4%) were married. The mean age was 31.01 ± 6.87 years. The vast majority (97.6%) were non-religious. There were 453 participants (43.6%) whose initial education level was an advanced diploma, and 732 participants' highest education level was undergraduate (70.5%). For work-related characteristics, the mean working years were 9.60 ± 7.50 years. Moreover, 40.8% of participants were senior nurses, and 78.7% were general nurses. More than half (64.1%) of nurses worked in the oncology department of a general hospital.

EOL care characteristics

Information on EOL care is shown in Table 2. Among the 1038 nurses, about 434 (41.8%) had bereavement experience, and more than half (61.4%) of them cared for less than 30 EOL patients. 482 (46.4%) "sometimes" shared their experience of caring for EOL patients with their colleagues. Most nurses believed that the hospital and head nurse had a "supportive" or "very supportive" attitude towards EOL care. The majority of nurses indicated that they felt "great" or "very great" difficulty in the care of EOL patients. During their employment, 556 (53.6%) participants did not complete palliative care courses, 526 (50.7%) did not take EOL care courses, but 650 (62.6%) received communication training courses. Similarly, in terms of nursing students , 603 (58.1%) participants did not receive palliative care education, 559 (53.9%) did not receive EOL care courses, and 60.1% received communication skills training courses.

Prevalence of behaviors toward EOL care

The prevalence of behaviors toward EOL care is shown in Table 3. The mean score for behaviors toward EOL care among Chinese

Table 1 *Demographic Characteristics Of The Participants (N = 1038).*

Variable	Category	*n*	%
Gender			
	Men	20	1.9
	Women	1018	98.1
Marital status			
	Married	627	60.4
	Unmarried	411	39.6
Age (years)			
	≦25	234	22.5
	26 ~ 30	355	34.2
	31 ~ 35	211	20.3
	36 ~ 40	126	12.1
	41 ~ 55	112	10.8
Religious beliefs			
	No	1013	97.6
	Yes	25	2.4
Initial educational level			
	Diploma	367	35.4
	Advanced diploma	453	43.6
	Bachelor's degree or above	218	21.0
Highest level of nursing education			
	Diploma	15	1.4
	Advanced diploma	280	27.0
	Bachelor's degree	732	70.5
	Master's degree or above	11	1.1
Years of nursing experience			
	≦5	388	37.4
	6 ~ 10	319	30.7
	11 ~ 15	122	11.8
	16 ~ 20	87	8.4
	21 ~ 25	72	6.9
	26 ~ 30	50	4.8
Working position			
	General nurse	817	78.7
	Nurse group leader	133	12.8
	Specialist nurse	40	3.9
	Area head nurse	40	3.9
	Department head nurse	8	0.8
Type of Work Unit			
	Specialist Oncology hospital	373	35.9
	Oncology department of general hospital	665	64.1
Personal monthly income (RMB)			
	<2500	28	2.7
	2500 ~	246	23.7
	5000 ~	343	33.0
	7500 ~	297	28.6
	10000 ~	124	11.9
Professional title			
	Nurse	350	33.7
	Senior nurse	423	40.8
	Supervisor nurse or above	265	25.5

Table 2 *Information Of Care Of End-of-life Patients By Oncology Nurses (N = 1038) .*

Variable	Category	*n*	%
Loss of an important family member or a friend			
	Yes	434	41.8
	No	604	58.2
Number of EOL patient care cases			
	1 ~ 10	384	37.0
	11 ~ 30	253	24.4
	31 ~ 50	108	10.4
	51 ~ 100	162	15.6
	101or above	131	12.6
Frequency of sharing EOL care experience with colleagues			
	Never	63	6.1
	Seldom	291	28.0
	Sometimes	482	46.4
	Often	182	17.5
	Always	20	1.9
Level of hospital support for EOL patient care			
	Against/neutral	195	18.8
	Supportive	697	67.1
	Very supportive	146	14.1
Level of head nurse support for EOL patient care			
	Against/neutral	97	9.3
	Supportive	693	66.8
	Very supportive	248	23.9
Nurse's perceived support in care of EOL patients			
	Very supportive	299	28.8
	Non-supportive	739	71.2
Nurse's perceived difficulty in care of EOL patients			
	Very difficult	401	38.7
	Difficult	566	54.5
	No difficulty	71	6.8
Training status in palliative care as a nursing student			
	Yes	482	46.4
	No	556	53.6
Training status in EOL care as a nursing student			
	Yes	512	49.3
	No	526	50.7
Training status in communication as a nursing student			
	Yes	650	62.6
	No	388	37.4
In-service training status in palliative care			
	Yes	435	41.9
	No	603	58.1
In-service training status in EOL care courses			
	Yes	479	46.1
	No	559	53.9
In-service training status in communication			
	Yes	624	60.1
	No	414	39.9

Note. EOL = End Of Life.

oncology nurses was 118.68 ± 23.64. 50.5% of participants had average levels of behaviors toward EOL care. The mean item scores for the dimensions of physical care; family care; and spiritual care were 3.81 ± 0.76, 3.02 ± 0.86, and 2.37 ± 0.67, respectively.

Univariate analyses of factors associated with behaviors toward EOL care

Independent sample *t*-tests and ANOVAs revealed that nurses who were 41-50 years old, had 11–30 years of nursing experience, married, supervisor nurse or above, and nurse group leader or above had more EOL patient cases, a higher frequency of sharing EOL care experience with colleagues, greater level of head nurse support for EOL patient care, higher level of nurse perceived support, palliative care education, communication training, and EOL care courses had higher total behavior and for all three dimensions toward EOL care ($p < .050$). In addition, nurses with a bachelor's degree or above, personal monthly income over 5000 RMB, worked in oncology department of a general hospital, higher level of hospital support for EOL patient care, and training status in palliative care as a nursing student had higher total behavior ($p < .050$). Similarly, nurses who worked in oncology departments of general hospitals had higher physical care behavior, but who had higher level of nurse' perceived difficulty in care of EOL patients had lower physical care behavior ($p < .050$). Furthermore, nurses who had a bachelor's degree or above, had experience of losing an important family member or a friend, and had higher level of hospital support for EOL patient care had higher spiritual care behaviors ($p < .050$). Finally, nurses who had a higher personal monthly income; worked in the oncology department of a general hospital; had an experience of losing an important family member or a friend; had a higher level of hospital support for EOL patient care; and had palliative care education, communication training, and EOL care courses as a nursing student had higher family care behavior ($p < .050$, see Supplementary Table).

Regression analysis examining covariates of behaviors towards EOL care

Significant variables in univariate analyses were inputted to the multivariate regression analysis. Before the analysis, we examined the linear relationship, multivariate normality, and homoscedasticity of variables. As a result of the test of multicollinearity using the tolerance limit and the variation inflation factor (VIF) value, it was found that all variables did not have a multicollinearity problem (tolerance limit:.54~.93; VIF: 1.08~1.85). The results of regression analyses examining covariates of behaviors towards EOL care are presented in Table 4. In the total model, the frequency of sharing EOL care experience with colleagues, in-service received palliative care education, level of head nurse support for EOL patient care, number of EOL care cases, working position, and nurse's perceived support in care of EOL patients were significant correlates explaining 16.2% of the total model variance ($F = 11.58$, $p < .001$). In terms of physical care behavior, the frequency of sharing EOL care experience with colleagues, number of EOL care cases from 51 to 100, professional title of supervisor nurse or above, in-service EOL care courses, and type of work unit explained 8.9% of the total model variance ($F = 15.52$, $p < .001$). In terms of spiritual care behavior, the frequency of sharing EOL care experience with colleagues, in-service palliative care education, level of head nurse support for EOL patient care, number of EOL care cases from 11 to 30 and ≥ 51, specialist nurse, and nurse's perceived support were significant correlates explaining 11.9% of the total model variance ($F = 9.24$, $p < .001$). According to regression analyses, seven variables exerted an influence on family care behavior: frequency of sharing EOL care experience with colleagues, in-service palliative care education, level of head nurse support for EOL patient care,

Table 3 *The Prevalence of Behaviors Toward EOL Care Among Oncology Nurses (N = 1038).*

Dimension	Range	Minimum	Maxmum	Mean	Entry mean	sorting
Total score	40~200	51	187	118.68 ± 23.64	2.97 ± 0.59	
Body care behavior	13~65	18	65	49.50 ± 9.82	3.81 ± 0.76	1
Family care behavior	8~40	8	40	24.16 ± 6.92	3.02 ± 0.86	2
Spirtual care behavior	19~95	19	89	45.02 ± 9.82	2.37 ± 0.67	3

Table 4 *Regression Analysis Examing Covariates of Behaviors Towards End-of-life Care.*

Model	Total[a]					Body care behavior[b]					Spiritual care behavior[c]					Family care behavior[d]				
	B	SE	Beta	t	*p*	B	SE	Beta	t	*p*	B	SE	Beta	t	*p*	B	SE	Beta	t	*p*
(Constant)	90.34	5.34		16.93	<.001**	38.12	1.68		22.67	<.001**	32.34	2.56		12.63	<.001**	13.39	1.72		7.77	<.001**
X_1 Frequency of sharing EOL care experience with colleagues	4.54	.84	.17	5.40	<.001**	1.74	.35	.15	5.04	<.001**	1.94	.46	.13	4.23	<.001**	1.30	.25	.16	5.22	<.001**
X_2 In-service training status in palliative care	6.67	1.42	.14	4.69	<.001**	-	-	-	-	-	3.17	.78	0.12	4.07	<.001**	1.70	.48	.12	3.56	<.001**
X_3 Level of head nurse support for EOL patient care	4.09	1.24	.10	3.29	.001*	-	-	-	-	-	1.72	.68	.08	2.52	.012*	1.25	.37	.10	3.38	.001*
X_4 Number of EOL patient care cases																				
X_{41}11–30	4.32	1.90	.07	2.28	.023*	-	-	-	-	-	2.28	1.03	.07	2.21	.027*	-	-	-	-	-
X_{42}31–50	5.51	2.67	.06	2.06	.039*	-	-	-	-	-	-	-	-	-	-	1.62	.80	.06	2.04	.042
X_{43}51–100	9.06	2.31	.12	3.93	<.001**	2.23	.93	.07	2.40	.017	4.54	1.26	.12	3.62	<.001**	-	-	-	-	-
X_{44}101 or above	7.03	2.62	.09	2.68	.008*	-	-	-	-	-	3.69	1.44	.09	2.57	.01*	-	-	-	-	-
X_5 Working position																				
X_{51} Nurse group leader	6.11	2.30	.09	2.66	.008*	-	-	-	-	-	-	-	-	-	-	1.61	.69	.08	2.35	.019
X_{52} Specialist nurse	4.63	1.88	.08	2.46	.014*	-	-	-	-	-	2.80	1.03	.09	2.73	.007*	-	-	-	-	-
X_6 Nurse's perceived support	3.85	1.57	.07	2.46	.014*	-	-	-	-	-	2.32	.86	.08	2.71	.007*	-	-	-	-	-
X_7 Professional title																				
X_{71} Supervisor nurse or above	-	-	-	-	-	3.06	.76	.14	4.04	<.001**	-	-	-	-	-	-	-	-	-	-
X_8 In-service training status in eol care courses	-	-	-	-	-	1.76	.59	.09	2.98	.003*	-	-	-	-	-	-	-	-	-	-
X_9 Type of Work Unit	-	-	-	-	-	1.96	.61	.10	3.21	.014	-	-	-	-	-	1.57	.43	.11	3.64	<.001**
X_{10} In-service training status in communication	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1.11	.48	.08	2.34	.019

[a] $F = 11.58$, $p < .001$, $R^2 = 17.8\%$, $R^2_{adj} = 16.2\%$.
[b] $F = 15.52$, $p < .001$, $R^2 = 9.5\%$, $R^2_{adj} = 8.9\%$.
[c] $F = 9.24$, $p < .001$, $R^2 = 13.3\%$, $R^2_{adj} = 11.9\%$.
[d] $F = 8.49$, $p < .001$, $R^2 = 14.9\%$, $R^2_{adj} = 13.2\%$.

number of EOL care cases from 31 to 50, nurse group leader, type of work unit, and in-service communication training explained 13.2% of the variance ($F = 8.49$, $p < .001$).

Discussion

At present, more than 20.4 million people worldwide need palliative care annually. Approximately 19 million are adults, and 34% are patients diagnosed with cancer [3].The demand continues to grow, and nurses play an integral role in promoting palliative care for cancer patients and their families [25]. It is therefore necessary to understand the behavior of nurses toward EOL care. In this study, we assessed the EOL care behavior of 1038 Chinese oncology nurses with the Nurses' Behaviors of Caring for Dying Patients Scale. The results showed that the average score of EOL care behaviors among Chinese oncology nurses was 2.967 ± 0.59. This corresponds to a similar level of hospice care behavior compared with previous studies using the same questionnaire for clinical nurses in Taiwan [18]. Furthermore, oncology nurses usually give priority to patients' physiological requirements, which conforms to Maslow's theory of basic human needs. These findings are similar to previous reports [18,26,27].In this study, the average score for spiritual care behavior was only 2.37, indicating that nurses rarely performed this kind of behavior. However, in addition to the control of pain and other symptoms, it is equally important to meet the psychological, social, and spiritual needs and provide substantive support in EOL care [28]. Possible reasons for the lack of his care are as follows. First, nurses are too busy dealing with doctors' orders and providing treatment to have good communication with patients [29]. Secondly, spiritual care has only recently entered the realm of nursing in China compared with other countries. Over the past 5000 years, Chinese culture has developed a unique view on dying and death due to the profound influences of Taoism, Confucianism, and Buddhism [30,31]. However, Chinese nurses have insufficient understanding and ability to provide the necessary spiritual care [32,33]. Thirdly, due to the influences of Chinese traditional culture and death taboos, oncology nurses lack the confidence and proficiency to provide psychological care and communicate with patients' families [18]. Our results indicate that the behaviors of oncology nurses are insufficient for EOL care and underscore the need for health institutions to address this issue.

With regard to demographic and work-related factors, we found that a higher working position was positively related to behavior toward EOL care. Specialist nurses and nursing group leaders had higher scores in total caring behavior, possibly because they are appropriately trained, have better professional knowledge, and know how to deliver high-quality EOL care [34]. A research also showed that post and title were significant factors to behaviors toward EOL care [35].

With regard to EOL care factors, we found that a higher frequency of sharing EOL care experience with colleagues, in-service palliative care education, higher level of head nurse support for EOL patient care, number of cases of EOL care, and nurse's higher perceived support were positively associated with behavior toward EOL care. Oncological nurses who had treated 50–100 EOL patients had the most active EOL care behavior, which was consistent with the research results of Marjan and colleagues [36]. Some studies found the frequency of EOL care supportive behaviors was the factor affecting EOL care competency [37,38]. This is mainly because if a nurse has more EOL patient experience, the more positive their nursing attitude will be, and they are more willing to talk about EOL care problems and death [3,39]. Weigel and colleagues [40] proposed that this phenomenon occurs because nurses' various care skills, especially communication skills, develop as the number of patients increases. We also observed that the more frequently

oncology nurses shared their EOL patient care experiences with colleagues, the more frequently they engaged in nursing behaviors. Beckstrand et al. [41] assessed 1005 oncology nurses and concluded that listening to the experience, knowledge, and advice of senior oncology nurses contributed to the promotion of high-quality, compassionate EOL care. Our results showed that the level of head nurse support for EOL patient care was positively associated with behavior toward EOL care, which was consistent with previous reports [36,42,43]. This finding indicates that the head nurse's attitudes influence EOL care among clinical nurses. In addition, our results showed that nurse's perceived high level of support was positively associated with behavior toward EOL care. In previous studies, support for nurses has been proved to be a positive factor affecting their caring behavior toward EOL care [44].Furthermore, nurses who received palliative care education at work had higher scores on behaviors toward EOL care. Participation in a nationwide education program were factors that showed a significant association with adequate EOL care [38]. Therefore, it is especially important for nursing educators to provide EOL care courses suitable for conditions within China.

