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Review Article

Effects of Mind–Body Programs on Infertile Women: A Systematic Review and Meta-analysis of Randomized Controlled Trials

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SUMMARY

Purpose: This study was to systematically review randomized controlled trials and conduct a meta analysis. The results of randomized controlled trials were integrated and analyzed to assess the effects of mind-body programs on anxiety, depression, quality of life, and pregnancy rate in infertile women.
Methods: Using electronic databases (i.e., Research Information Sharing Service, Korean Studies Information Service System, Korean Medical Database, National Digital Science Library, Cochrane Library, PubMed, EMBASE, Cumulative Index to Nursing and Allied Health Literature, and PsycARTICLES), 10 of 2,259 studies were included for meta-analysis. To estimate the effect size, a meta-analysis of the studies was performed using RevMan 5.3.
Results: The mind–body program was effective in relieving anxiety [standardized mean difference (SMD) = −3.44; 95% confidence interval (CI) = −5.94, −0.95; $p = .007$; $I^2 = 69\%$] and depression (SMD = −5.79; 95% CI = −10.36, −1.22; $p = .010$; $I^2 = 86\%$). Furthermore, it was effective in enhancing the quality of life (SMD = 7.40; 95% CI = 2.92, 11.88; $p = .001$; $I^2 = 53\%$) and pregnancy rate (SMD = 2.06; 95% CI = 1.08, 3.95; $p = .030$; $I^2 = 73\%$). The mind–body program was found to relieve anxiety and depression in infertile women and improve their quality of life, thereby positively affecting the pregnancy rate.
Conclusion: The mind-body program was found to relieve anxiety and depression in infertile women and improve their quality of life, thereby positively affecting the pregnancy rate. The mind-body program needs to be considered to a wider audience for positive effects on emotions and pregnancy outcomes of infertile women.

Introduction

While 12.1% of 10,625 married women aged 15–49 years in Korea experienced infertility [1], the number of women diagnosed with infertility increased from 178,000 in 2007 to 198,000 in 2010 and 221,000 in 2016 [2]. In addition to the increase in the number of infertile women, the cost of medical treatment for infertility has more than doubled from 43.42 billion in 2017 to 115.03 billion in 2018 [3]. Despite the increase in the cost of infertility treatment, Korea has a low birth rate, with a total pregnancy rate of 0.92 in 2019 [4].

The emotions that infertile women experience include depression, anxiety, and stress [5], and the increase in these negative emotions can cause a threat to their quality of life [6]. In particular, infertility treatment is a major stressor, comparable with death in the family or divorce [7], and if the procedure fails, depression and anxiety increase to a higher level, remaining high even after 6 months of treatment [8]. Furthermore, because the stress and anxiety experienced by infertile women have a significant effect on their pregnancy rate after fertility treatment [9], it is necessary to take care of these negative emotions actively; this may contribute to enhancing their pregnancy rate.

To alleviate the negative emotions of infertile women and improve their quality of life, various psychosocial interventions have been conducted, including counseling interventions, focused educational interventions, and comprehensive educational programs [10]. The effects of these interventions on anxiety and depression, but not on women's pregnancy rates, were confirmed [10]. However, studies applying the mind–body program for

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infertile women such as those by Domar et al [11,12] have shown results with significant impact on improvement on pregnancy rate and alleviation of negative emotions. Since then, many countries such as Turkey, China, Iran, Brazil, and Israel are applying the mind–body program for treating infertile women. Mind–body interventions are defined as practices that focus on the interactions among the brain, mind, body, and behavior, with the intent to use the mind to affect physical functioning and promote overall health [13]. As per the National Center for Complementary and Integrative Health, it compasses a large group of therapies such as meditation, tai chi, yoga, and relaxation techniques (progressive relaxation, guided imagery, biofeedback, self-hypnosis, deep breathing exercises, and autogenic training) [14]. Hypnosis, meditation, yoga, biofeedback, tai chi, and visual imagery, which are included in the mind–body program, induce relaxation and enhance the mind's interaction with bodily function, which are considered to positively affect the cognitive, psychological, and physiological aspects in infertile women by causing relaxation in the relationship among the brain, mind, body, and behavior [15,16].

Hämmerli et al [17] conducted a meta-analysis by combining a total of 21 studies including cognitive behavioral therapy, mind–body intervention, counseling, education, and supportive therapy as psychosocial intervention and reported that these interventions did not have any significant effect on alleviation of negative emotions such as anxiety and depression [17]. On the other hand, Frederiksen et al [18] conducted a meta-analysis by combining a total of 39 studies including counseling, cognitive behavioral therapy, mind–body intervention; meditation, hypnosis, breathing, and muscle relaxation; psychoeducation, supportive therapy, and writing intervention as psychological intervention and reported that these interventions caused a significant effect on alleviation of negative emotions such as anxiety and depression, hence showing contrasting results [18] from those of the study by Hämmerli et al [17]. Moreover, both studies conducted by Hämmerli et al [17] and Frederiksen et al [18] targeted both infertile women and men and conducted an analysis by combining various types of psychosocial interventions apart from the mind–body program and also included not only randomized controlled trials (RCTs) but also non-RCTs for analysis. Recently, systematic literature reviews [19] about mind–body intervention for infertile women have been conducted, but as RCTs, non-RCTs, and uncontrolled trials were analyzed altogether, a strict control of confounding variables has not been implemented. In addition, as only the individual effect size of each study is suggested, grasping the synthesized effect size and difference of the studies included in the analysis is limited.

Therefore, this study defined the mind–body program as mediation that includes hypnosis, meditation, yoga, biofeedback, tai chi, and imagery, which have been mentioned in the definition of the mind–body program, or practices with confirmed relaxation effects such as relaxation and breathing techniques and qigong, and this study systematically reviewed RCTs in which mind–body programs were conducted for infertile women. Furthermore, a meta-analysis was performed to assess the effects of mind–body programs on alleviating negative emotions such as anxiety and depression in infertile women and improving their quality of life, along with their effect on pregnancy rates in infertile women, which is expected to provide a basis for possible interventions for infertile women.

The specific objectives are as follows: (1) assess the effect of mind–body programs on anxiety, depression, and quality of life in infertile women and (2) assess the effect of mind–body programs on pregnancy rates in infertile women.

Methods

This is a systematic literature review and meta-analysis, wherein the results of RCTs are integrated and analyzed to investigate the effects of mind–body programs on anxiety, depression, quality of life, and pregnancy rate in infertile women.

Core questions

This study used a PICO-SD (Participants, Intervention, Comparison, Outcomes, Study Design) tool as follows: (1) Population (P), infertile women; (2) Intervention (I), mind–body programs [16,19] (i.e., interventions including meditation, yoga, relaxation and breathing techniques, tai chi, qigong, hypnosis, and biofeedback); (3) Comparison (C), no treatment control group or a placebo group or an alternative group; (4) Outcome (O), anxiety, depression, quality of life, and the pregnancy rate; and (5) Study Design (SD), RCTs.

Search strategy and study selection

Data search was conducted from January 1, 2020, to April 1, 2020, and data were collected for the purpose of analyzing the effectiveness of mind–body programs in infertile women. Using a search engine, domestic studies were searched in the following databases: Research Information Sharing Service, Korean Studies Information Service System, Korean Medical Database, and National Digital Science Library. In addition, entire journals were searched using the websites of nursing-related societies such as the Korean Society of Nursing Science, Korean Society of Adult Nursing, Korean Society of Women Health Nursing, and Korean Academy of Community Health Nursing. International studies were searched in the Cochrane Library, PubMed, EMBASE, Cumulative Index to Nursing and Allied Health Literature, and PsycARTICLES. Keyword selection and search included both medical subject headings (MeSH) and life science term indexes (EMBASE TREE; EMTREE). The target keywords included “Infertility” [MeSH], “Infertile women,” “infertile*,” “Sperm Injections,” “Intracytoplasmic” [MeSH], “ICSI,” “Intracytoplasmic sperm injection,” “Fertilization in Vitro” [MeSH], “IVF” “In vitro fertilization,” “Infertility treatment,” “Assisted reproductive technologies,” and “ART.” Intervention keywords included “Mind-body,” “Body-Mind-Sprit,” “Mindfulness,” “Mindful*,” “Yoga.” “Meditation,” “Relaxation,” “Psychological” [MeSH], “Psycho-social,” “Breathing,” “Tai chi,” “Qigong,” “Hypnosis,” and “Biofeedback.” Outcome variables included “Depression” [MeSH], “Depress*,” “Anxiety” [MeSH], “Anxiety,” “Stress,” “Emotion,” “Quality of life,” “Wellbeing,” “Psycho*,” “Psychia*,” and “Pregnancy rate” or “pregnant,” along with the AND connector for each subject. To search all the researched studies, there was no limit set for the research period, but the studies were limited to human participants, and the language was limited to Korean and English. For domestic studies, the keywords included “Infertility,” “In vitro fertilization,” “Body and mind treatment,” “Mindfulness,” “Yoga,” “Meditation,” “Depression,” “Anxiety,” “Stress,” “Quality of life,” “Well-being,” “Psychology,” and “Emotion.”

The inclusion criteria for the literature were as follows: (1) intervention studies conducted using a mind–body program for infertile women, (2) RCTs, and (3) studies published in English or Korean in a peer-reviewed journal. The exclusion criteria were as follows: (1) unpublished theses, (2) case studies, (3) literature reviews, and (4) pilot studies that were not followed by main studies.

In this study, articles were selected based on core questions and the inclusion and exclusion criteria listed previously. The selection

process was described step by step using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses flowchart [20]. In the first search, 3,726 studies published in English were found in PubMed (619), Cochrane Library (82), Cumulative Index to Nursing and Allied Health Literature (2,943), and EMBASE (82), but Korean studies on the subject were not found, although searches were made in Research Information Sharing Service, National Digital Science Library, Korean Studies Information Service System, and Korean Medical Database. In total, 1,467 duplicates were excluded through RefWorks, resulting in a total of 2,259 studies. Subsequently, after they were reviewed with a focus on the title and abstract based on the data inclusion and exclusion criteria, 1,745 studies whose topics were not appropriate for the research topic and 406 duplicated studies were excluded. After a careful reading of the full text of the article in detail, 91 studies and seven reviews did not meet the inclusion criteria, which led to the final inclusion of 10 studies (Figure 1).

Two researchers conducted data selection and review, and they also checked the results after their respective reviews. In case of disagreement between the researchers in this process, a research meeting was convened so that the study in question could be reviewed together.

Quality assessment of the selected studies

The quality of the selected studies was evaluated using a revised tool for assessing risk of bias (RoB) 2.0 (The Cochrane Collaboration, England, London) [21] (Figure 2). RoB 2.0 consists of five domains: "randomization process," "deviations from intended interventions," "missing outcome data," "measurement of the outcome," and "selection of the reported result," which are evaluated as "low risk of bias," "high risk of bias," or "some concerns" [22]. Studies were graded as follows: (1) "low risk of bias" when a low risk of bias was determined for all domains, (2) "some concerns" if at least one domain was assessed as raising some concerns but not at high risk of bias for any single domain, or (3) "high risk of bias" when high risk of bias was reached for at least one domain or the study judgment included some concerns in multiple domains [22]. The evaluation of the quality of the selected studies was assessed independently by two researchers, and regarding the categories that were not in agreement, the relevant studies were evaluated together until a consensus was reached to draw a conclusion and entered into RevMan (The Cochrane Collaboration, England, London) to present the evaluation results for the risk [23].

Data analysis

The characteristics of the studies included in the systematic literature review were analyzed, and data were selected based on the author, the year of publication, the country of publication, the number of samples, the method used and number of interventions for experimental and comparative groups, and the outcome variables.

The effect size and homogeneity of the interventions in the selected studies were analyzed using RevMan 5.3 version of the Cochrane Collaboration. Heterogeneity for the main variables was tested using the Chi-square null hypothesis test. When I^2 is 0%, it means no heterogeneity; when I^2 is 30–60%, it means moderate heterogeneity, and when I^2 is $\geq$75%, it means high levels of heterogeneity [21]. In this study, quality of life with a heterogeneity of 0% was analyzed using a fixed-effects model. Variables with a heterogeneity of >60%, including anxiety, depression, and pregnancy rates, were analyzed using a random-effects model. A forest plot was used to confirm the direction of the effect and the

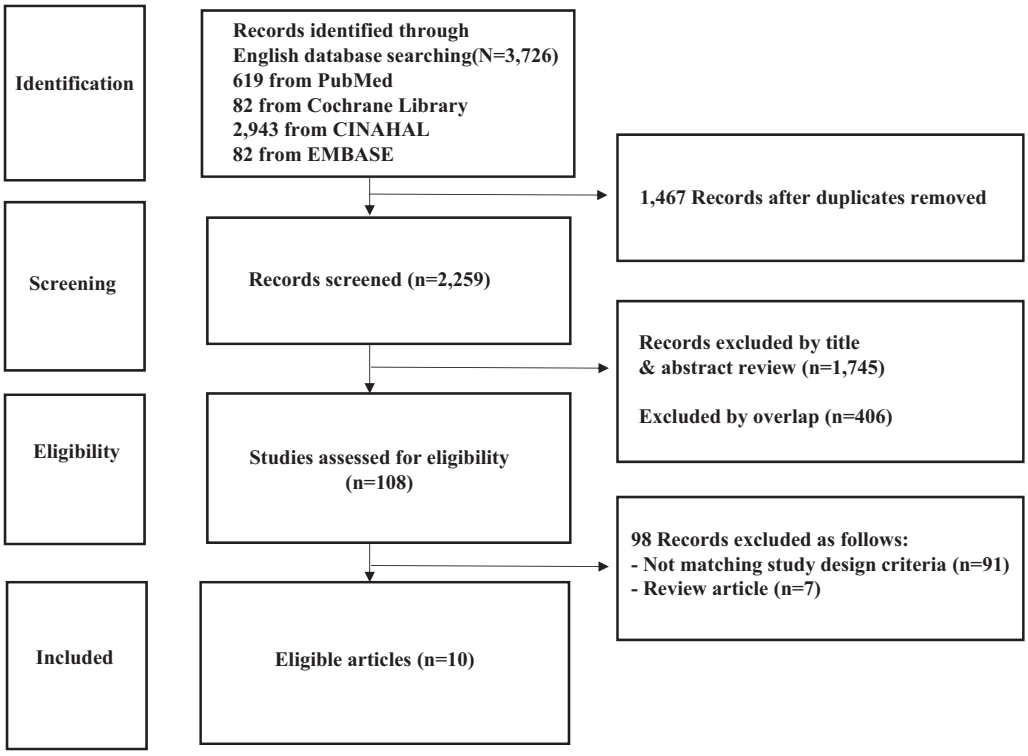


Figure 1. Flow diagram of study selection.
Note. CINAHL = Cumulative Index to Nursing and Allied Health Literature; KISS = Korean Studies Information Service System; NDSL = National Digital Science Library; RISS = Research Information Sharing Service.

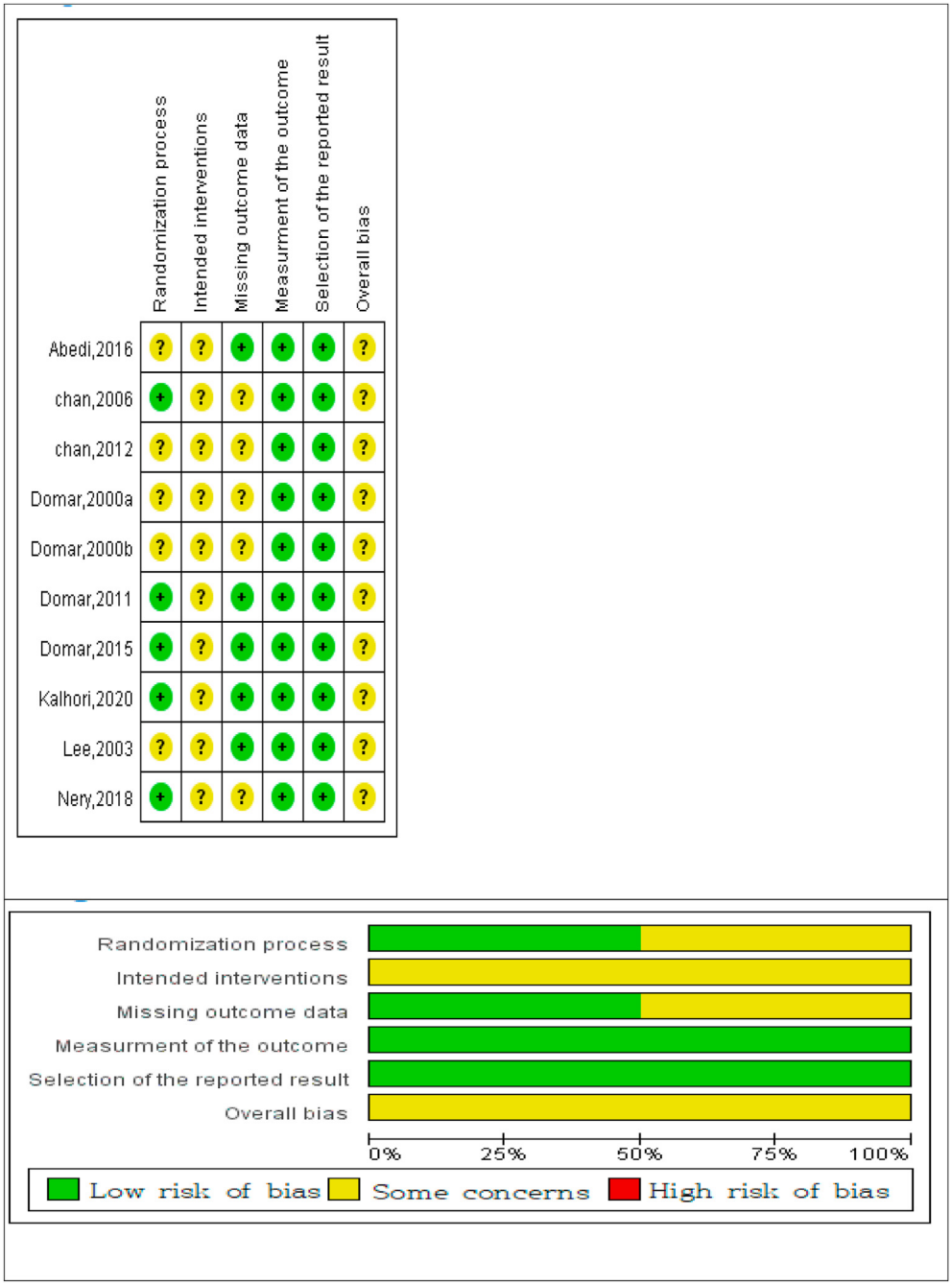


Figure 2. Risk of bias assessment.

confidence interval (CI), and the effect size of the result value was represented by standardized mean difference in case of continuous data such as anxiety, depression, and quality of life and by odds ratio, which is the ratio between the occurrence and nonoccurrence of specific events between groups, in case of binary data such as pregnancy rate. The statistical significance level for effect size was .05, and the CI was set at 95%. Fixed-effects and random-effects models were compared for each variable to conduct sensitivity analysis. Analysis was conducted to identify the differences in results, excluding studies with a large effect size or larger weights compared with other studies included in analysis. Finally, funnel plot analysis was used to examine publication bias to test the validity of the entire study. Egger's regression test was carried out to evaluate the relationship between the effect size and the standard error [24] to check the significance of asymmetry. Regarding the suspicion of publication bias, the trim-and-fill method [25] was used to reanalyze the method to verify its severity. It can eliminate nonsymmetric effect sizes from funnel plot analysis. Afterward, it fills the left and right sides of polled effect sizes symmetrically [25].

Results

Characteristics of the selected studies

The characteristics of the studies are indicated in Table 1.

A total of 10 studies were included, and the countries wherein these were conducted are as follows: Israel, four (40%) studies; China, two (20%) studies; Iran, two (20%) studies; and

Brazil and Taiwan, one (10%) study, each. The publication years of the studies are as follows: 2000–2010, four (40%) studies and 2010 onward, six (60%) studies. With regard to the number of samples, there were two studies (20%) with ≤100 participants, were six (60%) studies with 100–200 participants, was one (10%) study with 200–300 participants, and was one (10%) study with >300 participants. In terms of the number of interventions, there were two (20%) studies with 14 interventions, four (40%) with 10 interventions, two (20%) with eight interventions, and two (20%) with four interventions. With regard to the forms of intervention provision, there were eight (80%) studies with groups and two (20%) with individuals. In the measurement variables, there were five (50%) studies on anxiety, four (40%) on depression, five (50%) on pregnancy rates, and two (20%) on quality of life. In all the ten studies, the control groups received routine care.

Quality assessment of the selected studies

The methodological quality evaluation of the ten studies using RoB 2.0 indicated seven (70%) studies that had a low risk of bias with an appropriate method of random assignment. Relevant information on the proper methods of random assignment was not identified in three (30%) studies. There were five (50%) studies in which the assignment order was concealed through sealed envelopes, random numbers, and computer programs, and for the remaining five studies (50%), the appropriateness could not be identified because no clear method was described for concealing the assignment order. All ten studies evaluated baseline differences between intervention groups, which did not matter in the randomization process. Based on the aforementioned results, five studies were evaluated as "low risk of bias" in the randomization process and five studies were evaluated as "some concerns."

Regarding the area of "deviations from intended interventions," none of the studies clearly indicated blinding of the research participants and researchers, and ten (100%) studies did not explicitly state the blinding of the participants and researchers. There were five (50%) studies that described the blinding of the result evaluator and five (50%) that did not clearly indicate the blinding of the evaluator.

It was not possible to determine whether blinding of participants, researchers, or evaluators affected the results owing to unclear blinding or whether bias occurred in the study. Based on the aforementioned results, all ten studies were evaluated as "some concerns" in "deviations from intended interventions."

In the domain of "missing outcome data," five studies showed no missing data and were evaluated accordingly as "low risk of bias," and five studies were evaluated as "some concerns" because it was not possible to obtain clear information on whether data excluded from analysis such as missing data affected the existence of bias.

In terms of "measurement of the outcome," methods of measuring the outcome were appropriate in all ten studies, and measurement or ascertainment of the outcome did not show any difference between intervention groups, which led to an evaluation of all ten studies as "low risk of bias."

In terms of "selection of the reported result," all ten studies were analyzed based on a prespecified analysis plan and evaluated as "low risk of bias."

The overall risk of bias generally corresponds to the worst risk of bias in any of the domains [22]. Considering the aforementioned results together, all ten studies were evaluated as "some concerns" in terms of the overall risk of bias.

Effects of the mind–body program

Effects of the mind–body program on anxiety

For five studies that reported anxiety in the experimental and control groups participating in the mind–body program, the homogeneity test showed Q (Chi-square) = 12.81, df = 4 (p = .010), and I^2 = 69%. The effect size of anxiety was −3.44 (95% CI: −5.94, −0.95), and the anxiety between the experimental group and the control group showed a statistically significant difference (Z = 2.70, p = .007).

Effects of mind–body programs on depression

Based on our examination of four studies reporting depression in the experimental and control groups participating in the mind–body program, the homogeneity test showed the following results: Q (Chi-square) = 21.30, df = 3 (p < .001, and I^2 = 86%. The effect size of depression was −5.79 (95% CI: −10.36, −1.22), and the difference in depression between the two groups was statistically significant (Z = 2.48, p = .010).

Effects of mind–body programs on quality of life

For two studies that reported the quality of life of the experimental and control groups participating in the mind–body program, the homogeneity test showed Q (Chi-square) = 2.13, df = 1 (p = .140), and I^2 = 53%. The effect size of quality of life was 7.40 (95% CI: 2.92, 11.88), and the quality of life between the two groups showed a statistically significant difference (Z = 3.24, p = .001) (Figure 3).

Effects of mind–body programs on pregnancy rate

For five studies that reported the pregnancy rate of the experimental and control groups participating in mind–body programs, the homogeneity test showed Q (Chi-square) = 14.87, df = 4 (p = .005), and I^2 = 73%. The effective size of the pregnancy rate was 2.06 (95% CI: 1.08, 3.95), and there was a statistically significant difference between the experimental and control groups (Z = 2.19, p = .030).

Sensitivity analysis

Comparison of random-effects models that form the wider CI with a fixed-effects model to conduct sensitivity analysis revealed that the results of anxiety, depression, quality of life, and pregnancy rates showed no significant difference. The analysis was conducted with studies that analyzed anxiety except for the study by Chan (2006) [A2], with the largest weight among five studies. It showed that the effect size increased from −3.44 to −4.42, and the mind–body program was found to be significantly effective in relieving anxiety (p < .001). Analysis of studies except for the study by Domar (2000a) [A4], which had the largest effect, showed that the effect size decreased from −3.44 to −2.41, and the mind–body program was significantly effective in relieving anxiety (p = .008). Analysis except for that by Kalhori (2020) [A10], which had the largest effect among four studies that analyzed depression, showed that the effect size decreased from −5.79 to −3.58, and the mind–body program was significantly effective with regard to depression (p = .010). Analysis except for that by Domar (2000b) [A5], which had the largest effect among five studies that analyzed pregnancy rates, showed that the effect size decreased from 2.06 to 1.46, and the mind–body program was effective with regard to pregnancy rates (p = .040). It follows from this sensitivity analysis that the result of meta-analysis conducted in this study shows robustness (Figure 3).

Table 1 *Characteristics of the Included Studies (N = 10).*

Author, year, country	Group (n), mean age (yr)	Intervention				Format	Outcomes (tool)
		Type of treatment	Number of sessions	Intervention duration (weeks)	Session duration (hours)		
Abedi et al., 2016, Iran	Experimental group (30); control group (30)	**Mindfulness-based program** • Mindfulness meditation (eating, body scan, breathing) • Awareness (body, thought, feeling)	8	8	-	Group	Depression (GHQ28); anxiety (GHQ28)
Chan et al., 2006, China	Experimental group (69), age = 36; control group (115), age = 35	**EBMS intervention** • Tai chi exercises • Relaxation training (meditation, breathing technique) • Ancient Chinese philosophical writings • Education	4	4	3	Group	Anxiety (STAI); pregnancy rate
Chan et al., 2012, China	Experimental group (141), age = 34; control group (110), age = 34	**EBMS intervention** • Relaxation training (breathing exercises, body scan, meditation) • Ancient Chinese philosophical writing • Group activities (singing, journal writing, drawing)	4	4	3	Group	STAI (anxiety)
Domar et al., 2000a, Israel	Experimental group (20), age = 33; control group (14), age = 35	**Mind–body program** • Relaxation training • Cognitive restructuring • Emotional expression • Education (nutrition, exercise)	10	10	2	Group	Depression (BDI); anxiety (STAI)
Domar et al., 2000b, Israel	Experimental group (47), age = 33; control group (48), age = 35	**Mind–body program** • Relaxation training (meditation, progressive muscle relaxation, imagery, autogenic training) • Yoga • Cognitive restructuring • Education (nutrition, exercise)	10	10	2	Group	Pregnancy rate
Domar et al., 2011, Israel	Experimental group (46), age = 34; control group (51), age = 34	**Mind–body program** • Cognitive therapy • Relaxation training • Negative health behavior modification • Social support	10	10	-	Group	Pregnancy rate
Domar et al., 2015, Israel	Experimental group (70), age = 34; control group (59), age = 35	**Cognitive coping relaxation intervention** • Positive reappraisal • Relaxation training (diaphragmatic breathing, breath focus meditation, autogenic training)	14	2	-	Individual	Anxiety (STAI); quality of life (FertiQol); pregnancy rate
Lee, 2003, Taiwan	Experimental group (64), age = 31; control group (68), age = 32	**Nursing crisis intervention program**. • Self-hypnosis • Muscle relaxation training • Cognitive behavioral counseling	14	7	-	Individual	Anxiety (STAI); depression (SDS)
Nery et al., 2018, Brazil	Experimental group (62), age = 37; control group (37), age = 37	**Mindfulness-based program** • Mindfulness meditation • Relaxation training (autogenic training, guided imagery, biofeedback)	10	10	2	Group	Depression (BDI); quality of life (PGWBI)
Kalhori et al., 2020, Iran	Experimental group (45), age = 30; control group (45), age = 29	**Mindfulness-based program** • Mindfulness meditation (breathing, body scan) • Awareness of breathing and body • Emphasizing the perception of how to react to thoughts, feelings, and body sensations	8	4	1.5	Group	Depression (BDI)

Note. EBMS = Eastern Body–Mind–Spirit; BDI = Beck Depression Inventory; STAI = State-Trait Anxiety Inventory; PGWBI = Psychological General Well-Being Index; GHQ = General Health Questionnaire; SDS = Zung's self-administered depression scale.

Publication bias

Egger's regression test was conducted to objectively test the publication bias. The results showed that depression ($p = .824$) and the quality of life ($p = .144$) had no publication bias. However, anxiety ($p = .009$) and pregnancy rate ($p = .003$) posed the risk of publication bias. Therefore, the trim-and-fill method was carried out. Because three additional studies were added, the adjusted effect size of anxiety was −1.14 (95% CI: −1.92 to −0.37). The adjusted effect size of the pregnancy rate was 0.31 (95% CI: 0.11–0.52), while there was no additional study. The 95% CI for the adjusted effect size was statistically significant for both variables, so it can be interpreted that they were not errors that could affect the results of this study.

Discussion

A systematic review and meta-analysis were conducted to investigate the effects of mind–body programs on anxiety, depression, quality of life, and pregnancy rate in infertile women. Based on the results of systematic literature review, 10 RCT studies that were conducted in China, Taiwan, Iran, Israel, and Brazil were

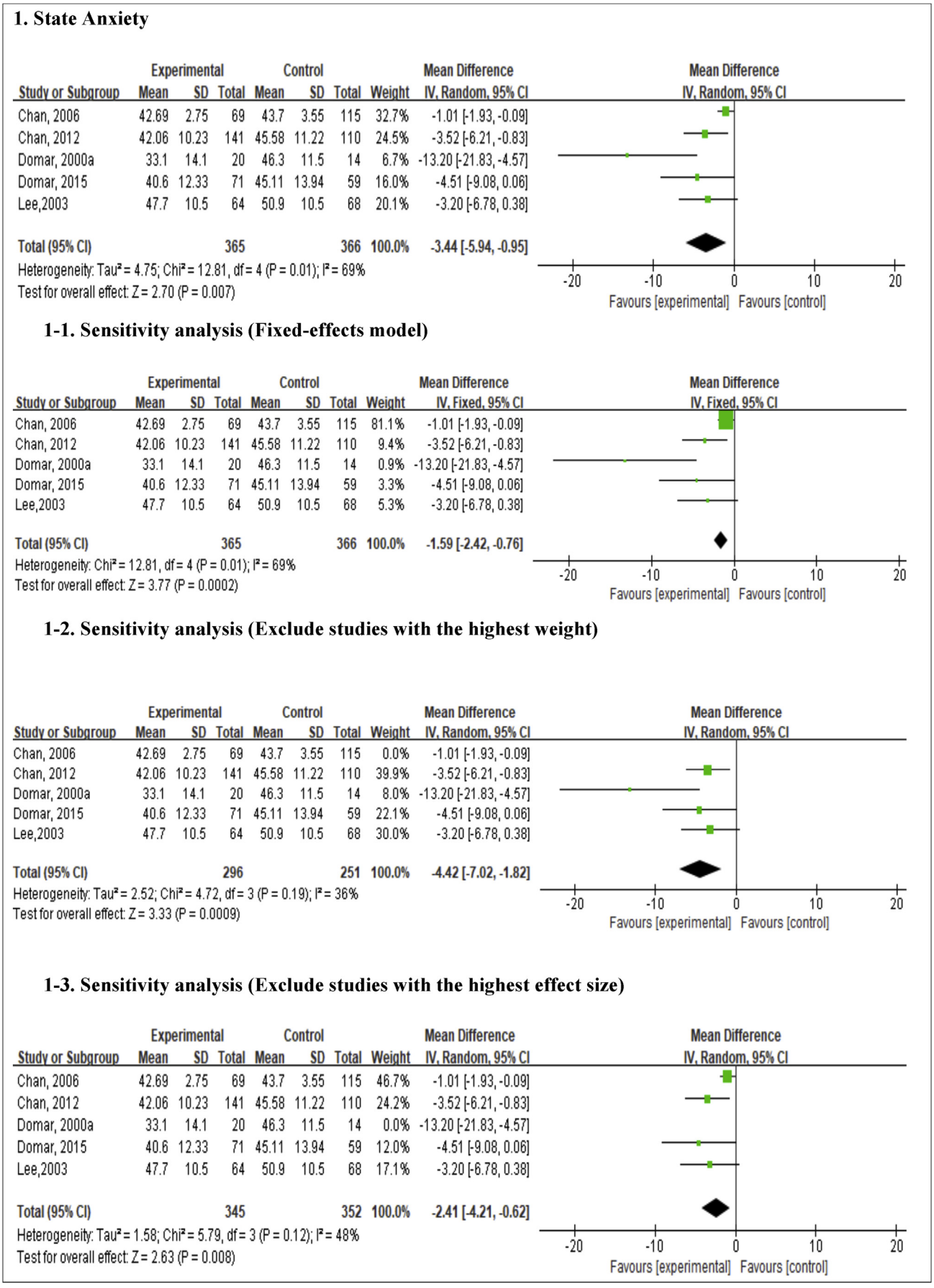
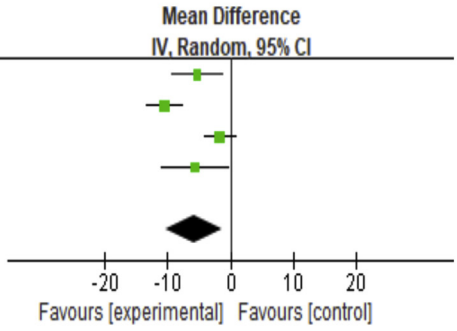


Figure 3. Comparison of anxiety, depression, quality of life, and pregnancy rate between the experimental and control groups.
Note. CI = confidence interval; SD = standard deviation.