We performed multiple regression analyses on the three dimensions of behavior toward EOL care. In addition to the variables previously analyzed into the total score model, we found that three variables related to physical care behavior (professional title, in-service EOL care courses, and type of work unit). It was found that oncology nurses who were supervising nurses and above exhibited more physical care behavior, which was similar to previous studies [19,45]. The reason may be that nurses with intermediate titles have more professional knowledge and life experience and are therefore more able to feel patients' pain and understand their needs. The work unit also affected the physical care behavior dimension score. This indicates that nurses working in oncology departments in general hospitals provide more physical care for EOL patients and suggests that nursing managers in oncology hospitals should pay more attention to training nurses in other aspects of EOL care. Indeed, we found that EOL care courses played an important role in affecting behavior toward EOL care. Offering these courses can help directly either by improving nurses' attitudes or enhancing direct patient care skills [39,46]. Systematic EOL care training generally includes death education, psychological and spiritual care, and communication skills [47]. The late Life Care Education course [47,48] was shown to have positive impacts on nurses' education about death on patients and family members, promotion of care skills, and care behavior. With regard to the family dimension, we found that receiving communication training during employment was positively associated with family care behavior. The reasons are as follows: compared with the other dimensions, family care requires good communication between family members and nurses, who can assist with grief counseling [49]. One study reported that completing a communication course improved nurses' knowledge and confidence in communication, as well as their ability to educate others [50]. Palliative care nurses should therefore incorporate communication skills into their practice.

To our knowledge, this is the first study to describe the behavior towards EOL patients in oncology nurses in China. A few groups have investigated nurses' caring behavior towards EOL patients here and abroad. However, most of the research tools are questionnaires designed by the investigators themselves, so there is a lack of systematic and comprehensive evaluation criteria and methods. Most were qualitative studies. Our results should be considered in the context of several limitations. First, the convenience sample limits the generalizability of the findings to nurses in 22 hospitals in Guangdong Province, China. Then, the predictive model in this study only explained 16.2% of the total variance. The reasons might be as follows: In previous studies, knowledge and attitude of nurses have been proved to be related to caring behavior, but this variable was not included in this study.In addition, because behavior toward EOL care is affected by many complex factors, including cultural factors, So, more research is needed to explore the influencing factors.

Conclusion

Our results demonstrate that Chinese nurses' behaviors toward EOL care for cancer patients mainly focus on physical care, ignoring patients' psychological and spiritual needs, and family care. Behaviors toward EOL care are affected by sociodemographic variables, EOL training, and other factors. Among them, availability of training for palliative care, EOL care, and communication are important. The level of head nurse support for EOL patient care and nurse's perceived support in care of EOL patients also affect behaviors. These findings may reflect that EOL care education is not well integrated into nursing education.Based on this findings, we recommend developing a training program for oncology nurses to improve knowledge and skill of EOL care. Well-trained nurses may provide better care for patients at their end of lives.These innovative programs should be developed in the context of traditional Chinese culture to improve the quality of care for patients with terminal cancer.

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Ethical approval

This study was approved by the Institutional Review Board of the S University (Approval no. 20170618).

Conflict of interest

The authors declared no conflict of interest.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.anr.2021.10.003.

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Research Article

The Development and Validation of a Perceived Nursing Support Scale for Mothers of Preterm Infants

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SUMMARY

Purpose: Many studies have maintained that nursing support is necessary and essential for mothers of preterm infants; however, the perceived nursing support for mothers of preterm infants has not been sufficiently measured. This study aimed to develop a perceived nursing support scale for mothers of preterm infants (PNSS-MP).

Methods: The preliminary items of the PNSS-MP were developed through a literature review and in-depth interviews with mothers of preterm infants. Content and face validities were assessed by experts and mothers of preterm infants. A pilot study was conducted to confirm the feasibility and comprehension of the scale. To validate the PNSS-MP, 223 mothers of preterm infants were surveyed. Exploratory factor analyses were performed to confirm construct validity. Convergent and discriminant validities were analyzed using a multitrait-multimethod (MTMM) matrix. Reliability was tested by calculating Cronbach's α and performing split-half testing.

Results: The PNSS-MP consisted of 27 items and was categorized into five factors, explaining 65.3% of the total variance. The factors were named: "baby care support" (7 items), "mental care support" (6 items), "maternal role support" (6 items), "introducing resources support" (4 items), and "information delivery support" (4 items). The overall reliability of the scale was .95.

Conclusion: The PNSS-MP adequately reflected the neonatal intensive care unit (NICU) in South Korea. Additionally, the PNSS-MP proved relatively valid and reliable; therefore, it can be used to measure nursing support in the NICU.

Introduction

Background

Advances in medical technology have led to improved health and care for premature infants [1]. However, these advances have increased the admission rate to the neonatal intensive care unit (NICU), causing a disconnection between mothers and their infants [2]. This disconnection often brings a crisis and conflict between family members as the mother is unable to perform an appropriate maternal role [2,3]. Preterm infants are also at high risk for developmental delays and emotional-behavioral problems because they spend most of their time separated from their parents [4]. In addition, mothers experience negative emotions, such as anxiety, frustration, and stress, due to the uncertain prognosis of their children [2,3,5]. Therefore, mothers expect nurses to explain how the infant is treated and wish to spend more time with the infant [3].

In this situation, nursing support is helpful to mothers of infants [3,5]. Nursing support places emphasis on interactions with patients and encourages their participation [3]. A mother of a premature infant who obtains information about the treatment process of her baby is comforted and regains her self-esteem as a mother with nursing support [5,6]. In addition, appropriate nursing support is useful for forming an attachment with the baby and is effective in improving maternal efficacy [3,7]. Families have also expressed that nursing support is useful for family-centered care in challenging situations, such as inpatient neonatal intensive care [3].

Nursing support is a unique concept in the nursing discipline [8]. Many studies have consistently attempted to validate the concept

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and its effects since the 1980s [8–10]. Nursing support is generally divided into three categories: educational support, which refers to providing information on diseases to patients being nursed; emotional support, which entails expressing sympathy and interest to the patient being nursed; and physical support, which is the provision of support to help the patient recover [8–10]. As described above, the concept of support may differ slightly depending on the provider and patient [8]. Ultimately, it includes activities intended to elicit positive outcomes from the patient [9,10].

Nursing support is provided in various ways in a NICU. Educational support is mainly offered in South Korea, and in the context of preterm births, educational support involves the provision of information about babies using videos, workbooks, and other means [11–13]. This has yielded positive outcomes, such as reducing maternal parental stress and anxiety and improving confidence in parental infant care [11–13]. More diversified nursing support in various areas has been provided in other countries. Tangible support, such as breastfeeding and kangaroo care, has been provided to facilitate infant growth and improve the attachment between parents and infants [7,14]. Moreover, other forms of nursing support involved introducing social or environmental resources such as helpful community-based programs or peer support [15,16].

Numerous studies and experts have argued that nursing support is essential for mothers of preterm infants [3,5]. However, the nursing support perceived by mothers of preterm infants has been insufficiently measured. The Nurse Parent Support Tool (NPST) developed by Miles [17] has been used to measure nursing support provided to parents in South Korea. This scale measures the following types of nursing support for mothers with hospitalized children: emotional support, esteem support, caregiving support, and information support. However, this scale was developed on the premise that mothers care for the hospitalized child directly, and it does not reflect the feelings and needs of mothers of preterm infants who are completely separated from their babies. Additionally, a major limitation of this scale is that it has been used without sufficiently ensuring the reliability or validity of a translated version. Furthermore, the effects of the nursing support provided to the parents of the hospitalized child have been measured using physiological variables (e.g., blood pressure, pulse, and blood sugar) or psychological variables (e.g., depression, stress, and anxiety), rather than measuring nursing support directly [9,10,18].

Purpose

Therefore, this study aimed to develop and validate a perceived nursing support scale for mothers of preterm infants (PNSS-MP). Specifically, the first aim was to develop a PNSS-MP based on concept analysis. The second aim was to psychometrically validate the developed scale. It will be useful to identify the diversity and degree of nursing support provided to mothers. In addtion, the measurement of nursing support perceived by mothers of preterm infants can be used as evidence-based data that can provide best nursing support practices for mothers of preterm infants.

Methods

Study design

This study employed a methodological design to develop and validate the PNSS-MP.

Scale development

Conceptual framework

The confirmation of the conceptual framework and the configuration of the scale components were based on the results of a previous study [3]. This study analyzed the concept of nursing support perceived by mothers of preterm infants using a hybrid model. At the theoretical stage, 16 articles published in South Korea and other countries regarding nursing support related to mothers of preterm infants were analyzed. At the field stage, in-depth interviews were conducted with 10 mothers of preterm infants. In the analytical phase, the attributes of nursing support identified during the theoretical and fieldwork phases were compared and analyzed. As a result, the nursing support perceived by mothers of premature infants consisted of 4 themes, 10 attributes, and 31 indicators. “Professional care” and “emotional care for the baby” were identified as attributes of baby care support. “Information related to the disease,” “inpatient environment,” “baby’s daily hospital life,” and “mother-centered care” were identified as attributes of information delivery support. “Empathy for mothers” and “therapeutic communication with the mother” were identified as attributes of mental care support. Lastly, “providing a chance for the mother to take care of the baby” and “reinforcement of the maternal role” were identified as attributes of maternal role support.

Composition of preliminary items

In total, 41 item pools were developed based on the 10 attributes and 31 indicators derived from previous concept analysis studies [3]. Subsequently, duplicated and ambiguous interpretations and grammatically incorrect statements were eliminated after consultation and review by two nursing professors and one specialist in Korean literature. Thirty preliminary items were extracted using clear and simple sentences, with each item presenting a single concept.

This scale used a Likert scale, which is widely used for measuring support or satisfaction and can determine the number of response categories according to the investigated phenomena and study objectives. This study used a 5-point Likert scale (“strongly agree” = 5 points; “strongly disagree” = 1 point) with a neutral point (3 points) based on evidence that forced-choice scales can elicit biased responses [19].

Content validity

For expert validation, experts in maternal and pediatric nursing examined content validity twice. Face validity was examined with mothers of preterm infants.

First expert content validity. The first expert content validity test was conducted from September 20 to October 4, 2018. The 30 preliminary items were reviewed by five nurses who had worked for ten years or more at the NICU and five professors of pediatric nursing and women’s health nursing.

After explaining the objective of the study and the concept of nursing support to each expert, the experts were asked to review the relevance of the contents of each item to the purpose of the scale. The degree of validity was evaluated as “not related at all” (1 point), “not related and revision is needed” (2 points), “related but revision is somewhat needed” (3 points), and “very related and concise” (4 points). If modifications were suggested, opinions on how to modify the items were collected.

Based on the content validity of the expert group, item-content validity index (I-CVI), scale-content validity index/average (S-CVI/Ave), and scale-content validity index/universal agreement (S-CVI/UA) were calculated. Content validity was determined when S-CVI/Ave$\geq$.90 and S-CVI/UA$\geq$.80 [20].

The result of the first expert content validity test showed that I-CVI ranged between .90 and 1.0, S-CVI/Ave was .93, and S-CVI/UA was .90. Items were then constructed concisely based on the first expert content validity test. Moreover, ambiguous or inaccurate items were corrected. There was an opinion that many items measured multiple attributes, such as "the nurse gave me an appropriate assessment and guided me in improving my baby caring." These items were, therefore, modified and separated. Finally, 34 preliminary items were identified.

Face validity. Face validity was assessed with five mothers of preterm infants who participated in the in-depth interviews in the concept analysis process. The interviews were conducted between October 15 and October 24, 2018. The results of the face validity test with the 34 items showed that the I-CVI ranged between .80 and 1.0, and the averages of the S-CVI/Ave and S-CVI/UA were .98 and .88, respectively. Regarding the items, "A nurse reacted immediately when my baby cried" and "A nurse responded immediately when my baby's monitor alarm sounded," mothers said that it would be difficult for a nurse to provide immediate care because each nurse takes care of several infants at the same time. Therefore, the word "immediately" was removed. In addition, the item "A nurse informed me about peer groups of mothers of preterm infants" was supplemented with the explanatory terms "online communities" and "local meetings," as the term "peer group" is unfamiliar in South Korea. The item, "A nurse sympathized with feeling guilty and sorry for the baby," was deleted as it might have caused negative thoughts and feelings within the mothers. Considering the opinion that the item, "A nurse comforted me as I was having a hard time," was too abstract because no specific situation was described, we added "giving birth to a preterm infant" to the end of the item. Lastly, the item, "A nurse saw me babysitting and corrected me if necessary," was deleted because of the opinion that it overlaps with the feedback-related item. Finally, 32 items remained.

Second expert content validity test. Based on the 32 revised items resulting from the first expert content validity and face validity tests, three nurses from the NICU, three doctoral students of pediatric nursing, and five professors of pediatric nursing and women's health nursing conducted the second expert content validity test. The test was conducted from November 1 to November 14, 2018. The results confirmed that the I-CVI was between 0.8 and 1.0, S-CVI/Ave was .99, and S-CVI/UA was .97. One of the opinions expressed in the second expert validity test was that it would be necessary for nurses to inform mothers about physical and medical condition changes in their babies, such as increases and decreases in weight and the progression of jaundice. Therefore, one item, "A nurse explained my baby's physical changes in a way I could understand," was added. Similarly, "I was provided enough information needed to me" was said to be too abstract and could give a sense of encompassing the items of support for information delivery; therefore, it was revised to "A nurse provided a sufficient amount of information, according to my needs." Thirty-three items were identified at this stage.

Pilot test

Based on the 33 items that had been validated by experts, the objectives and an explanation of this study were posted on the preterm mother's online social networking service (SNS) from November 28 to December 1, 2018. The pilot study included 25 participants.

It took 2–13 min (mean = 6.4 min, standard deviation = 2.6 min) to complete the questionnaire, and the degree of item comprehension was 4.08 ± 0.7 points, the appropriateness of the questionnaire arrangement was 4.07 ± 0.64, and the appropriateness of the item lengths was 4.24 ± 0.78 points, which were measured on a five-point Likert scale. Cronbach's α for the preliminary survey was .96.

Meanwhile, eight mothers expressed that they had difficulty determining which nurse should be the focus of the survey because there were substantial differences in the competencies of the nurses. Therefore, an additional instruction of "Mark with 'V' the most relevant response, recalling the overall nursing support that you received from the nurses of the NICU during your baby's hospitalization," was added to the introduction section of the scale. The main survey was conducted with 33 items confirmed through this process.

Scale evaluation

Setting and samples

The sample size was determined based on Devellis [19], who argued that 200 participants would be required for a stable scale evaluation if the number of items was 40 or fewer. In addition, based on evidence that 200 to 400 participants would be suitable for exploratory factor analyses (EFA) [21], 223 participants were recruited for this scale evaluation.

The participants in this study were limited to mothers with preterm infants who were admitted to the NICU. The specific selection criteria for the study participants were as follows: a) mothers who understood the purpose of this study and agreed to participate in it, b) mothers who gave birth to a baby of less than 37^{+0} gestational age, c) mothers of an infant without congenital malformations or genetic disorders, and d) mothers within a year of their delivery.

Data collection and ethical considerations

This study was approved by the Inje University Institutional Review Board (Approval no. 2017-11-006-003). The purpose and procedures of the study were explained to the participants. It was also explained that the data would be treated anonymously and used solely for research purposes. Participants were notified that they could withdraw from the study without any repercussions. Participants voluntarily agreed to participate in the study and provided their informed consent before completing the questionnaires.

The survey was conducted between December 3 and February 28, 2019. Offline recruitment was requested through the nursing departments with NICUs in Busan and Ulsan. However, it was difficult to recruit participants directly because of the closed environment of the NICU and possible invasions of privacy of patients. Therefore, 23 mothers were conveniently sampled from the NICU of one hospital that agreed to the data collection request. Other participants were recruited through a preterm mothers' online SNS on the N portal site. An online gift card was provided to the participants following their completion of the survey. In this process, missing questions were reconfirmed, and no participants were excluded because of insufficient responses.

Evaluation of the scale

The collected data were analyzed for testing item analysis and construct validity, including EFA, convergent validity, and discriminant validity. In addition, criterion validity was based on

the correlation between the finalized instruments and the Pediatric Family Satisfaction Questionnaire (PFSQ). The reliability was tested using Cronbach's alpha for internal consistency and first-second half split-half reliability of the data. IBM/SPSS Statistics for Windows (version 24.0; IBM Corp., Armonk, NY, USA) was used for the analyses.

Item analysis. For the item analysis, the mean, standard deviation, skewness, kurtosis, ceiling and floor effect, and corrected item-to-total correlation coefficient of each item were identified. The threshold of skewness was set to ±2, and kurtosis was set to ±10 [22]. The corrected item-to-total correlation coefficients were set between .30 and .80 [23]. The standards for the floor and ceiling effect were set to 25% [24]. If the items did not meet the above criteria, they were considered for deletion. Additionally, Cronbach's α, after item removal, was checked to confirm any items affecting the scale's reliability.

Exploratory factor analysis. Prior to the EFA, it was examined whether the collected data were suitable for EFA using Kaise-Meyer-Olkin (KMO) and Bartlett's test of sphericity. We checked whether the KMO value was .5 or higher and if the p-value of Bartlett's test of sphericity was lower than .05 [23].

Subsequently, principal component analysis using Varimax orthogonal rotation, which rotates the factor structure while maintaining the independence of the factors, was performed to understand the structure between the measured factors [25]. After that, it was checked whether the communality extraction value was .4 or more, the eigenvalue was ≥1.0 [26], and the range of the factor loading was .50 or more [25]. If these criteria were not met for certain items, they were considered for deletion.

Convergent and discriminant validity. A multitrait-multimethod matrix (MTMM) was used to determine convergent and discriminant validity for scale development. The convergent validity was considered satisfied when the correlation coefficient, which was corrected for overlap between the sub-factors to which item belongs, was more than .40 [27]. In addition, if the difference between the item-own and item-other subscale correlation was greater than two times the standard error of correlation coefficients, it was considered that the item's discriminant validity was established [27,28].

Criterion validity test. The Pediatric Family Satisfaction Questionnaire (PFSQ), which was developed by Budreau and Chase [29], and translated by Jeong and Kim [30], was used to test concurrent validity. The PFSQ was developed to measure the service satisfaction of inpatient children's families. It consists of three areas of satisfaction: 7 items for hospital services and accommodations, 12 items for nursing care, and 11 items for medical care. In the PFSQ, nursing care items included items regarding direct care for babies, such as, "Nursing care was caring and concerned" and "Nursing care checked the patient's condition closely." It also includes items regarding care provided to parents, such as, "Nursing care kept us informed" and "Nursing care answered our questions clearly." In this study, the participants answered the nursing care items in PFSQ with the PNSS-MP to establish concurrent validity, with a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). 'Nursing care' was chosen for establishing criterion validity as it is a broad concept involving nursing support [31]. Pearson correlation coefficients of items regarding nursing care and PNSS-MP were calculated.

Reliability test. The reliability of the PNSS-MP was tested using internal consistency reliability and split-half reliability. Cronbach's coefficient was calculated to confirm the internal consistency reliability. To check the split reliability, the items of this study were divided into the first part and the latter part, and the correlation coefficient between the scores of the two parts was calculated and tested using the Spearman-Brown formula and the Guttman split-half coefficient.

Results

General characteristics of participants

The general characteristics of the participants are presented in Table 1. The participants' mean age was 33.10 ± 4.08, and 156 (70%) had a bachelor's degree. The average monthly household income was KRW 3–4 million (28.3%). Most participants did not identify with a religion (47.5%). Mothers with their first child as a preterm infant were the most common (60.1%). The mean gestational age was 31.14 ± 3.23 weeks, and the mean birth weight was 1643.81 ± 623.55 gm. The mean length of hospitalization was 1.72 ± 0.96 months, and the mean age of the infants at the time of the survey was 5.61 ± 3.45 months.

Item analysis

The mean, standard deviation, skewness, and kurtosis of each item (33 items in total) were reviewed for the item analysis. The skewness value ranged from −0.66 to 1.70, and the kurtosis value was between −0.04 and 3.46, meeting the normality criteria. The item-total correlation coefficient for each item was between .37 and .78, which satisfied the standard (absolute value ≥ .30) [23]. Moreover, the changes in Cronbach's α were examined when an item was removed, and it was confirmed that no item affected the overall reliability.

Construct validity

Exploratory factor analysis

As the previous study divided nursing support into four components [3], this study designated four factors in the first factor

Table 1 *General Characteristics of Participants (N = 223).*

Variables	Category	Mean ± SD or N (%)
Age (years)		33.10 ± 4.08
Education	Junior college	30 (13.5)
	University	156 (70.0)
	Graduate school or above	37 (16.5)
Monthly income (million won)	<200	17 (7.6)
	200 ≤ and <300	57 (25.5)
	300 ≤ and <400	63 (28.3)
	400 ≤ and <500	34 (15.3)
	≥500	52 (23.3)
Religion	None	106 (47.5)
	Christian	65 (29.2)
	Catholic	25 (11.2)
	Buddhist	25 (11.2)
	Others	2 (0.9)
Birth order of preterm baby	First	134 (60.1)
	Second	61 (27.4)
	Third	26 (11.6)
	Fourth	2 (0.9)
Birth gestational age (weeks)		31.14 ± 3.23
Birth weight (gm)		1,643.81 ± 623.55
Duration of hospitalization in NICU (months)		1.72 ± 0.96
Age of baby at the time of survey (months)		5.61 ± 3.45

Note. NICU = neonatal intensive care unit.

analysis. The results of the first factor analysis showed that the total explained variance was 59.4%, the communality was between .41 and .75, and the factor loading was between .45 and .86.

After confirming that the total explained variance was relatively low when the number of factors was specified, a secondary factor analysis was conducted without specifying the number of factors. The secondary factor analysis extracted five factors and increased the total explained variance to 62.9%. The communality was between .44 and .78, and the factor loading was between .41 and .86. Item 8, "A nurse explained my baby's physical changes in a way I could understand," and item 11, "A nurse told me things about my baby's daily life that I could not observe," were deleted because their factors could not be distinguished clearly.

In the third factor analysis, five factors were extracted, and the cumulative explained variance was 64.1%. It was confirmed that the communality was between .45 and .78, and the factor loading was between .46 and .86. Item 27, "A nurse told me a story that encouraged me and told me that my baby was doing well," was deleted because it was not a universal item that could be applied to all mothers of preterm infants and its factor classification was unclear. Item 33, "A nurse helped me make the best decisions for baby-related matters," was deleted because classifying the factor was difficult.

Based on the above, a fourth factor analysis was performed, and five factors were extracted. The total explained variance was 64.3%. The communality was between .46 and .79, and the factor loading was between .43 and .88. Regarding item 9, "A nurse explained the behavioral characteristics of my baby so that I could understand them," the factor loading was below the threshold, and it overlapped with some items of information delivery support. Item 26, "A nurse used the items brought for my baby (e.g., breast milk,

Table 2 *Factor Analysis of PNSS-MP (N = 223).*

No	Items	Communality	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5
	A nurse…		Baby care support	Maternal role support	Mental care support	Introducing resources support	Information delivery support
3	Came and looked after my baby when my baby was crying	.60	.72	.13	.17	.14	.08
6	Expressed love and concern while looking after my baby	.62	.72	.09	.26	.11	.12
2	Took good care of my baby considering my baby's characteristics	.60	.62	.25	.24	.13	.28
7	Provided emotional stimulation (e.g., talking, hugging, and eye contact) to my baby	.59	.62	.24	.17	.34	.00
5	Helped my baby stay clean	.46	.62	.13	.00	.11	.22
4	Responded appropriately when my baby's monitor alarm sounded	.46	.61	.10	.20	.06	.20
1	Provided care for my baby based on their professional knowledge	.57	.58	.22	.19	-.17	.35
29	Allowed me to play my role as a mother by directly participating in baby care (e.g., feeding, medication and bathing)	.78	.19	.82	.02	.01	.27
30	Assessed my baby's care techniques (e.g., feeding, medication and bathing)	.74	.13	.80	.09	.19	.18
31	Gave me confidence that I could take good care of baby with feedback	.76	.22	.70	.33	.32	.09
28	Allowed me to feel maternal love through contact with my baby (e.g., holding hands and feet, hugging, and kangaroo care)	.58	.14	.70	.22	.09	.13
32	Encouraged me by saying that I could do a good job as a mother	.70	.25	.57	.41	.38	-.01
13	Taught me how to handle various situations that can happen when taking of my baby at home	.62	.38	.52	.06	.36	.26
24	Spoke to me in a friendly tone	.76	.19	.12	.78	-.09	.30
23	Welcomed me with a warm smile at each visit	.72	.27	.09	.76	.05	.26
25	Created a comfortable atmosphere for me to ask questions about my baby	.68	.14	.24	.64	.14	.40
22	Empathized with my feelings of being separated from my baby	.79	.29	.33	.57	.51	-.01
21	Comforted me as I was having a hard time giving birth to a preterm infant	.75	.30	.31	.55	.51	-.03
20	Listened carefully to my worries and concerns	.70	.38	.26	.49	.39	.30
16	Introduced me to a specialist who could help me with psychotherapy and counseling	.76	-.05	.07	.01	.86	.15
15	Informed me about peer groups of mothers of preterm infants (e.g., online communities and local meetings)	.68	.10	.19	.07	.78	.13
14	Provided resources that could help me economically (e.g., national financial support project)	.50	.28	.21	.09	.56	.24
12	Explained each section and the regulations of the NICU to me	.48	.30	.09	.09	.45	.41
18	Explained to me in an easy-to-understand manner and based on my level of knowledge	.77	.25	.26	.35	.18	.69
17	Tried to give an answer in other ways, if it was not possible to answer my question immediately	.63	.23	.19	.21	.22	.67
19	Provided a sufficient amount of information according to my needs	.73	.34	.27	.30	.30	.61
10	Explained my baby's treatment process in a way I could understand	.61	.40	.20	.33	.14	.53
	Eigen value		4.26	3.80	3.45	3.38	2.75
	Explained variance (%)		15.77	14.05	12.77	12.52	10.17
	Cumulative explained variance (%)		15.77	29.82	42.59	55.11	65.28

diapers, and mobiles) well on my behalf," overlapped with other mental care support items as it addressed consideration for mothers.

Finally, the fifth factor analysis was carried out based on the 27 items: KMO was .91, and Bartlett's test of sphericity was 3865.979 ($df = 351$, $p < .001$). Five extracted factors had an eigenvalue of 1.0 or higher, communality was between .46 and .79, and factor loading was between .45 and .87. The factor loading of item 20, "A nurse listened carefully to my worries and concerns," was .49, and item 12, "A nurse explained to me each section and regulations of the neonatal intensive care unit," was .45. While both factor loadings were below the threshold, they were not deleted because they were prepared based on content emphasized in the theoretical fieldwork phase in a previous study [3]. The results indicated that the items in each factor were generally grouped with the same attributes and had relatively high total explained variance.

Ultimately, from the 33 items, six items were removed. The variance of the first factor with seven items explained 15.8%, the second factor with six items explained 14.1%, the third factor with six items explained 12.8%, the fourth factor with four items explained 12.5%, and the fifth factor with four items explained 10.2%. The total variance explained 65.3% of the 27 items (Table 2).

Factor naming

Factor 1 reflects the meaning of the nurse's direct care of infants, so it was named "baby care support." Factor 2 relates to the involvement and promotion of the maternal role, and it was named "maternal role support." Item 13 of Factor 2 is "A nurse taught me how to deal with various situations that might arise when taking care of my baby at home," and it was classified as information delivery support; however, it was thought that it could be considered as "maternal role support" when focusing on providing information to help mothers properly perform a maternal role at home, and was, therefore, moved. As Factor 3 reflects empathy for the mother and good therapeutic communication, it was named "mental care support." Factor 4 was derived from the "information delivery support" factor in a previous study [3]. It was named "introducing resources support" because it contains content regarding the introduction of necessary resources to mothers. Factor 5 was named "information delivery support" because it reflects the purpose of delivering the necessary information to mothers according to the mothers' specific situations.

Convergent and discriminant validity

The MTMM matrix showed that the correlation coefficients of the 32 items with their respective factors all exceeded .40, with a range of .48 to .80; thus, convergent validity was confirmed. The success rate of convergent validity of the items was 100%. Furthermore, the correlation coefficients of each item with other factors ranged from .20 to .68. As each item correlated to a lesser extent with other factors than their respective factors, discriminant validity was established (Table 3). The correlations of the items and their respective factors exceeded the correlations with other factors by two times the standard error of correlation coefficients, except for items 32, 12, and 10. The success rate of discriminant validity was 92.6%.

Criterion Validity

The 12 items of nursing care in the PFSQ and PNSS-MP were strongly correlated ($r = .89$, $p < .001$). The correlation coefficients (r) between factors were significant and ranged between .72 and .88, indicating that criterion validity was secured (Table 4).

Reliability

Cronbach's α of the PNSS-MP was .95. Cronbach's α of baby care support was .85, maternal role support was .88, mental care

Table 3 *Convergent and Discriminant Validity (N = 223).*

Factors	No. of item	Factors					r-2SE
		Factor 1: Baby care support	Factor 2: Maternal role support	Factor 3: Mental care support	Factor 4: Introducing resources support	Factor 5: Information delivery support	
Factor 1	3	.64	.42	.47	.41	.46	.60
	6	.67	.39	.53	.34	.51	.63
	2	.67	.51	.57	.44	.60	.63
	7	.60	.51	.52	.46	.47	.56
	5	.54	.35	.36	.34	.43	.49
	4	.55	.38	.46	.36	.44	.50
	1	.56	.39	.43	.20	.54	.51
Factor 2	29	.43	.68	.42	.30	.47	.64
	30	.41	.74	.46	.41	.46	.71
	31	.50	.80	.63	.49	.56	.78
	28	.40	.62	.49	.33	.42	.58
	32	.49	.69	.65	.49	.52	.65
	13	.58	.60	.50	.57	.55	.56
Factor 3	24	.46	.39	.64	.24	.52	.60
	23	.52	.41	.68	.32	.56	.64
	25	.48	.51	.67	.41	.63	.63
	22	.54	.62	.75	.57	.56	.72
	21	.53	.59	.73	.56	.53	.70
	20	.63	.62	.74	.58	.68	.71
Factor 4	16	.18	.31	.33	.54	.32	.49
	15	.32	.44	.44	.60	.35	.56
	14	.44	.47	.49	.59	.46	.55
	12	.52	.40	.44	.48	.51	.43
Factor 5	18	.57	.64	.64	.48	.80	.78
	17	.50	.54	.54	.43	.63	.59
	19	.62	.66	.66	.54	.77	.74
	10	.61	.51	.60	.44	.64	.60

Note. SE = standard error of correlation coefficient.

Table 4 *Criterion Validity of PNSS-MP (N = 223).*

	Baby care support (Factor 1)	Maternal role support (Factor 2)	Mental care support (Factor 3)	Introducing resources support (Factor 4)	Information delivery support (Factor 5)	PNSS-MP
Nursing care in PFSQ	.83	.85	.88	.72	.85	.89
p-value	<.001	<.001	<.001	<.001	<.001	<.001

Note. PFSQ = pediatric family satisfaction questionnaire; PNSS-MP = perceived nursing support scale for mothers of preterm infants.

support was .88, introducing resources support was .74, and information delivery support was .86. In the split-half reliability analysis, the Cronbach's α of the first part was .89, and the latter part was .92. The Spearman-Brown coefficient was .89, and the Guttman split-half coefficient was .88, indicating good reliability [19] (Table 5).