2. Depression

Study or Subgroup	Experimental Mean	SD	Total	Control Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Domar, 2000a	4.3	1.19	20	9.6	7.6	14	24.4%	-5.30 [-9.32, -1.28]
Kalhori,2020	10.82	7.16	45	21.33	6.48	45	26.9%	-10.51 [-13.33, -7.69]
Lee,2003	55.2	7.3	64	56.9	7.1	68	27.6%	-1.70 [-4.16, 0.76]
Nery, 2018	7.91	8.05	30	13.6	11.21	23	21.1%	-5.69 [-11.10, -0.28]
Total (95% CI)			**159**			**150**	**100.0%**	**-5.79 [-10.36, -1.22]**

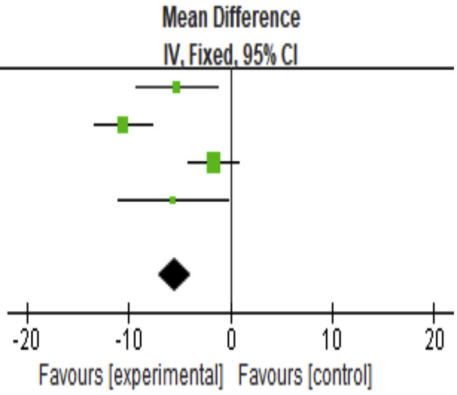
Heterogeneity: Tau² = 18.13; Chi² = 21.30, df = 3 (P < 0.0001); I² = 86%
Test for overall effect: Z = 2.48 (P = 0.01)



2-1. Sensitivity analysis (Fixed-effects model)

Study or Subgroup	Experimental Mean	SD	Total	Control Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Domar, 2000a	4.3	1.19	20	9.6	7.6	14	16.0%	-5.30 [-9.32, -1.28]
Kalhori,2020	10.82	7.16	45	21.33	6.48	45	32.4%	-10.51 [-13.33, -7.69]
Lee,2003	55.2	7.3	64	56.9	7.1	68	42.7%	-1.70 [-4.16, 0.76]
Nery, 2018	7.91	8.05	30	13.6	11.21	23	8.8%	-5.69 [-11.10, -0.28]
Total (95% CI)			**159**			**150**	**100.0%**	**-5.49 [-7.09, -3.88]**

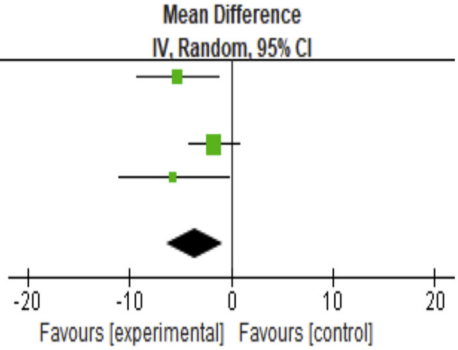
Heterogeneity: Chi² = 21.30, df = 3 (P < 0.0001); I² = 86%
Test for overall effect: Z = 6.69 (P < 0.00001)



2-2. Sensitivity analysis (Exclude studies with the highest effect size)

Study or Subgroup	Experimental Mean	SD	Total	Control Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Domar, 2000a	4.3	1.19	20	9.6	7.6	14	30.2%	-5.30 [-9.32, -1.28]
Kalhori,2020	10.82	7.16	45	21.33	6.48	45	0.0%	-10.51 [-13.33, -7.69]
Lee,2003	55.2	7.3	64	56.9	7.1	68	50.0%	-1.70 [-4.16, 0.76]
Nery, 2018	7.91	8.05	30	13.6	11.21	23	19.9%	-5.69 [-11.10, -0.28]
Total (95% CI)			**114**			**105**	**100.0%**	**-3.58 [-6.35, -0.81]**

Heterogeneity: Tau² = 2.41; Chi² = 3.28, df = 2 (P = 0.19); I² = 39%
Test for overall effect: Z = 2.53 (P = 0.01)



3. Quality of life

Study or Subgroup	Experimental Mean	SD	Total	Control Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Domar, 2015	71.58	14.23	72	66.46	17.04	60	68.2%	5.12 [-0.30, 10.54]
Nery, 2018	95.34	17.27	58	83.06	18.97	32	31.8%	12.28 [4.35, 20.21]
Total (95% CI)			**130**			**92**	**100.0%**	**7.40 [2.92, 11.88]**

Heterogeneity: Chi² = 2.13, df = 1 (P = 0.14); I² = 53%
Test for overall effect: Z = 3.24 (P = 0.001)

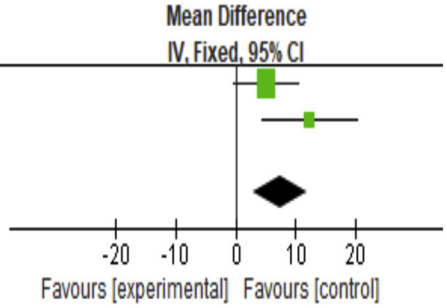
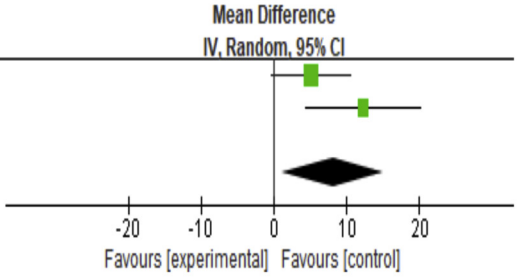


Figure 3. (*continued*).

3-1. Sensitivity analysis (Random-effects model)

Study or Subgroup	Experimental Mean	SD	Total	Control Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Domar, 2015	71.58	14.23	72	66.46	17.04	60	58.5%	5.12 [-0.30, 10.54]
Nery, 2018	95.34	17.27	58	83.06	18.97	32	41.5%	12.28 [4.35, 20.21]
Total (95% CI)			**130**			**92**	**100.0%**	**8.09 [1.18, 15.00]**

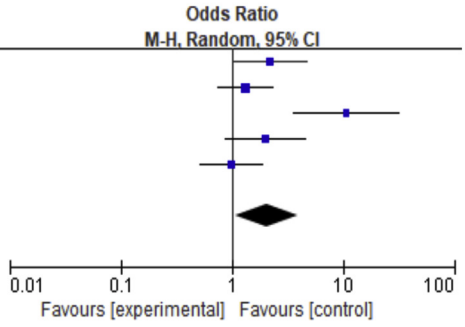
Heterogeneity: Tau² = 13.61; Chi² = 2.13, df = 1 (P = 0.14); I² = 53%
Test for overall effect: Z = 2.29 (P = 0.02)



4. Pregnancy rate

Study or Subgroup	Experimental Events	Total	Control Events	Total	Weight	Odds Ratio M-H, Random, 95% CI
Chan, 2006	18	65	16	108	20.3%	2.20 [1.03, 4.71]
Chan, 2012	41	141	26	110	23.0%	1.32 [0.75, 2.34]
Domar, 2000b	26	47	5	48	15.7%	10.65 [3.58, 31.67]
Domar, 2011	31	46	26	51	19.3%	1.99 [0.87, 4.54]
Domar, 2015	30	86	25	71	21.8%	0.99 [0.51, 1.90]
Total (95% CI)		**385**		**388**	**100.0%**	**2.06 [1.08, 3.95]**
Total events	146		98			

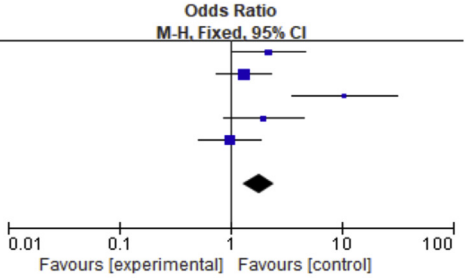
Heterogeneity: Tau² = 0.39; Chi² = 14.87, df = 4 (P = 0.005); I² = 73%
Test for overall effect: Z = 2.19 (P = 0.03)



4-1. Sensitivity analysis (Fixed-effects model)

Study or Subgroup	Experimental Events	Total	Control Events	Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Chan, 2006	18	65	16	108	15.1%	2.20 [1.03, 4.71]
Chan, 2012	41	141	26	110	36.0%	1.32 [0.75, 2.34]
Domar, 2000b	26	47	5	48	3.8%	10.65 [3.58, 31.67]
Domar, 2011	31	46	26	51	14.0%	1.99 [0.87, 4.54]
Domar, 2015	30	86	25	71	31.0%	0.99 [0.51, 1.90]
Total (95% CI)		**385**		**388**	**100.0%**	**1.80 [1.31, 2.48]**
Total events	146		98			

Heterogeneity: Chi² = 14.87, df = 4 (P = 0.005); I² = 73%
Test for overall effect: Z = 3.65 (P = 0.0003)



4-2. Sensitivity analysis (Exclude studies with the highest effect size)

Study or Subgroup	Experimental Events	Total	Control Events	Total	Weight	Odds Ratio M-H, Random, 95% CI
Chan, 2006	18	65	16	108	20.5%	2.20 [1.03, 4.71]
Chan, 2012	41	141	26	110	35.2%	1.32 [0.75, 2.34]
Domar, 2000b	26	47	5	48	0.0%	10.65 [3.58, 31.67]
Domar, 2011	31	46	26	51	17.4%	1.99 [0.87, 4.54]
Domar, 2015	30	86	25	71	26.9%	0.99 [0.51, 1.90]
Total (95% CI)		**338**		**340**	**100.0%**	**1.46 [1.03, 2.07]**
Total events	120		93			

Heterogeneity: Tau² = 0.01; Chi² = 3.14, df = 3 (P = 0.37); I² = 4%
Test for overall effect: Z = 2.11 (P = 0.04)

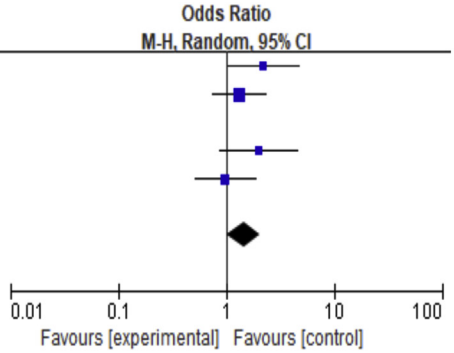


Figure 3. (*continued*).

included in the analysis. At least one relaxation technique was confirmed to have been included in each program in all of the 10 selected studies, and the relaxation techniques used included meditation, breathing technique, tai chi exercise, hypnosis, biofeedback, yoga, and autogenic training. The most commonly included relaxation technique was meditation, and mindfulness meditation, in particular, was being used most commonly in intervention. Based on the evaluation of quality of the literature, explanations about concealment of allocation order and randomized allocation were not clear. Thus, evaluating the relevance of the concealment was often impossible, and explanation about blinding researchers and participants was also unclear, indicating the possibility of performance bias. Therefore, future RCT studies must deal with this aspect for improving the quality of the literature.

The results showed that mind–body programs were found to have a significant effect on anxiety, depression, quality of life, and pregnancy rate in infertile women. Regarding anxiety, mind–body programs selected for analysis in this study included relaxation techniques. These relaxation techniques were found to be effective in relieving anxiety in some meta-analyses [26,27] and also had a significant effect on anxiety in this study. Anxiety is a typical negative emotion in infertile women, and it persists until after pregnancy through successful *in vitro* fertilization [8]; hence, an intervention is needed because anxiety increases the chance of uterine artery resistance, leading to negative outcomes, such as childbirth with low birth weight [28]. Therefore, it is necessary to continuously provide a mind–body program that includes relaxation techniques from before pregnancy through pregnancy to relieve anxiety and bring about a positive pregnancy outcome in infertile women.

With regard to depression, the mind–body program is an integrated intervention that affects cognitive, emotional, and physiological factors; mindfulness meditation, which is included in the mind–body program, strengthens cognitive reappraisal [29], promoting the resolution of negative emotions such as depression [30]. Thus, it was found that mind–body programs reduced depression in infertile women. Depression is associated with proinflammatory conditions during pregnancy [31], and depression during pregnancy may increase the chances of preterm delivery [32]. Therefore, to maintain a physically healthy state during pregnancy and prevent high-risk delivery, it is necessary to provide a mind–body program that includes techniques such as mindfulness meditation so that pregnant women can actively use it to relieve their depression.

The results of this study confirm that mind–body programs implemented for infertile women are effective in improving their quality of life. In a meta-analysis wherein the effect of a mind–body program on quality of life in patients with Parkinson disease was assessed, it was found to have a significant effect on improving quality of life [33], similar to our results. In the study by Kim and Shin [34], in which a model of quality of life was developed for infertile women, depression was the most influential factor affecting the quality of life of infertile women [34]. Because this study showed a significant reduction in depression through mind–body programs, this effect might have positively affected their quality of life. However, there were very few studies in the literature selected in this study that measured quality of life as an outcome variable, and studies that measured quality of life using subjective well-being tools were included. Thus, future studies must investigate the effect of the mind–body program on the quality of life of infertile women.

The results of this study showed that mind–body programs have a significant effect on the actual pregnancy rate and subjective emotions such as anxiety, depression, and quality of life. The increase in depression in infertile women is associated with a low pregnancy rate [35]. Therefore, there is a significant difference in depression between women who are successful and those who are not after *in vitro* fertilization [36]. Relieving negative emotions seems to influence women's pregnancy rate. In addition, the quality of life of infertile women was found to be significantly related to the success rate of *in vitro* fertilization procedures [37], so the improvement of quality of life in infertile women through the mind–body program seems to have affected their pregnancy rate. However, in the literature included in the present study, it was difficult to identify the actual effects of anxiety, depression, and quality of life on pregnancy rate; therefore, there is a need for future studies in this area.

On the other hand, infertility is a highly sensitive issue depending on the cultural context. For Chinese women, maternal instinct plays an essential role in the awareness of self, social status, and identity [38]. In China, carrying on an ancestral name alongside the preference of sons still exists today [38]. Thus, it leads to pressuring women to hide infertility issues from others [39]. Infertile women in North America understand infertility as a secret stigma or an abnormal condition [40]. In Arabian culture, pregnancy is considered an essential task of women, which leads to a lot of pressure for women, thus causing them to want to hide infertility [41]. In addition, in Nigeria, infertility is considered to be entirely an issue of women [42]. Not only in the cultural context but also in developed countries and developing countries, infertility has different meanings. In developing countries, owing to their patriarchal family structures, not having children is considered to be largely an issue of women's social responsibility regardless of the cause of infertility, while the value and identity of women are threatened [43] and criticized [44]. This is due to the fact that children are directly related to the problem of financial survival in later years. Infertile couples end up not participating even in family gatherings or religious events [45]. In a comparative study of Austrian and Moslem immigrants who were diagnosed with polycystic ovarian syndrome, the female Moslem immigrants were reported to have a significantly higher psychological pressure about pregnancy than the Austrian immigrants [46]. Therefore, in developing and applying interventions for Korean infertile women, attention should also be paid to ensure that they are in line with the sociocultural characteristics of Korea.

This study is meaningful in that it has established a basis for interventions for infertile women by verifying the contradictory results of previous meta-analysis studies that have identified the effects of mind–body programs on anxiety and depression in infertile women and by identifying their effect on women's quality of life and pregnancy rates. However, it is difficult to determine the causality because there are not many RCT studies that have conducted mind–body programs for infertile women. In addition, because none of the included studies were conducted in Korea, it is hard to make implication for Korean infertile women. However, because this study confirmed the significant effects of the mind–body program on anxiety, depression, quality of life, and pregnancy rate, it may be necessary to develop a mind–body program suitable for Korean culture and provide it to Korean infertile women. Therefore, it will be necessary to develop mind–body intervention programs for Korean infertile women and conduct RCT studies, examining the effects of the programs on their anxiety, depression, quality of life, and pregnancy rate, in future. Moreover, it will be beneficial to perform meta-analysis studies. In addition, based on the results of this study, improved quality of life and pregnancy rate for infertile women who visit infertility centers or public health centers are expected by providing medical treatment alongside the mind–body program, which includes meditation, relaxation and breathing, tai chi, yoga, and hypnosis. Consequently, it is expected to provide mind–body programs to

infertile women who use infertility centers and public health centers and to test their effectiveness. Moreover, based on the results, they can be continuously used in clinical practice.

Conclusion

In the present study, the effects of the mind–body program on anxiety, depression, quality of life, and pregnancy rate in infertile women were found to have a significant effect on all outcome variables. As the effects of a mind–body program could be improved when participants with low physical and psychological risks actively participate, positive effects on pregnancy results and emotions of infertile women could occur if nurses at Korean health centers and infertility centers could provide a mind–body program using various relaxation techniques. Furthermore, this is expected to lead to reduced budget for government support for infertile couples' medical expenses, which dramatically increase annually, and a cost-efficient management of the issue.

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Conflict of interest

The authors declared no conflict of interest.

Acknowledgments

None.

Appendix. References for studies included in Table 1

A1 Abedi Shargh N, Bakhshani NM, Mohebbi MD, Mahmudian K, Ahovan M, Mokhtari M, et al. The effectiveness of mindfulness-based Cognitive Group Therapy on Marital Satisfaction and General Health in Woman with infertility. Glob J Health Sci. 2015;8(3):230–35. http://doi.org/10.5539/gjhs.v8n3p230

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A3 Chan CHY, Chan CLW, Ng EHY, Ho PC, Chan THY, Lee GL, et al. Incorporating spirituality in psychosocial group intervention for women undergoing in vitro fertilization: A prospective randomized controlled study. Psychology & Psychotherapy: Theory, Research & Practice, 2012;85(4): 356-373. https://doi.org/10.1111/j.2044-8341.2011.02040.x

A4 Domar AD, Clapp D, Slawsby E, Kessel B, Orav J, Freizinger M. The impact of group psychological interventions on distress in infertile women. Health Psychol. 2000;19(6):568–75. https://doi.org/10.1037/0278-6133.19.6.568

A5 Domar AD, Clapp D, Slawsby EA, Dusek J, Kessel B, Freizinger M. Impact of group psychological interventions on pregnancy rates in infertile women. Fertil Steril. 2000;73(4):805–11. https://doi.org/10.1016/S0015-0282(99)00493-8

A6 Domar AD, Rooney KL, Wiegand B, Orav EJ, Alper MM, Berger BM, et al. Impact of a group mind/body intervention on pregnancy rates in IVF patients. Fertil Steril. 2011;95(7):2269–73. https://doi.org/10.1016/j.fertnstert.2011.03.046

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Research Article

Lived Experiences of Korean Young Adults After Heart Transplantation: A Phenomenological Approach

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ABSTRACT

Purpose: This study aimed to explore and describe the lived experience of young adult heart transplant recipients in Korea.
Methods: Fifteen young adult heart transplant recipients participated in this qualitative study. Data were collected from March to August 2019 through in-depth individual interviews and analyzed using Colaizzi's phenomenological method.
Results: Their experiences about the arduous journey of heart transplant surgery and life after surgery were captured in four themes: (1) unwelcome rebirth without vitality, (2) facing unreachable ordinary tasks in life, (3) lifestyle bordering between burdensome and self-valued, and (4) finding the true meaning of a newly given life.
Conclusion: Young adult heart transplant recipients struggled with the burdens of their health problems, which impacted their employment and relationships. The participants' lifelong challenges and psychological turbulence identified in this study provide guidance for health-care providers to understand this population.

Introduction

A heart transplant (HT) is the standard treatment for patients with end-stage heart failure. The cases of HT surgery are increasing in Korea owing to improved surgical techniques and immunosuppressive agents, legislation that recognizes brain death as death, and changes in the public's perception of brain death [1,2]. Over the last 10 years, the number of domestic HTs has increased more than 10 times [3].

In terms of age, the number of young adult recipients aged 19–34 years who have undergone HT has increased by approximately 15% over the past 5 years [3]. However, inadequate immunosuppression after transplantation still leads to complications including rejection, infections, malignancies, and chronic kidney disease, and maintaining a balanced immune status remains an important challenge [4]. As a result, HT recipients must take medication for their entire life to prevent rejection after transplantation and require comprehensive health care including infection prevention, lifestyle changes such as exercise and dietary improvements, and regular outpatient visits [5–7].

Studies have shown that HT recipients aged 60 years and older have low levels of negative emotions such as anxiety and depression, mental problems, and stress as well as high levels of social support, which suggests that they adjust well to their lives after HT [8,9]. However, studies have shown that younger recipients do not appear to adjust well after HT [10,11]. Recipients of an HT in their early adulthood experienced fatigue and lethargy owing to the side effects of immunosuppressive medications taken after the cardiac transplant, during the most active period of life [10].

In general, people in their young adult years are the healthiest and reach various social milestones such as marriage, childbirth, employment, and promotion. However, HT recipients do not fully experience these milestones because they are focused on their health [12]. For young people, HT is a major life challenge that causes difficulties in carrying out major life tasks and often requires adjustments in daily living.

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Thus far, studies on HTs have mainly focused on the quality of life of the recipients [8], experience with the side effects of immunosuppressants [10], and medication adherence [13], and these studies have used quantitative methods to analyze these factors. Although previous studies have used qualitative methods to examine life experiences of HT recipients in their twenties [11] and older than 50 years [9,14], these studies failed to fully portray the life experiences including various social milestones such as marriage, childbirth, and employment of young adult HT recipients. Therefore, the purpose of this study was to explore and describe the lived experiences of young adult HT recipients.

Methods

Study design

This study is a qualitative study using the phenomenological methodology proposed by Colaizzi [15] to understand the lived experiences of young adult HT recipients. The phenomenological methodology is a research method used to understand the meaning and essence of participants' experiences in a specific situation.

Setting and participants

Participants were HT recipients between the age of 19 and 34 years, which was defined as young adulthood [3,16]. Participants were selected as per specific criteria that included those who underwent HT surgery at least 3 months before the study, fully understood the purpose of the study, and voluntarily agreed to participate in the study. The exclusion criteria were those who could not communicate in in-depth interviews or had psychiatric diseases.

The participants were recruited from an outpatient HT clinic in a tertiary hospital in a city. The researchers approached patients in the clinic and determined whether each patient was eligible for the study or not. Those who were eligible and agreed to participate were explained in detail about the study, and informed consent was provided. In addition, more participants were recruited using a snowball technique, through which the participants introduced new patients to the study.

A total of 15 HT recipients participated in this study: seven women and eight men. In terms of diagnosis before HT, 12 patients had dilated cardiomyopathy, two patients had valve diseases, and one patient had congenital heart disease. The average postoperative period was 7.1 years (range: 1.6–13.7 years). The average age of participants at the time of the interview was 31.33 years (range: 25–34 years). Eleven participants were single, and four were married; eight participants were unemployed (Table 1).

Ethical considerations

This study was approved by the institutional review board of the Asan medical center, which the researcher is affiliated to (Approval no. 2019-0217). Before beginning the study, the researcher informed the participants about the purpose, procedures, goal, and plans for disseminating the results; thereafter, they provided written consent. Before the interview, the participants were informed that the interview would be recorded and were provided an accurate explanation of their confidentiality and the intended use of the collected data. Recorded data and transcribed manuscripts were used purely for research purposes and stored in a double-locked secured location. These were shredded and discarded after completion of the study.

Data collection

Having clinical experience as nurses in the cardiology and open-heart surgery units, the researchers had rich experience and knowledge about caring for HT recipients. In addition, the researchers are experts in qualitative research, and their works having been published in peer-reviewed journals. Considering the expertise in cardiology nursing and qualitative research methodology, we tried to elicit and illustrate the vivid experience of the participants as HT recipients.

We collected data from 15 participants from March 12 to August 31, 2019 (Table 1). We created the interview questions based on the previous literature [9,11] and clinical experience. After beginning with a basic question about the participant, the researchers asked semistructured questions such as “Please tell me about your lived experience of pre- and post- HT surgery,” to rule out potential researcher biases during the interview. The main questions were related to life before and after HT, changes in daily living or lifestyle, physical symptoms, current health status, the ways to overcome difficulties, any meaning derived from post-HT life, and so on. The types of interview questions ranged from general questions to specific ones, overall experience to personal ones, and factual observations to subjective inferences. The order of the questions varied to suit the natural flow of the interview (Table 2). Data collection for this qualitative study was conducted until no new information was obtained about a phenomenon, that is, when the content was saturated [17].

Table 1 *Demographic Characteristics of the Participants (N = 15).*

No.	Gender	Age (years)	Diagnosis	Duration of transplantation (months)	Religion	Marital status	Education	Occupation	Main income
1	F	33	DCMP	132	Yes	Single	University	None	Pension
2	M	34	DCMP	18	Yes	Married	University	None	Parents
3	F	25	DCMP	60	Yes	Single	High school	None	Parents
4	M	34	DCMP	118	Yes	Single	University	None	Parents
5	M	29	Congenital	50	Yes	Single	High school	Insurance planner	Himself/herself
6	M	34	DCMP	164	None	Single	University	None	Parents
7	F	32	DCMP	75	None	Single	University	Service industry	Parents
8	F	34	DCMP	165	Yes	Single	University	None	Parents
9	M	31	DCMP	20	None	Single	University	None	Parents
10	F	30	DCMP	118	Yes	Single	University	None	Parents
11	F	29	DCMP	36	Yes	Single	University	Public officer	Himself/herself
12	M	29	Valve	85	None	Single	High school	Self-employed	Himself/herself
13	F	28	DCMP	30	None	Married	High school	Housewife	Spouse
14	M	34	DCMP	96	None	Married	University	Public officer	Himself/herself
15	M	30	Valve	110	None	Married	High school	Service industry	Himself/herself

Note. DCMP = dilated cardiomyopathy.

Table 2 *List of Interview Questions.*

Type	Questions
Opening	Please tell me about your lived experience of pre and post HT surgery.
Details	Do you have any changes in daily living or lifestyle?
	a) If so, what were those changes?
	b)How do you feel about those changes?
	Have you ever struggle with any physical or psychological difficulties?
	a) If so, what were they?
	b) How was your coping with difficulties?
	c) Has anyone been providing support resources?
	Have your relationships with your family, friends or spouse/lover changed after HT?
	a) If so, how have you coping with those changes?
	b) What kind of support resources would you want?
	Do you have happy or sad memorable experiences in your life after HT?
	a) If so, what were those experiences?
	b) How do you feel about those experiences?
	Do you have advantages or disadvantages in your life after HT?
	a) If so, what are they?
	b) How do these affect your life?
	Do you have current fears in your life?
	a) If so, please specify them.
	b) What is the ways to overcome the fears?
	Do you need any help to improve quality of your life?
	a) If so, what specific help do you need?
	What does HT mean to the young adult HT recipient?
Ending	Is there anything you would like to add?

Note. HT = heart transplant.

We conducted interviews at a time and place that was suitable for each participant. Interviews were conducted at a seminar room in the chosen hospital or a café selected by the participant. We conducted one in-depth interview with each participant individually. Each interview lasted approximately 60–90 minutes. All interviews were digitally recorded and then transcribed.

Data analysis

Following the phenomenological methodology suggested by Colaizzi [15], data collection and analysis were conducted simultaneously. First, to analyze the data, the participants' experiences were described, and we read the participants' descriptions several times to understand the flow of each experience. Second, we found meaningful statements from the participants and listed them. Third, we tried to discover what was hidden in each significant statement and formulated meanings. Fourth, similar meanings, subtopics, were classified, and the main concepts, derived from meaningful phrases and sentences, were identified to derive the final theme. Finally, we validated this study by asking the participants if the findings captured the essence of their experience. During the analysis, we received feedback from two participants.

Rigor of the research

To ensure the qualitative rigor of this study, we aimed to improve credibility, fittingness, auditability, and confirmability as per four evaluation criteria suggested by Sandelowski [18]. To secure credibility, the transcripts were checked for accuracy by comparing recorded interviews with transcripts. In addition, the interview transcripts were confirmed by each participant for precision. For fittingness, two clinical nurses in HT wards and one nursing professor reviewed the interview transcripts and confirmed the experience of the participants that possibly occurred. Third, to improve auditability, the entire process of the study was recorded in detail as audit trails. Finally, to maintain confirmability, we attempted to eliminate bias during the analysis process and held regular data analysis meetings and received feedback from each other.

Results

In this study, 21 meaning units were extracted from the interview data of 15 participants, and these statements were integrated into four themes and ten subthemes (Table 3). Four themes were derived as follows.

Theme 1: unwelcome rebirth without vitality

The young adult participants had difficulty breathing because of their nonfunctional hearts. After surgery, the participants did not feel any immediate changes except their breathing. However, the chest scars, appearance changes, fatigue, and lethargy due to immunosuppressants have deprived them of their vitality. The participants' recovery after HT did not meet their expectations, given that they are young adults in the prime of their lives. The participants were unaware that the way they dress, eat, and sleep was different from their peers and that their appearance and energy were different before the surgery.

Lower expectations from new life

Before surgery, the participants had some physical symptoms such as shortness of breath, inability to run, general fatigue, and so on. The participants believed that an HT would be a turning point that would change their lives forever without those symptoms. However, they were frustrated that their health did not improve as expected in terms of the level of vitality and continued symptoms.

Although they longed for an ordinary life after HT, they encountered new kinds of symptoms owing to HT surgery and immunosuppressants. They could not eat foods they wanted to or sleep comfortably because of the timing of administering immunosuppressants. Their expectations of being able to live as vigorously as normal people were not met.

> *"I thought there would be a reversal of life, but I was mistaken. At my age, heart transplants are really a challenge. It is hard to accept that you have to worry about your health when you need it most. I miss the daily routine of eating, wearing clothes that I wanted, and playing with others before the surgery."* (Participant 3 – female – 25 years – single)

Incompatible with physical and emotional changes from drug side effects

The participants experienced side effects such as lethargy, acne, swelling, and hair loss caused by daily consumption of immunosuppressants, which were necessary to maintain their health after HT. The participants found it difficult to cope with large scars on the chest and changes in their appearance after surgery and found themselves withdrawn.

> *"I want to study or work more, but when I try, I get tired and I cannot concentrate. Do you know what it is like to feel your mind and body sinking below the surface? My whole being runs out of energy; therefore, it is hard to start a new job or make it persistent."* (Participant 4 – male – 34 years – single)

> *"I also was a leader among my friends, but I think my personality changed a lot after surgery. After surgery, my face was getting bigger, and I was getting ugly and had hair loss, body swelling, scar on my chest, and especially acne on my face and back, so I cover my*

Table 3 *Themes on Young Adult Heart Transplant Recipients' Experience.*

Themes	Subthemes	Meaning units
Unwelcome rebirth without vitality	Lower expectations from new life	Frustration with an incomplete physical condition
		Longing for an ordinary life
	Incompatible with physical and emotional changes from drug side effects	Lowered confidence due to appearance changes
		Feeling powerlessness with loss of vitality
Facing unreachable ordinary tasks in life	Feeling of alienation in social relationships	Burdens of having a limited lifestyle
		Having troubles in taking immunosuppressants regularly
	High barrier to job switch	Disappointed with the unfavorable employment system
		Unfair employment opportunities due to HT history
	Ambivalence to marriage and childbirth	Distress from indelible wound caused by people who oppose marriage
		Internal anguish on passing heart disease to children
Lifestyle bordering between burdensome and self-valued	Focusing on negative aspects	Obsession about being different from peers
		Feeling of being stuck in a tunnel of continued symptoms
		Constant fear of death
	Focusing on my own life	Living a self-confident life without being dominated by others' presence
		Acceptance of life's changes
Finding the true meaning of a newly given life	Recognizing the value of the family	Family as a driving force of life
		Gratitude for the existence of the family
	Being satisfied with the life given	Realizing the importance of health
		Awakened deeper happiness never felt before
	Taking a step further into a worthy life	Wishing to be a role model of hope
		Getting to know the meaning of sharing

face with a mask when I go outside, or I do not go out." (Participant 15 – male – 30 years – married)

Theme 2: facing unreachable ordinary tasks in life

The participants had a difficult time achieving life tasks smoothly such as relationships, employment, marriage, and childbirth. When they do meet their friends, they cannot drink or smoke, and they cannot eat any food between lunch and dinner so as to maintain an empty stomach for an evening immunosuppressant. In addition, the participants found it difficult to return to work because they felt they were not fully recovered. When they attempted to work, they were not successful. Even for participants with a job, they were unable to maintain economic stability.

Feeling of alienation in social relationships

The participants reported that many of their relationships had changed owing to their lifestyle changes, such as being unable to drink and smoke. After the transplant, friends were divided into two groups: those who understood them and those who did not. They complained that they could not meet with their friends because they had to take immunosuppressants at fixed times every day and had to fast for a period after dosing to maximize the drug's effectiveness.

"When I meet my friends, I have to eat, drink and play like other people, but after HT, I cannot drink alcohol and eat raw food like a sashimi. In addition, based on the time to take immunosuppressant, fasting time is required. Especially when I need to fast in the evening, it is very difficult to make an appointment with friends." (Participant 6 – male – 34 years – single)

High barrier to job switch

The participants reported that the hardest thing after HT was searching for a job. They needed enough recovery time—as little as 6 months to as much as 2 years—after cardiac surgery, which forced them to take a break from their preoperative career. This break in career resulted in a decrease in the participants' peer group. In particular, a male participant who received an HT at a young age had difficulty finding employment because of HT. Even if participants were lucky enough to obtain a job, they often reported unfair treatment or poor working conditions.

"I took a year off from work and it was not easy to get back to work. It is about two years since I got a transplant, so I feel better. It is nice to go back to my old job, but I am worried that my physical condition will change and I will need to change my job. It is hard for me to find a new job because I have to go to the hospital on a regular basis." (Participant 9 – male – 31 years – single)

"I did not go to the army and I got a transplant, so I was often rejected from employment. When I got a job, I began my work with a memorandum that I would not demand any compensation because of my health problems." (Participant 5 – male – 29 years – single

Ambivalence to marriage and childbirth

The female participants reported that they wanted to get married but could not afford it. The Korean culture associates marriage with childbearing, and some reported that their boyfriend's parents opposed to marrying a woman after an HT because of her risk of infertility. Many single female participants said that even if the HT had no significant effect on pregnancy, they were hesitant about marriage and childbirth owing to concerns about passing on the heart disease to their children.

"I have been broken several times so far. [My boyfriend's] parents were opposed to me because of my health condition … I want to get married and have children, but I cannot, so I have to give it up realistically. Even if I am married, I will worry about my child's health. If there is any chance of a genetic factor, I would give up getting married and having a child." (Participant 10 – female – 30 years – single)

"I want to have more children … there are few cases of childbirth in South Korea after transplant, and I think it is impossible to have more children without it threatening my life." (Participant 13 – female – 28 years – married)

At the same time, the male participants were less constrained than female participants in marriage and childbirth, and they experienced no real difficulties creating their own families.

"Luckily, I got a job, got married, and even had a baby. There are many young people around who have had a hard time with the transplant. Fortunately, I was less worried about pregnancy than women because I am a man." (Participant 14 – male – 34 years – married)

Theme 3: lifestyle bordering between burdensome and self-valued

The life participants gained after HT, somewhere between healthy living and being disabled, often confused the participants. Paradoxically, the participants reported that they felt both relief and fear. They felt relief that they were alive due to HT and fear that they might die unexpectedly despite their HT. Officially, disability is categorized into five levels [ranging from 1 (most severe) to 5 (mildest)], and Korea's HT recipients are diagnosed with having Disability Level 5. The participants wished to return to their normal lives after HT, but they struggled with their poor physical and mental condition.

Focusing on negative aspects

The participants pretend that they are enjoying life with their family and friends, but they know they are not like their friends. The participants envy ordinary lives such as getting a job, getting married, and raising children. They often feel worse now than before the transplant, and they have a hard time finding the way to live now. The participants reported that they were sad or depressed because they were unable to live a life similar to others.

"There is no job, no marriage, no hope, no fun in life. I feel like I live in a tunnel where there is no end every day. Others say I have a new life because I got a new heart, but I thought to myself sometimes it was better to die rather than live this difficult life. I think it is a shame now, but I have been taken to the emergency room after taking all the immunosuppressant at home, because I tried to commit suicide." (Participant 1 – female – 33 years – single)

The participants thought they were healthy after an HT but could not stop thinking about death. They reported trying to avoid thoughts of death, and some even became reluctant to attend funerals or visit hospitals.

"I am heart-transplanted and healthy, but waking up in the morning, I often feel anxious that today is my last day of living. Especially the days that I do not feel good, I am worrisome all day. My depressed feeling is passed on to my family and they feel sad too." (Participant 14 – male – 34 years – married)

Focusing on my own life

Over time, the participants recognized that they were physically and emotionally different from others and had to cope with reality. Moreover, the participants tried to focus on good things about their life after an HT and live positively.