Confirmation of the final scale

The PNSS-MP was developed to measure the nursing support perceived by mothers of preterm infants. Twenty-seven items of five factors were determined by validity and reliability tests. Items 1 to 7 concern baby care support, items 8 to 13 concern maternal role support, items 14 to 19 concern mental care support, items 20 to 23 concern introducing resources support, and items 24 to 27 concern information delivery support. The survey takes approximately 10 min to complete. The response to each item is measured using a 5-point Likert scale: "strongly disagree" = 1 point, "disagree" = 2 points, "neutral" = 3 points, "agree" = 4 points, and "strongly agree" = 5 points. A higher score indicates a higher level of nursing support perceived by mothers of preterm infants.

Discussion

This study developed a scale for measuring nursing support perceived by mothers of preterm infants. In this section, the scale development process and each component of the developed scale are discussed.

Scale development process

The study went through a concept analysis process [3] using a hybrid model to develop a realistic tool that can be applied to reflect the situation of the NICUs in South Korea. The researchers attempted to reflect NICU environments through interviews with mothers of preterm infants. Furthermore, by continually comparing the theoretical analysis and field analysis steps, we attempted to clearly elucidate the nursing support phenomenon that can be observed in the NICUs. Through this process, a scale reflecting the actual situation in South Korea was established. In addition, the usefulness and practicality of the tool have been improved through the utilization of various literature and interview data.

For ascertaining the validity of this tool, this study carried out three content validity tests, a construct validity test using EFA, an MTMM analysis, and a criterion validity test. Until 2013, 189 studies tried to develop a scale in nursing academia, but only 28 studies (14.8%) examined the three types of validity [32]. It is important to have an expert group with rich knowledge in the field of interest and a potential user group examine the content validity of a scale through a content validity test [20]. Therefore, considering this aspect, this study carried out the content validity test twice with academics majoring in pediatric or maternal nursing, a professor of nursing with experience in tool development, and nurses with more than 10 years of experience in NICUs in South Korea. This study also examined face validity with mothers of preterm infants, who were the target sample of this study, to increase the representativeness and validity of the items.

An EFA was conducted while considering that even if the loading for one factor is high, and if a loading of .32 or more is observed in the other factor, it should be deleted [32]. An issue found in the process of EFA was that it was difficult to clearly differentiate the factors of "information delivery support." It was confirmed that items providing information about the infant showed similar loadings to "mental care support." The mother could attain emotional stability through information support, and in that case, information support could also be construed as emotional support [33]. "Information support" focuses on delivering facts based on knowledge, and "emotional support" helps someone to express one's emotions. However, they are not clearly distinguishable in reality; therefore, studies have been conducted to determine the differences between them [33]. Considering this, it is necessary to further clarify the definition of subfactors of nursing support by repetitively analyzing this concept in the future. Thus, further efforts should be made to make each subfactor representative.

In scale development studies, confirmatory factor analysis (CFA) is generally used to quantify the quality of the factor structure by providing additional evidence of the construct validity, such as convergent and discriminant validity of the measurement [34]. However, this study was the first attempt to develop a nursing support scale, and the construct validity of this scale has not been

Table 5 *Reliability of PNSS-MP (N = 223).*

Category			Items	Cronbach's α
Total		PNSS-MP	27	.95
Factor 1		Baby care support	7	.85
Factor 2		Maternal role support	6	.88
Factor 3		Mental care support	6	.88
Factor 4		Introducing resources support	4	.74
Factor 5		Information delivery support	4	.86
Division	Cronbach's alpha	Correlation between a & b (p-value)	Spearman-Brown	Guttman
a. Pre	.89	.81 ($p < .001$)	.89	.88
b. Post	.92			

a. Pre: Items 1, 2, 3, 4, 5, 6, 7, 10, 12, 13, 14, 15, 16, 17
b. Post: Items 18, 19, 20, 21, 22, 23, 24, 25, 28, 29, 30, 31, 32

established. In addition, we were limited in the number of participants we were able to recruit because of concerns of invasion of privacy and the conservative environment of a NICU, making it difficult for us to perform a CFA. Therefore, convergent and discriminant validities were explored using MTMM in this study. As such, in the future, CFA can be conducted to verify the construct validity between the 27 items and 5 factors extracted through EFA.

In this study, convergent and discriminant validities were analyzed using the MTMM matrix. This approach has long been a recognized method for determining convergent and discriminant validities [34]. Convergent validity was established, and each item had consistently correlated with the factors to which they belonged. For discriminant validity, item 32 (factor 2: maternal role support), "A nurse encouraged me by saying that I could do a good job as a mother," item 12 (factor 4: introducing resources support), "A nurse explained each section and the regulations of the NICU to me," and item 10 (factor 5: information delivery support), "A nurse explained my baby's treatment process in a way I could understand," were not well differentiated from 'factor 3: mental care support'. It is believed that because mothers gain psychological stability and emotional benefits, such as reduced anxiety, through nursing support, mental care support is strongly correlated with other factors [13,14]. In addition, item 10 was not well differentiated from "factor 1: baby care support" as this was only possible with specialized knowledge about the baby's treatment. This is believed to be because some parents indirectly judged nurses' expertise in baby care through item 10. Since discriminant validity was not sufficiently secured in this study, it is necessary to re-verify the discriminant validity of the items with other subjects using other statistical methods in the future.

Twelve items related to nursing care in the PFSQ, which were used in criterion validity, were developed by the philosophy of "family-centered care." Most of the items in the PFSQ were related to nurses' direct care. This is why the correlation coefficient (.72) was relatively low for introducing resources support. It was believed that introducing resources support was composed of items that introduced social resources rather than the care directly provided by nurses. One limitation of this study was that it only checked the concurrent validity to secure criterion validity. Moreover, since this study secured concurrent validity using one scale, it is necessary to secure additional criterion validity through various variables related to the concept of nursing support in the future.

Since all coefficients of the reliability test were over .80, the scale was considered to have stable reliability. However, it could be higher than actual reliability because the internal consistency test is calculated with data that are computed in one batch, and it does not consider various factors of change [35]. It is recommended to secure the stability of the tool through methods such as test-retest reliability of the self-report questionnaire to address this shortfall [24]. However, this study could not conduct a test-retest reliability assessment because recruiting the study participants was very time- and effort-consuming, and it was difficult to access the participants. It is necessary to secure the stability of the tool through repeated examinations.

Factors of PNSS-MP

Five subfactors were derived from the PNSS-MP. Therefore, each attribute will be discussed separately.

The first factor, the "baby care support" of this tool, included all items derived from the conceptual analysis results of a previous study [3]. Baby care support refers to the quality of nursing care provided to babies, and it showed an explanatory power of 15.8% in this study. Items included in baby care support were composed of sentences expressing direct care provided to babies; therefore, it is believed that they were differentiated from other items, including nursing care provided to mothers. Thus, baby care support includes the items of professional and emotional care derived from the previous conceptual analysis [3].

The second factor, "maternal role support," had an explanatory power of 14.1% in this study. Item 33, "A nurse helped me make the best decisions for baby-related matters," was deleted in maternal role support. Instead, item 13, "A nurse taught me how to handle various situations that can happen when taking care of my baby at home," previously included in information support, was included.

Item 33 was emphasized in the theoretical analysis stage in the conceptual analysis and demonstrated the core philosophy of family-centered care. However, considering the situation of NICUs in South Korea, family-centered care is not yet common, and the opinions of medical staff are weighted more than those of families [12]. Moreover, it had been consistently pointed out during the expert validity process that item 33's "decision making related to a baby" was ambiguous and unclear. Reflecting this, the factor loading of this item was .32 or more in three factors. Item 33 reflects family-centered care and emphasizes the mother's autonomy. As this item is important to maternal role support, a revision of the item should be considered in the future while considering the situation of NICUs in South Korea.

Item 13, "A nurse taught me how to handle various situations that can happen when taking care of my baby at home," was classified as "information delivery support" in the preliminary questionnaire, but it was later classified as "maternal role support." Although it was classified as "information delivery support," with an emphasis on providing information, the focus of this item was to help the mother raise her child well at home. Since "maternal role support" focuses on providing maternal role experiences and strengthening the maternal role, it would be more suitable to classify item 13 as "maternal role support."

Factor 3 concerns "mental care support," which accounted for 12.8% of the explained variance in this tool. Two items deleted from Factor 3 were item 26, "A nurse used the items brought for my baby (e.g., breast milk, diapers, and mobiles) well on my behalf," and item 27, "A nurse told me a story that encouraged me and told me that my baby was doing well." Although item 26 reflected the situation of the NICU well, it was difficult to generalize and measure objectively because the range of items that mothers were allowed to bring to a hospital differed depending on the policy of each hospital. In addition, the factor loading was .32 or more in two factors. Therefore, item 26 was thought appropriate to be deleted. Item 27, "A nurse told me a story that encouraged me while telling me that my baby was doing well," was criticized in the expert validity test, but it was mentioned as an important and necessary form of emotional support in terms of giving hope to mothers in the fieldwork phase [3]. Although the participating mothers said that the nurses' encouraging words felt like mental care support, as their babies were discharged with relatively minor health problems, this item was deleted because there would be a limit to providing such support if the baby had serious complications or the baby's condition was poor.

Factor 4 concerns "introducing resources support," which showed 12.5% of explained variance. Items were extracted from "information related to hospitalization environment" in previous studies [3]. These items introduce the mother to resources around her to help her endure her baby's hospitalization well. This was thought to be different from providing information about the baby and was therefore separated as a different factor. Information related to the hospitalization environment mainly consisted of items that were considered important in foreign literature consulted in the theoretical analysis stage [3]. Introducing social resources to mothers of preterm infants is an important form of

support in foreign countries; however, it is still rare to introduce resources to mothers of preterm infants in South Korea [3]. In foreign countries, professional psychological counselors always stay in the NICU and provide professional counseling to mothers suffering from postpartum depression after childbirth [36]. In addition, through a program called veteran parents, parents of infants with similar gestational ages and diseases who have been successfully discharged from the NICU form a peer support group and help parents obtain information [16]. Even in South Korea, parents are provided with information on various projects offered by the government through the social work office since the time of admission. It is not common in Korea to introduce social resources yet; however, as the medical environment gradually changes from "disease-centered" to "patient-family-centered," [12] it is necessary to provide information related to helpful resources to parents.

The final factor concerns "information delivery support," which has an explanatory variance of 10.5%. It consists of items that focus on how information is delivered rather than what content is delivered. "A nurse explained my baby's physical changes in a way I could understand," "A nurse explained the behavioral characteristics of my baby so that I could understand them," and "A nurse told me things about my baby's daily life that I could not observe" were deleted from "information delivery support." The deleted items were related to the content of information delivery support. As a result, the items included in "information delivery support" were mainly related to the method of delivering information. It was confirmed from this that the mother perceived information delivery methods as stronger information support than the content aspect of information. Even in previous studies, mothers wanted information to be delivered to them in an easily understandable manner at the right time, rather than receiving all information [3]. Although most of the items related to the content of information delivery support were deleted, item 19, "A nurse provided a sufficient amount of information according to my needs," was believed to broadly cover the content aspect of information delivery support. Therefore, this factor is thought to be a tool that encompasses both the content and delivery aspects of informational support.

Conclusion

We developed a tool for measuring nursing support perceived by mothers of preterm infants, which was composed of 27 items and 5 factors reflecting the medical environment of NICUs in South Korea. This scale secured relatively adequate validity and reliability; however, discriminant validity has not yet been firmly established. Future studies will need to measure the applicability and sensitivity of the developed tool in practice by continuously refining, validating, and ensuring the reliability of the tool. Based on the statistical testing, PNSS-MP is considered a promising instrument for the evaluation of nursing support in the NICU. By using the scale, it will be possible to provide professional and intensive nursing support to mothers of preterm infants. Moreover, it will help improve the quality of nursing care and ultimately realize family-centered care in South Korea.

Authors statement

Im, Mihae: Substantial contributions to the conception or design of the work; the acquisition, analysis, and interpretation of data for the work, Drafting and revising the manuscript, Approve the fianl version of the manuscript. **Oh, Jina**: Analysis and interpretation of data for the work, Final approval of the version to be published, Drafting the work and revising it critically for intellectual content.

Additional comments

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Conflict of interest

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Research Article

Developing and Evaluating a Mobile-based Parental Education Program for Preventing Unintentional Injuries in Early Childhood: A Randomized Controlled Trial

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SUMMARY

Purpose: This randomized controlled experimental study verified the educational effect of a mobile-based parental education program for preventing unintentional early childhood injuries.
Design and Methods: From August 2019 to September 2019, 167 participants were recruited from parenting portal sites and randomly assigned to an e-learning group (n = 59), an electronic document distribution (EDD) group (n = 53), and a control group with no intervention (n = 55). Participants self-reported data regarding their safety knowledge and behavior before and after the experiment. Each intervention group received an e-learning program and electronic educational documents for two weeks and a satisfaction survey. Using an ADDIE (Analysis, Design, Development, Implementation, and Evaluation) model, the relevant e-learning contents were developed with the Storyline 360 program. The collected data were analyzed using 1-way ANOVA, 2-way ANOVA, and independent t-test.
Results: Results were as follows: (1) Postintervetion, no significant differences regarding safety knowledge were observed between the e-learning group, EDD group, and control group. (2) Postintervention, statistically significant differences regarding safety behaviors were observed between the three groups: 3.52 ± 0.28 (e-learning group), 3.51 ± 0.28 (EDD group), and 3.32 ± 0.25 (control group) ($F = 10.091$, $p < .001$). (3) No significant differences regarding education-related satisfaction were observed.
Conclusions: The mobile-based educational program for preventing unintentional injuries positively affected safety behavior in this study. Mobile-based parental education programs could contribute toward effectively preventing unintentional injuries in early childhood because many parents can use these without time and space constraints.

Introduction

Pediatric nursing aids children in growing up healthy and safe, which ranks highest among parents' wishes for their children [1]. Curious infants and toddlers actively explore their surroundings, but they are egocentric and often lack the cognitive ability to judge risks [2]. Therefore, they can be exposed to unexpected accidents. Although some injuries may be minor, others, including airway obstruction, road traffic injuries, drowning, fire-related burns, falls, and poisonings, can fatally impact children's health [3]. Of 1830 Korean child fatalities in 2016, 270 were deaths from accidents (14.8%). While this number showed a one-third decrease compared to the 2006 figure, every child death is a tragedy that we must strive to prevent [4]. According to an analysis of unintentional childhood injuries submitted by the Consumer Injury Surveillance System of Korea Consumer Agency in 2019, unintentional childhood injuries accounted for 34.2% of total unintentional injuries. These injuries occurred mostly in homes, followed by educational facilities and recreation facilities. In particular, injuries at home accounted for 68.8% of all childhood unintentional injuries. The most common injury causes were slipping, falling, and bumping into things; foreign substance ingestion and burns also occurred frequently [5].

Pediatric nursing practices should consider not only children, but also their families [1]. Parents, who tend to interact most closely with infants and toddlers, often influence their health and well-being the most. Therefore, one of pediatric nursing's essential

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goals is supporting and guiding parents in taking good care of their infants and toddlers, for which parental education is crucial. Many studies have discussed the positive effects of parental education for preventing unintentional injuries [6–10].