"I hated being different from other people in my early twenties. I do not know why I was so obsessed with living like others. I feel that because I am making a living these days, I do not have to suffer from the gaze or social perspective of others." (Participant 10 – female – 30 years – single)

"Having an HT does not mean that I am disabled, so it is important that I lead my life actively with my own identity." (Participant 7 – female – 32 years – single)

Theme 4: finding the true meaning of a newly given life

The participants explained that the process of adapting back to their daily lives after an HT was complicated and difficult, but they are happy to breathe and live their lives. They reported that they had learned to value the small moments of happiness with their families, which they had overlooked before surgery. They recognized that because of someone else's unfortunate events, a person's heart was transplanted into them, and they wanted to appreciate that benefit. Furthermore, some of the participants wanted to provide a positive example for other patients undergoing the post-transplant adaptation process.

Recognizing the value of the family

The participants said that having a family to support them was significant for a successful recovery. The parents, husbands, wives, and children who had taken the participants for granted were grateful for their existence. Participants who created a new family after transplant reported feeling happiness as an unexpected gift.

"If I had not had a heart transplant, I would still live my life like a jerk, doing whatever I wanted to, drinking and smoking. The best thing about the transplant is that I became mature, got married, and had children, and now I have my family. Living happily with my family is the main reason why I live now." (Participant 15 – male – 30 years – married)

Being satisfied with the life given

The participants said they were fiercely competitive, such as in terms of money or honors, before the HT, but realized that without health, everything was meaningless. In addition, after an HT, they realized that they were satisfied with their lives.

"I always thought to be happy, you have to make a lot of money and have a better economic status. But now I know that it is best to live happily in the condition given to me instead of wasting my emotions on useless things." (Participant 5 – male – 29 years – single)

Taking a step further into a worthy life

Some participants said they wanted to be a mentor or role model for young transplant recipients who are struggling after transplantation, by learning how to live confidently despite discrimination and difficulty.

"There are many young people who are still struggling in the adaptation stage who are having difficulty with their identity, health and marriage. I want to be a role model to share my experience and encourage them. I want to live a valuable life and share the life I have been endowed with in some way." (Participant 12 – male – 29 years – single)

Discussion

This study explored the lived experiences of recipients of an HT at a young age and describes in detail how HT affects all aspects of

their young adult life. Based on the 15 individual in-depth interviews, four themes have been identified: (1) unwelcome rebirth without vitality, (2) facing unreachable ordinary tasks in life, (3) lifestyle bordering between burdensome and self-valued, and (4) finding the true meaning of a newly given life.

Theme 1, "unwelcome rebirth without vitality," is contrary to the findings of previous studies [9], which also found participants' focusing on the joy of rebirth and expectation of a new life. Life satisfaction was reduced owing to lethargy, fatigue [10,19], and changes in appearance [20], which are typical side effects of continuous use of the immunosuppressant required to maintain new heart function after transplantation. As per a study by Massey et al. [21], young transplant recipients reported a 65% compliance rate for immunosuppressants, suggesting that the reason for lack of compliance may be due to these side effects.

The participants in this study were aware of the importance of immunosuppressants, which critically affected their life after transplant. Although the medication side effects are similar to those seen in previous studies [8–10], these participants, who are in their most energetic stage of life, were not satisfied with such effects, which may be tolerated better by older patients. For young adults, these side effects may be unacceptable and shocking [11,20,21], and thus, it is necessary to provide patients with information on the side effects of immunosuppressants and to observe and consult with them periodically. In particular, the degree of fatigue that interferes with daily life should be assessed, and effective intervention should be applied to help patients manage their fatigue [19]. In addition, multidisciplinary approaches are required in the pre-transplantation and post-transplantation treatment process to minimize cosmetic changes such as acne and scars on the chest.

Concerning Theme 2, for young HT recipients in this study, many life tasks were unreachable for them. In fact, young adult recipients' happiness was closely related to timely achievement of their capacity, autonomy, and social and mental development [21–23]. Family members and close friends play important roles in supporting HT recipients. Interpersonal relationships facilitate coping with stress and promote an optimistic outlook [24,25]; in particular, a spouse has positive effects on the overall health of a transplant recipient, including survival advantage, medical compliance, management of comorbidities, and emotional support [26]. Therefore, the health-care provider needs to strengthen social support for young HT recipients to have hope in achieving their life tasks.

Most participants stated that employment was a very important goal, similar to the results of previous studies [11,27]. For health reasons, such as supporting their immune systems after HT, participants with high-stress or high-intensity jobs were forced to switch jobs [28]. The participants in this study learned to be satisfied with obtaining any kind of job, given the difficulties in job search and unfair treatment in the employment process.

In Korea, which has a traditional Confucian ideology [29], it is considered impossible to marry a sick woman who may not be able to give birth. Most female participants reported that marriage became difficult after surgery, given the childbirth issue. However, a previous study [30] on pregnancy and childbirth after a liver transplant showed that it was a life-threatening pregnancy, but through that difficult process, childbirth eventually led to life satisfaction by having a family. Deshpande et al. [31] found that successful pregnancy outcomes are possible among all organ transplant recipients. Nevertheless, potential fetal side effects such as premature birth and low birth weight delivery and recipient side effects such as hypertensive disorders and graft rejection [31,32] are expected; thus, patients should be monitored closely by their health-care providers to ensure a safe pregnancy. HT recipients can have successful pregnancies by maintaining a stable organ function via multidisciplinary care support.

Regarding Theme 3, the participants were found to have adjusted to a "lifestyle bordering between burdensome and self-valued." This was a prominent problem in the early stages after transplantation. This is in contrast to findings that old-aged HT recipients have a positive outlook on life [8,9]. However, it is consistent with a previous study that found young adults were more isolated from their peers than older patients, resulting in less compliance with treatment [8,22].

This seems to be due to the uncertainty of life and their trauma of facing a fatal heart disease at a young age [11]. After a long wait, their HT was a miracle, but they continue to live in fear and under the shadow of the uncertainty of death [33]. Given their conflicting feelings, social support is necessary to help young adult HT recipients deal with negative emotions, and health-care providers should provide periodic counseling to allow them to express such emotions.

In a study by Waldron et al. [11], young adults were described as undergoing a life transition and that they yearned for "normal;" thus, they considered that they would return to normal life only when their social roles were properly achieved. Health identity in young adulthood is the driving force to endure life [11,23], so health-care providers and families should pay attention and help them to have an unshakable identity and positive attitude toward life.

For Theme 4, through trial and error and persevering despite difficulties, the participants accepted their new life, "finding the true meaning of a newly given life." Previous studies [8,34] on the quality of life of post-transplant recipients showed improved quality of life after transplantation, especially in terms of overall health, social functioning, and vitality. The findings of Theme 4 is consistent with a previous study [35] that HT recipients can achieve a satisfactory life by thinking positively, living in a stable family, and friendships, while avoiding strong negative emotions, overwork, and stress [24,35]. Therefore, HT recipients' physical and psychological well-being can be improved by following medical recommendations to protect the new heart and by promoting an optimistic attitude toward life.

Through this study, moving past the symbolic meaning that an HT is a gift of new life [9], young adult recipients have been able to expand their lives through their experience with fatal heart disease, rigorous procedures of transplantation, and medication side effects after surgery. They showed how they struggled through a series of stages to overcome difficulties [14]. However, most of the problems they face now have no fundamental solution, and they are living in a state of uncertainty without proper preparation for their future. Based on the findings of this study, health-care providers should have a deeper understanding of young adult HT recipients to provide tailored care before and after transplantation and effective interventions for adapting to life after transplantation.

Health-care providers need a multifaceted approach to help recipients accept and adapt to changes in life after HT. In particular, pre- and post-HT education needs to be developed to effectively manage the post-HT life. The education should comprise medication administration, information about appearance change, social relationship change, and infection control due to taking immunosuppressive drugs. In addition, health-care providers need to play an important role as information providers and active advisors to prevent young HT recipients from being dismissed as disabled and deprived of opportunities in their social life.

This study has several limitations. First, because this study's participants were enrolled from one tertiary hospital in a city, there should be caution for generalizability. Repetitive study on the given topic from different patient backgrounds is necessary. Second, the purpose of this study was to recruit young adult HT recipients; however, the results found that the post-HT duration varied from

1.6 years to 13.7 years. Further qualitative study is necessary to determine if there are any differences in the experience of HT based on the length of post-HT duration.

Conclusion

This study revealed young adult HT recipients' lived experiences within the Korean context. HT was a major challenge in young adult HT recipients' lives. HTs have hampered the completion of important life tasks, such as employment, marriage, and childbirth, and diminished their confidence in life. However, they gradually tried to embrace their new life rather than viewing themselves within the dichotomous norms of normal and abnormal. Furthermore, they felt gratitude for family and everyday moments and learned how to be satisfied in life. The results of this study will improve the understanding of young adult HT recipients and lay the groundwork for developing practical solutions to address employment and childbirth problems after transplantation.

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Conflict of interest

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Research Article

Development and Validation of the Happiness Scale for Middle-Aged Women Based on Existence, Relation, and Growth Theory

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ABSTRACT

Purpose: This study aimed at developing a happiness assessment scale for middle-aged women (HAS-MW) in Korea.
Methods: Preliminary items for the scale were drafted from the results of literature review and personal interviews and open-ended questions with women in the community. The interviews were based on the theory of existence, relatedness, and growth. After validating a preliminary scale, we analyzed the validity and reliability of the new scale items, and model fit. We surveyed 600 women aged 40 years to 64 years for exploratory factor analysis (EFA) and confirmatory factor analysis (CFA). Valid data were divided into 352 for EFA and 174 for CFA by multiplies of number 1 to 3.
Results: Using exploratory and confirmatory factor analyses, we extracted four primary factors—self-value, positive thinking, self-care, and family relationship—and with a total of 24 items for HAS-MW. The fit of the final model was evaluated as good showing $\chi^2/df = 2.10$, goodness of fit index = .80, comparative fit index = .85, root mean square error of approximation = .08, standardized root mean residual = .05. The HAS-MW had a significant positive correlation with the Oxford Happiness scale and showed a significant negative correlation with the Hwa-Byeong Scale. Cronbach's α for the new scale was .91, and the Spearman-Brown half coefficient was .93. The new scale used a five-point Likert scale with higher scores indicating greater happiness.
Conclusion: The HAS-MW is a reliable and valid one. It can be used to measure the level of happiness for middle-aged women. In addition, it might be applied to find low women and to evaluate the effect of intervention program related to happiness in woman of middle age.

Introduction

Women in middle age (approximately 40–64 years old) may face emotional crises, feeling psychologically low or worthless as menopause lowers estrogen levels [1]. However, it is also the period when they mature by looking back on their lives. Furthermore, middle-aged women's happiness also affects their families [2,3], as many enjoy sharing time with others with the clear perspective of those with accumulated experiences. Thus, middle age can be interpreted as the pinnacle of a new direction, not a downward curve in life. This period of adulthood can be made happy by actively embracing various internal and external changes and maintaining a positive balance in life [2,4].

The Korean Dictionary defines happiness as “a state of pleasure and contentment in life” [5]. The concept of happiness has three common yet diverse characteristics. First, it is subjective; second, it reflects active and positive aspects of life; finally, it involves an overall assessment of life [6]. The Subjective Happiness Scale measures overall subjective happiness based on the respondent's perspective [7]. Individuals' definitions of “happiness” may vary. Some may judge happiness in the moment; others may answer looking back on a year or their whole life. Thus, it is difficult to measure individual happiness with a simple question [8].

In addition, culture influences “happiness” conceptualization [9], as Westerners emphasize intrapersonal or internal experiences, whereas Chinese culture emphasizes the interpersonal or external. Furthermore, it is not certain that subjective well-being constitutes all the dimensions of happiness in Korean culture, such as positive

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relationships with others, self-acceptance, family identity, personal growth, love, academic concern, life purpose, responsibility for one's own life, sense of purpose, life goals or mission, health, and financial success [6].

The theoretical definition for happiness is "physical comfort and emotional pleasure related to satisfying personal needs in a specific social and cultural environment" [9]. It depends on personal characteristics and cognitive evaluation of the external situation. Furthermore, achievement of life goals means ultimate self-realization and meaningful outcomes in human relationships [10]. Among the happiness-related theories, such as Maslow's hierarchy of needs, self-determination theory, modernization and freedom of choice, and positive psychology, Alderfer condensed 3 dimension of the Existence, Relatedness, Growth (ERG) theory [11] from Maslow's 5 needs [12]. Specifically, existence needs include all material and physiological desires. Relatedness needs encompass social and external esteem; relationships with significant others such as family, friends, coworkers, and employers. Growth needs internal esteem and self-actualization; these impel a person to make creative or productive effects on himself and the environment. This ERG theory supports individual specific objectives depend on the uniqueness of each person ultimately [11]. The Happiness Index for Korean that renamed the Korean Happy Life Inventory [6] did not include the continuous interaction between women and the surrounding environment. A happiness assessment scale for middle-aged women (HAS-MW) in Korea should include internal external needs and the continuous interaction with surrounding environment to understand happiness for middle-aged women.

The next important factor to objectively measure happiness is the criteria for "happiness." These criteria depend on the economic, political, social, and cultural environments to which individuals belong [13] that lead to their perception of happiness [14]. Happiness has a positive effect on many parts of our lives. In particular, the happiness of middle-aged women is a subjective perception affecting not only their own lives but also their families and communities [3]. The use of abstract happiness as a measurement criterion requires an objectively measurable indicator (or something interpreted as an objective indicator) [15]. A scale for measuring happiness must reflect the subject's characteristics to ensure the subjective measurement method is valid and reliable. However, the only tool for measuring the happiness of middle-aged Korean was developed for all adults, regardless of gender [6,16]; few tools have been developed by identifying the original characteristics and components of happiness based on perspectives of middle-aged women. It is required to develop a happiness assessment scale reflecting characteristics or attributes of happiness in middle-aged women to consider gender and age.

Therefore, the first step in developing a happiness-measurement instrument is understanding the components of happiness for the target population. We identified nine components that comprise happiness for women in middle age [17], reflecting existence, relations, and growth needs of ERG theory [11]. Accordingly, we sought to develop a happiness-measurement tool reflecting middle-aged Korean women's physical, psychological, and sociocultural characteristics—based on nine components of their happiness [17]—to be used as the primary scale for evaluating happiness for women of this age. This HAS-MW will be first scale in Korea based on ERG theory for women in middle age and different from other happiness scales.

The conception of and sources of well-being or happiness may be different in collectivist cultures that emphasize harmony in relationships with others rather than individualism [13]. Thus, subjective well-being consists of three components: life satisfaction, presence of positive affect/absence of negative affect, and psychological well-being, based on the intensive integration of several theoretical domains including life span developmental perspectives, mental health, and clinical psychology [18].

Hence, we aimed to understand happiness for middle-aged women according to ERG theory [11] and to develop a HAS-MW. To verify that the scale would have a sufficiently empirical foundation, a previously published first phase of the instrument's development [17] involved concept analysis of in-depth interviews with middle-aged women. The results of that previous study yielded nine extracted components of happiness [17]. The present article describes phase two of our research: developing and validating the new scale, the HAS-MW, to be used to assess and evaluate happiness of women in middle age in a comprehensive and multidimensional way using physical, psychological, and social traits.

Methods

Study design

This methodological study included a cross-sectional survey to develop a HAS-MW. The framework of the conceptual model in this study is Alderfer's ERG theory [11]. Scale development process are shown in Figure 1.

Participants and data collection

Data were collected from February 1 to March 23, 2018, from middle-aged women aged between 40 and 64 years. Participants were assigned based on the population census—Statistics Korea 2015 [19] to Seoul metropolitan and six Korean provinces. Inclusion criteria were middle-aged (40-64 years) women in community. Women those who admitted in the facilities such as hospital or nursing home were excluded. A total of 600 questionnaires were distributed by mail or personal contact; 567 were collected (response rate = 94.5%). A total of 526 copies (92.8%) were used for final analysis; 41 were excluded owing to insufficient data (7.2%).

Participants provided their informed consent to participate, verifying that they understood the purpose and content of the study. The sample size needed was more than 300, or 5–10 times the number of items for exploratory factor analysis (EFA), and five times the number of items for confirmatory factor analysis (CFA) [20]. According to the previous explanation, sample size was decided to be 600 in total for EFA and CFA. Multiples of 1 and 2 were determined by the EFA group, and multiples of 3 were determined by the CFA group. In addition, data of participants were 352 for EFA and 174 for CFA exclusively by and these data were satisfied minimum requirement of sample size for EFA and CFA.

Ethical consideration

This study was approved by the Institutional Review Board of the Soonchunhyang University (Approval no. 1040875-201706-SB-02-2). Participants were informed of the purpose of the survey and agreed to answer our questionnaire.

Scale development

This scale development was conducted in accordance with reference of scale development [21].

Generate an item pool and format for measurement

Literature reviews were performed after searching PubMed, EMBASE, CINHAL, and KMBASE, KISS, KoreaMed, DBpia, Riss, and the National Assembly Library database. The publication period searched was January 1, 1980 to August 31, 2017, because research

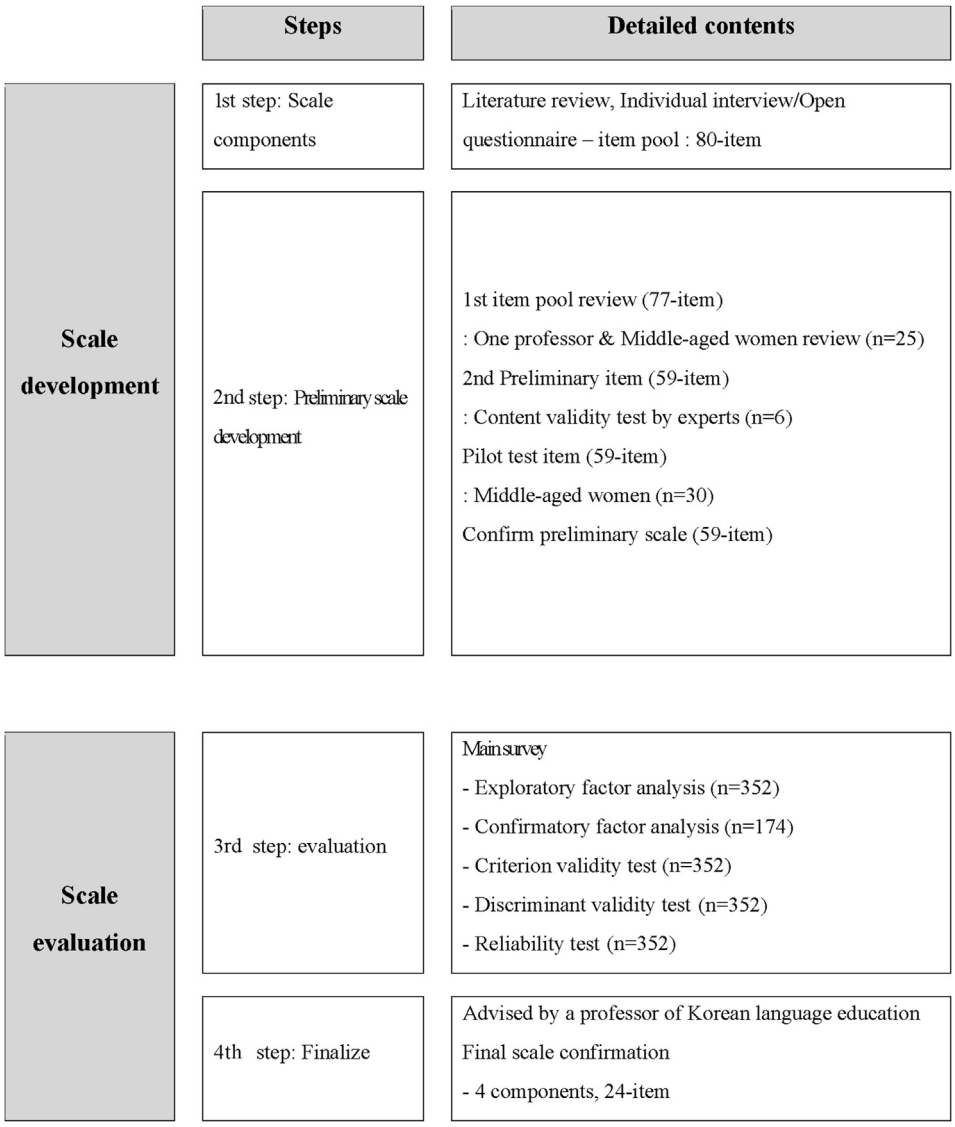

Figure 1. Scale development process.

on well-being, life satisfaction, and quality of life was published after 1980. The literature review of 133 articles and one-hour interviews with 25 middle-aged women revealed the attributes of middle-aged women, related factors, and components of happiness [17]. Women were asked to talk about main questions such as "How do you think about happy person as a middle-aged woman?", "When do you feel happy?", "What are you doing to be happy?", and so on. Through literature review and analysis of interviewed contents, we extracted a total of 80 initial items, composing 9 components of physical function factor, economical factor, appearance factor, family relations, social relations, self-esteem, mind control, positive thinking, and leisure life based on ERG theory.

Item formats for assessment of happiness is a Likert scale. Because Likert scaling is widely used in instruments measuring opinions, beliefs, and attitudes. Likert scale response options are a 5-point scale (1: Absolutely disagree. 2: Mostly disagree 3: Moderate 4: Mostly agree 5: Absolutely agree).

Item pool reviewed

Extracted items were reviewed by one professor and 25 middle-aged women. Twenty-five participants completed pooled items. It was also considered an average time to response and understandability.

Inclusion of validation items

Inclusion for validation items was performed by six experts. For validation items, based on established guidelines [22]. As a next step, pilot test was conducted using a 5-point Likert scale to 30 participants in 3 provinces.

Scale evaluation

Administering items to middle-aged women

Nunnally suggests that 300 people is an adequate number [19]. Tabachnick and Fidell reports that the sample size needed was more than 300, or 5–10 times the number of items for exploratory

factor analysis (EFA), and five times the number of items for confirmatory factor analysis (CFA) [21]. To prevent pitfall of small sample size, five times of survey items and about 20.0% drop rate, 600 in total were recruited, 400 for EFA, and 200 for CFA.

Evaluate the items

Descriptive statistics and reliability and validity tests were performed with SPSS Statistics 24.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics were used to determine frequency, range, mean, and standard deviation of the sample's demographic and clinical characteristics. All other tests were two-tailed, and a *p*-value of less than 5.0% was considered statistically significant.

To evaluate the performance of the individual items, analysis was conducted for item means, item variances, skewness and kurtosis, and item-scale correlations. The item performance, absolute values of skewness, and kurtosis were normally distributed: all absolute values satisfied with values less than 3.0 for skewness and less than 7.0 for kurtosis. Furthermore, confirmed item-scale correlations (≥.30) [21,23].

For construct validity, we performed EFA using IBM SPSS 24.0 and CFA using IBM SPSS AMOS 20.0 (IBM Corp., Armonk, NY, USA). Researchers used principal components analysis as the factor extract model to minimize information loss from minimum-factor prediction, and varimax rotation to know structures of independent factors by maximizing the sum of factor-loading variance [23], the Oxford Happiness Questionnaire (OHQ) was evaluated with principal component analysis and varimax rotation [24]. First, to confirm the appropriateness of materials for EFA, Kaiser-Mayer-Olkin (KMO) test, and Bartlett's test of sphericity were evaluated [25]. Bartlett's test of sphericity confirmed patterned relationships among the variables, as seen in the correlation matrix ($p < .001$). The KMO measure of sampling adequacy was ≥0.5, indicating the selection of sampling was adequate for factor analysis.

For extracting factors through EFA, the number of factors was determined by the following criteria: eigenvalue of 1 or above, factor loading (≥.40) [25], and accumulative variance of 50–60.0% [21,26]. For CFA model verification, the goodness of fit coefficients, Normed χ2 (χ2/df), the goodness of fit index (GFI), standardized root mean residual (SRMR), root mean square error of approximation (RMSEA), Tucker-Lewis index (TLI), and comparative fit index (CFI) were verified. In addition, the HAS-MW criterion validity and discriminant validity were compared.

For criterion validity, the OHQ [24] was used. Because it has been used as golden standard world wide, it was selected. Pearson's correlation coefficient was applied to determine the criterion validity of the HAS-MW's and the OHQ-Korean [27] scale. The twelve negative items among the 29-item OHQ were reverse-scored. The sum of the item scores was the overall measure of happiness, with higher scores indicating greater happiness. Cronbach's α of this study was .87, whereas the original version reported Cronbach's α of .90 [24].

For discriminant validity, Pearson's correlation coefficient was calculated for the HAS-MW and the Hwa-Byung Scale [28]. Hwa-Byung is a culture-related anger syndrome in Korea. And higher in the degree of hwa-byung, higher in depression or anger. Therefore, this scale is thought to be negatively related to happiness [29]. The Hwa-Byung scale comprises 15-items related to emotional and physical symptoms evaluated on a 5-point Likert scale. Cronbach's α at development was .92 [28]; Cronbach's α was .93 in this study.

Results

Participants' characteristics

Researchers used data of 352 of 526 participants for EFA. The participants' mean age was 50.6 (±7.17), and most of the women were married (84.4%), 53.7% had education levels of college or above, 74.7% had one or two children, 72.4% held jobs outside the home, 71.9% was religious, 68.5% had no diseases, and 58.2% had not ended their menstrual cycles. On the other hand, participants for the CFA were 174, and their mean age was 49.9 ± 7.51. Of them, 81.6% was married, 60.3% had an education level of college or higher, 33.3% finished high school. Of the participants, 73.0% had one or two children, 33.3% had some form of disease, and 37.9% had ended their menstrual cycles (Table 1).

Table 1 *Demographic Characteristics of Participants (N = 526).*

Characteristics	Categories	Total (n = 526)	EFA (n = 352)	CFA (n = 174)
		M ± SD or n (%)	M ± SD or n (%)	M ± SD or n (%)
Age (yrs)		50.3 ± 7.17	50.6 ± 7.17	49.9 ± 7.51
Marital status	Single	33 (6.3)	18 (5.1)	15 (8.6)
	Married	438 (83.3)	297 (84.4)	142 (81.6)
	Divorced	24 (4.6)	16 (4.6)	8 (4.6)
	Bereaved	19 (3.6)	13 (3.7)	6 (3.5)
	Remarried	9 (1.7)	8 (2.3)	1 (0.6)
	Others	3 (0.6)	0 (0.0)	3 (0.6)
Education	Elementary school	11 (2.1)	9 (2.6)	2 (1.2)
	Middle school	30 (5.7)	21 (5.9)	9 (5.2)
	High school	191 (36.3)	133 (37.8)	58 (33.3)
	Over college	294 (55.9)	189 (53.7)	105 (60.3)
Number of children	0	25 (4.8)	9 (2.6)	16 (9.2)
	1–2	390 (74.1)	263 (74.7)	127 (73.0)
	≥3	78 (14.8)	62 (17.6)	16 (9.2)
Job	No	145 (27.6)	97 (27.6)	48 (27.6)
	Yes	381 (72.4)	255 (72.4)	126 (72.4)
Religion	No	158 (30.0)	99 (28.1)	59 (33.9)
	Yes	368 (70.0)	253 (71.9)	115 (66.1)
Disease	No	357 (67.9)	241 (68.5)	116 (66.7)
	Yes	169 (32.1)	111 (31.5)	58 (33.3)
Menopause	No	313 (59.5)	205 (58.2)	108 (62.1)
	Yes	213 (40.5)	147 (41.8)	66 (37.9)

Note. CFA = confirmatory factor analysis; EFA = exploratory factor analysis; M = mean; SD = standard deviation; yrs = years.

Scale development

Generation of item pool and item selection

Generated 80-item pool was reviewed by one professor and by 25 middle-aged women. In this step, 3 items were excluded owing to redundancy.

Six experts (two psychologists with doctoral degrees, three psychiatrists, and one doctor of women's studies) verified item content for valid item selection to measure a happiness for women in middle age. Ten items (I-CVIs < .80) and 8 items (that were similar/identical) were excluded. Preliminary scale was developed with a 59-item.

Item evaluation for adequacy

As a next step, item evaluation for adequacy as a scale was conducted using a 5-point Likert scale to 30 participants in 3 provinces. 30 participants completed 59-item questionnaire in an average of 8 minutes; the mean of understandability was 3.20–3.70 (from four scores), indicating the participants found the questionnaire easy to understand. Item mean (±SD) for 59 items showed 3.57 (±0.35) and internal consistency was Cronbach's α .93. In this step, Bartlett's value was $\chi^2 = 8191.02$ ($p < .001$), and 59 items, a 5-point Likert scale was considered adequate for factor analysis.

Scale evaluation

In the scale evaluation step, using IBM SPSS 24.0 and AMOS 20.0 (IBM Corp., Armonk, NY, USA), exploratory factor analysis identified categories of similar statements and extracted 4 factors. Also validity was tested with the Korean version of OHQ [27] for criterion validity, and with Hwa-Byung [28] for discriminant validity. Item mean (±SD) for 59 items showed 3.44 ± 0.38 (minimum 2.29, maximum 4.68) with 352 participants. Through confirmatory factor analysis for model fit, the reliable and valid 24-item HAS-MW was developed.

Exploratory factor analysis

Number of factors. The number of factors was determined by the following criteria: eigenvalue of 1 or above, factor loading (≥.40) and accumulative variance of 50–60.0%. Ten items (having item-total correlation coefficients < .30) from a 59-item preliminary scale were excluded and 49-item was analyzed with the scree plot. Four factors were identified [Fig. 2a].

Item reduction. During four times of EFA, 6 items with loading lower than .40 and 8 items with one factor one item were removed (reduced to 35 items). Three redundant items were rejected after comparison with other items in the same factor and 32 items were extracted.

In the fifth EFA, all items' factor loadings were satisfactory (>.40). Through review of items (factor loading > .40), 4-items (Q31, Q49, Q52, Q56) were deleted that not fit any factor or show different meaning from other items. Finally, four factors, 28 items including three dimensions of ERG (existence, relation, and growth) theory were produced. These 28-items explained 53.2% of the variance for happiness in middle-aged women (Table 2, Fig. 2b).

Confirmatory factor analysis

Model fit. For CFA model verification of 4-factor, 28 items scale, we used the data not used in the EFA (n = 174). To improve model fit, we performed an analysis requesting modification indices. At first, for the estimates of CFA, identifying four items (Q6, Q10, Q33, Q42 in Table 2) with a critical ratio of 1.96 ($p < .05$) were excluded (Table 3). Second, the modified model fit resulted in a final scale of 24 items reflecting happiness in middle-aged women. Critical ratio was 4.809–10.040 ($p < .001$), and standardized regression weight was .394–.871. Two items of Q5, Q8 with estimates lower than .50, were kept into 24-items. Because both items were essential for the conceptual framework (Q5: I eat a healthy and well-balanced diet, Q8: I have my own way of relieving stress) (Table 3).

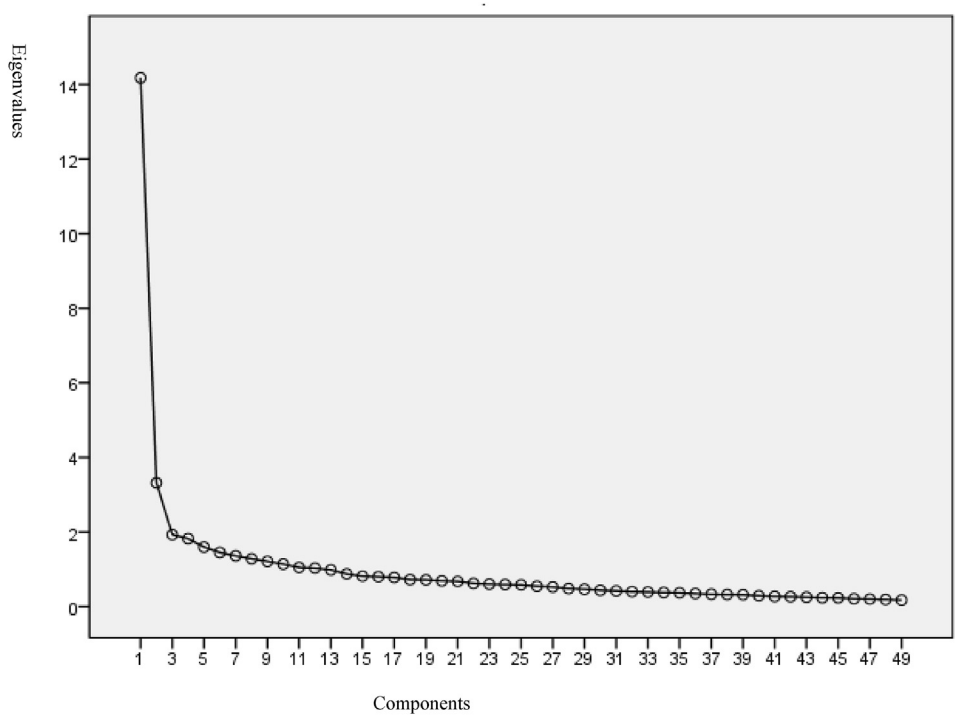

Figure 2. Scree plot and modeling of the happiness.

Model fit indices for the scale with four factors, 24 items were $\chi^2 = 517.63$ ($p < .001$). However, χ^2 is sensitive to sample size, so we performed further examination. GFI was .80, which is thought to indicate a comparatively good model fit. The RMSEA was .08, and the SRMR was .05, indicating satisfactory model fit [25]. The fit of the final model was verified to be good, having $\chi^2/df = 2.10$, GFI = .802, AGFI = .758, NFI = .749, IFI = .850, TLI = .829, CFI = .848, RMSEA = .080, and SRMR = .05 (Table 3). Based on the above CFA, the four-factor 24-item of the HAS-MW was considered as valid (Supplement 1).

Factor naming. Four factors composed of 24 items were extracted after CFA [Fig. 2b]. Factors were named as 'Self-value', 'Positive thought', 'Self-management', and 'Family relations' based on their content: Factor 1 included eight items (Q29, Q30, Q32, Q34, Q36, Q37, Q38, and Q40) meant "to be loved and be accepted as valuable by oneself" and was named 'Self-value'. Factor 2 included eight items (Q39, Q44, Q45, Q46, Q47, Q48, Q54, and Q55) meaning positive thought and joyful feeling and was named 'Positive thought'. Factor 3 included five items (Q5, Q8, Q57, Q58, and Q59) related to the physical/psychological leeway to do something and was named 'Self-management'. Factor 4 included three items (Q18, Q19, and Q21) related to interaction among family members and was named 'Family relations' (Table 3, Fig 2b).

Criterion validity and discrimination validity. Criterion validity was confirmed with the OHQ-Korean version [27]; the correlation coefficient between HAS-MW and the OHQ was r = .84 ($p < .001$). Discrimination validity was confirmed with Hwa-Byung [28], and the correlation coefficient between HAS-MW and Hwa-Byung was r = −.51 ($p < .001$), that is, negative relations.

Reliability. The internal consistency of HAS-MW was also evaluated using Cronbach's α and the Spearman-Brown half coefficient. Cronbach's α of the final 24-item scale was .91 for all items and Cronbach's α for component factors (Factor 1, 2, 3, 4) were .88, .81, .80, and .76, respectively. The Spearman-Brown split-half parallel reliability coefficient was .93. Hence, the. HAS-MW was considered reliable for measurement of happiness for middle-aged women.

Finalizing scale. Through confirmatory factor analysis, 24 items were verified as HAS-MW reliable and valid. Mean (±SD) for scale was 86.74 (±10.45) (range: 44~108). Item mean (±SD) was 3.61 ± 0.43. One professor of Korean language education confirmed text of final scale and it was translated [S1].

Table 2 *Exploratory Factor Analysis (N = 352).*

Item No. (Total items = 28)	Communality	Factors			
		F1	F2	F3	F4
Q33+	.80	**.73**	.64	.26	−.02
Q32	.74	**.66**	.29	.14	.07
Q34	.66	**.66**	.12	.28	−.04
Q38	.69	**.65**	.39	.05	.17
Q36	.68	**.64**	.38	.04	.32
Q30	.65	**.62**	.28	.08	.35
Q29	.67	**.55**	.40	.17	.17
Q37	.70	**.55**	.46	−.03	.31
Q40	.60	**.53**	.41	.27	.15
Q46	.67	.13	**.80**	−.05	−.01
Q47	.55	.21	**.70**	−.03	.03
Q45	.56	.33	**.58**	.13	.18
Q44	.58	.00	**.57**	.09	.08
Q48	.53	.21	**.57**	.18	.16
Q39	.53	.40	**.56**	.04	.10
Q55	.71	.26	**.51**	.15	.21
Q42+	.59	.16	**.47**	.16	.04
Q54	.69	.33	**.44**	.21	.14
Q10+	.63	−.05	.13	**.72**	.02
Q58	.76	.36	−.04	**.70**	−.03
Q6+	.66	.41	.05	**.68**	−.12
Q59	.72	−.11	.23	**.67**	.19
Q57	.72	.31	.04	**.65**	.16
Q5	.56	.17	.02	**.61**	.22
Q8	.62	.14	.38	**.54**	.14
Q18	.72	.11	.06	.10	**.79**
Q19	.72	.15	.22	.14	**.76**
Q21	.63	.10	.13	.12	**.74**
Eigen value		9.16	2.58	1.72	1.45
Explained variance (%)		16.39	15.74	12.38	8.71
Cumulative explained variance (%)		16.39	32.12	44.51	53.22

KMO = .906 Bartlett's test $\chi^2 = 4704.668$ ($p < .001$).
Bold means eigen values composing each factor.

Discussion

A growing number of social scientists are examining humans' more positive aspects, such as subjective well-being, psychological well-being, life satisfaction, happiness, and quality of life [13,14,30]. Also, researchers have tried to measure the achieved happiness, personality, attitude and value, and life-style domains of happiness as they have come to be defined in the literature. In this study, we tried to understand happiness for middle-aged women based on ERG theory [11] and developed the HAS-MW in Korea. Our findings suggest that the HAS-MW shows good psychometric properties. In this section, we discuss about internal consistency and validity, and components of a scale.

First, in the validity, criterion-related validity of this scale showed high correlation with the OHQ [24], the gold standard happiness measurement. The OHQ focuses on life satisfaction and emotional experience [24]. However, it does not include leisure, family relationships, self-achievement, or self-development, while the HAS-MW includes attributes of happiness in middle-aged women. In addition, people's literacy diminishes as they grow older [31], so we aimed to use the fewest items possible and make them easy to answer [27]. The HAS-MW composed of positive wording questions. Pooled item of HAS-MW included negative questions, but those kind of items were excluded naturally. The study excluded negative wording items of the OHQ and raised convenience [32] and positive wording might prevent potential response errors [33]. Furthermore, the HAS-MW has discriminant validity, showing a negative correlation with the Hwa-Byung Scale [28]. When compared with the results of the more severe Hwa-Byung, which includes items that negatively affect quality of life [34], the HAS-MW we developed has confirmed discriminative validity.

Second, the reliability of the HAS-MW in this study was established: Cronbach's α was 91, and the Spearman-Brown split-half reliability was .93. It has a reliable scale based on the standpoint that Cronbach's α is .60 or higher indicates good reliability of newly developed psychological and social scales [35]. Furthermore, the HAS-MW fits uses a five-point Likert scale, the most reliable scale for a subject-centered approach [36].

Third, the "happiness" components we included support the ERG theory [11]. The HAS-MW comprises four factors, among which "family relationship" corresponds to the relatedness needs in ERG theory; the others, "self-value," "positive thinking," and "self-management," correspond to the growth needs in ERG theory, which represent the desire for growth and achievement [11]. This feature of middle age expresses as a process of re-recognizing the value of oneself and discovering the value and life's meaning through internal reflection [4], suggesting the importance of

Table 3 *Measured Variable Estimates of the Confirmatory Factor Model (N = 174).*

Factors	No	Items	Unstandardized regression weight	SE	CR	Standardized regression weight
Self-value	Q32	I think life is a constantly changing and growing process for me.	1.00			.70
	Q36	I am a worthy person.	.94	.10	9.80	.82
	Q29	I have a lot of strong points.	.93	.10	9.07	.73
	Q38	I think positively about myself.	.91	.09	9.92	.82
	Q30	I value myself.	.90	.10	9.31	.76
	Q40	I am satisfied with myself.	.83	.11	7.98	.65
	Q37	I'm the one that others need.	.82	.10	8.45	.69
	Q34	I spare no cost about learning.	.73	.11	6.52	.52
Positive thought	Q47	I try to see others as they are.	1.00			.66
	Q55	As I experience difficulties I think it is an opportunity to learn.	.99	.14	7.25	.62
	Q44	I focus on what I can do well.	.96	.14	7.03	.63
	Q45	I am satisfied with the result I effort	.93	.13	6.94	.63
	Q39	I have a good personality.	.92	.14	6.83	.57
	Q48	When I talk to other person, I focus on them.	.81	.13	6.94	.63
	Q46	I am thoughtful others around me.	.78	.12	6.52	.60
	Q54	I think experience of menopause leads to a deeper understanding of life's meaning.	.73	.15	4.91	.41
Self-management	Q59	I do a hobby that I want.	1.00			.87
	Q58	I travel whenever I want.	.88	.09	10.04	.76
	Q57	I have enough spare time to enjoy my own time.	.60	.08	7.16	.58
	Q8	I have my own way of relieving stress.	.48	.09	5.61	.45
	Q5	I eat a healthy and well-balanced diet.	.39	.08	4.81	.39
Family relations	Q19	We cares about each other (including parents, siblings).	1.00			.87
	Q18	We have a good family relationship (including parents, siblings).	.86	.10	9.02	.74
	Q21	We have decided important things with discussions (including parents, siblings).	.79	.09	8.51	.67

χ^2	df	*P*	GFI	CFI	RMSEA	SRMR
517.63	246	<.001	.80	0.85	0.08	0.05

Note. GFI = goodness of fit index; CFI = comparative fit index; RMSEA = root mean squared error of approximation, SRMR = Standardized root mean squared residual. This table showed 24-items exception for four items Q6, Q10, Q33, Q42) with a critical ratio of 1.96 ($p < .05$) from 28-items in Table 2.

growth to the happiness of middle-aged Korean women. Some attributes of the HAS-MW differ from the Koreans' Happiness Scale of Life [6], although it is also based on the ERG theory and the Maternal Happiness Scale [37]; they share common traits but the factors that are most important vary depending on participants' characteristics. The factors of HAS-MW (See Supplement 1, [S1]) include self-value (self-worth), with eight items (Q1–Q8) that are important determinants of happiness. Prior researchers have identified these values which relate to being recognized by oneself and others [38]. Such recognition increases subjective happiness because self-esteem rises when one feels validated as an important and indispensable individual [39]. The Korean version of the Mental Health Continuum-Short Form [40] also recognizes self-value for happiness. Inclusion of the self-value factor items may signify a cultural shift from traditional values of collectivism to a modern values of individualism, reflecting the attitudes of middle-aged women who are actively moving toward becoming the center of their own lives, as individuals, and away from being submissive and passive wives or mothers in a male-centered society. This result also supports the thinking that individualistic and collectivistic cultures rely on different sorts of information in making life satisfaction judgments [41].

The second factor, positive thinking, comprises eight items (Q9–Q16) that strongly relate to happiness based on appreciation. Positive thinking relates positively to psychological well-being, life satisfaction, and the use of positivity to maintain psychological stability in everyday life [41]. The positive thinking factor also reflects how meaning in women's lives depends on their degree of acceptance of menopause [42]. That is, happiness in middle-aged women can be evaluated and experienced differently by different generations or individuals [13,14,43].

The third factor, self-management, expressed in five questions (S1: Q17–Q21), included factors related to leisure activities in life. The importance of leisure has been the focus of several studies of happiness in people of middle age [44]. The pleasant experience associated with a life of leisure reduced depressive symptoms, making it an important source of life in middle-aged and older adults [43]. In this factor of self-management, there are items that are different from the OHQ in Korean [27]. That is, items such as “I have a healthy and well-balanced diet” and “I have my own way of relieving stress” are expressed in specifically positive language for self-management in the HAS-MW. On the other hand, the OHQ is composed of pleasurable life, meaningful life and engaging life, does not include self-management.

Finally, the fourth factor, family relationship, comprises three items (S1: Q22–Q24). This factor was included in the Happiness index for Koreans [6] but not the Korean Youth Happiness Index [45]. This concept refers to how happiness depends on individuals and how they prioritize it in their lives in terms of their family relationships, which are seen as particularly important for middle-aged women. A stable and strong bond or meaningful relationship can invoke positive feelings and make women feel happy [9,43,46]. In particular, this study revealed the importance of family relations to the happiness of Korean middle-aged women, as evidenced by the items “We have a good family relationship (including parents, siblings)”, “We care about each other (including parents, siblings),”and “We make important decisions through discussions (including parents, siblings)”. This attribute is consistent with research that emphasizes emotional stability as a major dimension of happiness in women's happiness [43,47]. Hence, we suggest that the family relations factor should be considered for development programs to support women emotionally in the future.

The HAS-MW developed in this study is the first scale in Korea with its reliability and validity expressed in empirical language that reflects the attributes and properties of happiness in middle-aged women. It is meaningful to develop a scale that directly explores

and checks the components of happiness in middle-aged women. The 4 factors are related to each other, yet are independent and reflect individual and collectivist cultural characteristics [13,41].

A few limitations should be considered when interpreting the HAS-MW. This study did not provide a cut-off score for happiness. In general, to show a cut-off point, the golden standard must be used as the appropriate reference point. However, we used the OHQ [24] as the golden standard but it does not provide a cutoff point. Furthermore, happiness is relative based on individual differences [13,48]. Thus, it is difficult to conclude that a person with a low HAS-MW score is absolutely unhappy. Furthermore, since the factors that make contribute to great happiness vary by individual; the scores depend on the person rather than the tool used. The objective cut-off point should be decided through a careful and complex process which should be determined by a common consensus of experts. Also, model fit indices of CFI and TLI (>.80) are permitted, but it is not great (>.95). Further validation study is necessary to be reanalyzed and improve model fit.

In addition, the study only involved women in Korea; therefore, its validity in other cultures is unknown. Future research may use this scale as a basis for versions to fit various cultures globally. Despite limitations, it is expected that the HAS-MW would be useful for individuals and counselors to evaluate happiness-related factors of middle-aged women and to contribute to the creation of a bright and healthy society by improving their positive well-being.

The newly developed HAS-MW may also be useful in clinical assessment, where the happiness score might reflect recovery from psychological conditions such as anxiety, stress and depression. Also it could be used for women with low scores of HAS-MW to get counseling or treatment. It is required to explore the gender effects in happiness in middle-aged men and women and cultural impacts for multicultural background. Finally, under conditions of COVID-19, happiness needs to be reevaluated to see the change in middle-aged women who worked more for their families than before COVID-19.

Conclusions

This study developed the HAS-MW, considering their pursuit of happiness, and it measures happiness based on the fulfillment of ERG needs. It is a significant development in illuminating and measuring positive aspects of happiness, particularly for Korean women in middle age.

The HAS-MW is a reliable and valid scale to measure happiness in middle-aged women and is composed of four factors, “self-value,” “positive thinking,” “self-management,” and “family relationship,” comprising 24 items. Happiness is measured using 5-point Likert scores, and higher scores indicate happier women. This scale may also be useful in clinical assessment for psychological conditions such as anxiety, stress, and depression. It is required to show the similarity and difference from the attributes for happiness in middle-aged men. We suggest future studies not only women with diseases and those with multicultural backgrounds but also middle-aged men.

Conflict of interest

All authors declare no potential conflicts of interests.

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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.2020.12.002.

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Research Article

Development and Validation of the Humanistic Practice Ability of Nursing Scale

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ABSTRACT

Purpose: The purpose of this study was to develop a Humanistic Practice Ability of Nursing (HPAN) scale adapted to China and validate its psychometric properties.
Methods: The original HPAN scale was revised through a literature review. Sixteen experts who met the inclusion criteria were consulted 2 rounds by the Delphi method. According to their suggestions and opinions, the structure, content, and semantics of each item of HPAN were modified, and a HPAN scale was preliminarily developed. The HPAN scale was validated through item analysis, exploratory factor analysis, convergent validity, and reliability. The data came from 406 first-class hospital nurses.
Results: A 5-dimension, 29-item HPAN scale demonstrated satisfactory fit with significant factor loadings. The split-half reliability coefficient of the scale was .98, the split-half reliability coefficient of each dimension was .86–.99, Cronbach's α coefficient was .96, and the Cronbach's α coefficient of each dimension was .87–.98. The model fit of the scale was good, and the items of the scale showed convergent and discriminant validity.
Conclusion: The HPAN scale indicated that the reliability and validity were good. It is easy to imply factors of HPAN. This scale can be used to assess the HPAN.

Introduction

The concept of the Humanistic Practice Ability of Nursing (HPAN) begins in humanistic physician practice skills. Nursing is a different discipline to medicine as it focuses on patients rather than the disease itself [1]. Care is the core and focus of nursing, and so, it is necessary to practice more humanism for patient care in nursing. Humanistic nursing is the internal requirement of nursing science that is needed for social development and harmonious nurse–patient relationships in China. Humanistic practice is the foundation of an essential attribute of nursing [2,3], but the humanistic characteristics that are essential for providing quality care are often overlooked [4]. This leads to the frequent occurrence of unequal status in the relationships between nurses and patients sometimes resulting in conflict. At present, the nursing profession pays major attention to the development of HPAN [5].

The development of nursing humanistic care has formed a training mode of "idea internalization–ability development" in developed countries [6,7]. For example, cross-cultural nursing theory is used to discuss nurses' care for patients [8]. The theories of self-care and humanistic nursing have been applied to expound nurses' care for patients with enterostomy [9]. These studies are often combined with the existing nursing theory for more detailed research studies.

Most nursing humanistic practice studies in China focus on humanistic care ability, the humanistic quality of nurses, and other related research concepts [10]. Nursing humanistic care has an inherent quality and state of rationality that makes it difficult to objectively embody in practice. However, nursing humanistic practice is an external manifestation of sensibility, a kind of activity or form that integrates humanities into nursing activities, and a conscious work attitude and behavior. It allows the subjective ideas of nursing staff as part of the human spirit to reflect in the external and objective form.

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The HPAN as an entity or an independent concept has been rarely described, and there is a lack of a mature HPAN assessment scale. In 2014, we preliminarily developed the HPAN measurement tool [11] that contained 23 items in 5 dimensions: nursing communication ability, psychological adaption ability, nursing esthetic ability, legal application ability, and caring practical ability. The Cronbach's α coefficient was .93. The HPAN has been used in China; since its development, it has demonstrated several shortcomings in practice.

The HPAN is a complex construct that defies simplistic measurement [12]. To build a reliable and effective assessment tool, the process needs to progress from rough to fine and from simple to deep. It also has to go through the practice of repeated testing, continuous revision, and improvement to gradually become mature. It is necessary to develop a scientific and standardized scale of the HPAN. Through a survey of the HPAN, the mechanism of influence and the internal need for nursing staff to have a humanistic ability and consequence variables can be correctly analyzed. This is beneficial for the cultivation of HPAN. The improvement of the HPAN can allow more realistic people-centered nursing, and it improves the satisfaction and prognosis of patients to promote patient health and reduce medical expenses [13,14]. HPAN is an effective way to improve the comprehensive quality of nurses and is an important sign of hospital nursing quality [15].

The introduction of HPAN is of great significance in promoting the cultivation of nursing humanistic spirit, humanistic clinical practice, and the development of humanistic nursing education [16]. For nursing science, the HPAN improves its knowledge structure, enriches its theoretical system, and promotes its development. Accordingly, taking the evaluation indicators from the previous study as a framework, this study further developed a more systematic, scientific, standardized, and effective HPAN model. This advanced the HPAN model to establish a strong foundation to explore the relationships between the HPAN and various cause and effect variants.

Methods

Scale development

Conceptual framework

Based on the comprehensive analysis of nursing [17], nursing practice ability [18,19] and humanistic practice ability [20,21], the concept of the HPAN was proposed by reviewing related literature before developing the preliminary items of the HPAN scale.

Broadly, the HPAN refers to the ability of nursing staff to carry out caring behaviors for nursing objects with the goal to respect the value of life after specific cultural education. This allows nurses to take care of patients from physical, psychological, and social perspectives. Specifically, the HPAN is the practical working ability of nursing staff to deal with the holistic health of the person and patient illness or patient's response to their disease. The HPAN integrates humanistic knowledge, humanistic skills, and humanistic spirit with nursing professional knowledge and skills. The purpose of the HPAN is to attach importance to the respect and care for people that can harmonize the relationships between nurses and patients and provide quality services for nursing objects.

The HPAN has six key characteristics as follows:

(1) The ability that nursing staff must have to be competent in nursing work.
(2) The integration of nursing professional knowledge and skills with humanistic knowledge and skills. These two are inseparable.
(3) Respect for life values of nursing objects. This requires nursing staff to help nursing objects realize the value of life when they are depressed owing to diseases or pain so that they can obtain spiritual pleasure and overall harmony [22].
(4) The expression of care by nursing staff through emotions and consciousness to give an emotional contribution to the service objects [23].
(5) To meet the needs of the nursing object's personality. Nursing staff make the nursing object with a unique personality to ensure the proper support, encouragement, and affirmation when help is needed.
(6) The purpose of the HPAN is to obtain harmony between nurses and their patients.

The HPAN model

Based on the HPAN competency model from previous studies [11], the concept of the HPAN was developed to fully consider the objective conditions of clinical nursing (especially in China). The HPAN model was perfected to improve the connotation of each concept in the competency structure and to minimize overlap. The revised HPAN model (Figure 1) was formed that includes nursing communication ability, psychological adjustment ability, ethics and legal application ability, nursing esthetic ability, and caring practical ability. To maintain humanistic practice in a changing environment, nursing staff must have five kinds of interactive behaviors and abilities. The operational definitions of the five kinds of abilities are as follows:

(1) Nursing communication: the ability to achieve desired goals or to meet the needs of the patient through communication.
(2) Psychological adjustment: the ability of people to respond to environmental pressures in a variety of ways that are beneficial to the individual or group and enable the individual or group to survive better.
(3) Ethics and legal application: the ability of nurses to identify and analyze professional legal issues that contribute to the final overall decision in nursing practice.
(4) Nursing esthetic: the ability of nurses to accept, understand, evaluate, and create nursing beauty in the nursing practice.

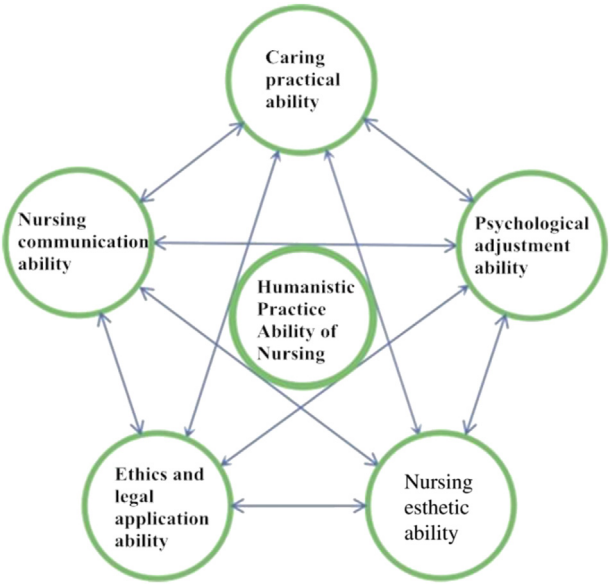

Figure 1. Humanistic Practice Ability of Nursing Competency Model.

(5) Caring practical: the ability to effectively express the nursing humanistic spirit in nursing practice.

The main points of the HPAN model include the process of the internalization of nursing humanistic practice concept in which nursing communication ability plays an important role [24] as a bridge to ensure other subcapabilities function properly. Each subcapability is closely related to the quality of nursing. The five dimensions of the HPAN influence and act with each other. To improve HPAN on the whole, it is necessary to maintain coordination across the five HPAN subcapabilities.

In short, the HPAN can only be improved by considering HPAN subcapabilities and considering it from a holistic and systematic perspective.

The development of the HPAN measurements

Based on the conceptual framework, the HPAN model, reviewing related literature and using the original HPAN evaluation index as framework, 5 first-level indicator abilities were established. Specifically, these were (behavior) nursing communication ability, psychological adjustment ability, ethics and legal application ability, nursing esthetic ability, and caring practical ability. From these first-level indicators, 31 second-level indicators were then drafted.

Sixteen experts with senior professional titles engaged in humanistic nursing research were enrolled in the questionnaire through a two-round consultation. When classified by profession, of the 16 experts, 6 experts were in nursing education, 5 were in clinical nursing, and 5 were in nursing management. When classified by area, of the 16 experts, 6 worked in public university nursing colleges, 3 worked in private university nursing colleges, and 7 worked in first-class hospitals from 6 provinces. The authority coefficient of the experts was calculated according to the academic level authority, judgment basis, and the degree of familiarity with the scale. The authority coefficient of the experts in this study was .85.

The theoretical and operational definitions of the scale concept were sent to every expert. The content validity experts were asked to rate the clarity and relevance of each item on a 4-point scale (4 = very relevant; 3 = relevant but needs minor revision; 2 = unable to assess relevance without item revision; 1 = not relevant). Comments were elicited for each item. The content validity index (CVI) for each item was the proportion of experts who rated it 3 or 4. As a CVI more than .80 is generally considered to have high validity, items with ratings lower than .80 were deleted after review. At the same time, the semantics and accuracy of the scale items were also consulted. When the opinions of the experts were accordant, the consultation ended.

According to the suggestions and comments of the experts in round 1, the main modifications were as follows:

(1) Nursing communication: In this subcapability, text stating that nurses should “Be able to use various communication skills flexibly to ensure effective communication” was added. The description of some items was also revised. For example, “Clear and orderly language expression” was changed to “Be able to communicate with service objects in plain language”.
(2) Psychological adjustment: According to work pressures, occupational hazards, and the current occupational violence in hospitals (especially in China), nursing staff should have emotional control ability, so the item of “Control one's emotions effectively” was added.
(3) Ethics and legal application: The item to “Clarify the rights, obligations and responsibilities of serving objects in legal affairs” was inappropriate as “clarify” may not be sufficient and it needs to be practiced. This item was revised into “Be able to protect the legitimate rights and interests of service objects from infringement”. The item stating to “Make nursing records according to the nursing document writing requirements” was associated with professional practice ability and was inconsistent with humanistic practice ability. This was deleted and items on ethics and discretion were added.
(4) Nursing esthetic: The item of “With esthetic awareness” had poor operability. The item of “Apply the basic knowledge of nursing aesthetics to nursing practice” repeated other items, and so both of these two items were deleted.
(5) Caring practical: “Putting the needs of service objects first” was changed to “Meet the health needs of service objects actively”.

The experts did not raise objections in round two, and a measurement scale with 29 items in 5 dimensions was preliminarily formed.

The HPAN scale includes nursing communication ability, psychological adjustment ability, ethics and legal application ability, nursing esthetic ability, and caring practical ability. The scale includes 29 items in 5 dimensions rated on a five-point Likert scale (1 point: strongly disagree, 2 points: disagree, 3 points: uncertain, 4 points: agree, 5 points: strongly agree). The total value of the scale ranged from 29 to 145 points. Nursing staff were evaluated according to their actual situations and a higher score indicated a higher HPAN.

Evaluation of the HPAN scale

Setting and samples

Data were collected from 430 first-line clinical nurses in 4 first-class hospitals using the random number table sampling method.

The selection criteria were as follows: a nursing education background, have worked as a nurse for at least one year, have obtained a nurse practice qualification, have worked in internal medicine, surgery, obstetrics and gynecology, pediatrics, oncology, or the intensive care unit. All participants entered the study under informed consent and voluntary participation.

The exclusion criteria were as follows: nurses who were not on the regular payroll (e.g. interns and students) and nurses who do not work in the hospital while the scale was in progress (e.g. people on sick leave or who had retired).

According to the provisions of statistics on the survey sample size, the total sample should be calculated by 10 times that of the maximum items. In this study, there were 29 items, and so the total sample size should be 290. In addition, according to the recommendations of Osborne and Costello [25], an item ratio of 20:1 to the sample has higher accuracy (70%) compared with the 10:1 (60%) and the 5:1 (40%). As a larger sample improves the survey, based on 29 items and a dropout of 20.0% and considering the constraints of expenditure and a dropout rate of 15.0%, the final sample size was established to be 430. A total of 430 scales were issued. Four hundred twenty four scales were returned, and 406 valid scales were issued. The effective rate of the questionnaire was 95.8%. The first 290 of the 406 questionnaires were used to analyze exploratory factor analysis (EFA), and the last 116 questionnaires were used to analyze confirmatory factor analysis (CFA).

Data collection and input

Phase 1 was a scale survey. The investigators were composed of the members of the research group. The members were trained before the investigation. The training contents included the

purpose, significance, and procedure of the survey. The scales took 15 minutes to fill out and were completed anonymously. All the participants acted under written informed consent. The scales were collected immediately after completion. The investigators checked and verified the scales to ensure the credibility of the investigation. Experimental data were entered into Epidata, version 3.0 (The Epidata Association, Odense, Denmark), software by two members of the research group on two separate computers. The two independent data sets were compared and analyzed using a computer inspection program to ensure the accuracy of the data.

Data analysis

The collected data were analyzed using SPSS, version 15.0 (IBM. Corp., Armonk, NY, USA), and AMOS, version 17.0 (IBM. Corp., Armonk, NY, USA), software programs as follows:

(1) The characteristics of the participants such as frequency, percentage, and mean were analyzed by descriptive statistics.
(2) Item analysis was assessed using item-total correlation coefficients. The items that had correlation coefficients less than 0.4 [26] were deleted.
(3) In EFA, the principal axis factor was used to extract meaningful structures common to all items. Factor rotation was performed using the Varimax method of orthogonal rotation to facilitate the interpretation of the factor structure. To determine if the collected data were suitable for factor analysis, a Kaiser–Meyer–Olkin measure and Bartlett's test for sphericity were used.

The selection criteria for factors and items were as follows: The common factor eigenvalue was greater than 1.0 [27]; the factor load was greater than .40 [28,29]; the item was deleted and it was considered as being cross-loaded on two factors; and the difference of factor loading value was less than 0.2 [29].

4) In CFA, the fit indices were calculated by the χ^2 statistic (p-value), normed χ^2 [Chi-square minimum/degree of freedom], goodness of fit index, adjusted goodness of fit index (AGFI), comparative fit index (CFI), Tucker–Lewis Index (TLI), relative fit index (RFI), incremental fit index, normed fit index (NFI), and root mean square error of approximation (RMSEA). The reference values for each fitness index were $p > .05$ for χ^2, Chi-square minimum/degree of freedom < 3.0, AGFI > .80, NFI > .90, TLI > .90, CFI > .90, RFI > .90, RMSEA < .08 [30].
5) Convergent validity and discriminant validity were analyzed by construct reliability, average variance extracted, and Pearson correlation coefficients.
6) The reliability of the HPAN scale was assessed by the corrected item-total correlation and Cronbach's α, the internal consistency coefficient.

Ethical considerations

Every participant was informed of the study purpose, and written informed consent was obtained before the study. The participants voluntarily took part in the study, and all personal information remained confidential. The study was approved by the Ethical Review Board for Life Sciences of Xinxiang Medical University (Approval no. #2016-0310-01) and conformed to the requirements of the Declaration of Helsinki. Approval from the participating institutions was also obtained.

Results

General characteristics of participants

All the participants were women of which 70.4% were from an urban environment, 54.4% had a working age of less than 5 years, 51.7% were with junior college graduates, 43.8% had a bachelor's degree or higher qualification, and 80.8% had junior professional titles (nurses and senior nurses).

Validity and reliability of the scale

(1) Content validity: Based on the ratings from 16 experts on item relevance, the item CVI of 29 items was .97–1.00, and the scale CVI of the HPAN scale was .98. A minimum item CVI of .83 and scale CVI of .90 are acceptable according to the criteria recommended by Polit et al. [31]. The HPAN scale was judged as having excellent content validity.
(2) Item analysis: Item analysis was assessed using correlation coefficients, and all the items of correlation coefficients reached a level of significance, $p < .001$.
(3) EFA: SPSS, version 15.0, was used to determine the EFA. The Kaiser–Meyer–Olkin test of the factor analysis was .95, and Bartlett's spherical test χ^2 was 35882.97, $p < .001$. These data indicated that the variable was suitable for factor analysis. Principal component analysis method was adopted, and the maximum value method was used for direct rotation. The eigenvalue >1 [27] was the standard of the factor extracting in 5 common factors. The cumulative explained variation was 78.2% (Table 1). The eigenvalues of the five common factors,

Table 1 *The Component Matrix after Rotation of the Scale.*

Items	Component				
	1	2	3	4	5
Q29	.92	.20	.19	.18	.16
Q28	.92	.22	.19	.17	.16
Q25	.92	.22	.18	.16	.18
Q23	.91	.21	.18	.17	.17
Q27	.91	.22	.19	.17	.14
Q26	.90	.20	.20	.16	.17
Q24	.50	.35	.19	.29	.28
Q15	.21	.82	.25	.15	.09
Q12	.21	.82	.27	.18	.08
Q17	.23	.82	.27	.17	.11
Q13	.23	.74	.14	.14	.21
Q16	.25	.74	.14	.15	.20
Q14	.21	.64	.17	.22	.29
Q18	.23	.52	.21	.21	.21
Q4	.16	.24	.81	.06	.09
Q7	.16	.22	.81	.04	.09
Q3	.15	.17	.69	.19	.14
Q2	.14	.03	.66	.18	.15
Q5	.21	.19	.58	.13	.27
Q1	.17	.20	.58	.20	.12
Q6	.18	.22	.52	.24	.33
Q22	.26	.21	.22	.88	.22
Q19	.25	.22	.22	.88	.21
Q21	.24	.23	.23	.87	.21
Q20	.24	.23	.22	.87	.20
Q8	.24	.19	.23	.14	.85
Q11	.24	.18	.23	.15	.85
Q9	.16	.22	.19	.28	.70
Q10	.24	.19	.24	.28	.56
Eigenvalue explained	6.05	4.57	4.12	3.91	3.14
Variance (%) total	24.0	15.8	14.2	13.5	10.7
Variance (%)	78.2				

The extraction method used is principal component analysis. The rotation method used is the maximum variation method. Factor loadings ≥ .40.

the explained variances, the item loadings of each item, and the component matrix after rotation of the scale are shown in Table 1. As the scale was modified based on the original evaluating indexes and was perfected according to the experts consultation before the EFA, there were no items deleted in the EFA.

The final scale consisted of 29 items in 5 dimensions including 7 items of caring practical ability, 7 items of ethics and legal application ability, 4 items of nursing communication ability, 4 items of nursing esthetic ability, and 7 items of psychological adjustment ability. The last 14 items repeated EFA, changing the ordering of the eigenvalues of nursing communication ability and nursing esthetic ability. The communality of all the items was good with levels ranging from .49 to .92. The same items loaded on the same factors.

(4) CFA: The construct validity of the HPAN was examined using CFA. χ^2/df = 2.99, AGFI = .89, NFI = .97, TLI = .98, CFI = .98, RFI = .97, incremental fit index = .98, RMSEA = .05. The model fit indices met the criteria for goodness of fit (Table 2). The standardized regression weights for each item were .53-.88, demonstrating high factor loadings for each factor.
(5) Convergent and discriminant validity: The results of the correlation analysis between the factors are shown in Table 3. The construct reliability was also .82–.93, which was higher than the reference value of .70. These data indicated higher convergent validity [32]. The discriminant validity was tested using the average variance extracted values of all the subscales that were larger than the square of the correlation coefficients (R^2) (Table 2).
(6) Reliability test: The odd-even split-half method was used to calculate the split-half reliability. The split-half reliability coefficient of the scale was .98, and the Spearman–Brown coefficient of each dimension was .86–.99. The Cronbach's α coefficient of the scale was .96, and the Cronbach's α coefficient of each dimension was .87–.98 (Table 3). The correlation coefficients were all greater than 0.7 [33] indicating good stability of the HPAN scale.

Selection of HPAN measurement model

According to the reliability test of the HPAN scale and the EFA and CFA results, it was observed that the HPAN measurement model (Figure 2)—involving 29 items in 5 dimensions—can be used to calculate and analyze when measuring the HPAN. In addition, the simplified measurement model involving only 5 dimensions can be used to achieve the same results.

Table 3 *The Scale and Split-Half Coefficient.*

Dimensions	Items	Spearman–Brown coefficient	Cronbach's α coefficient
Nursing communication ability	7	.87	.87
Psychological adjustment ability	4	.86	.88
Ethics and legal application ability	7	.93	.93
Nursing esthetic ability	4	.96	.99
Caring practical ability	7	.99	.98
Total	29	.98	.96

Discussion

This study aimed to develop and improve the preliminary HPAN scale that has been previously reported by the authors. The purpose of the study was to enhance the mutual understanding of the psychometric properties of the HPAN scale among Chinese nurses. In this study, an HPAN scale consisting of 29 items was developed. On the theoretical framework of the previous scale, a new scale with high validity and reliability was developed.

Different standards and methods were used to develop the HPAN scale to represent the concept being measured. Content validity, item analysis, and EFA were used to ensure the number of the items. In the original assessment tool, we found that it was necessary to add items or use concrete terms. For example, the item "Clear and orderly language expression" was changed to "Be able to communicate with service objects in plain language" so that the item could be measured more easily.

As a result of the EFA, 5 factors were derived, and the total explanatory power was 78.2%, exceeding the standard value of 60% [34]. The total variance of the original HPAN assessment tool was 64.29%. In the HPAN scale, the eigenvalue of caring practice ability was 6.06, followed by ethics and legal application ability (4.57), nursing communication ability (4.12), nursing esthetic ability (3.91), and psychological adjustment ability (3.11). The eigenvalues of the five factors were similar.