Several related studies have focused on parents, who often play an essential role in preventing unintentional childhood injuries in the home. These include research measuring knowledge, safety beliefs, and safety practice behaviors to identify related factors; research on parental education program development; and research confirming the effect of parental education intervention [11]. Parental education programs have taken on various forms, including home visits, one-time or multi-session educational interventions, kiosk-based education interventions installed at medical institutions [12], and smartphone applications [13]. Although home-visit education interventions can effectively diagnose and correct home environments, they are expensive and time-consuming; furthermore, such interventions may be limited in scope because parents may not want home visits. Moreover, group education interventions may pose time and distance constraints for busy contemporary parents. The effectiveness of medical institution-based kiosk education interventions can vary depending on the suggested treatment and the medical staff's disposition.

A study analyzing mothers' demands regarding infant and toddler safety-related education [14] indicated that mothers wanted parental education to continuously and effectively provide safety education for their children. Several parental safety education studies have conducted interventions involving group education. In Korea, the Korea Children Safety Foundation provides face-to-face safety education for parents and early childhood education teachers. The Korea Consumer Agency, the local health center, and the National Institute for Lifelong Education regularly publish and distribute booklets regarding this subject. However, as the number of double-income families increases, parents may find it challenging to make time for face-to-face education [15]; an internet based interventions can also allow many parents to avail the educational opportunities, in contrast to on-site education, which benefits only a limited number of people [16].

The world is moving toward a hyperconnected society where all people, objects, and spaces are connected as part of the fourth Industrial Revolution [17]. Thus, parental education using Internet technology could meet future needs by expanding the scope of nursing beyond face-to-face interactions to a mobile medical environment. Mobile-based education provides the advantage of allowing individual parents to choose the intervention time and place based on their own needs. In addition, the widespread use of the Internet and smartphones makes it a cost-effective method for educating a large number of people compared to home visits or group education. There have been few studies that verified the effects of non-face-to-face parental interventions to prevent children's unintentional injuries, except those studies that educated parents through smartphone applications. Therefore, it is necessary to confirm the effect of non-face-to-face parental interventions through further research; this study focused on verifying the effect of mobile-based parental education interventions. E-learning content can be classified into static and dynamic content. Static content consists of pictures and text, wherein interactivity and engagement are limited; in contrast, dynamic content uses video and audio, making user interaction possible [18]. This study divided the intervention group into an e-learning group (Intervention Group 1) and an electronic document distribution group (Intervention Group 2) to compare the e-learning content format differences. The aim was to (1) develop and apply a parent-oriented e-learning program and electronic documents for preventing unintentional injuries to infants and toddlers, and (2) compare the program effect among Intervention Group 1, Intervention Group 2, and the control group.

The study hypotheses were as follows.

1) Hypothesis 1: There will be differences in terms of safety knowledge regarding unintentional childhood injuries among Intervention Group 1 (e-learning group), Intervention Group 2 (electronic document distribution [EDD] group), and the control group.
2) Hypothesis 2: There will be differences in terms of safety behavior regarding unintentional childhood injuries among Intervention Group 1 (e-learning group), Intervention Group 2 (EDD group), and the control group.
3) Hypothesis 3: There will be differences in terms of education satisfaction among Intervention Group 1 (e-learning group) and Intervention Group 2 (EDD group).

Methods

Study design

This study utilized a randomized controlled pre and post-experimental design to evaluate parental education programs for preventing unintentional injuries in early childhood (Supp. Figure 1).

Samples

This study recruited 167 participants between August and September 2019 from parenting portal sites in the Republic of Korea (Momsholic Baby and Bebe House). The participant inclusion criteria were as follows: (1) primary caregivers, including parents or relatives caring for infants and toddlers; (2) availability of Internet access through computers, mobile phones, or tablets; and (3) those who understood the study's purpose and agreed to participate.

We used the G* Power 3.1.9.2 program to estimate the sample size. The desired sample size was calculated based on the effect size $d = 0.25$ (medium), significance level $\alpha = .05$, and power $1\text{-}\beta = .8$ in comparing the three groups [19]. The calculated sample size was 159 (53 in each group). The sample size was determined to be 175, considering a 10% dropout rate. A total of 175 people (60 in the e-learning group, 58 in the EDD group, and 57 in the control group) responded to a pretest. Eight people did not respond to the posttest. Finally, data of 167 participants (59 in the e-learning group, 53 in the EDD group, and 55 in the control group) were analyzed (Figure 1).

Procedure

The study recruitment announcements were posted on the two parenting portal sites (Momsholic Baby and Bebe House). Interested parents were screened through eligibility questions. Those who met the study's inclusion criteria and signed the consent form were provided with access to the online survey site. They were then randomly assigned to Intervention Groups 1 and 2 and the control group using the random redirect tool [20]. Participants were blinded for concealment purposes, so they did not know if they were assigned to an intervention group or a control group.

All participants in Intervention Groups 1 and 2 and in the control group responded to a pretest survey regarding general characteristics and safety knowledge and behavior. After the pretest, Intervention Group 1 (e-learning group) received a link to the e-learning program (e-learning program for preventing unintentional

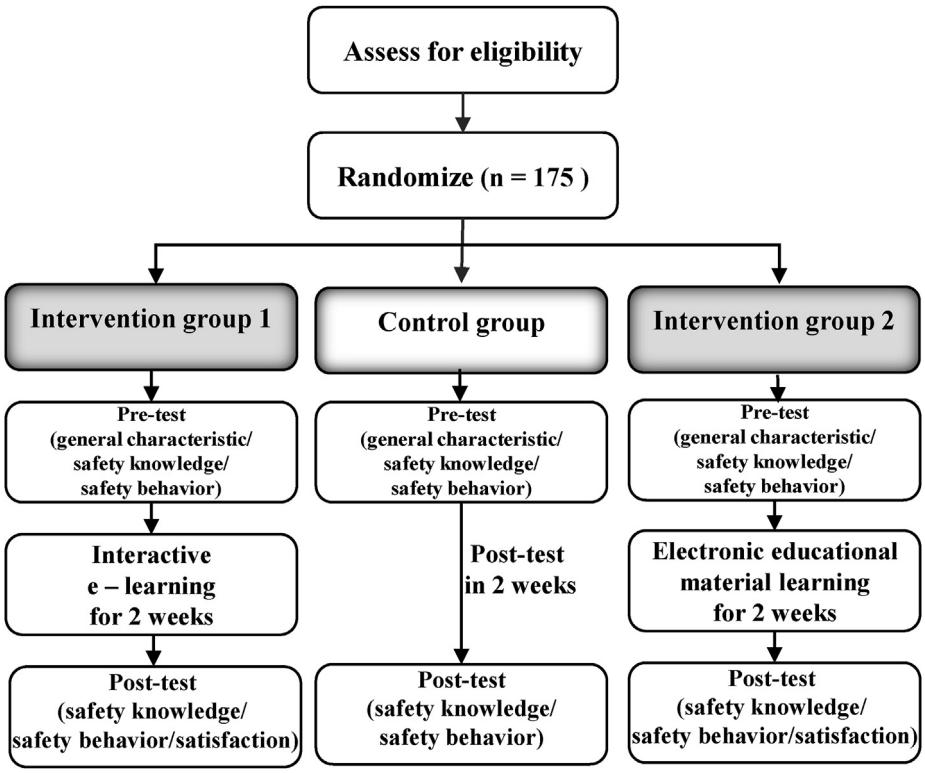

Figure 1. Flow Diagram

injuries in early childhood: "I am also a safety expert!"), while Intervention Group 2 (EDD group) received a link to a converted PDF file with content from the e-learning program. Participants in Intervention Groups 1 and 2 were asked to learn by themselves for two weeks. No intervention was provided to the control group.

After two weeks, Intervention Groups 1 and 2, as well as the control group, were assessed again for safety knowledge and safety behavior. Intervention Groups 1 and 2 were also assessed regarding their education-related satisfaction. Participants who completed the education programs and both surveys received incentives (gift cards).

Program development: An e-learning program for preventing unintentional injuries in early childhood

This study's intervention was in the form of an e-learning program for preventing unintentional injuries in early childhood; we developed it using the Storyline 360 e-learning development software program (Articulate Global Inc.) [21]. To develop the program, we used the ADDIE (Analysis, Design, Development, Implementation, and Evaluation) model [22], which contained five steps: Analysis, Design, Development, Implementation, and Evaluation.

We searched the parenting sites to understand the types of queries parents have about unintentional childhood injuries. The child health question and answers (Q&A) at parent portal site Naver Cafe Momsholic Baby [23] and the knowledge Bebe Q&A [24] at the parenting portal Bebe House included questions about children bumping into furniture corners, trapping fingers in the doors, being scalded in hot water from water purifiers, slipping in the bathtub, and swallowing disposable bandages.

The developed e-learning program reflected our review of extant research and the realistic requirements of contemporary parents with busy schedules. The program introduction provided information regarding the causes of and current statistics for unintentional childhood injuries to induce learning motivation. Furthermore, the program emphasized parents' essential role in ensuring their children's safety and suggested some basic principles for preventing injuries. The program's learning contents were classified based on six common locations: bedroom, living room, bathroom, kitchen, the outdoors, and car. Each location-based learning content was categorized under suffocation, aspiration, falls, poisoning, body damage, drowning, or burn prevention. Each program screen comprised the core content and made use of simple pictures to enhance the user's ability to understand health information and to allow them to form a clear visual image.

Based on previous studies on educational material development, the current study utilized the following methods to develop its e-learning program:

- using simple everyday words instead of professional terms
- making sentences as short as possible (10–15 words)
- using positive and active voice
- using easy-to-read text font and size
- emphasizing important parts with bold font and circles
- presenting 5–8 lines of textual information per slide
- using simple and straightforward images

We designed an e-learning program for preventing unintentional injuries in early childhood that contained 44 slides with the introduction, prevention methods based on location, and an epilogue. The training time was about 30 minutes; when the program could not be completed within 30 minutes, it offered the functionality of dividing the content so that it could be taken multiple times. The program slides automatically advanced to the next slide after the narration was completed and stopped at the quiz at the end of the session. After the quiz and the feedback, the slide would proceed to the next session.

The introduction of the program included the importance of prevention, statistics related to injuries, parents' role, and basic principles for preventing injuries. The prevention methods based on place included critical points, prevention methods, and a quiz dealing with child safety in bedrooms, living rooms, bathrooms, kitchens, the outdoors, and cars. At the end of the program, users were presented with a content summary, safety-related website links with additional information, and references (Supp. Figure 2).

The major program features were as follows: health literacy considerations, latest statistics and news reports in order to motivate learning, two videos ("How to choose safe toys" and "Visiting a bathroom"), 11 interactive quizzes, a presentation of simple and straightforward action methods, and an introduction to child safety products available in the market.

Using Storyline 360 functions, we converted the e-learning program into a PDF format, which was distributed to the EDD group. The converted PDF contained the slides from the e-learning program, excluding its video and audio features.

Instruments

Safety knowledge regarding unintentional childhood injuries

Parents' safety knowledge regarding unintentional childhood injuries was measured using a tool developed by Kim et al [25]. This tool contained 20 items that were divided into the following categories: fall, fire, poisoning, suffocation, first aid, play, and burn. Examples of items from the tool include: "What is the best way to prevent poisoning in infants and young children?" and "What is the proper method to install an infant car seat?" The scores for each item were calculated on the following basis: 1 point for a correct answer and 0 points for an incorrect answer (20 points total).

Safety behaviors regarding unintentional childhood injuries

A tool developed by Kim et al. was used to assess parents' safety behaviors in response to unintentional childhood injuries [26,27]. This tool has 40 items and 9 categories: safety measures and coping, drug management, electrical appliance management, fire prevention, burn prevention, parental supervision and education for safety, drowning prevention, vehicle safety, and home environment inspection. Example items are as follows: "I always keep hot electrical appliances out of the reach of children after using them," "I make sure my child's toys are safe," and "I do not allow children to play alone near water." This tool utilized a four-point Likert scale (1 = "not at all" to 4 = "very much"). A higher score indicated a higher degree of safety behavior regarding unintentional childhood injuries. Negative questions were analyzed by processing the reverse questions as positive questions. While in the previous study [27], Cronbach's α was .78, in this study, Cronbach's α was .86.

Education-related satisfaction

Education-related satisfaction was measured using a tool developed by the researcher of the current study. This tool utilized a five-point Likert scale containing eight items, which assessed parents' degree of satisfaction concerning difficulty, motivation, duration of education, technical stability, and achievement level after receiving the e-learning intervention or the electronic documents. Example items from the tool are as follows: "The educational contents were clear and easy to understand," "The educational contents were interesting and motivational," and "The educational contents helped to raise awareness of Preventing Unintentional Injuries in infants and young children." Items were scored as follows: 1 = "not at all" to 5 = "very much"; a higher score indicated a higher degree of satisfaction. In this study, Cronbach's α was .89.

Ethical considerations

The Institutional Review Board of Eulji University approved this study (Approval no. EU19-31). At the time of data collection, participants received explanations regarding the study's purpose, method, and participation withdrawal; thus, the study was conducted with voluntary consent. Participants were assured that the collected data would be used only for research purposes. A serial number would be given to the data after removing personal identifiers in order to ensure protection of personal information. Participant data would be discarded after three years.

Data analysis

The collected data were analyzed using the SPSS 25.0 statistical program. The participants' general characteristics were analyzed using frequency, percentage, mean and standard deviation. Participant's safety knowledge and behavior regarding unintentional childhood injuries were analyzed using the mean and standard deviation. Differences in terms of safety knowledge and safety behavior among the three groups were analyzed using a one-way ANOVA; furthermore, *post hoc* analysis was performed using the Scheffé test and Bonferroni correction method. Differences in terms of education-related satisfaction between the two intervention groups were analyzed using an independent sample t-test.

Results

Homogeneity test

A homogeneity test for general characteristics showed no significant difference in terms of gender, age, education level, occupation, number of children, relationship with children, and unintentional injury experiences among the three groups; so, homogeneity among the participants of the three groups was confirmed (Table 1).

The homogeneity test for the dependent variables of the e-learning, EDD, and control groups showed no significant differences in terms of safety knowledge and behavior, hence, the three groups' homogeneity was confirmed (Supp. Table 1).

Hypothesis verification

Safety knowledge

The three groups showed no statistically significant difference regarding safety knowledge after the intervention: 15.90 ± 2.25 in the e-learning group, 16.45 ± 2.05 in the EDD group, and 15.85 ± 2.20 in the control group (Table 2). Therefore, Hypothesis 1 was rejected.

Safety behavior

Postintervention, the safety behavior was 3.52 ± 0.28 in the e-learning group, 3.51 ± 0.28 in the EDD group, and 3.32 ± 0.25 in the control group. There were statistically significant differences between the three groups ($F = 10.09$, $p < .001$). *Post hoc* analysis showed that the e-learning and EDD groups had a statistically significant growth in safety behavior compared to the control group (Table 3, Supp. Figure 3).

Statistically significant differences were observed between the three groups for the following categories: safety behavior, drug management ($F = 4.80$, $p = .009$), electrical appliance management ($F = 6.31$, $p = .002$), vehicle safety ($F = 7.39$, $p = .001$), and home environment inspection ($F = 6.88$, $p = .002$). *Post hoc* analysis

Table 1 *Homogeneity Test for General Characteristics among Three Groups (N = 167).*

Variables	Categories	e-learning (n = 59)	EDD (n = 53)	Control (n = 55)	χ^2	*p*
		n (%)	n (%)	n (%)		
Age(year)	20–29	11(18.6)	5(9.4)	9(16.4)	3.91	.419
	30–39	39(66.1)	41(77.4)	42(76.4)		
	≥40	9(15.3)	7(13.2)	4(13.2)		
Gender	Male	5(8.6)	7(13.2)	4(7.3)	1.20	.549
	Female	53(91.4)	46(86.8)	51(92.7)		
Education	High school	4(6.8)	4(7.5)	4(7.3)	0.71	.950
	College	46(78.0)	38(71.7)	42(76.4)		
	Graduate school	9(15.3)	11(20.8)	9(16.4)		
Job	Homemaker	19(32.2)	19(35.8)	29(52.7)	7.84	.250
	Office worker	13(22.0)	9(17.0)	10(18.2)		
	Professional	17(28.8)	17(32.1)	13(23.6)		
	Others	10(16.9)	8(15.1)	3(5.5)		
Number of children	1	38(64.4)	31(58.5)	38(69.1)	1.32	.516
	≥2	21(35.6)	22(41.5)	17(30.9)		
Relation	Mother	51(86.4)	43(81.1)	50(90.9)	3.69	.449
	Father	6(10.2)	7(13.2)	5(9.1)		
	Others	2(3.4)	3(5.7)	0(0.0)		
Injury experience	Yes	13(22.0)	16(30.2)	17(30.9)	1.40	.498
	No	46(78.0)	37(69.8)	38(69.1)		

Note. EDD = electronic document distribution.

showed that the e-learning and EDD groups had higher safety behavior scores than the control group.