In the original HPAN assessment tool, the eigenvalue of nursing esthetic ability was 3.74, followed by nursing communication ability (3.01), caring practical ability (2.91), legal

Table 2 *Results of Correlations and Confirmatory Factor Analysis (N = 406).*

Factors	Correlation between factors				AVE	CR
	1(r)	2(r)	3(r)	4(r)		
1 Nursing communication ability (n = 7)					.75	.93
2 Psychological adjustment ability (n = 4)	.43				.69	.86
3 Ethics and legal application ability (n = 7)	.36	.41			. 68	.89
4 Nursing esthetic ability (n = 4)	.40	.39	.38		.63	.82
5 Caring practical ability (n = 7)	.42	.37	.42	.49	.70	.91

Fitness index	χ^2 (*p*)	CMIN/df	AGFI	NFI	TLI	CFI	RFI	IFI	RMSEA
Reference values	<.05	<3.0	>.80	>.90	>.90	>.90	>.90	>.90	<.08
Model	.00	2.99	.89	.97	.98	.98	.97	.98	.05

Note. AGFI = adjusted goodness of fit index; AVE = average variance extracted; CFI = comparative fit index; CMIN/df = Chi-square minimum/degree of freedom; CR = construct reliability; IFI = incremental fit index; NFI = normed fit index; RFI = relative fit index; RMSEA = root mean square error of approximation; TLI = Tucker– Lewis Index.

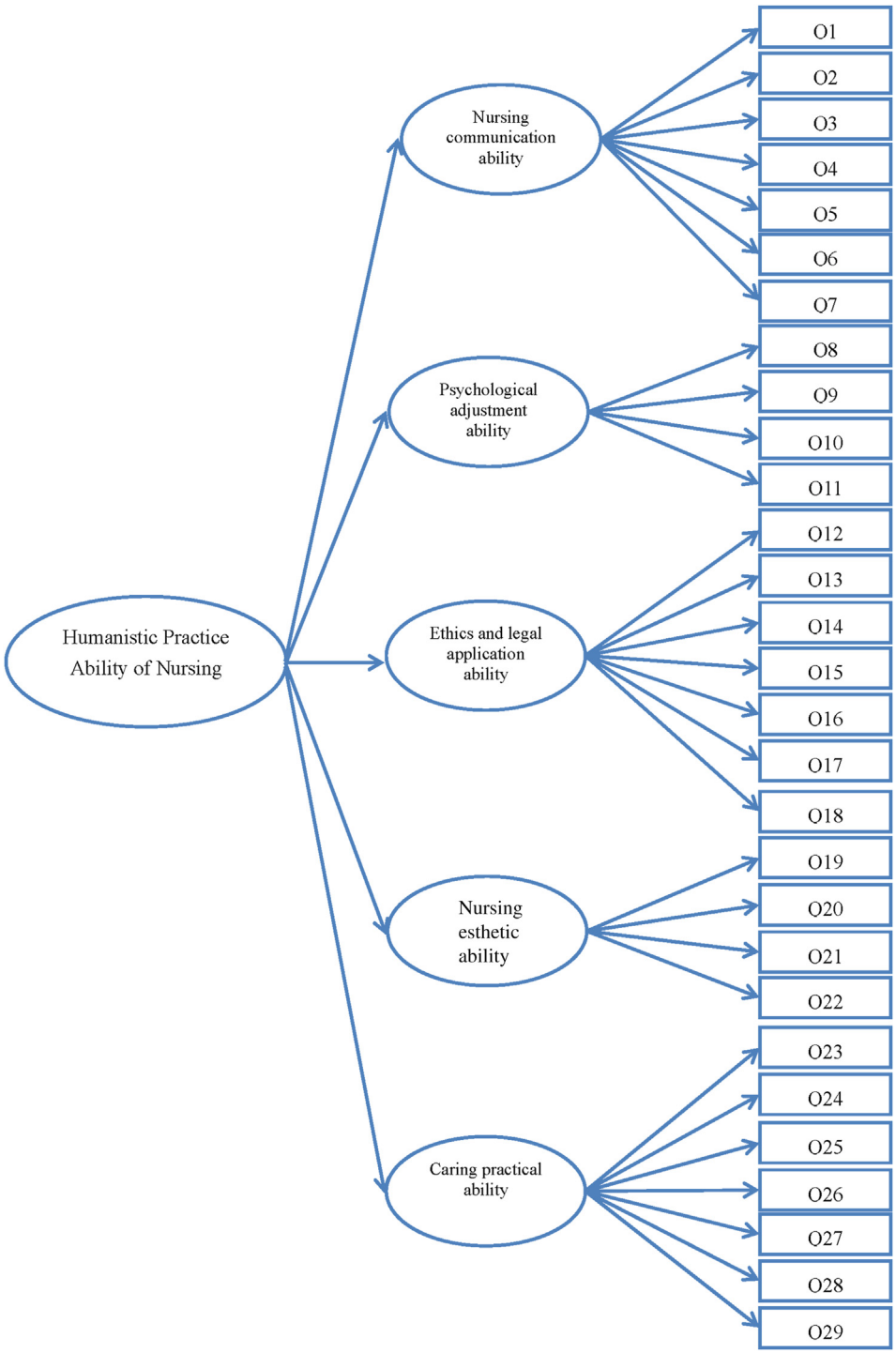

Figure 2. Humanistic Practice Ability of Nursing Measurement Model.

application ability (2.86), and psychological adaption ability (2.25) [11]. The eigenvalues of the five factors were similar too. These findings indicated that in both the HPAN scale and the original assessment tool, the caring practical ability, ethics and legal application ability, nursing communication ability, nursing esthetic ability, and psychological adjustment ability accounted for a comparable percentage of variance in the item scores. In addition, the HPAN scale was found to be an effective scale as the factor loadings of all the items belonging to each factor exceeded 0.5 [26].

Analyses of the model fit through CFA showed that all fit indexed met the recommended criteria [28,32]. These data indicated that the 5 factors fitted well as first-level indicators of the scale and could better evaluate the internal structure of HPAN. In addition, the results of convergent validity and discriminant validity analyses show that the items constituting each factor of the HPAN scale were correlated with each other while at the same time were different from the items constituting the other factors. The five factors are interrelated and together measuring the unique attributes of HPAN.

The Cronbach's α value of the HPAN scale factors was between .87 and .99, and the Spearman–Brown coefficient ranged from .86 to .99. These results indicated that the scale had good internal consistency. Internal consistency reliability is influenced by the number of items, and the more the items, the higher the reliability [35].

A major source of response bias is carelessness due to fatigue, and it is suggested to keep the number of items to a minimum [36]. However, as the number of items decreases, so does the Cronbach's α [34]. In the development of the HPAN scale with 29 items, it was important to maintain adequate reliability.

This study developed a valid and highly reliable measurement model to provide an objective, quantitative, and operational standard to evaluate the HPAN. This study also provided a basis for future empirical research to explore the complex relationships between HPAN and various causal variables.

The limitations and suggestions to improve this study are as follows:

(1) The measurement of HPAN in this study was a subjective measurement item. Although subjective measurements are generally accepted in behavioral science, objective measurement items should be considered in future studies.
(2) This article only established the HPAN measurement model. Empirical research is still needed in future studies to continuously apply and optimize the design of the scale and to further explore the relationship between HPAN and complex various antecedents and consequences. Time series data should be used to avoid the limitations of cross-sectional data and truly determine the relationships between exploratory variables.
(3) Owing to regional constraints, the cultural views and homogeneity of the participants are limited in this study. It is necessary to conduct a survey on nurses in different regions in the future to reevaluate the psychometric properties of the HPAN scale in different samples of various cultures.

Conclusions

The present study defined the concept and the operational definition of five subcapabilities of HPAN. We also developed and tested the HPAN scale with 5 factors and 29 items to establish the measurement model of HPAN. The findings presented in this study provided psychometric evidence for the application of the HPAN scale among clinical nurses. As the HPAN is of great importance in nursing, this scale is expected to be widely used in the research and further development of HPAN. Larger samples in various cultures and regions studies are needed to estimate the reliability and validity of the HPAN scale.

Ethics approval and consent to participate

Every participant was told of the study purpose, and informed consent was obtained orally and in writing before the survey, which assured their participation in the study was voluntary. This study was approved by the Ethical Review Board for Life Sciences of Xinxiang Medical University (Approval no. #2016-0310-01) and conformed to the requirements of the Declaration of Helsinki. Approval from the participating institutions was also obtained. The data of the participants were kept confidential and used for academic research only.

Consent for publication

The authors and participants all consent to publication.

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Conflicts of interest

The authors declare 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.2020.12.003.

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Research Article

Personal Listening Device Use Habits, Listening Belief, and Perceived Change in Hearing Among Adolescents

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ABSTRACT

Purpose: This study aimed to identify personal listening device (PLD) usage habits, listening belief, and perceived change in hearing, and to investigate how the variables related to perceived change in hearing among adolescents.
Methods: The participants were 183 middle school students and 233 high school students from Ulsan. Data were collected by self-reported questionnaires from August 1, 2019, to October 22, 2019, and analyzed with descriptive statistics, χ^2 test, Mann–Whitney U test, and hierarchical multiple logistic regression.
Results: Most students started to use PLDs from elementary school, and mean preferred listening level was 70.13 dB. Mean perceived susceptibility to music-induced hearing loss (MIHL) and perceived barriers to prevent MIHL were 5.18 and 3.40, respectively. Perceived change in hearing was reported on 14.2% of middle school students and 32.2% of high school students, and as the average score of perceived barriers to prevent MIHL increases by one point, the odds of decrease in hearing increase by 2.05 times ($p < .001$) and 1.35 times ($p < .05$), respectively.
Conclusion: Considering that most adolescents are exposed to PLD in elementary schools and about a quarter experienced a decrease in hearing after PLD use, educational programs on hearing conservation are required to start as early as in schools. Particularly, knowledge and skills to overcome barriers to prevent MIHL should be emphasized in educational programs.

Introduction

Noise-induced hearing loss is caused by damage to the inner ear sensory cells after prolonged exposure to noise environment [1], and as this damage begins to progress slowly, people do not recognize the hearing damage until a serious irreversible level is reached [2]. It has been mainly related to noise exposure to work, but in recent years, personal noise exposure has been increasing in leisure activities, and health concerns about it have increased [1]. Personal listening devices (PLDs) from cassette tapes to smartphones are major sources of noise during leisure activities [3]. More than 90% of Korean adolescents use mobile phones or smartphones [4], and 98.8% of them enjoy listening to music through the Internet, watching videos, and playing online games as leisure activities [5].

Hearing damage caused by noise is cumulative, so the longer the exposure time to noise, the greater the risk of hearing loss [6], as well as negative consequences impacting individual cognitive function, social well-being or quality of life, and academic achievement or employment opportunities [1,7]. Therefore, adolescents are thought to be especially vulnerable to noise and important period in their life to prevent hearing loss. Most adolescents expose to PLDs daily or several times per week for longer periods [8] and more than half of the PLDs users exceed the daily noise limit [9], but most are unaware of the risk because the negative consequence occurs later [10]. According to a previous study, 17.0% of first-year Korean middle and high school students revealed hearing loss during their hearing screen test in 2016 [11]. Therefore, healthy listening behavior such as PLDs use of safe listening volume is very important for adolescents to prevent hearing loss.

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Accordingly, the maximum permissible volume of portable sound systems has been newly amended as per the Noise and Vibration Control Act (Article 45-3) to limit the maximum volume to 100 dB [12], but the peak volume of PLDs released since 2014 was still measured over 100 dB [13,14]. The situation is similar in other countries. For example, in Canada, modern digital audio players tended to exceed the noise exposure limit because the measured maximum volume among modern digital audio players was from 101 to 107 dB [15]. That is, it is necessary but insufficient to enact regulations at the national level to prevent hearing loss among PLDs users. In particular, like most adolescents, although the peak volume levels of PLDs keep under the noise exposure limit, prolonged listening time cannot avoid the risk of hearing loss [16]. Fortunately, PLDs users can minimize the exposure level of noise by adjusting the volume or listening times voluntarily unlike occupational noise sources.

As the risk of hearing loss because of unhealthy listening behaviors with PLDs among adolescents is increasing, a few studies have identified the relationship between personal factors, PLDs usage habits, and hearing loss among adolescents. Besides listening volume [9], hearing loss during leisure activities including PLDs use has known to be related to ear diseases such as tinnitus [8] or ear infection [11], daily exposure time [3,17], exposure duration [18], and headphone use [11]. Recently, cognitive variables such as belief about listening volume (listening belief) have been considered as risk factors of PLDs usage habits. Health beliefs are well-known factors that influence health behaviors, and Health Belief Model [19] has been identified as particularly effective in explaining the relationship between health beliefs and preventative health behaviors [20]. Listening belief was measured using listening habits questionnaire developed according to Health Belief Model [19], and was shown the relation to the preferred listening level (PLL). Adolescents' PLL increased with increasing perceived barriers to prevent music-induced hearing loss (MIHL) and decreased with increasing perceived benefits of preventing MIHL. However, the relationship between listening belief and change in hearing among adolescents has not been reported in the previous study [21]. Even in Korea, the studies to investigate PLDs usage habits, listening belief, and their relation to change in hearing among adolescents are currently very limited.

Under the background, this study was aimed to identify PLDs usage habits, listening belief, and perceived change in hearing, and to investigate how the variables related to perceived change in hearing among adolescents in Korea. Meanwhile, high school students showed more PLDs users, longer listening time, and higher level of volume than middle school students did in previous studies in Korea [17,22]. Considering the differences in PLDs use characteristics according to school level, we tried subgroup analyses according to school level.

Methods

Study participants

The participants of this cross-sectional study were first-year students at general middle and high schools in Ulsan, currently listening to music using their PLDs with earphones, who understood the purpose and method of this study, and agreed to participate in it by themselves and their parents. The students of the special purpose of schools and arts high schools were excluded due to different patterns of school life compared to those who attend the general schools. The sample size of this study was calculated using G·Power version 3.1.9.4 [23]. The significance level was set at (α) .05, statistical power at (1-β) .85, and the effect size at $P_1 = .20$, $P_2 = .48$, which is calculated from the previous study that analyzed the relationship between listening levels and hearing loss among 17-year-old Swedish adolescents [8]; the proportion of adolescents exposed to high-level noise above 85 dB was 20.0% in the normal hearing group and 48.0% in the hearing loss group. Likewise, according to a study [11], 17.0% of adolescents reported hearing loss during the Korean adolescent health screening test, and the ratio of the hearing loss group to the normal hearing group was considered to be 1:5. Within this condition, the minimal number of samples required was 167 (normal hearing group: 139; hearing loss group: 28), and considering the 25.0% dropout rate, 208 participants with an additional 42 participants were required. Participants in this study were separately sampled from middle schools and high schools, and this number comprised 2.0% of 10,148 first graders from middle school and 10,308 first graders from high school as of 2019 in Ulsan [24].

The participants were recruited with two stages stratified sampling; school level (middle vs. high) and gender (boy vs. girl). About 60 middle schools and 52 high schools, six middle schools (1 girls', 1 boys', and 4 coeducational schools), and seven high schools (1 girls', 1 boys', 3 coeducational, and 2 vocational schools) were agreed to participate in the study. One class was randomly selected from each school, and all students in the class were asked to participate in the study. Finally, 183 middle school students (93 boys and 90 girls) and 233 high school students (110 boys and 123 girls) were included in the study.

Study instruments

The tools for this study were a structured self-administered questionnaire composed of explanatory variables (general characteristics, PLDs usage habits, listening belief) and an outcome variable (perceived change in hearing).

General characteristics included gender, school level, and history of ear diseases (tinnitus, ear pain, or ear infection) based on the previous studies [8,11]. PLDs usage habits included the number of PLDs, the first time that PLDs was used, the common place of PLDs use, type of earphones, listening days per week and listening hours per day, and PLL. The period of PLDs use was calculated from the difference between age and the first time PLDs were used. The type of earphones is presented with pictures of earphones, over the ear type, earbuds type, and in-ear type, and one selected type of earphone is usually used. The listening time per week was calculated as the product of listening days per week and listening hours per day, which were also presented with a picture of a 24-hour clock to minimize the recall bias. PLL was measured by asking to select their typical setting on the volume control from 1 to 15 steps while listening to the provided music, and the volume at the setting was converted to dB according to Min's [25] study. For measuring PLL, many researchers assessed it using a self-reported questionnaire because of difficulties while listening to music with earphones [11,26]. However, the validity of self-reported method for PLL measurements has not yet been established, and is unclear how well they reflect actual PLL [21]. Although the laboratory measurements using either a microphone-in-real-ear technique [27] or a technique using a manikin with an ear-simulating microphone [28] are more accurate and reliable than self-report measurements, we could not use those measurements because of lack of equipment. Instead, we additionally asked the participants to rate the preferred volume using a 10-point visual analog scale, when the maximum volume of their PLDs was assumed to be 10. For example, if a student usually listens to music at level 6 using a PLD with 12 levels of volume, he/she was asked to mark 5 on the scale. Both methods showed good agreement with .60–.70 of intraclass correlation coefficient [29]. As PLL was not met the

normality assumption, in the analysis process, we classified it based on 70 dB (>70 dB and ≤70 dB), which means loud noise [30].

Listening belief was measured with Listening Habit Questionnaire [21]. After obtaining permission from the author, the researcher translated the questionnaire into Korean and two experts, a bilingual English teacher and a nursing professor, reviewed original and Korean translations to evaluate the validity of the translated tools and the appropriateness of words and phrases. After the first preliminary survey with five middle school students and five high school students who were not eligible for the research, the meaning of the Likert score was expressed in Korean to make it clear. Original listening habits questionnaire includes five variables and 26 items; four items of perceived susceptibility to MIHL, six items of perceived severity of MIHL, seven items of perceived benefits to prevent MIHL, four items of perceived barriers to prevent MIHL, and five items of perceived self-efficacy for taking action to prevent MIHL. Each item is a seven-point Likert scale from "Not at all (1 point)" to "Very much so (7 points)," indicating the higher the score, the higher perceived susceptibility, severity, benefits, barriers, and self-efficacy, respectively. The average score for each variable is calculated but not the total sum for all variables [21]. At the listening habits questionnaire development stage, the correlation between the listening level measured by a laboratory test and the self-reported measurement was from .31 to .68, and the Cronbach's α was from .81 to .89 [21]. In this study, Cronbach's α was .63 and .66 for perceived susceptibility, .86 and .92 for perceived severity, .85 and .85 for perceived benefits, .87 and .86 for perceived barriers, and .89 and .87 for perceived self-efficacy for middle school students, and high school students, respectively. After deleting item number 4 item, the Cronbach's α of perceived susceptibility were improved on .71 and .69, respectively. The values were almost recommended level [31], so we measured perceived susceptibility with 3 items.

Perceived change in hearing was defined as "no change," "slightly worse," "worse" to the question, "After PLDs use, have you ever experienced any change in hearing ability?" In the analysis process, "slightly worse" and "worse" were classified as "decreased" (1), and "no change" was classified as "no change" (0).

Data collection

Data were collected from August 1, 2019, to October 22, 2019. The researcher visited the study schools in person and explained the purpose and method of this study to the principals and teachers and asked for cooperation. Schools participating in this study posted notices for recruitment on the first grade bulletin board and school health office bulletin board 1 week before the survey. Students who were willing to take part in the survey were provided with assent and consent forms from the school nurse, and then were asked to read the explanations with their parents at home and sign the consent form. Students who agreed to participate in the study visited the survey site (a school nurse's office or an empty classroom, which was provided by the school) on a prescribed date, submitted the consent form to the researcher, and completed the questionnaire. After completing the questionnaire, the student measured the listening level in the same place. To measure the PLL, the researcher provides in-ear earphones (QuietComfort® 20 of Bose Corporation, Framingham, USA) connected to the smartphone to the student and asked them to wear the earphones, and then while listening to music, Hyuk-Oh's Tom Boy, and asked the student to inform the student of the usually comfortable listening level with raising the level step by step according to student's response. During the measured listening level test, the range of background noise was from 45 to 53 dB, which was measured by a noise meter (TES-53S, Taiwan) within 50 cm of the student in a quiet environment. The collected survey and measured data were encrypted and stored in the locker storage box and the researcher's computer. The students who participated in this study were offered a small gift (school supplies).

Data analysis

The collected data were tested on both sides at significance level (α) .05 using the IBM SPSS win (version 26) program (IBM Corp., Armonk, NY, USA); the specific analysis method is as follows:

1. The variables in the study were analyzed by frequency and percentage or average and standard deviation, and were compared according to school level with χ^2 test and Mann–Whitney *U* test.
2. The relationship between explanatory variables and outcome variable was analyzed using the χ^2 test and Mann–Whitney *U* test according to school level.
3. Hierarchical multiple logistic regression analysis was conducted to identify the related factors of perceived change in hearing according to school level. Multicollinearity was assessed based on the correlation coefficient ≥ .85. Variables were entered into the model in a series of steps, and the order for entry was general characteristics, PLDs usage habits, and listening belief. The relationship between each variable and perceived change in hearing was determined by the odds ratio and 95% confidence intervals.

Ethical consideration

This study was approved by Pusan National University Institutional Review Board (Approval no. 2019-69-HR) and was conducted according to the criteria approved by the committee. Written informed assent and consent were obtained from all participants and their parents after informing them about the possibility of withdrawal from this study, and kept confidentiality of participants' information.

Results

Characteristics of the variables in the study according to school level

The results of analyzing the variables in the study are presented in Table 1. For middle school students, 73.8% of them have had a history of ear diseases, most of them have used a smartphone as PLDs and in-ear type of headphone, mean total period of PLDs use was 3.52 years, and mean listening time per week was 15.34 hours. Mean PLL was 70.57 dB and 31.7% of them showed greater than 70 dB. Mean perceived susceptibility and barriers was 5.02 and 3.02, respectively, and 14.2% of them showed a decrease in hearing after PLDs use. For high school students, 85.8% of them have had a history of ear diseases, most of them have used a smartphone as PLDs and in-ear type of headphone, mean total period of PLDs use was 6.26 years, and mean listening time per week was 20.14 hours. Mean PLL was 69.79 dB and 34.8% of them showed greater than 70 dB. Mean perceived susceptibility and barriers were 5.31 and 3.70, respectively, and 32.2% of them showed a decrease in hearing after PLDs use.

Therefore, middle school students showed a higher mean score of the perceived benefits ($p = .036$), perceived self-efficac < ($p = .004$), and lower perceived barriers ($p < .001$) than high school students. However, history of ear disease ($p = .002$), the period of PLDs used ($p < .001$), listening to PLDs at school ($p < .001$),

listening hours per week ($p = .012$), perceived susceptibility ($p = .005$), and perceived change in hearing ($p < .001$) were higher in high school students than in middle school students.

The relationship between explanatory variables perceived change in hearing

The results of bivariate analysis between explanatory variables and perceived change in hearing are presented in Table 2. The perceived change in hearing was related to gender ($p = .034$), history of ear diseases ($p = .027$), period of PLDs use ($p = .002$), PLL ($p = .029$), perceived susceptibility ($p = .008$), perceived benefits ($p = .011$), perceived barriers ($p < .001$), and perceived self-efficacy ($p < .001$). For middle school students, the perceived change in hearing was related to only listening belief such as perceived susceptibility ($p = .048$) and perceived barriers ($p < .001$). For high school students, PLL ($p = .022$), perceived barriers ($p < .001$), and perceived self-efficacy ($p < .001$) were related to perceived change in hearing.

The related factors to perceived change in hearing

According to the results of multiple logistic regression in Table 3, the perceived change in hearing was influenced by perceived susceptibility, perceived severity, and perceived barriers. As the average score of perceived susceptibility and perceived barriers increases by one point, the odds of decrease in hearing increase by 1.83 times ($p < .001$) and 1.58 times ($p < .001$), respectively. For both middle and high school students, the perceived change in hearing was influenced by perceived susceptibility and perceived barriers. As the average score of perceived barriers increases by one point, the odds of decrease in hearing increase by 2.05 times ($p < .001$) and 1.35 times ($p < .05$), respectively.

Discussion

Regarding the PLDs usage habits, the most common PLDs were smartphones, regardless of school level, which reflects the increase in the use of smartphones by teenagers [4]. Most participants started to use PLDs at grades 4–6 of elementary school, therefore, in order to establish healthy PLDs usage habits, appropriate hearing conservation programs should be initiated at least the first year of elementary school. Most adolescents spend about 2.5 hours a day on their PLDs on average, indicating an increase in listening time compared to a previous study [22]. This finding may be explained not only by improving the prolonged battery life of PLDs and large amount of PLDs' storage space [32], but also by a data collection method. That is, we presented a picture of a clock to collect data on the time spent listening to PLDs to minimize the memory bias of the participants and fluctuations by the day of the week for PLDs usage. For listening level, which is a pivotal factor for hearing loss [8], about a third of the middle and high school students selected

Table 1 *Characteristics of the Variables in the Study According to School Level (N = 416).*

Characteristics	Categories	n(%) or mean ± SD			X^2/Z^a	*p*
		Total (n = 416)	Middle school students (n = 183)	High school Students (n = 233)		
General characteristics						
Gender	Boys	203 (48.8)	93 (50.8)	110 (47.2)	0.53	.465
	Girls	213 (51.2)	90 (49.2)	123 (52.8)		
History of ear diseases		335 (80.5)	135 (73.8)	200 (85.8)	9.52	.002
PLD use habits						
Type of PLDs	Smartphone	404 (97.1)	179 (97.8)	225 (96.6)	0.57	.450
(multiple responses)	Laptop/Desktop	162 (38.9)	64 (35.0)	98 (42.1)	2.17	.141
	Tablet PC	69 (16.6)	32 (17.5)	37 (15.9)	0.19	.662
	MP3 player	24 (5.8)	13 (7.1)	11 (4.7)	1.07	.301
Number of PLDs	Mean ± SD	1.58 ± 0.66	1.57 ± 0.67	1.59 ± 0.66	−0.38	.713
First time to use PLDs	Before ES	32 (7.7)	11 (6.0)	21 (9.0)	17.75	<.001
	ES 1 to 3	160 (38.5)	75 (41.0)	85 (36.5)		
	ES 4 to 6	187 (44.9)	92 (50.3)	95 (40.8)		
	Middle school	37 (8.9)	5 (2.7)	32 (13.7)		
Period of PLDs use (years)	Mean ± SD	5.06 ± 2.48	3.52 ± 1.86	6.26 ± 2.22	−11.10	<.001
Place of PLDs use	On the road	238 (57.2)	98 (53.6)	140 (60.1)	1.79	.181
(multiple responses)	At school	93 (22.4)	21 (11.5)	72 (30.9)	22.28	<.001
	At home	367 (88.2)	162 (88.5)	205 (88.0)	0.03	.865
	Others	173 (41.6)	70 (38.3)	103 (44.2)	1.50	.221
Headphone type	In-ear	341 (82.0)	147 (80.3)	194 (83.3)	0.81	.666
	Over-ear	48 (11.5)	24 (13.1)	15 (6.4)		
	Earbud	27 (6.5)	12 (6.6)	24 (10.3)		
Listening time (hours per week)		18.00 ± 17.08	15.34 ± 14.92	20.14 ± 18.42	−2.50	.012
Preferred listening level	≤70	277 (66.6)	125 (68.3)	152 (65.2)	1.61	.448
(dB)[b]	>70, <85	114 (27.4)	50 (27.3)	64 (27.5)		
	≥85	25 (6.0)	8 (4.4)	17 (7.3)		
	Mean ± SD	70.13 ± 8.01	70.57 ± 6.55	69.79 ± 9.00	1.73	.083
Listening belief						
Perceived susceptibility to MIHL		5.18 ± 1.12	5.02 ± 1.15	5.31 ± 1.07	−2.78	.005
Perceived severity of MIHL		6.44 ± 0.86	6.44 ± 0.79	6.44 ± 0.91	−1.39	.165
Perceived benefit to prevent MIHL		5.86 ± 0.87	5.98 ± 0.82	5.77 ± 0.90	−2.10	.036
Perceived barriers to prevent MIHL		3.40 ± 1.52	3.02 ± 1.39	3.70 ± 1.54	−4.35	<.001
Perceived self-efficacy to prevent MIHL		5.48 ± 1.09	5.65 ± 1.02	5.34 ± 1.12	2.89	.004
Outcome variable						
Perceived change in hearing	No change	315 (75.7)	157 (85.8)	158 (67.8)	18.03	<.001
	Decreased	101 (24.3)	26 (14.2)	75 (32.2)		

Note. ES = elementary school; MIHL = music-induced hearing loss; PC = personal computer; PLDs: personal listening devices; SD = standard deviation.
[a] Mann–Whitney *U* test.
[b] Listening level measured in stage was converted to dB according to Min's study [25].

Table 2 *Relationship Between Explanatory Variables and Perceived Change in Hearing (N = 416).*

Characteristics	Total (n = 416) n (%) or mean ± SD		X^2/Z[a]	*p*	Middle school students (n = 183) n (%) or mean ± SD		X^2/Z[a]	*p*	High school students (n = 233) n (%) or mean ± SD		X^2/Z[a]	*p*
	No change	Decreased			No change	Decreased			No change	Decreased		
General characteristics												
Gender Boys	163 (51.7)	40 (39.6)	4.51	.034	82 (52.2)	11 (42.3)	0.88	.349	81 (51.3)	29 (38.7)	3.24	.072
Girls	152 (48.3)	61 (60.4)			75 (47.8)	15 (57.7)			77 (48.7)	46 (61.3)		
History of ear diseases	246 (78.1)	89 (88.1)	4.90	.027	113 (72.0)	22 (84.6)	1.84	.175	133 (84.2)	67 (89.3)	1.11	.292
PLDs use habits												
Number of PLDs	1.57 ± 0.66	1.64 ± 0.67	−1.10	.270	1.55 ± 0.66	1.73 ± 0.72	−1.28	.202	1.58 ± 0.66	1.61 ± 0.66	−0.41	.686
Period of PLDs use (yrars)	4.84 ± 2.49	5.72 ± 2.33	−3.09	.002	3.48 ± 1.91	3.77 ± 1.56	−0.84	.400	6.20 ± 2.25	6.40 ± 2.17	−0.68	.499
PLDs use on the road	174 (55.2)	64 (63.4)	2.06	.151	81 (51.6)	17 (65.4)	1.71	.192	93 (58.9)	47 (62.7)	0.31	.579
In-ear type headphone	255 (81.0)	86 (85.1)	0.91	.340	125 (79.6)	22 (84.6)	0.35	.553	130 (82.3)	64 (85.3)	0.34	.560
Listening time (h/wk)	17.21 ± 16.49	20.45 ± 18.69	−1.53	.126	14.36 ± 13.31	20.71 ± 21.37	−1.32	.187	20.04 ± 18.75	20.36 ± 17.82	−0.37	.709
Preferred listening level (dB)[b]	69.58 ± 7.67	71.85 ± 8.81	−2.19	.029	70.31 ± 6.37	72.10 ± 7.45	−1.17	.241	68.86 ± 8.74	71.76 ± 9.27	−2.29	.022
Listening beliefs												
Perceived susceptibility to MIHL	5.09 ± 1.17	5.47 ± 0.87	−2.66	.008	4.95 ± 1.19	5.45 ± 0.78	−1.98	.048	5.24 ± 1.14	5.47 ± 0.91	−1.30	.194
Perceived severity of MIHL	6.45 ± 0.90	6.41 ± 0.71	−1.60	.109	6.44 ± 0.83	6.44 ± 0.45	−1.23	.219	6.46 ± 0.98	6.40 ± 0.78	−1.47	.141
Perceived benefit to prevent MIHL	5.92 ± 0.89	5.69 ± 0.80	−2.54	.011	6.00 ± 0.87	5.85 ± 0.49	−1.44	.151	5.84 ± 0.91	5.63 ± 0.87	−1.66	.097
Perceived barriers to prevent MIHL	3.12 ± 1.49	4.26 ± 1.27	−6.49	<.001	2.85 ± 1.36	4.07 ± 1.10	−3.92	<.001	3.40 ± 1.55	4.33 ± 1.32	−4.27	<.001
Perceived self-efficacy to prevent MIHL	5.62 ± 1.05	5.03 ± 1.08	−4.55	<.001	5.69 ± 1.05	5.45 ± 0.82	−1.30	.194	5.55 ± 1.05	4.89 ± 1.13	−4.06	<.001

Note. MIHL = music-induced hearing loss; PLDs = personal listening devices; SD = standard deviation.

[a] Mann–Whitney *U* test.

[b] Listening level measured in stage was converted to dB according to Min's study [25].

Table 3 *The Related Factors to Perceived Change in Hearing (N = 416).*

Characteristics	Total (n = 416) OR (95% CI)			Middle school students (n = 183) OR (95% CI)			High school students (n = 233) OR (95% CI)		
	Step 1	Step 2	Step 3	Step 1	Step 2	Step 3	Step 1	Step 2	Step 3
General characteristics									
Boys	0.65 (0.41–1.02)	0.64 (0.40–1.03)	0.67 (0.40–1.12)	0.74 (0.32–1.74)	0.56 (0.20–1.55)	0.68 (0.23–2.03)	0.61 (0.35–1.07)	0.57 (0.32–1.01)	0.61 (0.33–1.14)
History of ear diseases	1.95 (1.00–3.79)*	1.73 (0.87–3.42)	1.41 (0.67–2.96)	2.01 (0.65–6.26)	1.85 (0.57–5.97)	1.74 (0.45–6.75)	1.52 (0.65–3.56)	1.51 (0.63–3.63)	1.30 (0.50–3.36)
PLDs use habits									
Number of PLDs		1.09 (0.77–1.54)	1.12 (0.76–1.63)		1.22 (0.65–2.27)	1.23 (0.62–2.43)		1.08 (0.70–1.67)	1.08 (0.68–1.71)
Period of PLDs use (yr)		1.11 (1.01–1.23)*	1.09 (0.98–1.22)		0.95 (0.73–1.24)	0.93 (0.69–1.26)		1.02 (0.89–1.16)	1.06 (0.92–1.23)
PLDs use on the road		1.18 (0.71–1.95)	1.19 (0.69–2.06)		1.50 (0.59–3.83)	1.51 (0.53–4.30)		1.19 (0.63–2.22)	1.12 (0.56–2.22)
In-ear type headphone		1.08 (0.57–2.08)	1.03 (0.51–2.08)		0.96 (0.27–3.36)	0.88 (0.22–3.63)		1.08 (0.49–2.38)	1.05 (0.45–2.44)
Listening time (h/wk)		1.00 (0.99–1.02)	1.00 (0.99–1.02)		1.02 (0.99–1.05)	1.02 (0.99–1.05)		0.99 (0.98–1.01)	1.00 (0.98–1.01)
Preferred listening levels (dB)[a]		1.03 (1.00–1.06)*	1.01 (0.98–1.05)		1.03 (0.96–1.11)	1.01 (0.94–1.08)		1.04 (1.01–1.07)*	1.02 (0.98–1.06)
Listening belief									
Perceived susceptibility to MIHL			1.83 (1.36–2.47)***			1.99 (1.15–3.45)*			1.65 (1.14–2.39)**
Perceived severity of MIHL			0.69 (0.48–0.98)*			0.67 (0.31–1.45)			0.73 (0.48–1.11)
Perceived benefit to prevent MIHL			0.88 (0.63–1.23)			0.82 (0.41–1.65)			0.94 (0.63–1.39)
Perceived barriers to prevent MIHL			1.58 (1.30–1.93)***			2.05 (1.37–3.01)***			1.35 (1.06–1.72)*
Perceived self-efficacy to prevent MIHL			0.77 (0.58–1.01)			0.95 (0.55–1.66)			0.70 (0.50–0.97)*
Nagelkerke R^2	.03	.08	.26	.02	.08	.28	.03	.06	.21

Note. CI = confidence interval; MIHL = music-induced hearing loss; OR = odds ratio; PLDs = personal listening devices.
*$p < .05$, **$p < .01$, *** p lt; .001.
[a] Listening level measured in stage was converted to dB according to Min's study [25].

more than 70 dB as PLL. However, considering that the PLL was measured in a quiet environment in this study, it is expected that most adolescents expose to loud noise level during daily life. The mean PLL in this study were lower than results from Malaysia adolescents using in-ear earphones [22]; and Israel girls with ear-bud earphones [10]. The difference among studies may reflect the actual listening level, but it might be related to the difference in earphone type. PLL decreased significantly as the location of the earphones was far from the eardrum, in the order of headphones, ear-bud earphones, and in-ear earphones [33].

Among the listening belief constructs, perceived severity showed the highest and perceived barriers were the lowest for both middle and high school students, which was the similar order to the previous study in the United States [21]. That is, adolescents strongly agree that hearing loss will make life uncomfortable. By school level, high school students showed higher perceived susceptibility, perceived barriers, as well as lower perceived benefits and perceived self-efficacy than middle school students. Students with severer hearing symptoms (ear pain, tinnitus, and hearing loss) are known to have more concern about their hearing and negative attitude toward the noise [34]. In this study, those who have a history of ear diseases and perceived change in hearing are higher in high school students than middle school students, which seems to be related higher perceived susceptibility in high school students. In addition, high school students became accustomed to loud levels of PLDs with prolonged use, but they have little chances to learn how to prevent MIHL because of lack in educational programs on hearing conservation [35]. According to the serial mediation approach to Health Belief Model, those with exposure to campaign or education to prevent MIHL may perceive fewer barriers, those who perceive fewer barriers may perceive more benefits to prevent MIHL, and those who perceive more benefits may participate in healthy listening behaviors to prevent MIHL [36]. Meanwhile, this study participant felt more susceptible to MIHL than US adolescents in a Portnuff et al.'s study [21], which may be related to cultural difference. Adolescents in the United States expose more diverse noise sources not only music and leisure activities but also shooting/use of firearms and lawn mowing [37], and may feel less susceptible to hearing loss because of listening to music. However, considering the poor internal consistency of perceived susceptibility in this study, and small sample size (n = 26) in Portnuff et al.'s study [21], further studies are recommended to identify the consistency of the findings.

About one in four adolescents perceived change in hearing after PLDs use, which shows higher hearing impairment compared to the 15.6% of health examination in 2016 [11]. However, this study finding depends on the subjective responses, there may be information bias. By school level, high school students had twice as much perceived change in hearing as middle school students. Considering that mean PLL is similar in both groups, it is thought that high school students have been exposed to PLDs for a longer period than middle school students. Regardless of the school level, perceived change in hearing was consistently related to perceived barriers to MIHL. Those who perceive higher barriers to prevent MIHL showed a higher possibility to experience a decrease in hearing after PLDs use. Perceive barriers as one of the components of the Health Belief Model has been used to explain the relation to health behaviors [19,20], and it has been reported that perceived barriers to prevent MIHL is related to PLL in adolescents [21]. In a study with adolescents in Sweden, the barriers to prevent hearing loss can affect the hearing protective behaviors such as use of hearing protector devices [38]. In four meta-analyses assessing the relation between the constructs in the Health Belief Model and health behaviors, perceived barriers have consistently shown as one of the most powerful single related factors to preventive health

behaviors [36], and also known to be a related factor to PLL among adolescents [21]. However, few studies have directly investigated the relationship between perceived barriers and a health problem such as hearing loss. As health behaviors are well known to be important to prevent health problems, we can assume that perceived barriers affect health behavior, which in turn affects health problem. That is, the higher adolescents perceive barriers to prevent MIHL, a the lower they do preventive health behaviors such as safe listening level or short-term listening to music, which may result in decrease in hearing. Therefore, hearing conservation programs should include educational interventions to inform them how to overcome the barriers to prevent MIHL. That is, when students were not sure about how to keep their listening level safe in noisy places, they can learn the knowledge and skills on how to overcome barriers through education and apply them in noisy places.

Meanwhile, perceived susceptibility also is one of the important factors of preventive health behaviors [36], and it is known that as the perceived susceptibility increases, the likelihood of taking preventive actions increases [19]. However, in this study, as perceived susceptibility increases, the likelihood of decrease in hearing increases, which is opposite to what we can expect based on the relationship between perceived barriers and change in hearing. This finding may be explained that adolescents who had a higher level of susceptibility to MIHL perceived the change in hearing well. Or, adolescents who have already experienced a decrease in hearing because of listening to loud music perceived the vulnerability to MIHL more than their counterparts [34,39].

Strength and limitations

To the best of our knowledge, studies to investigate PLDs usage habits, listening belief, and their relation to change in hearing among adolescents are currently very limited both domestically and abroad. In particular, this study was the first attempt to measure listening belief using tools that are systematically developed based on the Health Belief Model [19,21] and how it related to perceived change in hearing among adolescents in Korea. And, as we tried to subgroup analysis by school level, these findings can provide basic data to understand their PLDs usage habits and prepare effective interventions for middle and school students. PLL was measured by selecting a volume setting during listening to music. This measurement may have more accurate than other subjective method using a 10-point visual analog scale that the participants experienced difficulties in using during pilot tests. However, this study has several limitations, and needs to have a careful approach in interpreting the results. First, as this study collected data by self-reported questionnaire, it was possible for them to respond in a positive direction. However, it may be minimized by explaining confidentiality during acquiring assent, and by answering a questionnaire individually in a quiet environment. Second, the listening time was intended to improve the accuracy of the answers by presenting a picture of a clock and displaying the time when listening to PLDs, but the risk of recall bias remains. In addition, the listening time per week was calculated as the product of listening days per week, and listening hours per day, which were measured the average amount of time spent listening to PLDs every day for the past week. Although the listening time of adolescents may be different between weekdays with school and weekends without school, we could not adjust this difference to measure the listening time per week. Third, PLL was measured subjectively and in a quiet environment where the background noise was from 45 to 53 dB. So PLL may be less accurate than objective measurements and the actual listening levels may be underestimated. Last, the participants recruited in one region have limitations in generalizability to adolescents in other regions. Last, as this study was performed by a cross-sectional design, it is hard to confirm the temporality and a causal relationship.

Clinical implications

Several interventions such as education, use of hearing protection, and noise control have been identified as components of hearing conservation programs in occupational settings, education is the first step and one of the most important parts of hearing conservation programs for adolescents [34]. Danhauer et al. [40] addressed a hearing conservation program such as hearing health and safe PLDs use for high school students and stated that it should be mandatory education during health classes to prevent hearing loss due to MP3s in the United States. However, considering that none of the contents of the high school health textbooks, developed after the 2015 revised curriculum in Korea, were related to hearing protection [35], the results of this study remind us of the need for hearing protection training for adolescents and are expected to help in preparing effective educational interventions.

Conclusion

The majority of adolescents are exposed to PLDs from their early teens and about a quarter experienced a decrease in hearing after PLDs use. In particular, high school students experience decrease in hearing twice more than middle school students. Therefore, educational programs on hearing conservation are required to start as early as in various levels of schools from elementary to high schools. Particularly, as adolescents with higher perceived barriers to prevent MIHL show higher likelihood of decrease in hearing, knowledge, and skills to overcome barriers should be emphasized in educational programs.

Conflict of interest

The authors declare no conflicts of interest.

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Research Article

Psychological Resilience of Second-Pregnancy Women in China: A Cross-sectional Study of Influencing Factors

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ABSTRACT

Purpose: The aim of the study was to evaluate the status of psychological resilience among women in their second pregnancy and to investigate the possible influencing factors.
Methods: A total of 275 women in their second pregnancy and who met the criteria were surveyed from two public hospitals in China from July 2018 to January 2019. The instruments included the General Self-designed Questionnaire, Connor–Davidson Resilience Scale, Social Support Rate Scale, and 36-item Pregnancy Stress Rating Scale.
Results: The total psychological resilience score of second-pregnancy women was relatively low. Multivariate regression analysis identified five factors associated with psychological resilience: intimacy with husbands, social support utilization, gender of the first child, high-risk pregnancy of the first child, and the stress caused by worrying about the health and safety of the mother and fetus.
Conclusion: Women in their second pregnancy represent a unique population, and their low psychological resilience score deserves attention. Identification of factors contributing to decreased psychological resilience may enable us to design prevention and intervention strategies and to deliver specific psychological supports to pregnant women at high risk of developing negative psychology.

Introduction

Pregnancy represents a dramatic event in a woman's life, and it inevitably imposes significant physiological and psychological impacts [1]. Pregnant women are prone to negative psychological changes caused by hormone alterations [2], physiological adjustment and pregnancy reactions, such as vomiting, dizziness, and fatigue [2,3], complications of pregnancy, and potential stress due to changes in family and social life [4]. Prenatal anxiety and depression are commonly observed in pregnant women worldwide, with the prevalence varying from 6.0% to 57.0% and 8.5% to 44.4%, respectively [5]. In addition to anxiety and depression, pregnant women may manifest other mental disorders, including emotional instability, agitation, and difficulties in interpersonal relationships. The negative psychological impacts affect the health of pregnant women and increase the risk of pregnancy complications, leading to poor birth outcomes [6]. Antenatal maternal stress is found to be associated with cognitive, emotional, and behavioral problems in a child [1].

Second pregnancy experience is usually different from first pregnancy experience. Normally, women in their second pregnancy are expected to have better psychological adjustment than those in their first pregnancy owing to their improved pregnancy-related knowledge, information, and self-care ability based on experiences from their first pregnancy, which may reduce their uncertainty [7]. However, numerous studies have reported even more psychological problems and a higher prevalence of antenatal depression among women in China in the second pregnancy than those in the first pregnancy [8,9].

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China implemented the one-child policy for more than 30 years. However, the birth control policy was modified in 2015 to allow couples to have two children [10]. Women in their second pregnancy are facing multiple complex psychological challenges owing to the abrupt policy changes. One is the advanced reproductive age that more than 60% of these women (i.e., those with one child) are older than 35 years, and more than half of the women are older than 40 years in China [11]. Given the advanced reproductive age, concerns about the risks of pregnancy, delivery, and fetal health have led to increased stress among women in their second pregnancy [12]. Stress also comes from the change in procreation conception and family structure in China [13]. Owing to the current typical 4-2-1 family structure (i.e., four grandparents, two parents, and one child) [14], couples will face increased pressure after their second childbirth (e.g., taking care of their infant, dealing with the issues of their adolescent children, and taking care of elderly parents simultaneously) and incur additional costs for education and housing for the second child [13]. Other concerns such as gender preference in Chinese traditional procreation conception, different fertility intentions from the older generation, and pregnant women's potentially hindered career development impose substantial stress and burden related to second pregnancy [15].

Szegda et al. [16] reported that stress experienced by pregnant women is related to high risk of preterm birth. However, others reported that psychological stress and social stress during pregnancy are not necessarily associated with birth outcomes [17]. In addition, no relationship was observed between perinatal abnormalities and stress caused by disasters [18]. The controversial results implicate the perspective of positive psychology that may promote pregnant women's mental health and birth outcomes [19]. However, most of the existing studies focus on psychopathology, such as prenatal anxiety and depression among pregnant women. Few studies focus on psychological resilience for the mental health of pregnant women [5], and no report that specifically focuses on psychological resilience during second pregnancy can be found.

Psychological resilience is defined as an individual's ability to positively adjust and adapt to adversity to maintain mental health [20]. Different from negative psychology, psychological resilience focuses on the protective psychological mechanisms that help an individual to deal with negative emotions [20]. Psychological resilience is a key factor for harmful stress and psychological health [21]. For pregnant women, Li et al. [22] observed that psychological resilience can mediate the relationship between prenatal pressure and sleep quality. A study by Garcia-Leon et al. [23] showed that pregnant women with high psychological resilience had low levels of pregnancy-specific stress and psychopathological symptoms during the third trimester, which means the potential utility of psychological resilience to improve the health of pregnant women and their neonates.

Psychological resilience is a dynamic process that is affected by multiple systems or factors, including life events or stressors, individual characteristics and experiences, family dynamics and support, and social network [24]. Given that no study related to factors of psychological resilience in second pregnancy has been identified and considering that women in their second pregnancy face complex psychological challenges, various potential factors, including demographic characteristics of pregnant women, current and first pregnant characteristics, family support, social support, and pregnancy stress, are included to obtain a comprehensive understanding of this topic. Therefore, the present study aims to examine psychological resilience and its associated factors among women in their second pregnancy in China.

Methods

Study design

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

Setting and sample

This cross-sectional study was conducted in obstetric clinics of two public hospitals in China from July 1, 2018, to January 30, 2019. The sample size was calculated by using G*Power 3.1 statistics software (Heinrich Heine University, Düsseldorf, Germany). With a power of 90% to detect a medium effect size of .15 at a 5.0% level of significance, the 33 variables included in our study, and approximately 10.0% attrition [25], the minimum sample size required for this study was 261 participants.

Women in their second pregnancy were recruited when they came for general maternity examination. Pregnant women who satisfied the following criteria were included: (1) those 18 years old or older, (2) those pregnant with their second child, and (3) those who can communicate in Chinese. Participants with psychiatric disorders and/or cognitive impairments were excluded. Participants with a remarriage were also excluded, considering more complex family relationships that impose an additional psychological burden on pregnant women. All participants were fully informed about the study and signed informed consent.

Instruments

Demographic and clinical characteristics

Demographic and clinical characteristics included four parts: (1) general demographic information, including education level, marital status, monthly household income, payment of treatment costs, current working status, and current working pressure, and (2) second-pregnancy characteristics, including gestational week, mode of delivery, history of abortion, and reasons for the second pregnancy. Other second-pregnancy characteristics, such as whether the pregnant woman is in advanced maternal age, high-risk pregnancy, whether the pregnancy is planned, and if the pregnancy is by personal will; (3) first pregnancy characteristics, including the gender of the first child, mode of delivery, experience of delivery, and whether the first pregnancy was a high-risk pregnancy; (4) family support of women in their second pregnancy, including the biggest supporter of their second pregnancy, prospective caregivers of the second child, the primary caregiver of the first child, economic pressure of the second pregnancy, family atmosphere, intimacy with the husband, intimacy with parents-in-law, and whether living with parents-in-law.

Psychological resilience

The Connor–Davidson Resilience Scale (CD-RISC) was used to evaluate the psychological resilience of the second-pregnancy women. The original CD-RISC was designed by Connor and Davidson in 2003 [26]. The Chinese version of the CD-RISC was translated and revised from the original CD-RISC by Yu and Zhang [27] in 2007. The scale included 25 items and 3 dimensions (tenacity, strength, and optimism), with a Cronbach's α of .91 [28]. Each item was rated on a 5-point scale (0 to 4), with high scores reflecting great psychological resilience.

Social support

Social support is defined as the assistance and protection available from others [29]. The Social Support Rate Scale (SSRS) was used to evaluate the social support given to the second-pregnancy women. The scale was designed by Liu et al. [29] and contained 10 items and 3 dimensions (objective social support, subjective social support, and social support utilization). Subjective social support refers to the subjective or emotional experience and satisfaction to be supported by others; objective support represents the objective, actual, or perceived support; social support utilization indicates the individual utilization of social support [29]. The Cronbach's α of the SSRS ranged from .89 to .94 for different dimensions [29]. High scores indicate high social support.

Pregnancy stress

Pregnancy stress refers to the pregnancy-related stress experienced by pregnant women [30]. The 36-item Pregnancy Stress Rating Scale (PSRS) was adopted to evaluate the pressure experienced by pregnant women. The scale was first designed by Chen et al [30] and revised by Li et al [31]. The revised 36-item Pregnancy Stress Rating Scale contained 30 items and 3 dimensions (stress caused by worrying about the health and safety of the mother and fetus, stress caused by identifying with the maternal role, and stress caused by worrying about the changes in body shape and physical function), with a Cronbach' α of .9 [31]. Each item was rated on a 4-point scale (1 to 4), with high scores reflecting great stress.

Ethical consideration

The guidelines of the Declaration of Helsinki were followed. The study was approved by Lianyungang Maternal and Child Health Care Ethics Committee (Approval no. 2018-LFY-0516). All participants were fully informed about the study and the voluntary nature of participation. Informed consent was obtained from each participant. All collected data were kept confidential and anonymous. This study is a survey research and caused neither harm nor discomfort to the mother and fetus.

Data collection

Researcheres obtained the permission to survey the participants in two obstetric clinics. A total of 537 pregnant women were identified. Of these pregnant women, 301 were in their second pregnancy and met the eligibility criteria, as verified by clinical physicians. Eventually, 277 participants were included, and 24 patients refused to participate in the study (participation rate: 92.0%). All investigators were trained before collecting data. Data were collected by face-to-face investigations using the self-reported questionnaires with unified and standard instructions. Each participant needed 10–15 min to finish questionnaires. All questionnaires were checked immediately after completion.

Statistical analysis

Statistical analyses were performed using SPSS 19.0 (IBM Corp., Armonk, NY, USA). Categorical data are presented as number (percentages), and continuous data are presented as mean ± standard deviation. The independent samples t test and one-way analysis of variance were used to compare the scores for variables with normal distribution. Pearson's correlation analysis was used to analyze the correlation between psychological resilience, social support, and pregnancy stress. A multivariate linear regression model was used to determine the predictors of psychological resilience in second pregnancy. An α value of .05 was adopted as the level for statistical significance.

The data met the assumptions of multivariate regression. First, the scatterplots showed that the relationship between each independent variable and the dependent variable was linear. Second, the data showed no multicollinearity because the variance inflation factor scores were well lower than 10, and tolerance scores were higher than 0.2 (variance inflation factor = 1.07–2.43; tolerance = 0.41–0.93). Third, the values of residuals were independent, with the obtained value close to 2 (Durbin–Watson = 1.67). The P–P plot for the model suggests the assumption of normality for the residuals.

Results

General characteristics

A total of 277 questionnaires were filled out by eligible women in their second pregnancy, and 275 questionnaires were valid. The effective response rate was 99.3%. Tables 1–3 present the distributions of general demographic characteristics, current- and first-pregnancy characteristics, and family support of women in their second pregnancy. The mean age was 32.55 ± 4.64 years (19–44 years), with 113 participants (41.1%) aged older than 35 years. The total psychological resilience score was 64.73 ± 13.68 (scoring rate: 64.7%), and the scores of three dimensions were 32.83 ± 7.56 (scoring rate: 63.1%, tenacity), 21.18 ± 4.81 (scoring rate: 66.2%, strength), and 9.72 ± 2.63 (scoring rate: 60.8%, optimism).

Univariate analysis of psychological resilience and its influencing factors

Tables 1–3 show the results of univariate analysis of psychological resilience of women in their second pregnancy. The mean psychological resilience scores were significantly different with regard to educational levels ($p = .003$), monthly household income ($p = .018$), payment of treatment costs ($p = .027$), whether the second pregnancy was by personal will ($p = .009$), whether the first pregnancy was high-risk pregnancy ($p < .001$), gender of the first child ($p = .037$), prospective caregivers of the second child ($p = .033$), economic pressure of the second pregnancy ($p = .006$), current working pressure ($p = .009$), family atmosphere ($p < .001$), and intimacy with the husband ($p < .001$).

Correlation analysis of psychological resilience with social support and pregnancy stress

Table 4 presents the results of correlation analysis of social support and pregnancy stress with psychological resilience of women in their second pregnancy. Psychological resilience was positively and significantly correlated with the total SSRS scores ($r = .31$, $p < .001$) and their dimensions (objective social support, subjective social support, and social support utilization) ($r = .18$, .21, and .32, respectively, all $p < .001$). In addition, psychological resilience was negatively and significantly correlated with pregnancy stress ($r = -.40$, $P < .001$) and its dimensions (stress from worrying about the health and safety of mothers and children, stress from identifying with the role of mothers, and stress from worrying about changes in body shape and function) ($r = .37$, .33, and .33, respectively, all $p < .001$).

Multivariate regression analysis of psychological resilience and its influencing factors

A total of 17 significant variables in univariate and correlation analyses were inputted to the multivariate regression analysis

Table 1 *Association Between Demographics and Psychological Resilience of Women Pregnant With Their Second Child (N = 275).*

Items		n (%)	CD-RISC total score ($\bar{x}\pm s$)	F/t	*p*
Educational level	High school or lower	171 (62.2%)	62.81 ± 13.94	9.18	.003
	Bachelor degree or higher	104 (37.8%)	67.88 ± 12.68		
Marital status	Unmarried	2 (0.7%)	62.50 ± 20.51	0.05	.818
	Married	273 (99.3%)	64.74 ± 13.67		
Monthly household income (China yuan)	<5000	60 (21.8%)	61.18 ± 16.06	4.09	.018
	5000–10000	155 (56.4%)	64.74 ± 12.11		
	>10000	60 (21.8%)	68.25 ± 14.26		
Payment of treatment costs	Self-paying	119 (43.3%)	62.65 ± 14.72	4.92	.027
	Social insurance	156 (56.7%)	66.31 ± 12.65		
Current working status	No job	106 (38.5%)	63.11 ± 13.47	1.81	.165
	Working	130 (47.3%)	65.11 ± 13.82		
	Maternity leave	39 (14.2%)	67.85 ± 13.49		
Current working pressure	No job	106 (38.5%)	63.11 ± 13.47	3.96	.009
	No pressure	59 (21.5%)	66.83 ± 14.41		
	Pressure	99 (36.0%)	66.42 ± 12.49		
	High pressure	11 (4.0%)	53.73 ± 16.54		

Note. CD-RISC = Connor–Davidson Resilience Scale; x̄ = Mean; s =standard deviation.

model. Multivariate regression analysis included six factors associated with psychological resilience (Table 5). Among these factors, intimacy with the husband and social support utilization were positively associated with psychological resilience (β = .14 and .19, respectively), whereas having a son as the first child, high-risk pregnancy of the first child, and stress from worrying about the health and safety of the mother and fetus were negatively associated with psychological resilience (β = −.13, −.14, and −.18, respectively).

Discussion

Researchers surveyed the psychological resilience of second-pregnancy Chinese women and analyzed the factors contributing to psychological resilience. The mean score (64.73 ± 13.68) of psychological resilience among the women in their second pregnancy was relatively lower than that (ranging from 65.21 to 69.99) of the pregnant women reported in previous studies [32,33], maybe because most of the pregnant women surveyed in previous studies were in their first pregnancy, who were at relatively younger ages

Table 2 *Association Between Pregnancy Characteristics and Psychological Resilience of Women Pregnant With Their Second Child (N = 275).*

Items		n (%)	CD-RISC total score ($\bar{x}\pm s$)	F/t	*p*
Current pregnancy					
Advanced maternal age	Yes	113 (41.1%)	62.27 ± 14.09	2.20	.139
	No	162 (58.9%)	65.75 ± 13.33		
Gestational week	1~12	28 (10.2%)	61.89 ± 12.62	0.80	.451
	13~27	125 (45.4%)	65.49 ± 13.52		
	28~40	122 (44.4%)	64.60 ± 14.08		
High-risk pregnancy	Yes	138 (50.2%)	63.37 ± 14.21	2.75	.099
	No	137 (49.8%)	66.09 ± 13.03		
Fetal gender expectation	Yes	94 (34.2%)	63.54 ± 12.41	1.07	.302
	No	181 (65.8%)	65.34 ± 14.29		
Mode of delivery expectation	Natural labor	207 (75.3%)	64.71 ± 13.45	<0.01	.971
	Caesarean	68 (24.7%)	64.78 ± 14.46		
Abortion experience (including spontaneous and artificial abortion)	Yes	159 (57.8%)	65.32 ± 13.85	0.71	.401
	No	116 (42.2%)	63.91 ± 13.46		
Planned pregnancy	Yes	172 (62.5%)	65.32 ± 13.37	0.86	.354
	No	103 (37.5%)	63.74 ± 14.19		
Pregnancy from personal will	Yes	257 (93.5%)	65.29 ± 13.48	6.83	.009
	No	18 (6.5%)	56.67 ± 14.30		
Reasons for pregnancy	Accompany yourself	14 (5.1%)	57.50 ± 16.31	1.54	.205
	Expectations from family members	65 (23.6%)	64.20 ± 12.86		
	Accompany the first child	189 (68.7%)	65.47 ± 13.62		
	Others	7 (2.6%)	64.00 ± 15.91		
First pregnancy					
High-risk pregnancy	Yes	28 (10.2%)	55.96 ± 14.28	13.37	<.001
	No	247 (89.8%)	65.72 ± 13.28		
Gender of the first child	Boy	116 (42.2%)	62.72 ± 12.83	4.39	.037
	Girl	159 (57.8%)	66.19 ± 14.12		
Mode of delivery	Natural labor	187 (68.0%)	64.30 ± 13.64	0.56	.456
	Caesarean	88 (32.0%)	65.63 ± 13.79		
Experience of delivery	Not smooth	21 (7.6%)	66.24 ± 9.59	0.43	.649
	Smooth	126 (45.8%)	63.94 ± 14.83		
	Very smooth	128 (46.6%)	65.26 ± 13.10		

Note. CD-RISC = Connor–Davidson Resilience Scale; x̄ = Mean; s =standard deviation.

Table 3 *Association Between Family Support and Psychological Resilience of Women Pregnant With Their Second Child (N = 275).*

Items		n (%)	CD-RISC total score ($\bar{x}\pm s$)	F/t	p
Biggest supporter of the second pregnancy	Yourself	58 (21.1%)	66.19 ± 12.97	1.98	.140
	Husband	170 (61.8%)	65.19 ± 13.46		
	Parents	47 (17.1%)	61.23 ± 14.98		
Prospective caregivers of the second child	Yourself	51 (18.6%)	62.14 ± 14.90	2.96	.033
	Couple	112 (40.7%)	63.74 ± 12.53		
	Parents	106 (38.5%)	66.32 ± 13.80		
	Nanny	6 (2.2%)	70.00 ± 14.90		
Primary caregiver of the first child	Yourself	62 (22.6%)	61.16 ± 13.00	2.27	.080
	Couple	79 (28.7%)	64.38 ± 14.39		
	Parents	129 (46.9%)	66.58 ± 13.21		
	Nanny	5 (1.8%)	66.60 ± 17.42		
Economic pressure of the second pregnancy	No pressure	80 (29.1%)	68.78 ± 13.97	5.21	.006
	Pressure	175 (63.6%)	63.22 ± 13.47		
	High pressure	20 (7.3%)	61.70 ± 11.25		
Family atmosphere	Not harmonious	18 (6.5%)	55.83 ± 17.96	11.28	<.001
	Harmonious	97 (35.3%)	61.42 ± 12.25		
	Very harmonious	160 (58.2%)	67.73 ± 13.14		
Intimacy with the husband	Not intimate	4 (1.5%)	48.25 ± 5.80	13.76	<.001
	Intimate	126 (45.8%)	61.06 ± 13.21		
	Very intimate	145 (52.7%)	68.37 ± 13.08		
Living with parents-in-law	Yes	131 (47.6%)	64.29 ± 14.23	0.26	.614
	No	144 (52.4%)	65.13 ± 13.19		
Intimacy with parents-in-law	Not intimate	29 (10.5%)	61.14 ± 13.40	2.50	.084
	Intimate	185 (67.3%)	64.32 ± 13.48		
	Very intimate	61 (22.2%)	67.66 ± 14.08		

Note. CD-RISC = Connor–Davidson Resilience Scale.

than those in our study. The relatively lower level of psychological resilience of the participants in our study indicates that women in second pregnancy lack appropriate psychological protection under complex psychological challenges and are more likely to have mental disorders. The findings suggest the need to focus on the mental health of these women to strengthen their psychological resilience to help them cope better with pregnancy-related stress and maintain their mental health.

In this study, researchers discovered that psychological resilience of women in their second pregnancy can be influenced by various factors. Intimacy with the husband and social support utilization were positively associated with psychological resilience. However, having a son as the first child, high-risk pregnancy of the first child, and stress caused by worrying about the health and safety of the mother and fetus contributed negatively to psychological resilience.

Table 4 *Correlation Between Social support, Pregnancy Pressure, and Psychological Resilience of Women Pregnant With Their Second Child (N = 275).*

Variables	Tenacity	Strength	Optimism	CD-RISC total score
Objective social support	.16**	.17**	.15**	.18**
Subjective social support	.20**	.20**	.15**	.21**
Social support utilization	.30**	.31**	.25**	.32**
Total SSRS score	.29**	.30**	.24**	.31**
Stress caused by worrying about the health and safety of the mother and fetus	−.32**	−.35**	−.36**	−.37**
Stress caused by identifying with the maternal role	−.29**	−.33**	−.31**	−.33**
Stress caused by worrying about the changes in body shape and physical function	−.26**	−.36**	−.30**	−.33**
Total PSRS score	−.34**	−.39**	−.38**	−.40**

**$p < .001$.

Note. CD-RISC = Connor–Davidson Resilience Scale; PSRS = Pregnancy Stress Rating Scale; SSRS = Social Support Rating Scale.

Researchers observed that intimacy with the husband was positively associated with psychological resilience. Family atmosphere also showed significant associations with psychological resilience in the univariate analysis, but only intimacy with the husband was a positive predictor of psychological resilience in the multivariate regression analysis model. Kitamura et al. [34] pointed out that pregnancy-related affective disorder is characterized by the negative response of the husband with low intimacy. Conjugal relation is the most intimate relationship in interpersonal relationships. Whisman et al. [35] also reported that marital discord has a significant predictive effect on depression and results in low life satisfaction. Thus, a couple's affection has an important impact on an individual's subjective well-being, which can promote positive emotion directly in pregnant women. On the other hand, pregnant mothers' interpersonal relationships with the members of their extended family (grandmother, aunt, and sister) or very close friends may be affected by pregnancy. The husband's ability to balance these relations can alleviate the temporary interpersonal crisis [36]. A temporary absence of social relations or roles can be observed in several pregnant mothers, which leads to emotional dependence on their husbands. Moreover, intimacy with the husband reflects husband support. Women in their second pregnancy have psychological risk factors stemming from their history or previous experience with pregnancy and delivery; the husband's ability to fulfill special functions will improve pregnancy experience and relieve stress [36]. The confidence of pregnant women in raising children together with their husband can be markedly influenced by their husband's emotional availability. For all these reasons, intimacy with their husband can influence psychological resilience of second-pregnancy mothers significantly.

Social support and psychological resilience are regarded as important external and internal factors, respectively, affecting pregnant women's ability to actively cope with the stress of pregnancy and maintain positive psychology [37]. For pregnant women, social support can effectively alleviate pressure, reduce the negative impact of life events, and maintain physical and mental balance [36]. As researchers mentioned previously, social support includes

Table 5 *Multivariate Regression Analysis of Predictors of Psychological Resilience in Second-Pregnancy Women.*

Model	B (95% CI)	Standard error	β	t value	*p*	VIF
Constant	27.48 (7.19–47.77)	10.30		2.67	.008	
Gender of the first child	−3.62 (-6.47 to −0.76)	1.45	−.13	−2.50	.013	1.07
High-risk pregnancy of the first child	−6.09 (-10.79 to −1.39)	2.39	−.14	−2.55	.011	1.09
Intimacy with the husband	3.62 (0.44–6.79)	1.61	.14	2.25	.026	1.52
Stress caused by worrying about the health and safety of the mother and fetus	−0.46 (-0.86 to −0.05)	−0.21	−.18	−2.22	.027	2.43
Social support utilization	1.50 (0.61–2.38)	0.45	.19	3.33	.001	1.27

Note. CI = confidence interval; VIF = variance inflation factor.

objective social supports, subjective social supports, and social support utilization. In our present study, social support utilization was positively associated with psychological resilience, which is consistent with the results of the study conducted by Zhang et al [37]. Pregnant women can select and use different supports, provided that they are available. Different individuals have various support utilization, even when they are provided with the same or similar social supports. Women with pregnancy experience are likely to actively access and use resources to cope with negative life events positively and obtain a high level of psychological resilience during pregnancy. However, this study showed that objective and subjective social supports had no predictive effect on psychological resilience in the multivariate regression analysis model. Objective social support includes material support, medical insurance, and a basic social security system [37]. In China, the living standard of residents has undergone tremendous changes in the past decades. Medical insurance and the basic social security system provide effective safety nets, which may explain why objective support had no significant effect on psychological resilience of second-pregnancy women. Subjective social support means the emotional experience of being supported and understood. With a relatively strong tradition of family values in China, most Chinese women receive high levels of emotional support from consanguinity and their family in dealing with life predicament during pregnancy. This condition might have contributed to the lack of remarkable effect of subjective social support on psychological resilience.

Researchers observed that the gender of the first child had a negative predictive effect on psychological resilience in our study. Specifically, pregnant women whose first child is a boy have a lower psychological resilience during their second pregnancy than those whose first child is a girl. This result was unexpected considering the strong preference for sons in Chinese society [38]. However, a boy's family bears the main cost of his later marriage, including housing, cars, and furniture, which results in a remarkably higher future cost of bearing sons than bearing daughters [39]. Therefore, if the first child is a boy, the couple will wish the second to be a girl, leading to psychological pressure. A survey of 7810 samples from 29 provinces in China showed that having a boy as a first child significantly reduced the parents' desire to have a second child for fear that the second child will be a boy [40]. If a couple can have two children, most mothers would prefer one son and one daughter, whereas the proportion of mothers expecting two daughters is notably higher than that of mothers wanting two sons [41]. Lin and Zhao [42] confirmed that the fertility of sons significantly reduces the well-being of parents. Older mothers may have low economic and family status because of the birth of sons [43]. These factors may lead to great psychological stress and low psychological resilience in second-pregnancy women whose first child is a son.

High-risk pregnancy of the first child contributed negatively to psychological resilience of second-pregnancy women in our study. High-risk pregnancy may endanger the health of the mother and infant and lead to poor perinatal prognosis [44]. Huang [45] reported that pregnant women at high risk of pregnancy are likely to suffer from perinatal post-traumatic stress disorder (PPTSD). As per a systematic review conducted in 2017, the prevalence rate of PPTSD in women with normal pregnancy reached 3.3%, whereas that in women with high-risk pregnancy, it was 15–18.9% [46]. Michelet et al. [47] reported that the prevalence rate of PPTSD reached 64% in women who experienced serious high-risk pregnancies. PPTSD can last for months, years, or decades [45]. In our study, whether the second pregnancy was of high risk made no difference in psychological resilience in univariate analysis. However, only high-risk pregnancy of the first child was a negative predictor of psychological resilience in the multivariate regression analysis model. We assumed that PPTSD played an important role in this process. The core symptoms of PTSD are increased alertness and traumatic reexperience [48]. The adverse experience of the first high-risk pregnancy keeps women on high alert and pressure during their second pregnancy. In addition, with the increase in age, pregnant women realize that their physical condition declines and they are subject to a higher risk of abnormal pregnancy and delivery than their first pregnancy. Thus, high-risk second pregnancy alone is insufficient to weaken the psychological resilience of pregnant women, whereas high-risk pregnancy of the first child can negatively predict psychological resilience of women in their second pregnancy.