Thus, Hypothesis 2 was supported.

Education-related satisfaction

Satisfaction with education was 4.08 ± 0.58 in the e-learning group and 4.26 ± 0.51 in the EDD group, and there was no statistically significant difference in terms of education-related satisfaction between the two groups (p = .097, Table 4). Therefore, Hypothesis 3 was rejected.

Discussion

Developing an e-learning program for preventing unintentional injuries in early childhood

The importance of preventing an unintentional injury is often recognized only after the injury. Therefore, it is essential to improve parents' safety awareness and behavior regarding unintentional childhood injuries; proper education is one way to improve such awareness. Since the Internet is available without any location or time constraint, and portable electronic devices are widely used in Korea [28], mobile-based e-learning education is convenient for parents with limited time. It is also more cost-effective than home visits or group education.

E-learning is becoming increasingly popular in school education, professional refresher education [29], and language education [30]; thus, it can satisfy the contemporary educational needs. E-learning has also been recognized for its effectiveness, and is now replacing traditional classroom education [31]. However, since this study's e-learning program was not a compulsory component, we considered the interest of potential users, program interactivity, and health literacy to motivate learning while developing the program.

A study on effective development of health education materials suggested that, when developing educational materials, it is necessary to enable learners to read and understand content easily [32]. In short, users' ability to develop health literacy and understand and use health information by themselves [33] should be prioritized. Furthermore, a study on e-learning content showed that the visual design strategies used for presenting textual information significantly affected users' understanding of textual contents [34].

The parents were introduced to child safety products available in the market. However, unlike the “Make Safe Happen” application developed by the Nationwide Children's Hospital in the United States [13], which uses a link to a vendor and is available for purchase, our program did not list any purchasing information to avoid possible conflicts of interest.

The current program's total required e-learning time was about 30 minutes. The study's program for promoting and developing parental safety education to prevent infants' and toddlers' unintentional injuries [35] included four timeslots of 40–90 minutes of classroom education and six e-mail newsletters. The study's intervention for assessing the effectiveness of parental safety education in preventing childhood unintentional injuries [36] involved offline participation for 3 hours at one time.

A relatively short learning time can be an advantage for those who have little time to spare; however, this can have the disadvantage of not providing extensive and in-depth learning. The present study's one-time e-learning program emphasized overall knowledge and principles. However, any e-learning program that is provided regularly to learners could be effective for improving learners' in-depth safety knowledge and safety behavior.

Table 2 *Comparison of Changes in Safety Knowledge among Three Groups (N = 167).*

Variables		e-learning (n = 59)	EDD (n = 53)	Control (n = 55)	F	*p*
		M ± SD	M ± SD	M ± SD		
Safety knowledge	Pretest	14.88 ± 3.15	15.40 ± 2.04	15.25 ± 2.00	0.54	.586
	Posttest	15.90 ± 2.25	16.45 ± 2.05	15.85 ± 2.20	1.28	.282
	Mean difference	1.02 ± 2.82	1.06 ± 1.76	0.60 ± 1.81	0.98	.378

Note. EDD = electronic document distribution.

Table 3 *Comparison of Changes in Safety Behavior between the Three Group (N = 167).*

Safety behavior categories		e-learning (=a) (n = 59)	EDD (=b) (n = 53)	Control (=c) (n = 55)	F (*p*)	*Post hoc* Scheffé
		M ± SD	M ± SD	M ± SD		
Total	Pretest	3.36 ± 0.31	3.33 ± 0.29	3.30 ± 0.26	0.60(.549)	
	Posttest	3.52 ± 0.28	3.51 ± 0.28	3.32 ± 0.25	10.09(<.001)	a, b > c
	Mean difference	0.16 ± 0.28	0.17 ± 0.27	0.02 ± 0.17	9.61(<.001)	a, b > c
Safety measure and coping	Pretest	3.12 ± 0.38	3.10 ± 0.37	2.96 ± 0.39	2.75(.067)	
	Posttest	3.29 ± 0.39	3.29 ± 0.37	3.04 ± 0.40	7.83(.001)	a, b > c
	Mean difference	0.17 ± 0.35	0.19 ± 0.42	0.07 ± 0.26	2.19(.117)†	
Drug management	Pretest	3.46 ± 0.46	3.48 ± 0.47	3.53 ± 0.34	0.45(.642)	
	Posttest	3.60 ± 0.42	3.59 ± 0.37	3.45 ± 0.45	2.30(.104)	
	Mean difference	0.14 ± 0.41	0.11 ± 0.45	−0.08 ± 0.38	4.80(.009)	a, b > c
Electrical appliance management	Pretest	3.06 ± 0.40	3.10 ± 0.52	3.21 ± 0.47	1.71(.185)	
	Posttest	3.29 ± 0.43	3.36 ± 0.50	3.22 ± 0.42	1.31(.273)	
	Mean difference	0.23 ± 0.46	0.25 ± 0.42	0.00 ± 0.33	6.31(.002)	a, b > c
Fire prevention	Pretest	3.43 ± 0.48	3.35 ± 0.45	3.40 ± 0.49	0.36(.699)	
	Posttest	3.57 ± 0.38	3.42 ± 0.46	3.41 ± 0.44	2.59(.078)	
	Mean difference	0.14 ± 0.42	0.06 ± 0.41	0.00 ± 0.21	2.51(.086)†	
Burn prevention	Pretest	3.44 ± 0.47	3.48 ± 0.39	3.46 ± 0.41	0.10(.903)	
	Posttest	3.57 ± 0.41	3.64 ± 0.39	3.53 ± 0.42	1.08(.343)	
	Mean difference	0.13 ± 0.48	0.17 ± 0.47	0.06 ± 0.43	0.67(.511)	
Parental supervision and education for safety	Pretest	3.42 ± 0.43	3.39 ± 0.45	3.20 ± 0.53	3.51(.032)	
	Posttest	3.53 ± 0.39	3.64 ± 0.39	3.24 ± 0.46	13.35(<.001)	a, b > c
	Mean difference	0.11 ± 0.44	0.25 ± 0.49	0.04 ± 0.42	3.04(.051)	
Drowning prevention	Pretest	3.52 ± 0.50	3.48 ± 0.50	3.32 ± 0.50	2.56(.080)	
	Posttest	3.65 ± 0.42	3.64 ± 0.43	3.37 ± 0.41	7.96(.001)	a, b > c
	Mean difference	0.13 ± 0.44	0.16 ± 0.47	0.05 ± 0.40	0.85(.429)	
Vehicle safety	Pretest	3.58 ± 0.42	3.53 ± 0.33	3.54 ± 0.29	0.34(.709)	
	Posttest	3.75 ± 0.30	3.67 ± 0.33	3.49 ± 0.31	10.31(<.001)	a, b > c
	Mean difference	0.18 ± 0.39	0.14 ± 0.33	−0.05 ± 0.28	7.39(.001)	a, b > c
Home environment inspection	Pretest	3.18 ± 0.42	3.17 ± 0.53	3.16 ± 0.35	0.05(.950)†	
	Posttest	3.42 ± 0.44	3.39 ± 0.47	3.16 ± 0.38	5.74(.004)	a, b > c
	Mean difference	0.23 ± 0.49	0.23 ± 0.49	0.00 ± 0.29	6.88(.002)†	a, b > c

Note. EDD = electronic document distribution, †Welch test.

Effects of educational intervention

The study results showed that, after experiencing the educational intervention, both intervention groups significantly improved their safety behavior compared to the control group. This finding is consistent with that of another study [10], where an educational intervention positively affected the safety behavior of parents of infants. These results imply that mobile-based e-learning or education using electronic documents and traditional classroom education can improve parents' safety behavior. Therefore, it suggests that an educational e-learning method can fit the lifestyle of people who face the paucity of time.

Regarding safety knowledge, no statistically significant difference was observed between the e-learning group, the EDD group, and the control group. This may have been because many of the items measured could be responded through common sense. In addition, the participants who are parenting portal sites users are likely to be highly concerned and aware of parenting issues, including safety issues.

In one study that verified retest validity based on the test type by using general mental ability (GMA), the interval between the test and retest was set at six weeks in order to minimize the testing effect [37]. In the current study, the interval between the pretest and posttest was two weeks, and the same measuring tool was used. Another reason for the absence of a significant difference in terms of safety knowledge may have been that the control group's safety knowledge score increased due to the testing effect. If a testing effect is expected in the study design, it is necessary to increase the test interval or use another tool for retesting.

This study showed that e-learning programs for preventing unintentional injuries in early childhood could help parents improve their safety behavior. Since preventing unintentional injuries could reduce social costs, this could be achieved most effectively if parents of infants and toddlers were obligated to receive unintentional injury prevention education. Such education could be delivered during prenatal care visits at the hospital immediately after childbirth while the parents and babies are staying at the postpartum care center, during a pediatric wellness-check visit, or online. Safety education can be mandatory, however, implementing this may cause various difficulties. Instead, it would be most effective to provide incentives. For example, The Korea National Police Agency operates a mileage system that reduces driver's license penalties for drivers who do not violate traffic laws for one year. Beam Dental Insurance [38] in the United States analyzes dental care data through the provided smart toothbrush and calculates premiums. People who take good care of their teeth will pay fewer insurance premiums. Thus, if users receive appropriate benefits when completing safety education, or when such programs are promoted through public service advertising campaigns, the education completion rate could be increased.

Table 4 *Comparison of Satisfaction with Education between e-Learning Group and EDD Group (N = 112).*

Variable	e-learning (n = 59)	EDD (n = 53)	t	*p*
	M ± SD	M ± SD		
Satisfaction with education	4.08 ± 0.58	4.26 ± 0.51	1.676	.097

Note. EDD = electronic document distribution.

The safety behavior of the EDD group, which used static content produced by converting dynamic content into PDF format, did not significantly differ from that of the e-learning group. This indicates that well-designed educational materials regarding health literacy and motivation were used for the EDD group. Moreover, it is consistent with Chan et al's study, which rapidly disseminated essential information related to COVID-19 using well-designed educational materials in clear and actionable formats [39]. Therefore, we suggest that future studies elaborate the strategies of educational static contents design, which requires relatively less cost, time, and effort than dynamic content.

In this study, both intervention groups were satisfied with the educational intervention; "satisfaction with education" received more than 4 points. This result is consistent with that of a study on parents' need for smartphone-based health education [40], where parents with young children were found to have higher demands for smartphone-based health education than parents with children of other ages. However, no differences in terms of education-related satisfaction were observed between the e-learning group and the EDD group in the intervention. This could be attributed to the fact that the conversion of e-learning contents into electronic documents can make the relevant content easier to understand; furthermore, some people prefer the form of readable documents to videos. Considering the parents' responses to the open-ended questionnaire, e-learning content could increase education-related satisfaction by subdividing the learning contents based on age, situation, risk factors, shortening of learning time, and regular sending of education links to the target audience.

According to one systematic review of mobile-based health behavior interventions [41], 20 experimental studies out of 34 extracted studies produced significant positive results in terms of health behavior changes. The review study also recommended the use of mobile-based interventions for younger age groups. However, it is necessary to consider using mobile-based education with already familiar methods, such as sending YouTube video links or using a text messaging service for grandparents or older relatives who take care of infants and toddlers.

Since producing e-learning video contents is costly, the distribution of well-planned electronic documents with good visual design and health literacy when educating parents in a mobile medical environment can be a cost-effective method that produces high satisfaction. However, e-learning content that utilizes video is expected to increase educational effect and satisfaction if the demonstration video can enhance the user's understanding of important subjects, including cardiac pulmonary resuscitation (CPR), first aid of fracture and burn, parental training for foreign body aspiration, and proper car seat installing method.

We suggest that further research be conducted on mobile-based programs in order to educate parents about first aid for infants' unintentional injuries and CPR.

Limitations

Despite its contributions, this study has some limitations. First, we recruited participants from parenting portal sites; these parents are likely to be highly concerned and aware regarding parenting issues, including child safety issues. Thus, the study sample may not represent the general population of Korea. Second, as data were collected via the self-report method, the outcomes of this study may be affected by various biases. Therefore, we recommend that future studies include inspection of homes or behavioral measures as measurement strategies. Third, despite our efforts, such as text messaging to encourage participants to use the learning program and incentives, it was challenging to confirm whether the participants had completed the program. Therefore, we suggest utilizing technology to confirm participants' completion of e-learning programs in future research.

Conclusions

The study results showed that the mobile-based education program for preventing unintentional injuries in early childhood did not improve safety knowledge; however, it was proven to increase safety behavior.

If an educational program utilizes this study's results, it can be used as an intervention method for preventing unintentional injuries in early childhood. Mobile-based educational programs, with both static and dynamic content, could contribute to the effective prevention of unintentional injuries in early childhood, as many people can use them without being limited by time and space constraints. Furthermore, this study has prepared primary data that could be applied to expand nursing care from a face-to-face environment to a more mobile-based medical environment.

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Declaration of competing interest

The authors have no conflict of interest to declare.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.anr.2021.12.001.

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Research Article

Development and Feasibility Test of a Mouth Contactless Breathing Exercise Solution Using Virtual Reality: A Randomized Crossover Trial

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SUMMARY

Purpose: The purpose of this study was to develop a novel mouth contactless breathing exercise solution based on virtual reality (VR), and to test its feasibility.
Methods: We developed the Virtual Reality-based Breathing Exercise System (VR-BRES), a self-regulating biofeedback breathing exercise with gaming characteristics and a soft stretch sensor. The feasibility and efficacy of the VR-BRES prototype were investigated through a randomized crossover trial. Fifty healthy adults participated in the trial, and their respiratory parameters and user evaluation of the VR-BRES were compared with conventional deep breathing (CDB) exercises.
Results: The respiratory parameters, forced vital capacity ($Z = 4.82, 4.95$, $p < .001$), forced expiratory volume in one second ($t = 6.02, 6.26$, $p < .001$), and peak expiratory flow ($t = 5.35, 5.68$, $p < .001$) were significantly higher during breathing exercises using the VR-BRES. User evaluation was also significantly higher for the VR-BRES in terms of efficiency ($Z = 3.86$, $p < .001$), entertainingness ($Z = 5.00$, $p < .001$), and intention to use ($Z = 3.22$, $p = .001$) compared to CDB. However, there was no difference in convenience between the two methods ($Z = -0.90$, $p = .369$).
Conclusion: The VR-BRES has the potential to be an efficient breathing exercise solution. We recommend a clinical study that evaluates the effects of the VR-BRES for a certain period of time for people who need breathing exercises.

Introduction

As the population ages and environmental pollution becomes more serious, respiratory health problems are on the rise. According to statistics on the cause of death in Korea, the mortality rate from pneumonia has increased by more than 30% in the past 10 years, and pneumonia is considered the most common cause of death among infectious diseases in older adults [1]. Chronic obstructive pulmonary disease (COPD), which has a socioeconomic burden due to its high prevalence and mortality worldwide, is the seventh leading cause of death in Korea [1]. In addition, the number of patients with chronic pulmonary fibrosis has also been increasing rapidly in recent years as a sequelae of epidemic or pandemic respiratory infections such as severe acute respiratory syndrome, Middle East respiratory syndrome, and COVID-19 [2].

For most patients with respiratory diseases, rehabilitation interventions such as education, physical exercise, and breathing exercises are as important as pharmacological treatment for long-term symptom control. In particular, it has been reported that breathing exercises were effective in improving quality of life as well as respiratory function in patients with COPD [3]. Recently, the number of chronic patients who manage respiratory symptoms while maintaining daily activities at home rather than being hospitalized has been increasing, and Holland et al. [4] found that an at-home rehabilitation program for COPD was not significantly different from institutional rehabilitation in terms of effectiveness. Furthermore, according to a qualitative study, chronic respiratory patients preferred rehabilitation at home because of its flexibility and convenience [5].

One of the most common breathing exercises is inspiratory muscle training through deep breathing. Inspiratory muscle training is a method of expanding and exercising the lungs by maximally moving the thorax and diaphragm, and it can induce

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positive effects such as control of breathing and coughing and increased lung capacity [6,7]. Although breathing exercises are a low-cost and low-effort intervention, it is difficult to learn the accurate procedure and to maintain motivation for exercise. Therefore, in most cases, devices that can assist with breathing exercises are used. The incentive spirometer (IS) and inspiratory muscle trainer (IMT) have been two of the most commonly used devices in medical institutions and at home. The IS, whose indicator moves when the user inhales, is effective in maintaining or increasing lung volume, so it is used to prevent pulmonary complications after surgery. Although the IS is a relatively simple device, it is not easy to learn how to use it accurately, and its effectiveness in chronic respiratory patients is still controversial [8,9]. The IMT is an exercise device that uses a spring valve to give resistance to the user's inspiratory muscles, and is known to be more effective than the IS in improving lung function. However, because the IMT should be used with the help of a specialist, such as a respiratory therapist, it is not suitable for daily training performed by the user themselves [6,10]. In addition, diaphragmatic breathing exercise training using real-time ultrasound images, inspiratory muscle resistance exercise based on virtual reality (VR), and breathing games using Internet of Things (IoT) devices have been proposed [11,12]. All of these devices adopt a method in which the user inhales and exhales through the mouthpiece. If only the flow of ventilated air is sensed, direct effects of breathing exercises such as actual respiratory muscle contraction and thoracic expansion cannot be confirmed. Moreover, it may increase the risk of infection transmission because the user must breathe through the mouthpiece of the device.

Recently, the use of VR has been attracting attention in various healthcare fields including nursing. VR provides an experience of actually being there by taking advantage of the fact that the essence of human experience is information processed in the brain [13]. VR therapy has been reported to have positive effects in the treatment of posttraumatic stress disorder, the management of anxiety, pain relief, and in various types of rehabilitation [14–16]. VR-based digital cognitive rehabilitation has a faster EEG transmission speed than computer and tablet-based, and VR's high immersion and sense of presence has the effect of improving compliance behavior through engagement and sense of control [17]. It can be assumed that realistic training content using VR would be helpful in maintaining motivation for and compliance with breathing exercises among respiratory disease patients.

In this study we describe a novel breathing exercise system that is easy to use and entertaining by using VR technology. In addition, there is no risk of infection transmission. The purpose of this study was to provide a basis for clinical application of a newly developed Virtual Reality-Based Breathing Exercise System (VR-BRES). The effects and user evaluation of the VR-BRES were compared to conventional deep breathing (CDB) exercises. The specific objectives were (1) to investigate the effect of the VR-BRES on respiratory parameters, and (2) determine the feasibility of the VR-BRES.

Methods

Design

This study adopted a randomized crossover design in which the VR-BRES and the CDB intervention were applied twice each to all participants by changing the order. The respiratory parameters depend on age, gender, and physique, so we have applied two training methods to one participant to compare the effect. We randomized the order of the first intervention to reduce period effects and set a washout period of 1 hour between each training session to reduce the carryover effect [18]. The washout time was set to 60 minutes based on the relevant studies that reported the respiratory recovery time was at least 10 minutes after breathing exercise [19,20].

Participants

Participants were healthy adults aged 18 years or older who were able to communicate without any restrictions. Exclusion criteria were (1) having a diagnosis of a respiratory disease, such as asthma, COPD, pneumonia, or lung cancer; (2) having a hearing or visual impairment; (3) diagnosed with cognitive impairment; and (4) previous or current experience of breathing exercise training.

We calculated the sample size using the G*power 3.1.9.4 program. With a significance level set at $\alpha = .05$, power $(1\text{-}\beta) = .80$, and effect size $= 0.41$ [21], the minimum sample size required for a paired t-test for comparison between two interventions was 49. A total of 50 participants who were selected through stratification sampling participated in this study. We recruited participants publicly until the minimum sample size was met, and once a participant was recruited, the respiratory training was provided individually. There was no participant who did not complete this process.

Measurements

Participant characteristics

Data on participants' age, gender, and regular exercise were collected through a questionnaire survey, and their body mass indices were measured with InBody270, a bioelectrical impedance analyzer (InBody Co., Korea).

Respiratory parameters

We measured the respiratory parameters of participants with a portable spirometry, Pony FX (COSMED, USA). The respiratory parameters consisted of forced expiratory volume (FVC), forced expiratory volume in 1 second (FEV1), and peak expiratory flow (PEF). FVC is the amount of air (L) exhaled when breathing with maximum force. FEV1 is the expiratory volume (L) in the first second of maximum respiration. PEF stands for the highest flow rate (L/sec) during exhalation. FVC and FEV1 are standard parameters of respiration, and PEF is used as a highly reliable indicator for the evaluation of COPD [22]. We measured the respiratory parameters three times (1^{st}, 5^{th}, and 10^{th} breath) for every VR-BRES and CDB exercises, and used the average values for the analysis. All spirometry measurements were performed by one trained research assistant. For accurate measurement, the participants were asked to sit with their backs straight in a chair with a backrest, and the measurer gave sufficient explanations and demonstrations to the participants.

User evaluation

We conducted the user evaluation of the VR-BRES and CDB exercises using a questionnaire. The questionnaire items were generated by the authors, and were revised and supplemented by one respiratory specialist and one nursing professor. The final questionnaire consisted of four items asking about convenience, efficiency, entertainingness, and intention to use. Participants responded to each item using a 5-point Likert scale where 1 = "strongly disagree" and 5 = "strongly agree." The user evaluation questionnaire was administered after all breathing exercises were finished. At the end of the questionnaire, the participants were asked to freely describe the part they would like to revise or supplement among the features of the VR-BRES prototype.

Intervention: VR-BRES

The VR-BRES is a VR-based Breathing Exercise System that was designed by integrating self-regulation, biofeedback, immersion,

and entertainment concepts. In the VR-BRES prototype production, not only the authors but also sensor developers, VR content creators, respiratory nurses, intensive care unit nurses and head nurses, rehabilitation nurses, and rehabilitation physicians were involved. The final prototype was developed based on more than 15 product development meetings from February to October 2020.

The VR-BRES is basically composed of a VR device, a sensor, and deep breathing exercise content. We utilized an Oculus Rift CV1 head-mounted display (HMD) and controller (Oculus, USA), a VR device, and a soft stretch sensor based on a liquid metal printing technique (FeeltheSame Inc, Korea). We created our own breathing exercise content. The VR device and the sensor were connected by wire, and the content was uploaded to a designated server and then accessed online. In the VR-BRES, the HMD was a device that blocked out the physical surroundings so that the user could fully engage in the breathing exercise (immersion). The sensor was an essential element of biofeedback that converted the breathing into a visual signal (biofeedback). We implemented a mouth contactless respiration measurement by detecting the change in thoracic expansion with a soft stretch sensor. Breathing exercise content was created for the purpose of controlling the intensity and frequency of one's deep breathing while watching the signal transmitted by the sensor (self-regulation). In order to add an entertainment aspect, we configured the breathing exercise in a game format in which a running rabbit jumps over obstacles when the user takes a deep breath over a certain intensity (entertainment). These four unique characteristics of the VR-BRES were developed as measures to increase the user's compliance with and sustainability of the breathing exercise (Fig. 1).

The breathing exercise training was performed while sitting in a comfortable chair with a backrest, and the research assistant helped the participant wear the HMD and attach the soft sensor. We placed the sensor on the participant's upper abdomen or lower chest, where they most expanded during full inspiration [23]. Because the sensitivity of the sensor that detects chest wall expansion may be different depending on individual body characteristics, the sensitivity was adjusted to suit each participant during the calibration stage. During this process, participants were also able to set their own goals for deep breathing intensity.

We created VR content that reflects visual appeal and rewarding characteristics to make the breathing exercise training easier and more fun. When the training mode is turned on, the rabbit appears on the VR screen with background music and announcements and prepares to run. Users can move their eyes according to the guidance voice to see the VR screen in 360°. Before starting the main breathing exercise, the user must go through a calibration process. While the user takes five deep breaths, the VR-BRES adjusts the sensor sensitivity and sets a personal goal for the degree of chest expansion. When the user starts a deep breathing exercise according to the guiding voice, the soft sensor detects the chest expansion and delivers this signal into VR in real time. As the chest expands and the signal increases, the avatar rabbit on the VR screen gathers strength to jump over obstacles. If the signal level reaches 80% or more of the set goal, the rabbit jumps over the obstacle with a cheerful sound effect at the moment the user exhales. If the signal level does not reach 80%, the obstacle will fall with a disappointing sound effect and the rabbit will run towards the next obstacle. Each time the rabbit successfully crosses an obstacle, the user earns one carrot. One set is completed with a total of 10 breaths, and both, numbers of deep breaths attempted and carrots obtained are recorded.

Conventional deep breathing

The participants performed CDB exercises in a posture with their backs straight while sitting in a chair with a backrest. Participants were asked to breathe in slowly, hold it for 3 seconds, and then exhale as much as possible. The rate of inhalation and exhalation was controlled by the participant, but the research assistant verbally guided the procedure and counted the number of breaths so that the participant could inhale and exhale sufficiently. Before starting the main training, the research assistant provided explanations and demonstrations on the deep breathing technique. A set of CBD consisted of 10 deep breaths.

Procedure

The trial to investigate the effectiveness and feasibility of the VR-BRES was conducted from January 24, 2021 to March 31, 2021. After IRB approval for the study, we publicly recruited participants by posting on the bulletin boards at D University and a community sports club. The participant recruitment notice included the study title, purpose, participants, study procedure, and researcher's contact information. Those individuals who expressed their intention to participate in the study were screened for eligibility based on the inclusion/exclusion criteria.

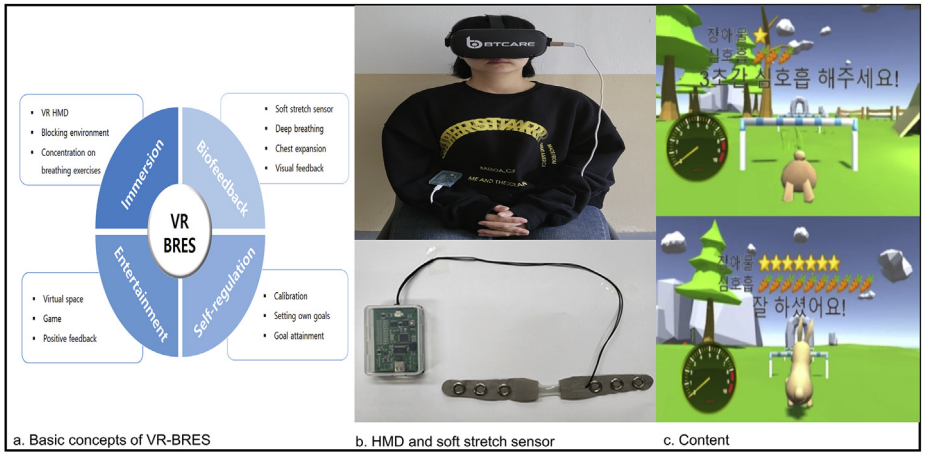

Figure 1. Virtual Reality based BReathing Exercise System (VR-BRES).
Note. HMD = head mounted display.

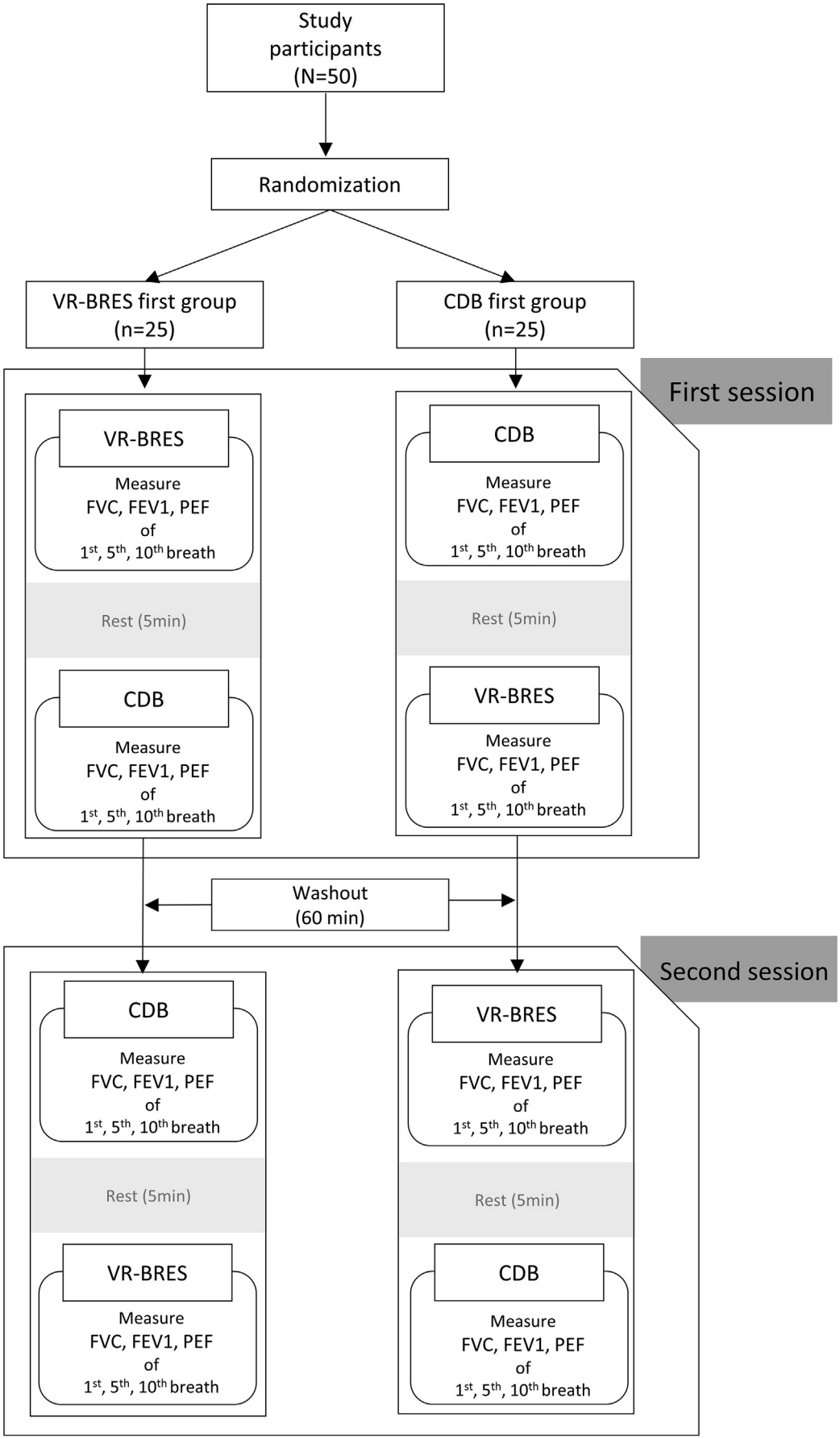

Figure 2. Study flow diagram. CDB = conventional deep breathing; VR-BRES = virtual reality based breathing exercise system.