Perceived stress has been well established as a risk factor, leading to poor psychological outcomes, while psychological resilience can mediate the negative effects of stress [19,22]. Our study reveals that three domains of stress caused by worrying about the health and safety of the mother and fetus, identifying with the maternal role, and the changes in body shape and physical functioning show significant associations with psychological resilience in the correlation analysis. However, only the stress caused by worrying about the health and safety of the mother and fetus is an independent predictor of psychological resilience in the multivariate regression analysis model. This finding is consistent with those of the study by Ren [49]. Previous studies reported that the first concern and worry of women in their second pregnancy are their (mother and fetus) health and safety rather than their maternal role or body shape [50]. Women in their second pregnancy can cope better with the stress related to the maternal role and body shape because of their experiences from their first pregnancy, but the stress related to the risks of pregnancy, delivery, and fetal health is an obvious psychological burden for women pregnant with their second child who are at a relatively advanced age and have decreased physical function [50]. Our study implies that comprehensive stress management for women in their second pregnancy should prioritize the management of the stress caused by worrying about their health and safety to enhance their psychological resilience.

Conclusions

To our knowledge, this research is the first study to assess psychological resilience and its influencing factors among women in their second pregnancy. Our results present that second-pregnancy women in China had low psychological resilience. Among various family and social support variables, intimacy with the husband and social support utilization play the most important role that positively promotes psychological resilience. With the second pregnancy as a reexperience of pregnancy, high-risk pregnancy of the first child can negatively predict psychological resilience. In addition, the stress that leads mostly to low psychological resilience is worrying about the health and safety of the mother and fetus. Moreover, based on the Chinese background, having a son as the first child negatively affects psychological resilience. The present findings provide useful information for designing a prevention and intervention strategy to effectively identify women with fragile psychological resilience during their second pregnancy and to deliver specific psychological supports to this population.

Ethical statement

This study was approved by the Human Ethics Committee of Maternal and Child Health Hospital of Lianyungang City (Approval no. 2018-LFY-0516).

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Author contributions

X.J., L.S., and Z.W. planned the research. X.X., J.Q., Z.X., and L.S. collected the data. X.J. and X.X. analyzed the data. X.J. and L.S. did manuscript preparation.

Conflict of interest

There is no conflict of interest to claim.

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Research Article

Level of and Related Factors to Diabetes Awareness among Diabetic Adults by Gender: Based on Data from the Korean National Health and Nutrition Examination Survey

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ABSTRACT

Purpose: This study aimed to determine the level of awareness about diabetes mellitus (DM) and identify the associated factors among diabetic adults in Korea by sex, using data from most recent nationwide representative survey.

Methods: Secondary data analysis was conducted using data obtained from the Korean National Health and Nutrition Examination Survey VII (2016–2018). In total, 2,026 participants (1,049 men, 977 women) aged ≥30 years with DM were included. Data were analyzed using a complex sample analysis considering the combined sampling weight for 3 years. Odds ratios and 95% confidence intervals were calculated using stepwise multiple logistic regression analysis to identify the association between DM awareness (DA) and sociodemographic and health-related factors.

Results: Researchers observed that 60.2% of men and 68.4% of women had DA. DA levels in both men and women were higher in those who were older, less educated, had normal weight, had hypertension and/or dyslipidemia, and had a family history of DM than in their counterparts. Having undergone a health screening in the past 2 years was associated with DA levels in men, whereas glycated hemoglobin levels of 5.7–6.4% were associated with higher DA levels in women.

Conclusion: The level of DA is unsatisfactory. Although the DA level is slightly higher in women than in men, it needs to be improved regardless of gender. Most of the factors associated with DA levels are similar in both men and women. Nurses in the community setting should provide health education, conduct campaigns, and promote referral to medical services by targeting the high-risk groups with lower DA identified in this study.

Introduction

Diabetes mellitus (DM) is characterized by hyperglycemia owing to the loss or dysfunction of β-cells in the pancreas and causes long-term metabolic disorders and complications if not treated well [1]. According to the Korean National Health and Nutrition Examination Survey (KNHANES), the prevalence of DM in adults aged ≥30 years was 12.4% in 2017, which represents a significant increase from the value of 9.7% in 2007 [2]. The longer an individual has DM and uncontrolled blood sugar levels, the greater is the risk of vascular complications [3]. Therefore, it is important for people to monitor their blood sugar levels and initiate appropriate treatment based on a diagnosis by a physician as early as possible to reduce the risk of DM complications.

DM awareness (DA) is defined as the recognition of DM by being diagnosed with a doctor [2]; it influences DM treatment and control [4]. Unfortunately, there are few studies on DA in Korea, and one study using data from the National Sample Cohort Database of the National Health Insurance Service reported a DA level of 61.8% [5]. However, it is difficult to identify the current DA level, given that the data in the previous study were collected in 2013. The Korea Ministry of Health and Welfare continues to make efforts to increase the DA level as one of the strategies for preventing and managing cardiovascular diseases via public health centers [6], and

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the National Health Insurance system in Korea supports health screening every 2 years to promote early detection of various diseases including DM [7]; thus, the recent DA level may have changed from that in 2013. Moreover, although the cohort database used in the previous study is known to be representative and accurate, there was a difference in health screening participation rates by socioeconomic status, which may have increased the risk of selection bias [5]. Therefore, studies conducted using more representative data that are less affected by socioeconomic status are needed. In most studies on DA, including previous domestic studies, DM diagnosis was based only on fasting blood sugar levels [5,8–13]. Considering that the glycated hemoglobin (HbA1c) level is widely used for the diagnosis of DM [1], HbA1c and fasting blood sugar levels should be measured for the diagnosis of DM.

With regard to the factors associated with the DA level, socioeconomic factors such as age; gender; educational level; current employment status; household income; health-related factors such as smoking status, physical activity, body mass index (BMI), hypertension, and dyslipidemia; and family history of DM have been investigated [5,8–13]. Some socioeconomic and health-related factors have shown inconsistent results or have been considered in limited studies. For example, some studies reported that the education level was related to the DA level [9,11,12], while some studies did not report this relationship [8,10,13]; some studies reported that the education level was not related to the DA level [5]. Most national and foreign studies have identified factors associated with the DA level regardless of sex [5,9–13], but it may be necessary to identify whether factors affecting the DA level differ by sex because some studies have reported that the DA level differs by sex [5,11,12]. Based on a literature review, we aimed to identify the DA level and factors associated with DA among Korean adults by gender, using data from most recent nationwide representative survey.

Methods

Aims

This study aimed to evaluated the level of DA and identify the associated factors among Korean adults with DM, using data from the KNHANES VII (2016–2018), the most recent and Korea representative survey.

Participants

This study analyzed KNHANES VII data, which had been collected by the Korea Centers for Disease Control and Prevention from 2016 to 2018. The KNHANES is a biennial, nationwide cross-sectional survey that assesses the health and nutritional status of the general population in Korea [2]. The sample of KNHANES VII was selected using a two-stage stratified cluster sampling method for enumeration districts and households, and a health survey, health screening, and nutrition survey were conducted to appropriate household members. Among 31,689 members of the target population, total 24,269 participated in the KNHANES VII (2016-2018) survey (average response rate: 76.6%). The inclusion criteria for this study were as follows: no missing data for sampling weight, over the age of 30, those with DM, and no missing data for the variables associated with DA. DM was defined as satisfying at least one of the following three criteria, based on American Diabetes Association [1]: (1) self-reporting of history of diagnosed DM, (2) a fasting plasma glucose of ≥126 mg/dL, and (3) A1C of ≥6.5%. Total 2,026 participants (1,049 men, 977 women) met those inclusion criteria (Figure 1).

Variables and definitions

The variables in this study included the sociodemographic and health-related factors that have been reported to affect the DA level in previous studies [5,8–13], and the DA. Sociodemographic factors included gender, age, educational level, currently working, and household income. Collected data were reclassified based on the objectives of the study. Age was categorized as “30–39 years”, “40–49 years”, “50–59 years”, “60–69 years”, and “70 years or older”. However, due to the small sample size of “30–39 years” group, we incorporated “30–39 years” and “40–49 years” group to “30–49 years”. Educational level categories were “elementary school and below”, “middle school”, “high school”, and “college and above”. Currently working was categorized as “yes” or “no” based on the current employment status. Household income was categorized by quartile as “low” (less than 1 million won per month), “lower-middle” (between 1 million and 2 million won), “upper-middle” (between 2 million and 3 million won), and “high” (more than 3 million won).

Health-related factors included a health screening in the past two years, current drinking, current smoking, physical activity, BMI, comorbidity (hypertension, dyslipidemia), A1C level, and family history of DM. Current risk behaviors were defined in two stages. First, drinking and smoking were categorized as “never”, “former”, and “current” based on response to the survey question on drinking status or smoking status. Second, they were recategorized as “neither”, “drinking only”, “smoking only” and “both” based on whether or not they currently drink or smoke. Physical activity was categorized as “yes” or “no” based on “pa-aerobic” variable built by KNHANES team, which was defined as moderate intensity activity for at least two and half hours or high intensity activity for at least one hour 15 minutes, or combined activity a week [2]. BMI was calculated with the formula body weight (kg)/height^2 (m^2). Based on the classification of the Korean Society for the Study of Obesity [14], BMI was categorized as “underweight (BMI <18.5),” “normal weight (BMI: 18.5–22.9)”, “overweight (BMI: 23–24.9)”, and “obese (BMI ≥25).” However, the sample size of “underweight” group was very small and negligible (4 in men, 6 in women), thus we incorporated underweight and normal weight to “normal weight” group. Comorbidity was defined as affirmative response to the survey question on history of diagnosed hypertension or dyslipidemia, and categorized into “neither”, “hypertension only”, “dyslipidemia only”, and “both”. A1C level was measured in the central laboratory by collecting blood and categorized as “<5.7%” (normal), “5.7–6.4%” (prediabetes), “≥6.5%” (diabetes) for A1C [1]. Family history of DM was defined as any of the parents or siblings' affirmative responded to the survey question on history of diagnosed DM. The DA was defined as the proportion of individuals who showed affirmative response to the survey question on history of diagnosed DM among all individuals with DM [5].

Statistical analysis

The data were analyzed with SPSS 23.0 statistical software (IBM Corp., Armonk, NY, USA) using a complex sample analysis, and the combined sampling weight of two years was calculated by multiplying weight by the ratio of the number of survey units by year according to the KNHANES manual [2]. Statistical significance was set at $p < .05$. For the data on the general characteristics, health-related factors, and the DA level, categorical variables were presented as unweighted frequencies and weighted percentages, and continuous variables were presented as means and standard errors. Odds ratio (OR) and 95% confidence interval (CI) were calculated using a simple logistic regression analysis to evaluate DA in terms of sociodemographic and health-related factors. With significant

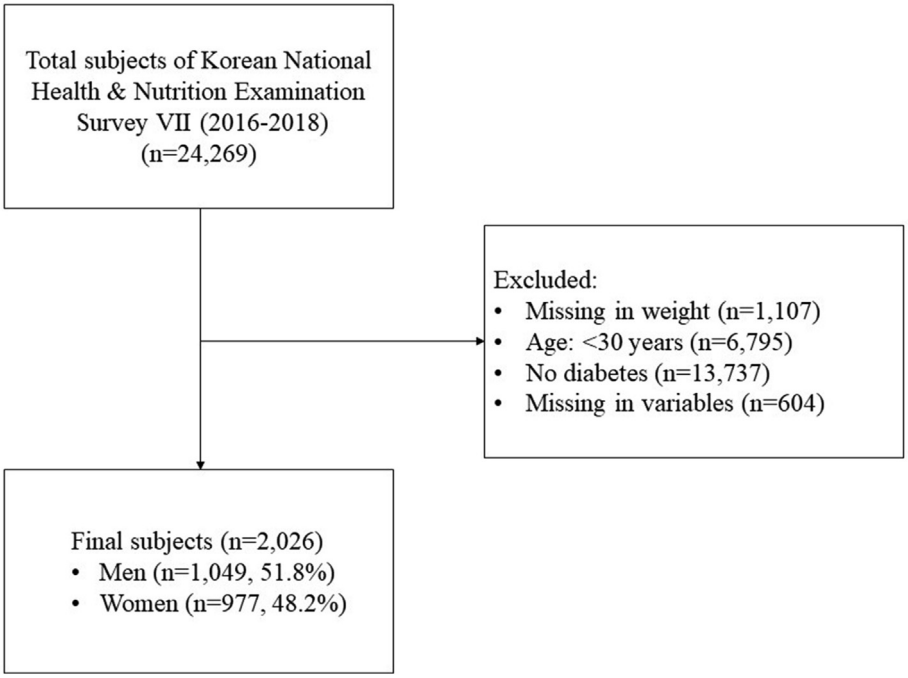

Figure 1. Flowchart of study participants' selection.

variables from the simple logistic regression analysis as explanatory variables, we calculated odds ratios (ORs) and the associated 95% confidence intervals (CIs) through stepwise multiple logistic regression analysis after confirming no deviation from the assumption of multicollinearity using less than .80 of coefficient of determination [15].

Meanwhile, a sensitivity analysis was done to check the robustness of the findings on the DA level and factors associated including those who were excluded because of missing in explanatory variables. That is, we compared the characteristics of between those who were included in this study and excluded because of missing in explanatory variables using χ^2 test, and all characteristics were significantly different each other except A1C among women (Supplementary Tables 1 and 2).

Ethical considerations

This study was conducted after receiving permission for the use of data from the website of the National Health and Nutrition Survey, and approval of exempt review (Approval no. 05-2019-053) from the Institutional Review Board of the Pusan National University Hospital.

Results

Sociodemographic and health-related characteristics of the participants

Table 1 presents the sociodemographic and the health-related characteristics of the participants by gender in the KNHANES VII study. Among 1,049 men, mean age was 57.48 years, and most of them were educated above high school level (68.0%), and in the upper-middle and high income group (54.2%), had undergone a health screening within the past two years (73.5%), and 22.8% had history diagnosed hypertension and dyslipidemia. Among 977 women, mean age was 62.66 years, and 45.5% of them were

Table 1 *Sociodemographic and Health-Related Characteristics and Awareness of Diabetes Mellitus (N = 2,026).*

Characteristics		Men (N = 1,049)	Women (N = 977)	*p*
		n (%)†	n (%)†	
Age (yrs)	30–49	198(25.8)	123(15.4)	<.001
	50–59	258(31.6)	202(25.8)	
	60–69	305(25.0)	278(24.8)	
	≥70	288(17.6)	374(34.0)	
	mean ± standard error	57.48 ± 0.44	62.66 ± 0.46	
Educational level	Elementary school or less	234(16.9)	479(45.5)	<.001
	Middle school	167(15.1)	164(15.9)	
	High school	353(35.3)	242(28.7)	
	College or higher	295(32.7)	92(9.9)	
Currently working	Yes	699(73.7)	376(40.1)	<.001
	Low	273(21.3)	384(35.9)	<.001
Household income (in quartile)	Lower-middle	271(24.5)	253(25.8)	
	Upper-middle	263(28.1)	190(21.2)	
	High	242(26.1)	150(17.1)	
Ever health screening in past 2 yrs	Yes	770(73.5)	646(65.0)	.001
Current drinking and smoking	Neither	185(15.2)	526(50.9)	<.001
	Drinking only	499(48.4)	421(46.1)	
	Smoking only	66(6.0)	8(1.0)	
	Both	299(30.4)	22(2.0)	
Physical activity	Yes	413(41.8)	292(32.3)	<.001
Body mass index (kg/m^2)	≤22.9 (normal)	265(23.9)	236(23.4)	.360
	23–24.9 (overweight)	267(25.0)	226(22.2)	
	≥25(obesity)	517(51.1)	515(54.4)	
Comorbidity	Neither	383(40.4)	226(25.1)	<.001
	Hypertension only	293(24.6)	238(22.5)	
	Dyslipidemia only	127(12.2)	165(17.8)	
	Both	246(22.8)	348(34.6)	
Glycated hemoglobin (%)	<5.7 (normal)	54(4.8)	34(3.5)	.421
	5.7–6.4 (prediabetes)	248(24.0)	240(25.2)	
	≥6.5 (diabetes)	747(71.2)	703(71.3)	
Presence of family history of DM	Yes	416(42.9)	440(45.0)	.417
Awareness of DM	Yes	678(60.2)	684(68.4)	.001

Note. DM = diabetes mellitus; yrs = years.
† Data are expressed as weighted percent.

elementary school and below, 40.1% were currently working, and 34.6% had history diagnosed hypertension and dyslipidemia. Men showed significantly different from women in characteristics except BMI, A1C level, and family history of DM.

The level of and factors associated with DA

The overall DA level was 63.7%, and significantly higher in women (68.4%) than in men (60.2%) (Table 1).

According to Table 2, the DA level in men was significantly different by age, educational level, currently working, household income, receiving health screening in the past two years, current drinking and smoking, BMI, comorbidity, and family history of DM. As a result of a multiple logistic regression analysis, the DA level was higher in men aged 50 years or older than in reference group under the age of 49 years, in men with elementary school and less (OR = 1.76), or high school (OR = 1.66) education than men with college and above education, in men with health screening in past two years than men without (OR = 1.89), with BMI of 22.9 or less than men with BMI of 25 or more (OR = 1.77), with either hypertension or dyslipidemia than without both of them, and with family history of DM than men without (OR = 2.23).

According to Table 3, the DA level in women was significantly different by age, educational level, currently working, BMI, comorbidity, A1C level and family history of DM. As a result of a multiple logistic regression analysis, the DA level was higher in women aged 70 years or older than in reference group under the age of 49 years (OR = 2.15), in women with elementary school and less than women with college level and above education (OR = 1.82), with BMI of 22.9 or less than women with BMI of 25 or more (OR = 1.70), with either hypertension or dyslipidemia than without both of them, with family history of DM than women without (OR = 1.91), and showed higher in women with A1C of 5.7-6.4% (OR = 2.63) than under 5.7%.

Sensitivity analyses

According to a sensitivity analysis, the DA level was 61.6% in men and 69.7% in women, and the factors associated with the DA level showed the similar trends to the results when using only those who met the inclusion criteria among both men and women. However, educational level was not significantly related with the DA level among women although those who were elementary school or less showed the highest level of DA (Supplementary Tables 3 and 4).

Discussion

DA is critical for the positive treatment and control of DM [4]. This study determined the DA level and identified factors associated with DA using data from a recent nationwide representative survey. The overall DA level in this study was slightly improved compared to the value of 61.8% in a previous study conducted in Korea [5], but the DA level still needs improvement, especially in men. However, a direct comparison between the two findings should be made carefully considering the differences in data sources, inclusion criteria based on age, and definitions of DM. The DA level was higher in women than in men in this study, which supports the findings of several previous studies performed in Korea [5], the Southern Cone of Latin America [8], and China [11]. Considering that the risk of complications is predicted to be high in

Table 2 *Factors Associated with Awareness of Diabetes Mellitus in Men (N = 1,049).*

Characteristics		DA (n = 678) n (%)†	Unadjusted OR (95% CI)	*p*	Adjusted OR (95% CI)	*p*
Age (yrs)	30–49	74(34.7)	1		1	
	50–59	157(60.9)	2.92(1.94–4.39)	<.001	2.32(1.47–3.64)	<.001
	60–69	223(73.0)	5.07(3.29–7.82)	<.001	4.14(2.44–7.02)	<.001
	≥70	224(77.9)	6.61(4.24–10.31)	<.001	5.52(3.03–10.05)	<.001
Educational level	Elementary school or less	177(74.3)	3.33(2.22–4.90)	<.001	1.76(1.03–3.02)	.039
	Middle school	123(69.5)	2.62(1.62–4.24)	<.001	1.63(0.92–2.90)	.097
	High school	227(62.0)	1.87(1.31–2.67)	.001	1.66(1.08–2.54)	.020
	College or higher	151(46.5)	1		1	
Currently working	Yes	422(56.7)	1		1	
	No	256(70.0)	1.78(1.30–2.44)	<.001	0.96(0.63–1.46)	.861
Household income (in quartile)	Low	201(68.5)	1.59(1.07–2.38)	.023	0.92(0.54–1.57)	.750
	Lower-middle	166(55.7)	0.92(0.62–1.36)	.673	0.72(0.44–1.16)	.174
	Upper-middle	168(60.0)	1.10(0.73–1.66)	.660	1.14(0.72–1.79)	.575
	High	143(57.7)	1		1	
Ever health screening in past 2 yrs	Yes	523(64.2)	1.87(1.36–2.55)	<.001	1.89(1.33–2.66)	<.001
	No	155(49.0)	1		1	
Current drinking and smoking	Neither	139(70.5)	2.23(1.38–3.60)	.001	1.42(0.79–2.55)	.238
	Drinking only	327(61.4)	1.48(1.05–2.09)	.025	1.09(0.74–1.60)	.666
	Smoking only	45(65.9)	1.80(0.94–3.45)	.077	0.97(0.45–2.07)	.931
	Both	167(51.8)	1		1	
Physical activity	Yes	255(59.4)	0.95(0.71–1.28)	.737		
	No	423(60.7)	1			
BMI (kg/m^2)	≤22.9 (normal)	187(68.1)	1.88(1.29–2.75)	.001	1.77(1.11–2.80)	.016
	23–24.9 (overweight)	183(66.8)	1.78(1.22–2.60)	.003	1.37(0.89–2.11)	.156
	≥25(obesity)	308(53.2)	1		1	
Comorbidity	Neither	172(39.4)	1		1	
	Hypertension only	207(65.6)	2.93(2.02–4.26)	<.001	2.42(1.61–3.64)	<.001
	Dyslipidemia only	103(81.9)	6.96(3.78–12.82)	<.001	6.57(3.32–13.00)	<.001
	Both	196(79.2)	5.85(3.84–8.92)	<.001	5.87(3.74–9.22)	<.001
Glycated hemoglobin (%)	<5.7 (normal)	32(55.6)	1			
	5.7–6.4 (prediabetes)	150(55.9)	1.01(0.49–2.11)	.977		
	≥6.5 (diabetes)	496(61.9)	1.30(0.67–2.50)	.436		
Presence of family history of DM	Yes	296(64.7)	1.39(1.03–1.89)	.033	2.23(1.57–3.18)	<.001
	No	382(56.8)	1		1	

Note. BMI = body mass index; CI = confidence interval; DA = diabetes awareness; DM = diabetes mellitus; OR = odds ratio; yrs = years.
† Data are expressed as weighted percent.

Table 3 *Factors Associated with Awareness of Diabetes Mellitus in Women (N = 977).*

Characteristics		DA (n = 684) n (%)†	Unadjusted OR (95% CI)	p	Adjusted OR (95% CI)	p
Age (yrs)	30–49	53(48.6)	1		1	
	50–59	135(64.8)	1.94(1.15–3.27)	.013	1.27(0.69–2.34)	.444
	60–69	200(70.3)	2.49(1.53–4.07)	<.001	1.31(0.67–2.56)	.432
	≥70	296(78.6)	3.88(2.32–6.47)	<.001	2.15(1.04–4.47)	.040
Educational level	Elementary school or less	367(74.8)	2.56(1.51–4.34)	<.001	1.82(1.00–3.30)	.049
	Middle school	119(69.6)	1.98(1.10–3.57)	.023	1.78(0.94–3.37)	.076
	High school	151(62.5)	1.44(0.86–3.43)	.165	1.61(0.94–2.77)	.084
	College or higher	47(53.6)	1		1	
Currently working	Yes	239(62.0)	1		1	
	No	445(72.6)	1.63(1.20–2.22)	.002	1.35(0.94–1.92)	.102
Household income (in quartile)	Low	291(72.6)	1.49(0.93–2.38)	.101		
	Lower-middle	179(67.3)	1.16(0.70–1.90)	.572		
	Upper-middle	124(65.9)	1.09(0.65–1.81)	.754		
	High	90(64.1)	1			
Ever health screening in past 2 yrs	Yes	464(70.9)	1.39(0.99–1.95)	.057		
	No	220(63.6)	1			
Current drinking and smoking	Neither	392(72.9)	1.39(0.41–4.68)	.598		
	Drinking only	270(63.0)	0.88(0.26–2.94)	.833		
	Smoking only	6(85.2)	2.96(0.36–24.13)	.310		
	Both	16(66.0)	1			
Physical activity	Yes	205(70.2)	1.14(0.80–1.62)	.465		
	No	479(67.5)	1			
BMI (kg/m^2)	≤22.9 (normal)	177(71.6)	1.37(0.92–2.03)	.124	1.70(1.08–2.66)	.022
	23–24.9 (overweight)	169(73.5)	1.51(1.02–2.23)	.039	1.55(0.97–2.48)	.069
	≥25(obesity)	338(64.8)	1		1	
Comorbidity	Neither	106(45.2)	1		1	
	Hypertension only	177(74.6)	3.55(2.26–5.57)	<.001	2.98(1.77–5.02)	<.001
	Dyslipidemia only	132(80.4)	4.95(2.92–8.38)	<.001	4.94(2.86–8.54)	<.001
	Both	269(75.0)	3.62(2.46–5.33)	<.001	3.25(2.05–5.17)	<.001
Glycated hemoglobin(%)	<5.7 (normal)	18(51.1)	1		1	
	5.7–6.4 (prediabetes)	184(75.2)	2.90(1.21–6.96)	.017	2.63(1.02–6.82)	.046
	≥6.5 (diabetes)	482(66.8)	1.92(0.86–4.30)	.111	2.18(0.93–5.13)	.074
Presence of family history of DM	Yes	332(73.7)	1.58(1.15–2.17)	.005	1.91(1.33–2.74)	<.001
	No	352(64.0)	1		1	

Note. BMI = body mass index; CI = confidence interval; DA = diabetes awareness; DM = diabetes mellitus; OR = odds ratio; yrs = years.
† Data are expressed as weighted percent.

men because the high prevalence of DM [5,16], the need to improve the DA level is more urgent in men than in women.

The DA level was associated with age, educational level, BMI, comorbidities such as hypertension and dyslipidemia, and a family history of DM in both men and women. Higher DA levels were seen in those who were older, especially those aged ≥50 years among men and ≥70 years among women; less educated; had normal weight (BMI ≤22.9 kg/m^2); had comorbidities such as hypertension and dyslipidemia; and had a family history of DM, regardless of sex. These findings have several implications. First, the DA level increased with age, as observed in many previous studies [5,8–13]. Elderly people are more concerned about their health conditions, more interested in health-promoting behaviors [17], and more willing to gain awareness of their medical conditions than younger people who are less aware of their health risks [13]. Among people in their 40s and those aged <40 years, both the level of participation in national health screening (men 67.5%, women 55.8%) and the DA level were the lowest in both men and women. The DA level was high in those with an elementary school or lower education level than in those with a college or higher education level. This finding may be explained by the significant negative correlation between age and educational level ($\rho = -.42$ in men, $\rho = -.57$ in women, both $p < .001$) found in an additional analysis in this study. For both men and women aged ≥70 years, elementary school education was the most common (Supplementary Table 5). As mentioned previously, because of the high DA level among those aged ≥70 years, it seems that the DA level was high in people with an elementary school or lower education level. Therefore, health education programs and campaigns about regular blood glucose tests and doctor consultation should be further emphasized among young adults and adults with a high level of education in Korea. Such health programs could be started in universities as a part of the health-related curriculum [13] or at workplaces as health promotion programs.

People with obesity (BMI ≥25 kg/m^2) are less likely to be aware of their hyperglycemic condition, which supports the findings of a previous study in Korea [5]. However, several studies on the DA level did not show a significant relationship between obesity and the DA level [11,13], and this difference may be related to the BMI criteria considered for classifying obesity. A BMI ≥25 kg/m^2 is considered to indicate obesity in Korea [14], but a BMI ≥28 or ≥30 kg/m^2 was considered to indicate obesity in previous studies in China [11] and Malaysia [13], respectively. Obesity is well known to be associated with DM [18–20]; thus, people with obesity should be aware of their hyperglycemic condition. However, people with obesity with a BMI ≥25 kg/m^2 was even lower than that of people with a BMI ≤22.9 kg/m^2 (normal weight), regardless of sex. Nurses should arrange "know my blood sugar level" time as a part of weight control programs for people with obesity and emphasize the importance of regular blood glucose tests and awareness of their hyperglycemic condition during the program.

People with hypertension or dyslipidemia showed above-average DA levels and were more likely to be aware of their hyperglycemic condition than people without these conditions, as observed in previous studies [9,10]. Considering that hypertension and dyslipidemia are well-known risk factors for DM [21,22] and that people at high risk of DM should be aware of their hyperglycemic condition, this finding is encouraging. However, only approximately 4 in 10 people without both hypertension and dyslipidemia were aware of their DM status, and thus, it is

important to educate adults who do not have underlying diseases such as hypertension and dyslipidemia to be mindful of their health conditions and undergo regular health screening.

People with a family history of DM showed significantly higher DA levels regardless of gender, which is consistent with the findings of previous studies [5,11,13]. People with a family history of diseases perceive themselves to be more vulnerable and susceptible to diseases [23] and undergo screening more often than those without a family history of diseases [23], which may lead to an increase in disease awareness. To increase the level of DA among people with no family history of DM, efforts should be made to educate them that DM occurs in conjunction with genetic and environmental risk factors [24].

Having undergone health screening in the past 2 years was associated with the DA level only in men, while the HbA1c level was associated with the DA level only in women. As undergoing health checkups is known to lead to an increase in the DA level [25], the higher participation in health checkups in men than in women may have contributed to findings observed in this study. In 2017, the rate of participation in national health screening was 79.7% among men, which was higher that the value of 77.2% among women [26]. Women with prediabetes (HbA1c levels of 5.7–6.4%) showed the highest DA level. Surprisingly, only two-thirds of women with HbA1c levels above 6.5% were aware of DM, which was not significantly different from that in those with a normal glycemic condition. As HbA1c is an index of long-term glycemic control [27], people with a high level of HbA1c are vulnerable to diabetic complications. Therefore, it is necessary to establish a system at the national level and to inform people through campaigns that dietary management and regular blood sugar tests are needed in the prediabetes stage.

Household income was not related to DA levels in both men and women. Findings on household income levels and DM have been inconsistent across studies: either a proportional relationship [9] or no relationship [10]. Findings from another study indicated that those with very low or very high household income levels showed higher DA levels than the others [13]. As people in Korea have more opportunities for checking their blood glucose levels every 2 years via a free health screening [28] or by visiting clinics or public health centers (levels can be assessed at a low cost under the National Health Insurance Program), they can be aware of their hyperglycemic condition regardless of their economic status. Smoking status, drinking status, and physical activity were not related to DA levels in both men and women. The results for the relationship between smoking status and DA levels were consistent with those of previous studies [8,11,13]. The results of the relationship between drinking status and DA levels were inconsistent in previous studies: no relationship [8] or negative correlation [11]. In addition, the results for the relationship between physical activity and DA levels were inconsistent in previous studies: no relationship [11,13] or the relation of high DA levels with low physical activity levels [8]. Therefore, it is necessary to further investigate the relationship between drinking status and physical activity and DA.

This study has several strengths. First, to the best of our knowledge, this is the first study to identify the level of DA and associated factors according to gender using the most recent nationwide community-based data in Korea and to show sex-specific findings. In particular, the KNHANES involved nationally representative data and was conducted using a standardized questionnaire in accordance with a standardized protocol by trained investigators, which increases the generalizability and validity of our findings. Second, we used both fasting blood glucose test results and HbA1c test results for selecting people with DM. DM in previous studies was defined based only on fasting blood glucose test results [5,8–13], even though HbA1c is widely used by healthcare professionals to diagnose DM [1]. Third, we confirmed the robustness of the findings through a sensitivity analysis including those who were excluded because of missing in explanatory variables. Therefore, the findings of this study may be applied to those aged ≥30 years with DM.

However, caution must be exercised when interpreting our results because of the following limitations: First, we could not use the data of the oral glucose tolerance test (OGTT) to select people with DM because it was not performed during the KNHANES. If OGTT data had been included, the number of patients with DM would most likely have been higher, which could affect the level of DA. Second, in this study, BMI was classified according to guidelines from the World Health Organization (in its publication, the Asia-Pacific Perspective) and the Korean Society for the Study of Obesity; therefore, caution should be exercised when generalizing these results to other populations, even to Westerners. Third, those who had missing values on explanatory variables (sociodemographic and health-related factors) among subjects aged ≥30 years with DM were excluded from this study. Finally, because this was a cross-sectional study, it may be necessary to conduct studies with longitudinal data to avoid reverse causation bias.

Conclusion

Approximately 60.2% of men and 68.4% of women aged ≥30 years with DM are aware of their DM status; these values need to be improved in both men and women. Except for two factors, namely, participation in health screening in the past 2 years and HbA1c levels, all factors associated with DA levels were similar in both men and women. The level of DA was particularly low in those aged ≤49 years, with a higher level of education, with obesity, and without both hypertension and dyslipidemia, regardless of sex. Therefore, nurses in the community setting should identify high-risk populations with lower DA levels based on the present study findings, provide health education and conduct campaigns using mass media and social networks, and promote the use of medical services for people to become aware of their hyperglycemic condition.

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Conflict of interest

The authors declared no conflict of interest.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.anr.2021.01.003.

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Research Article

Evaluation of a Mobile-based Maternal Feeding Education Program for Overweight Prevention in Infants

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SUMMARY

Purpose: The purpose of this study was to evaluate a mobile-based maternal feeding education program for overweight prevention in infants based on breastfeeding attitude, breastfeeding self-efficacy, breastfeeding duration, recognition of hunger and satiety cues of infants, and knowledge regarding providing solids foods.

Methods: A nonequivalent control group pretest-posttest design was used for the study. Participants included 15 primiparas in the experimental group and 14 primiparas in the control group in all the follow-up tests. Using self-reported questionnaires in electronic format, data were collected four times (before the intervention, 1 month after childbirth, 3 months after childbirth, and 6 months after childbirth). Using SPSS 24 version, independent *t*-test and repeated-measures analysis of variance were used to test the effects of the mobile-based maternal feeding education program.

Results: The experimental group showed significantly more positive breastfeeding attitude ($F = 5.28$, $p = .008$), higher breastfeeding self-efficacy ($F = 3.50$, $p = .041$), and increased breastfeeding duration ($t = -2.09$, $p = .046$) than the control group. In addition, the experimental group showed significantly improved knowledge regarding providing solid foods to the infants ($F = 4.86$, $p = .009$) in comparison with the control group. However, for education on recognizing hunger and satiety cues of infants, the mobile-based maternal feeding education program was not effective ($F = 0.23$, $p = .878$).

Conclusion: According to the results of this study, the mobile-based maternal feeding education program has the potential to contribute to overweight prevention in infants.