Participants went through a total of four training sessions including two VR-BRES and two CDB sessions, and the order was randomly assigned. We made 25 cards marked “A” or “B,” put them in 50 nontransparent envelopes, sealed the envelopes, and asked participants to choose one envelope. Participants who selected “A” performed the VR-BRES first and participants who selected “B” performed the CDB first.

The trial was conducted in a laboratory at D University and consisted of two sessions. The second session proceeded in the opposite direction of the first. Participants performed a total of four sets of breathing exercises during two sessions. A 60-minute washout period was provided between the first and second sessions to ensure sufficient rest for the participants. Both the VR-BRES and CBD exercises were conducted after explanation and demonstration by the research assistant. We measured the respiratory parameters of the participants with a spirometer during the 1st, 5th, and 10th breaths in each set. Given that neither the VR-BRES nor CDB exercises require the use of a mouthpiece, spirometry measurements were possible while the user was breathing. After all breathing exercise training was completed, a user evaluation questionnaire was administered (Fig 2).

Statistical analysis

We analyzed the data using the IBM SPSS statistics 25.0 program. Participants' characteristics, respiratory parameters, and user evaluation data were analyzed using descriptive statistics, including the median, interquartile range, mean, and standard deviation. We compared the characteristics between groups according to the order of intervention using the independent t-test and Mann–Whitney test. For differences in respiratory parameters and user evaluation data between the two methods, normally distributed variables were analyzed using the paired t-test, and variables that were not normally distributed were analyzed using the Wilcoxon signed rank test.

Ethical considerations

This study was approved by the Institutional Review Board of Dong-A University (Approval no. 2-1040709-AB-N-01-202010- HR-045-02). After the purpose and procedures of the study were explained to the participants, all participants provided written consent.

Results

Participant characteristics

A total of 50 healthy adults participated in the study. Their mean age was 42.52 ± 15.76 years, and 46.0% were men. The mean BMI was 23.74 ± 3.57 kg/m^2. Most of them (78.0%) did not exercise regularly. The baseline respiratory parameters of the participants were FVC = 3.65 ± 0.77, FEV1 = 2.83 ± 0.71, and PEF = 4.95 ± 2.02. Twenty-five participants performed the VR-BRES first and then CDB exercises in the first session. In the second session, CDB exercises was conducted first, followed by VR-BRES. The order was reversed for the other 25 participants. There were no significant differences in participants’ characteristics and the baseline respiratory parameters according to the training sequence (Table 1).

Differences in respiratory parameters during VR-BRES and CDB exercises

We compared the respiratory parameters during VR-BRES and CDB exercises for each session. The mean of the same methods was analyzed within each session, and the results are shown in Table 2. The mean FVCs during the first session were 2.81 ± 0.73 for the VR-BRES and 2.20 ± 0.80 for CDB exercises, which was significantly higher for the VR-BRES ($Z = 4.82$, $p < .001$). The mean FEV1s were 2.16 ± 0.63 for the VR-BRES and 1.62 ± 0.69 for CDB exercises, indicating that the mean for the VR-BRES was significantly higher ($t = 6.02$, $p < .001$). The mean PEFs were 3.35 ± 1.43 for the VR-BRES and 2.29 ± 1.05 for CDB exercises, and the VR-BRES mean was significantly higher ($t = 5.35$, $p < .001$).

The mean FVCs during the second session were 2.82 ± 0.71 for the VR-BRES and 2.29 ± 0.76 for CDB exercises, which was significantly higher for the VR-BRES ($Z = 4.95$, $p < .001$). The mean FEV1s were 2.17 ± 0.62 for the VR-BRES and 1.70 ± 0.56 for CDB exercises, indicating that the mean for the VR-BRES was significantly higher ($t = 6.26$, $p < .001$). The mean PEFs were 3.48 ± 1.56 for the VR-BRES and 2.45 ± 1.02 for CDB exercises, and the VR-BRES mean was significantly higher ($t = 5.68$, $p < .001$).

User evaluation

The user evaluation results for the VR-BRES and CDB exercises are presented in Table 3. The Convenience scores were 3.66 ± 1.10 for the VR-BRES and 3.80 ± 0.78 for CDB exercises, and there was no significant difference between the two methods ($Z = -0.90$, $p = .369$). The Efficiency scores were 4.06 ± 0.79 for the VR-BRES and 3.50 ± 0.89 for CDB exercises, and the VR-BRES mean score was significantly higher ($Z = 3.86$, $p < .001$). The Entertainingness scores were 4.18 ± 0.83 for the VR-BRES and 3.00 ± 1.07 for CDB exercises; the VR-BRES mean score was significantly higher ($Z = 5.00$, $p < .001$). The Intention to Use scores were 3.84 ± 0.89 for the VR-BRES and 3.26 ± 0.90 for CDB exercises, and the VR-BRES score was significantly higher ($Z = 3.22$, $p = .001$).

Discussion

This study investigated the effectiveness and feasibility of the Virtual Reality-based Breathing Exercise System (VR-BRES), a novel VR-based respiratory exercise solution. We compared the respiratory parameters during the VR-BRES and conventional deep breathing (CDB) exercises, and compared user evaluations of the two methods. Because respiratory function is a variable that differs between individuals, we adopted a randomized crossover design in which one participant is subjected to both interventions in a different order to minimize intersubject variability. The results of the study showed the mean scores for all three respiratory parameters were higher for the VR-BRES than for CDB exercises. In addition, among the user evaluation items, scores for efficiency, entertainingness, and intention to use were significantly higher for the VR-BRES.

The results that all three respiratory parameters were higher during VR-BRES training suggest that the VR-BRES is an effective breathing exercise solution. These positive effects may be due to the biofeedback and self-regulating features of the VR-BRES. In our study, the VR-BRES provided feedback by visualizing the user's breathing signal as an avatar rabbit's jump. This is consistent with the results of previous studies indicating that visual feedback helps in breathing exercises. Jang et al [11] evaluated the immediate effect after providing a breathing exercise with visual feedback of an ultrasound image of the diaphragmatic motion to women with limited thoracic movement. They found the group receiving additional visual feedback had significantly higher respiratory parameters. Blum et al. [24] developed a short breathing exercise using VR for the purpose of relieving psychological stress. They reported that breathing was more stable and user satisfaction was higher in the group that provided respiration-induced abdominal movements as

Table 1 *Participants' Characteristics (N = 50).*

Variables	Categories	Total	VR-BRES first group	CDB first group	χ^2 (*p*)	t or Z (*p*)
		n (%) or M ± SD (median, IQR)	*n* (%) or M ± SD (median, IQR)	*n* (%) or M ± SD (median, IQR)		
Gender	Man	23 (46.0)	14 (56.0)	9 (36.0)	2.01	
	Woman	27 (54.0)	11 (44.0)	16 (64.0)	(.156)	
Age		42.52 ± 15.76	40.84 ± 14.51	44.20 ± 17.04		−0.68[a]
(years)		(40, 22.25)	(40, 16.00)	(41, 27.00)		(.497)
BMI		23.74 ± 3.57	24.70 ± 3.65	22.77 ± 3.28		0.28[b]
(kg/m^2)		(23.38, 4.53)	(23.84, 4.92)	(22.99, 4.78)		(.055)
Regular exercise	Yes	11 (22.0)	4 (16.0)	7 (28.0)	1.05	
	No	39 (78.0)	21 (84.0)	18 (72.0)	(.306)	
Baseline respiratory parameters	FVC (L)	3.65 ± 0.77	3.77 ± 0.79	3.52 ± 0.74		1.14[b]
		(3.52, 1.06)	(3.61, 1.24)	(3.44, 0.88)		(.262)
	FEV1 (L)	2.83 ± 0.71	2.94 ± 0.74	2.77 ± 0.69		0.85[b]
		(2.83, 0.89)	(2.94, 0.98)	(2.77, 0.66)		(.401)
	PEF (L/s)	4.95 ± 2.02	5.14 ± 2.10	4.76 ± 1.98		0.09[b]
		(5.01, 2.68)	(5.34, 2.80)	(4.64, 2.89)		(.517)

Note. BMI = body mass index; CDB = conventional deep breathing; FEV1 = forced expiratory volume in one second; FVC = forced vital capacity; IQR = interquartile range; PEF = peak expiratory flow.
[a] Mann–Whitney U test.
[b] Independent *t*-test.

Table 2 *Comparison of Respiratory Parameters during VR-BRES and CDB Exercises (N = 50).*

Outcome	First session			Second session		
	VR-BRES	CDB	t or Z (*p*)	VR-BRES	CDB	t or Z (*p*)
	M ± SD (median, IQR)	M ± SD (median, IQR)		M ± SD (median, IQR)	M ± SD (median, IQR)	
FVC	2.81 ± 0.73	2.20 ± 0.80	4.82[a]	2.82 ± 0.71	2.29 ± 0.76	4.95[a]
	(2.68, 0.84)	(2.14, 1.06)	(<.001)	(2.64, 0.69)	(2.25, 0.83)	(<.001)
FEV1	2.16 ± 0.63	1.62 ± 0.69	6.02[b]	2.17 ± 0.62	1.70 ± 0.56	6.26[b]
	(2.08, 0.86)	(1.53, 0.87)	(<.001)	(2.17, 0.72)	(1.72, 0.72)	(<.001)
PEF	3.35 ± 1.43	2.29 ± 1.05	5.35[b]	3.48 ± 1.56	2.45 ± 1.02	5.68[b]
	(3.08, 1.84)	(2.19, 1.36)	(<.001)	(3.14, 1.85)	(2.43, 1.47)	(<.001)

Note. CDB = conventional deep breathing; FEV1 = forced expiratory volume in one second; FVC = forced vital capacity; IQR = interquartile range; PEF = peak expiratory flow.
[a] Wilcoxon's signed-ranks test.
[b] Paired *t*-test.

biofeedback along with VR exercise. In our VR-BRES, the expansion of the chest or abdomen due to inspiration was converted into visual signals and fed back to the user in real time. Such biofeedback can serve as a motivation or goal for breathing exercise [25]. In particular, the visual biofeedback makes it easy for the user to observe their breathing immediately and judge whether they are breathing well, and the positive audiovisual feedback itself acts as a reward that reinforces the exercise behavior [24].

We also ensured participants' self-regulation by allowing them to set different goals themselves each time during the calibration process before starting the main exercise training. The reason that the respiratory parameters measured during the breathing exercises in our study were lower than the baseline values seems to be because the participants self-regulated their pace in the training that required 10 deep breaths. Self-regulation is one of the theories frequently mentioned in health psychology to induce behavioral changes in patients. According to this theory, self-regulation of one's thoughts, actions, and emotions helps maintain motivation and achieve goal attainment [26]. Motivation is an essential element in sustaining healthy behaviors such as exercise. In particular, it is known that immediate and autonomous forms of motivation rather than intrinsic motivation are more strongly related to the continuation of exercise [27]. In addition, self-regulation of respiration helps to manage anxiety, stress, and other emotional disorders by lowering the sympathetic dominance of the autonomic nervous system [28]. It will be helpful for VR-BRES users to carry out and continue breathing exercises by setting their own goals and gaining confidence while achieving them.

Table 3 *Comparison of User Evaluation on VR-BRES and CDB exercises (N = 50).*

Item	VR-BRES	CDB	Z[a]	*p*
	M ± SD (median, IQR)	M ± SD (median, IQR)		
Convenience	3.66 ± 1.10	3.80 ± 0.78	−0.90	.369
	(4.00, 1.00)	(4.00, 1.00)		
Efficiency	4.06 ± 0.79	3.50 ± 0.89	3.86	<.001
	(4.00, 1.25)	(3.00, 1.00)		
Entertainingness	4.18 ± 0.83	3.00 ± 1.07	5.00	<.001
	(4.00, 1.00)	(3.00, 2.00)		
Intention to use	3.84 ± 0.89	3.26 ± 0.90	3.22	.001
	(4.00, 1.25)	(3.00, 1.00)		

Note. CDB = conventional deep breathing; IQR = interquartile range.
[a] Mann-Whitney U test.

In terms of breathing exercise training, VR-based biofeedback has several advantages. First, VR increases the user's motivation and immersion by creating a stronger audiovisual feedback stimuli for breathing exercise through HMD [29]. Second, because the training environment is virtual, infinite changes and adjustments are possible, and the user can select the preferred training environment. This feature also helps to promote user safety and emotional relaxation [30]. Third, blocking from harmful surroundings is possible to a certain extent. In particular, if the training environment is a hospital or intensive care unit, users can enter a therapeutic space alone, free from noxious stimuli such as noise and light [31].

Despite these advantages, the user evaluation indicated that the participants were not satisfied with the VR-BRES in terms of convenience. Among the comments submitted on the user evaluation, there were many positive comments, such as “very fun,” “authentic,” and “I do breathing exercises without even knowing it.” However, there were also some negative comments. In particular, there were opinions such as “the headset device is heavy,” “inconvenient,” “hot,” and “the connection line to the sensor is cumbersome.” When modifying and supplementing the VR-BRES, it is necessary to consider providing Bluetooth-based wireless sensors and optional 2-dimensional training content given these opinions on usability.

A unique aspect of our study is that we utilized the thoracic expansion from inspiration for the visual feedback using a sensor without a mouthpiece. A mouth contactless device has the advantage of infection control as well as being applicable to patients with facial masks on or various oral tubes inserted. The recommended breathing exercise for successful weaning after ventilator treatment is inspiratory muscle training [32]. Conventional IMT devices are not applicable to endotracheal intubated patients. However, because the VR-BRES does not involve a mouthpiece, it can be applied to intubated patients and breathing training can be performed before extubation; therefore, it is also expected to contribute to successful weaning.

Recently, due to the development of related technologies, VR has been recognized as an accessible and affordable technology, and has been spotlighted as a promising intervention modality in that it can provide a controllable environment for maximum training. In the field of nursing, VR has been mainly used in nursing education and training [33]. The use of VR in nursing clinical practice such as pain and anxiety management [34] and sleep improvement [28] has been gradually increasing. The application areas of VR are expected to expand further by the combining of big data, wearable sensors, and artificial intelligence technology [35]. Considering the above, the VR-BRES developed in our study is likely to be utilized as a nursing intervention for patients who need breathing exercises due to acute or chronic respiratory problems.

The limitations of this study are as follows. First, the VR-BRES we tested was a prototype. It is necessary to upgrade the VR-BRES to reflect the opinions of the users who participated in this study. Second, double-blindness procedures could not be maintained due to the characteristics of the bulky HMD device, so this should be taken into account when interpreting the study's results. Third, we evaluated the respiratory parameters during training, and not the accumulated results of respiratory exercise. This was a necessary process to investigate the feasibility of the prototype. A clinical study designed to evaluate the effects of the VR-BRES on respiratory indicators and other health-related outcomes after applying the VR-BRES for a certain period is needed.

Conclusion

We developed the Virtual Reality-Based Breathing Exercise System (VR-BRES), a mouth contactless breathing exercise solution based on virtual reality, and evaluated its effectiveness and feasibility. The VR-BRES is based on the principles of biofeedback, self-regulation, entertainment, and immersion, and consists of virtual reality devices, soft stretching sensors, and breathing exercise content. Respiratory parameters were evaluated and compared during VR-VRES and conventional deep breathing exercises, and a user evaluation was conducted on both exercise programs. The VR-BRES showed promise as an efficient and feasible breathing exercise solution. We recommend a clinical study that evaluates the effect of the VR-BRES for a certain period of time for people who need breathing exercises.

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Declaration of competing interest

None.

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