Introduction

Infancy is a developmental stage when the formation of feeding patterns and eating habits causing overweight in childhood [1]. In this regard, rapid weight gain might easily develop in infancy, and rapid weight gain during infancy is significantly associated with the development of overweight and obesity in childhood after infancy [2]. In previous studies, overweight infants had 3.1-fold and 17.5-fold increased likelihood of overweight and obesity in preschool age and adolescence, respectively [3,4]. Therefore, infancy was considered to be a critical period for the early prevention of overweight and obesity in children [5]. In particular, as overweight in infancy resulted from excessive energy intake and overnutrition via feeding [5], Cloutier et al. [6] emphasized the need for a maternal feeding education program for overweight prevention in infancy.

According to a model for the development of an early childhood obesity prevention program, the maternal feeding education program for the prevention of excessive weight gain in infants might increase the maternal positive attitude and self-efficacy in breastfeeding and providing food to the infants by helping recognize and respond sensitively to the hunger and satiety cues of the infants [6]. Infantile feeding and eating patterns for the prevention of excessive weight gain were formed on the basis of the maternal feeding behaviors [6]. In existing family-based and parental programs for overweight prevention of infants, educational content has mainly focused on improving positive breastfeeding attitudes, breastfeeding self-efficacy, sensitivity to recognize hunger and satiety cues of infants, and knowledge about the correct solid foods to be given to infants [7–10]. Therefore, as an early life intervention for the prevention of overweight in infants, maternal feeding

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education programs should focus on addressing the key factors responsible for the formation of maternal feeding patterns.

According to previous studies, the maternal feeding education programs for the prevention of excessive weight gain of infants were mainly provided by postpartum home visits and face-to-face meetings [8–10]. However, in the Korean health care system, a postpartum home visiting program is not provided for parenting education and health care of mothers and their infants. In addition, Korean mothers traditionally limit contact with other people for approximately 3 months postpartum. Therefore, maternal education based on a home visiting program and face-to-face meetings might be inappropriate intervention strategies during postpartum periods in Korean society.

However, mobile-based parental education programs have been actively developed because most Korean people use smartphones [11,12]. Mobile websites might contain various educational contents, such as pictures, figures, and videos required for modeling a parental education program [13]. The success rates and satisfaction levels with the online education programs were high because of the availability of repeated learning and practice by frequently using mobile websites [13]. In addition, for mothers with newborns who cannot receive education at a fixed place and time [14], mobile-based education programs can prove to be highly user friendly, helping the mothers receive education at a place and time convenient for them.

Therefore, the purpose of this study was the development and evaluation of a mobile-based maternal feeding education program for the prevention of overweight in infants. We proposed the following hypothesis. The mothers who participated in the intervention would have an increased (1) positive breastfeeding attitude, (2) breastfeeding self-efficacy, (3) breastfeeding duration, (4) sensitivity to recognize hunger and satiety cues of their infants, and (5) knowledge regarding providing solid foods for overweight prevention in infants.

Methods

Study design

A nonequivalent control group pretest-posttest design was used to test the effects of the mobile-based maternal feeding education program for overweight prevention in infants.

Participants

The participants of the study were first-time pregnant mothers with more than 36 weeks gestational age, recruited from two different obstetrics and gynecology clinics located in Daejeon (metro city), South Korea. We used a convenience sampling method to select the clinics and participants. From each of the clinics, participants for the experimental and control groups were selected according to the inclusion and exclusion criteria. The inclusion criteria were as follows: (1) mothers who gave consent to participate, (2) mothers who were primary caregivers of their infants, and (3) mothers of infants born after more than 37 weeks and weighing more than 2500g at birth. The exclusion criteria were as follows: (1) mothers with twin infants, (2) mothers of infants with congenital deformities (e.g., cleft palate) and other health issues related to feeding difficulties, and (3) mothers who had participated in other maternal feeding education programs for overweight prevention in infants within 1 year of this study.

Using the G-3.1.2 power program, 24 was the required sample size with a medium effect size of 0.25 [15], a significance level of 0.05, statistical power of 0.80, two groups, four measures, and two-way repeated-measures analysis of variance (ANOVA). When considering a 20% dropout rate similar to a previous study with mobile-based health education [11], 29 might be the appropriate number for the final sample size. From July to August 2019, 19 and 14 mothers for the experimental and control groups, respectively, were selected. After the pretest, four mothers in the experimental group refused to participate in this study because of increased burden of caring for infants. Thus, 15 mothers in the experimental group were involved in all follow-up tests. Among the 14 mothers in the control group, there were no dropouts during the study process (Figure 1).

Ethical consideration

All the procedures and methods of this study were approved by the institutional review board of the research institute at the Chungnam National University, where a researcher of this study was involved (Approval no. 201903-SB-034-01). The researcher and a trained research assistant explained the purpose, procedures, methods of the study, informed the participants that the participation was voluntary and they could leave the study at any stage, and that the study respected individual rights and all information collected from the participants would be used confidentially and only for this study. Written informed consent was obtained from all the participants. Approximately 20 US dollars (20,000 won in Korea) was provided at every stage of evaluation, including pretest and follow-up tests.

Measures

To verify homogeneity of characteristics in the experimental and control groups, characteristics of infants and mothers were evaluated with risk factors for overweight in infancy. Characteristics of infants involved sex (female or male), gestational age (weeks), birth weight (grams), and delivery type (vaginal delivery or cesarean section). In addition, maternal characteristics involved current age (years), marital status (married or other), educational level (high school, 2-year and 4-year college, or more than 4-year college), perceived current socioeconomic status of family (high, middle, or low), weight gain during pregnancy (kilograms), smoking experience during pregnancy (yes or no), diagnosed with diabetes mellitus during pregnancy (yes or no), and diagnosed or treated for depression by certified psychiatrist during pregnancy (yes or no).

To evaluate the effects of the mobile-based maternal feeding education program, breastfeeding attitude, breastfeeding self-efficacy, and breastfeeding duration were assessed. In addition, recognition of hunger and satiety cues of infants and knowledge regarding providing solid foods for overweight prevention in infants were assessed with the mothers.

Breastfeeding attitude

Breastfeeding attitude was assessed using the Iowa Infant Feeding Attitude Scale, originally developed by De la Mora and Russell [16] and translated and validated in Korean by Ra and Chae [17]. The instrument consisted of 17 items, and responses toward each item were available on a 5-point Likert scale (1 = *strongly disagree* to 5 = *strongly agree*). Possible total scores ranged from 15 to 85 points, where a higher score indicates a more positive breastfeeding attitude. Cronbach's α is .86 in a study by De la Mora and Russell [16] and .72 in a study by Ra and Chae [17]. Cronbach's α in this study was .64–.82 according to the follow-up test of experimental and control groups.

Breastfeeding self-efficacy

Breastfeeding self-efficacy was assessed using the Breastfeeding Self-efficacy Scale-Short Form, originally developed by Dennis [18] and translated and validated in Korean by Ra and Chae [19]. The

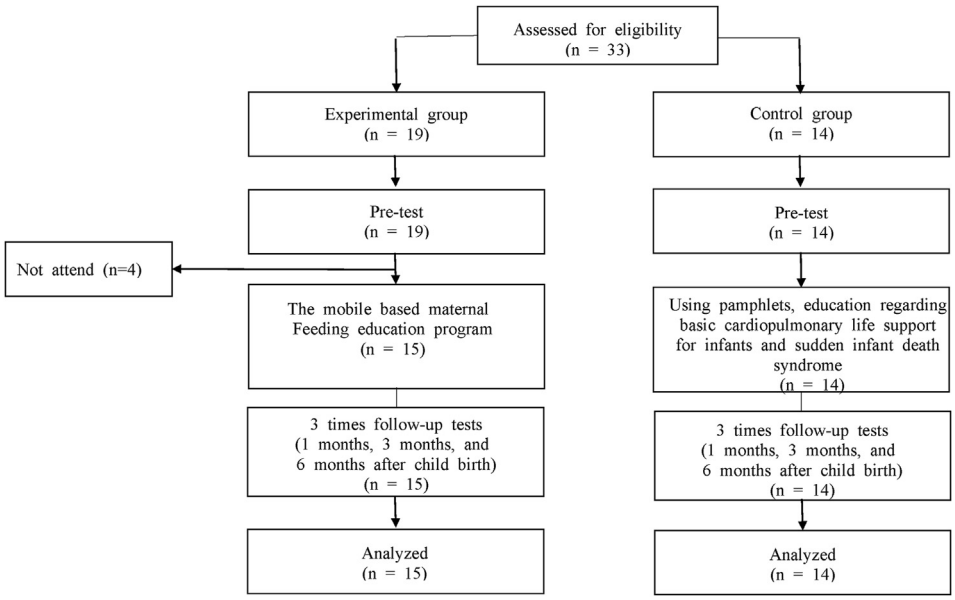

Figure 1. Flow diagram for participants.

instrument consisted of 14 items, and response toward each item was available on a 5-point Likert scale (1 = *never confident* to 5 = *always confident*). Possible total scores ranged from 14 to 70 points, where a higher score indicated higher breastfeeding self-efficacy. Cronbach's α is .96 in a study by Dennis [18] and .94 in a study by Ra and Chae [19]. Cronbach's α in this study was .84–.92 according to the follow-up test of experimental and control groups.

Breastfeeding duration

Breastfeeding duration was assessed from a single question. Participants were asked to indicate for how many days they had breastfeed until 6 months (180 days) after childbirth.

Recognition of hunger and satiety cues by infants

Recognition of hunger and satiety cues by infants was assessed through four items of the Infant Feeding Questionnaire, originally developed by Baughcum [20] and translated and validated in Korean by Ra, Jeong, and Kim [21]. Response toward each item was available on a 5-point Likert scale (1 = *strongly disagree* to 5 = *strongly agree*). The mean score per item ranged from 1 to 5 points, where a higher score indicated increased recognition of hunger and satiety cues by infants. Cronbach's α is .70 in a study of Baughcum [20] and 75 in a study by Ra et al [21]. Cronbach's α in this study was .70–.85 according to follow-up test of experimental and control groups.

Knowledge regarding providing solid foods for overweight prevention in infants

Knowledge regarding providing solid foods for overweight prevention in infants was assessed with four items in the instrument, which evaluated infant feeding knowledge of mothers [22]. One correct response for each item scored 1 point, and higher score (ranged 0–4 points) indicated increased knowledge regarding providing the solid foods, which would not cause overweight in infants.

Intervention procedures

Development of mobile-based maternal feeding education program for overweight prevention of infants

Themes, subthemes, and content development of the education program

For the development of themes, subthemes, and the content of the education, a literature review was conducted. According to the review, maternal feeding behaviors associated with overweight in infants was formula feeding with/without breastfeeding [1,23]; regular feeding pattern in fixed schedules and overfeeding without considering hunger and satiety cues of infants [1,24]; early providing of solid foods (<4 months) [25]; and providing of sweet beverage, juices, and high calories snacks with solid foods [1,24]. Thus, breastfeeding, responsive feeding considering hunger and satiety cues of infants, and providing appropriate solid foods were categorized as the themes. In addition, according to the themes, the subthemes and the content were developed, which included textbooks, currently developed educational material that is open to the public, and educational articles (Table 1).

Then, five pediatricians and five professors in child health nursing confirmed the contents' validity. They suggested the need for educational content for understanding childhood overweight or obesity (e.g., causes, problems because of childhood overweight or obesity, and prevention methods). Consequently, themes, subthemes, and contents of education regarding childhood overweight or obesity were added. Finally, according to content validity from five pediatricians and five professors in child health nursing, the content validity index was calculated as 3.2–4.0 points.

Mobile website construction

For mobile website construction, the researcher developed storyboards including short and core subtitles, pictures, figures, and videos according to the contents. Also, narrations were developed for each storyboard. Pictures, figures, and videos were used from the web with the permission of the copyright holder. If permission was not provided for using of pictures, figures, and video, illustrations replaced them. A total of 58 storyboards were developed, with 53 containing educational content, two for instruction on the program, and three for summary and wrap-up. Three professors in child health nursing and one pediatrician confirmed the content validity of the storyboards and narration.

In initial meetings, two web designers and the researcher designed the web pages, including layout, background color, letter

Table 1 *Themes, Subthemes, and Contents of the Mobile-Based Maternal Feeding Education Program.*

Themes	Subthemes	Contents
Childhood overweight/obesity	1. Characteristics of childhood overweight/obesity	1) Characteristics of childhood overweight/obesity. (Increased number and size of fat cells) 2) The need for childhood overweight/obesity prevention in early life, including infancy.
	2. Diagnosis of childhood overweight/obesity	1) Diagnostic criteria for childhood overweight/obesity. 2) Interpretation methods of children's weight status based on the developmental growth curve.
	3. Causes of childhood overweight/obesity.	1) Causes of childhood overweight/obesity.
	4. Problems associated with childhood overweight/obesity.	1) Physical, psychological, social health problems associated with childhood overweight/obesity.
Breastfeeding	1. Beneficial effects and methods of breastfeeding.	1) Beneficial effects of breastfeeding for growth and development in infancy. 2) Methods of breastfeeding initiation and maintaining and precautions for breastfeeding. 3) Postures for breastfeeding. 4) Methods to stop breastfeeding. 5) Understanding the satiety cues of breastfed infants.
	2. Overweight prevention during breastfeeding in infancy.	1) Overweight prevention effects of breastfeeding, compared with formula feeding, and mixed feeding with formula feeding and breastfeeding. 2) Composition of breast milk for overweight prevention in infants. 3) Improving self-regulation ability via breastfeeding for the prevention of obesity in infants. 4) Overweight prevention effects based on breastfeeding duration.
Responsive feeding	1. Responsive feeding according to hunger and satiety cues of infants.	1) Overweight prevention effects of responsive feeding according to hunger and satiety cues.
	2. Hunger and satiety cues.	1) Understanding of hunger cues in infants. 2) Understanding of satiety cues in infants.
	3. Similar cues compared with hunger cues.	3) Causes associated with similar cues (crying and irritation) in comparison with hunger cues.
	4. Caring according to causes of similar cues, in comparison with hunger cues.	4) Caring according to causes of similar cues (crying and irritation), in comparison with hunger cues.
Providing solid food	1. General methods and precautions for providing solid food.	1) Need for solid food and precautions related to providing solid food. 2) Methods for the provision of solid food according to age in months.
	2. Providing solid food for overweight prevention in infants.	1) Significance of solid food for obesity prevention in infants. 2) Association between the early provision of solid food and overweight in infants. 3) Limiting food for overweight prevention in infants when providing solid food. 4) Methods of providing solid food for overweight prevention in infants.

style and colors, and symbols according to the educational contents. Designed web pages were revised several times by the researcher and the web designers, and narration was finally recorded by a professional audiobook narrator for every web page.

Contents of mobile web were mainly categorized into three sections, including the introduction of the program, educational contents, and summary and wrap-up. In the introduction section of the program, the purpose of the program, using methods from the web, and the contact number of the researcher were presented. In the educational contents section, detailed education was provided according to the themes, subthemes, and educational content. Finally, in the summary and wrap-up section, summary and key points were presented according to the themes. Considering the attention span of 10–15 minutes in adults [26], all the educational content was provided within 10-minute blocks (4–9 minutes).

To make the website user friendly, icons representing the main three sections were placed on the homepage. In addition, touch icons for accessing detailed educational contents were provided. To revisit the information, icons for returning to previous pages of the educational contents were provided. In addition, icons for narration were placed to assist repeated hearing of the narration. On every last page, icons representing the educational contents were placed for accessing the subthemes. In addition, on every last page, icons for asking questions and giving opinions were also provided according to the themes. The researcher and two research assistants with doctoral degrees in nursing managed the website and answered any questions and comments from the participants. The web address is https://www. Healthybaby. online.

Through a model operation with three professors in child health nursing, five registered nurses with more than five years of working experience in pediatric wards, two web designers, and five first-time mothers of infants, the benefits, accuracy, comprehension of the website components, functionality, purpose, interactivity, confidentiality, and reliability of the website were evaluated (4.5~4.9 points/5 points) [11].

Implementation and data collection

For the experimental group, the feeding education program for overweight prevention in infants was provided through mobile from 38 weeks gestation to 6 months after childbirth. To ensure better understanding and recall by repetition, the researcher and

the research assistants encouraged the mothers to access the website at least once every 2 days, considering that memory from once accessed learning might be maintained up to 24 hours [27]. In addition, they confirmed the mothers' attendance every day and measured their access rates from the initial introduction section to the final summary and wrap-up section to guarantee completion of the entire educational content. For mothers who accessed the same educational contents for 3 days in a row and/or discontinued accessing the educational contents for 3 days, the researcher and research assistants sent text messages to encourage them to access the entire educational contents in the program.

Pamphlets containing information pertaining to basic cardiopulmonary life support for infants and prevention of sudden infant death syndrome were distributed to the control group participants. Using self-reported electronic questionnaires, data collection was conducted four times: before participation in the intervention and 1 month, 3 months, and 6 months after childbirth.

Statistical analysis

Statistical analysis was conducted using SPSS 24 version (IBM Corp., Armonk, NY, USA). Chi-square and independent *t*-tests were used for testing homogeneity characteristics of the participants and baseline breastfeeding attitude, breastfeeding self-efficacy, recognition of hunger and satiety cues of infants, and knowledge regarding providing solid foods for overweight prevention in infants between experimental and control groups, in the pretest. In addition, an independent *t*-test was conducted for comparing the mean values of breastfeeding duration until 6 months (180 days) after childbirth, between the experimental and control groups, in the final follow-up test (6 months after childbirth). A repeated-measures ANOVA was used to compare the changes in mean values of breastfeeding attitude, breastfeeding self-efficacy, recognition of hunger and satiety cues of infants, and knowledge regarding providing solid foods for overweight prevention in infants between the two groups in a pretest and three times in the follow-up test. A p-value <0.05 was considered to be statistically significant. A Bonferroni test was conducted for a post hoc test of the repeated-measures ANOVA. For statistical significance, the Bonferroni corrected p-value needed to be<.0083 (.05 of original significance level/6 of number of test).

Table 3 *Homogeneity of Outcome Variables Between Experimental and Control Groups.*

Variables	Exp (n = 15), M±SD	Cont (n = 14), M±SD	*t*	*p*
Breastfeeding attitude	57.20 ± 4.41	57.79 ± 2.91	0.43	.675
Breastfeeding self-efficacy	44.80 ± 6.99	41.50 ± 12.97	−0.86	.397
Recognition of hunger and satiety cues of infants	2.93 ± 0.40	2.89 ± 0.61	−0.21	.832
Knowledge regarding providing of solids foods	1.60 ± 0.63	1.93 ± 0.73	1.30	.205

Note. Cont. = control group; Exp. = experimental group; M = mean; SD = standard deviation.

Results

Homogeneity of characteristics of infants and mothers and outcome variables between experimental and control groups

There were no statistically significant differences in the characteristics (of infants and mothers) between the experimental and control groups (Table 2). In addition, in the pretest, there were no statically significant differences in breastfeeding attitude, breastfeeding self-efficacy, breastfeeding duration until 6 months (180 days) after childbirth, recognition of hunger and satiety cues of infants, and knowledge regarding providing solid foods for overweight prevention in infants between the two groups (Table 3) (See Table 4).

Effects of mobile-based maternal feeding education program for overweight prevention in infants

Regarding breastfeeding attitude, statistically significant differences were noticed across time points ($F = 11.84$, $p < .001$) and interactions between the groups and times ($F = 5.28$, $p = .008$),

Table 2 *Homogeneity of Characteristics of Infants and Mothers Between Experimental and Control Groups.*

Variables		Exp (n = 15) n (%)/M ± SD	Cont (n = 14) n (%)/M ± SD	t/χ^2	*p*
Infants' characteristics					
Sex	Boy	6 (40.0)	4 (28.6)	0.42	.518
	Girl	9 (60.0)	10 (71.4)		
Gestational age (wk)		39.22 ± 1.22	39.04 ± 1.02	−0.44	.661
Birth weight (g)		3,066.00 ± 264.60	3,080.93 ± 283.08	0.15	.884
Delivery type	Vaginal delivery	10 (66.7)	6 (42.9)	1.66	.198
	Cesarean section	5 (33.3)	8 (57.1)		
Maternal characteristics					
Current age (yr)		32.07 ± 4.15	31.14 ± 4.07	−0.69	.499
Marital status	Married	15 (100)	14 (100)		
	Others	0 (0.0)	0 (0.0)		
Educational level	High school,	0 (0.0)	2 (14.3)	3.19	.363
	2-yr and 4-yr college	14 (93.3)	10 (71.4)		
	More than 4-yr college	1 (6.7)	2 (14.3)		
Perceived current socioeconomic status of family	High	2 (13.3)	0 (0.0)	2.17	.338
	Middle	11 (73.4)	11 (78.6)		
	Low	2 (13.3)	3 (21.4)		
Weight gain during pregnancy (kg)		10.94 ± 2.77	12.24 ± 4.19	0.99	.329
Smoking experience during pregnancy	Yes	0 (0.0)	0 (0.0)		
	No	15 (100)	14(100)		
Diagnosed or treated for diabetes mellitus during pregnancy	Yes	1 (6.7)	3 (21.4)	1.33	.249
	No	14 (93.3)	11 (78.6)		
Diagnosed or treated for depression during pregnancy	Yes	0 (0.0)	0 (0.0)		
	No	15 (100)	14(100)		

Note. Cont. = control group; Exp. = experimental group; M = mean; SD = standard deviation.

Table 4 *Effects of the Mobile-Based Maternal Feeding Education Program.*

Variables	Group	Before intervention	1 mo after child birth	3 mo after child birth	6 mo after child birth	Source	F/t	p
		M±SD						
Breastfeeding attitude	Exp. (n = 15)	57.20 ± 4.41	52.87 ± 3.23	60.20 ± 4.89	61.27 ± 5.13	Group	1.09	.305
						Time	11.84	<.001
	Cont. (n = 14)	57.79 ± 2.91	55.36 ± 2.27	57.14 ± 4.42	57.21 ± 4.12	Group × time	5.28	.008
Breastfeeding self-efficacy	Exp. (n = 15)	44.80 ± 6.99	43.87 ± 6.20	47.67 ± 7.10		Group	5.34	.029
						Time	5.64	.007
	Cont. (n = 14)	41.50 ± 12.97	37.07 ± 9.38	38.43 ± 11.45		Group × time	3.50	.041
Breastfeeding duration (over 180 d)	Exp. (n = 15)	-	-	-	134.27 ± 46.75		−2.09	.046
	Cont. (n = 14)	-	-	-	94.36 ± 55.95			
Recognition of hunger and satiety cues of infants	Exp. (n = 15)	2.93 ± 0.40	3.17 ± 0.34	3.38 ± 0.43	3.70 ± 0.34	Group	0.17	.685
						Time	27.71	<.001
	Cont. (n = 14)	2.89 ± 0.61	3.25 ± 0.61	3.43 ± 0.42	3.80 ± 0.32	Group × time	0.23	.878
Knowledge regarding appropriate providing of solids foods	Exp. (n = 15)	1.60 ± 0.63	2.60 ± 0.63	2.73 ± 0.59	3.20 ± 0.56	Group	3.31	.080
						Time	22.01	<.001
	Cont. (n = 14)	1.93 ± 0.73	2.29 ± 0.61	2.36 ± 0.50	2.50 ± 0.52	Group × time	4.87	.009

Note. Cont. = control group; Exp. = experimental group; M = mean; SD = standard deviation.

although there was no significant between-group difference ($F = 1.09$, $p = .305$). According to the Bonferroni test, although breastfeeding attitude score at 1 month after childbirth was significantly lower compared with the baseline score (95% confidential interval [CI]: −4.80 to −1.96, $p < .001$), breastfeeding attitude scores were significantly higher at 3 months (95% CI: 2.48–6.64, $p < .001$) and 6 months after childbirth (95% CI: 3.21–7.04, $p < .0.001$) than the score at 1 month after childbirth.

Furthermore, for breastfeeding self-efficacy, statistically significant differences were noted between the groups ($F = 5.34$, $p = .029$) across time points ($F = 5.64$, $p = .007$) and interactions between the groups and times ($F = 3.50$, $p = .041$). According to the Bonferroni test, breastfeeding self-efficacy score at 1 month after childbirth was significantly lower when compared with the baseline score (95% CI: −4.61 to −0.75, $p = .008$). According to the Bonferroni test, breastfeeding self-efficacy score at 1 month after childbirth was significantly lower when compared with the baseline score (95% CI: −4.61 to −0.75, $p = .008$). However, the breastfeeding self-efficacy score significantly increased at 6 months after childbirth (95% CI: 2.17–7.04, $p = .001$) than the score at 1 month after childbirth. In addition, breastfeeding self-efficacy score at 6 months after childbirth increased significantly than the score at 3 months after childbirth (95% CI: 0.59–3.46, $p = .008$).

Regarding breastfeeding duration until 6 months (180 days) after birth, the mean breastfeeding duration of the experimental group (134.27 ± 46.75 days/180 days) significantly increased compared with the control group (94.36 ± 55.95 days/180 days; $t = -2.09$, $p = .046$).

With regard to recognition of hunger and satiety cues of infants, although there was a statistically significant difference across time points ($F = 27.71$, $p < .001$), there was not a statistically significant difference between the groups ($F = 0.17$, $p = .685$) and interaction between the groups and times ($F = 0.23$, $p = .878$). According to the Bonferroni test, the score of recognition of hunger and satiety cues of infants significantly increased from the baseline score after the intervention.

Regarding knowledge of providing solid food for overweight prevention in infants, statistically significant differences were noted across time points ($F = 22.01$, $p < .001$) and interactions between the groups and times ($F = 4.87$, $p = .009$), although there was no significant difference between the groups ($F = 3.31$, $p = .080$). According to the Bonferroni test, knowledge scores regarding appropriate providing of solid foods at 1 month (95% CI: 0.36–1.00, $p < .001$), 3 months (95% CI: 0.48–1.09, $p < .001$), and 6 months after childbirth (95% CI: 0.84–1.33, $p < .001$) increased significantly compared with the baseline score. In addition, the knowledge score regarding providing appropriate solid foods at 3 months (95% CI: 0.478–1.09, $p < .001$) and 6 months after childbirth (95% CI: 0.84–1.33, $p < .001$) increased significantly compared with the score at 1 month after childbirth.

Discussion

This study identified the effects of a mobile-based maternal feeding education program developed for overweight prevention in infants. According to the results in this study, the experimental group showed significantly more positive breastfeeding attitude, higher breastfeeding self-efficacy, and increased breastfeeding duration than the control group. In previous maternal education programs using various educational materials including pamphlets and lectures [28,29], breastfeeding education had a significant effect on increased positive breastfeeding attitude, breastfeeding self-efficacy, breastfeeding practice, and longer breastfeeding duration.

According to a conceptual framework explaining maternal breastfeeding practice based on social cognitive theory [30], social support such as advice and educational programs from health care providers can improve knowledge, positive attitude, and self-efficacy toward breastfeeding, leading to increased breastfeeding behaviors. On the same lines, Meedya et al [31] also reported that breastfeeding attitude and self-efficacy were significant modifiable factors influencing breastfeeding intention and duration. In detail, as breastfeeding attitude was a strong predictor of feeding choice, the breastfeeding attitude had maximum effect on the breastfeeding intention of mothers [32]. In addition, maternal breastfeeding attitude was influenced by relationships with significant people in close social networks, including family members and health care providers [33]. In detail, hearing about the benefits of breastfeeding from various sources such as health care providers was associated with increased positive breastfeeding attitude, which led to improved breastfeeding intention [34]. Furthermore, as increased breastfeeding self-efficacy was significantly associated with longer breastfeeding duration for 6 months after childbirth [31], maternal breastfeeding self-efficacy was influenced by increased knowledge, positive breastfeeding attitudes, and social support such as guidance from health care providers that plays an important role in the onset and continuation of breastfeeding [33]. In this context, Parsa et al [35] emphasized the importance of social support for a more positive breastfeeding attitude and increased breast self-efficacy, leading to successful breastfeeding after

childbirth. Therefore, the mobile-based maternal feeding education program might improve positive breastfeeding attitude and breastfeeding self-efficacy, which can lead to increased breastfeeding duration with high breastfeeding intention, by providing advice and knowledge regarding breastfeeding methods and benefits of breastfeeding, such as overweight prevention in infants. In particular, the intention to breastfeed by Korean mothers might be influenced by significant family members such as their mothers and mothers-in-law. This is in line with Korean culture, where, as in other Asian countries, parenting practices for young children tend to be followed with advice from grandparents [19]. However, Korean grandparent's knowledge about breastfeeding was less than that of Korean mothers of infants and undergraduate students [36]. Therefore, the mobile-based maternal feeding education program will be helpful in improving breastfeeding attitudes and breastfeeding self-efficacy from increased accurate knowledge, which could lead to increased intention to breastfeed among Korean mothers.

In addition, the experimental group showed significantly increased knowledge regarding providing solid foods for overweight prevention in infants than the control group. According to a previous study, a video-based maternal feeding education for overweight prevention in infants was also effective for improving maternal infant feeding knowledge and behaviors [22]. As parents and primary caregivers, mothers are key people for structuring early feeding; according to the family ecological model, parental practices for obesity prevention of their children were determined by child and parental factors [37]. Among the parental factors, increased parental agreement on weight management of their children with high knowledge about behaviors to reduce obesity risk was a significant factor [37]. In this context, the mobile-based maternal feeding education program containing information regarding providing solid foods for overweight prevention in infants might contribute to maternal feeding practice by improving maternal agreement and behaviors.

However, regarding the improvement of recognition of hunger and satiety cues by infants, the mobile-based maternal feeding education program was not effective. To sensitively recognize the hunger and satiety cues, it is important that infants send clear cues to their mothers, and mothers should distinguish the characteristics of each cue and interpret them accurately [38].

Mothers should acquire the skills to recognize their infant's unique hunger and satiety cues expressed by body movement, facial expressions, and vocalization [39]. However, the mobile-based maternal feeding education program only included education about common and classic hunger and satiety cues. In addition, maternal recognition of their infant's hunger and satiety cues might be improved with high-quality interaction between mothers and infants, which is influenced by various factors, including socioeconomic status, environment, and perception of the infant's weight [39]. Therefore, to develop sensitive recognition of their infant's hunger and satiety cues, mothers might need repeated and varied experiences of interaction with their infants as well as knowledge-based education. In this context, the effectiveness of the mobile-based maternal feeding education program for providing information regarding hunger and satiety cues of infants might be limited.

The study had certain limitations. Owing to the small sample size, statistical power was insufficient. Participants were recruited from only two obstetrics and gynecology clinics located in a metro city. Therefore, further studies are needed with sufficient participants from multiple obstetrics and gynecology clinics from diversely populated urban and rural areas. Next, this study did not test the effects of mobile-based education against other educational material. Therefore, in future studies, which compare educational effects according to educational material, the effects of mobile-based education should be verified. Finally, this study did not confirm the effects related to adiposity of infants. Therefore, further studies might be required for test effects on adiposity of infants, with longer follow-up periods.

Conclusion

The results of this study showed that a mobile-based maternal feeding education program for overweight prevention in infants was effective in improving positive breastfeeding attitudes, breastfeeding self-efficacy, breastfeeding duration, and knowledge regarding providing appropriate solid foods to infants. Furthermore, mobile-based education is an extremely user-friendly method as mothers can access necessary information such as healthy maternal feeding practices without any physical contact and at a place and time convenient for them.

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Conflict of interest

The author declares that they have no conflict of interest.

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Research Article

The Adaptation of the Buddhist Death Acceptance Scale for Vietnamese Persons with Cancer

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ABSTRACT

Purpose: This study reports on selected psychometric properties of the adapted Buddhist Death Acceptance Scale (BDAS) for Vietnamese persons with cancer.
Methods: The original 13-item BDAS was developed based on Buddhist perspectives toward death and life and was translated from Thai into Vietnamese. Item content checking with five Vietnamese local experts suggested three items of the original BDAS were irrelevant in Vietnamese culture and hence should be excluded. Psychometric properties of the 10-item BDAS Vietnamese version were tested using a convenience sample of 193 Vietnamese Buddhists with cancer.
Results: The internal consistency coefficient of the scale was found to be 0.73. Exploratory factor analysis showed that the 10 items of the BDAS Vietnamese version constituted 2 factors, explaining 51.1% of the variance of death acceptance. The first factor was "acceptance of natural process of death" and the second was "preparing for death." Both factors reflected explicitly Buddhist viewpoints toward death acceptance and were consistent with the original Thai BDAS. However, although similar factors were found, some items in the Vietnamese BDAS did not load to same factors as in the Thai BDAS.
Conclusions: The BDAS Vietnamese version provides an initial suitable measurement for death acceptance among Vietnamese Buddhists. Its availability will enable cross-cultural research to investigate death acceptance among Buddhist patients with cancer in Vietnam. However, the differences in item loadings between the Thai and Vietnamese scales suggest that further conceptual and empirical works to refine the measurement are needed.

Introduction

Studies on death and dying have long focused on death anxiety and death fear. Death anxiety and death fear illustrate patients' negative viewpoints toward their deaths [1]. Death acceptance, on the other hand, reflects how the patient is psychologically prepared for the final exit. Hence, studies of death acceptance appear to be a good approach to help nurses understanding how patients think, from a positive viewpoint, about their death and dying.

The importance of understanding patients' death acceptance has been highlighted by a few other researchers and scholars. According to Wong and Tomer [2], "we need to learn how to talk about death in a way that is liberating, humanizing, and life-enhancing. Through an increased understanding of death acceptance, we may learn to treat each other with respect and compassion (p.101)." McLeod-Sordjan [3] proposed that nurses should understand the patient's attitude toward death acceptance before initiating any conversation aimed toward end-of-life caring activities.

Importantly, because religion might influence ones' viewpoint toward death, the study of death acceptance should take the patient's religious perspectives into account. Buddhism, similar to other religions, has a unique philosophy about life, death, and dying. In fact, the central teachings of Buddha are about life, suffering, death, and the way out of these. Particularly, death is considered an inevitable part of life. And for the Buddhist, denying death and clinging to life is wrong [4]. Voluntarily accepting death

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and proper thoughts/behaviors at the last moments of life are considered some of the most important practices of Buddhists to have a good rebirth [5]. In Vietnam, Buddhists are an important part of the community, and Buddhism is the second largest religion of the country [6]. Cancer is a significant health problem of Vietnamese [7], and the Vietnamese Buddhist population is not an exception. However, no scale measuring death acceptance in this group is found in the literature.

Health care nowadays is borderless because people are traveling from country to country to seek affordable, accessible, and quality health-care services [8]. Moreover, there is movement between countries for economic and political reasons. That movement requires nurses to have cultural competency to understand, communicate, respect the differences, and address the needs of patients [9]. Therefore, cross-cultural studies, which bring nurses knowledge about culturally sensitive issues, are increasingly important. However, such studies are enabled only by the availability of valid instruments, which allow for comparisons across populations and cultures [10].

Although a previous qualitative study identified themes from the experience of death acceptance among Vietnamese people, no study has investigated death acceptance among Vietnamese Buddhists [11]. As the first step of a research exploring death acceptance among Vietnamese Buddhists and comparing such results with those in Thai population, this study aims to adapt and preliminarily examine selected psychometric properties of the Buddhist Death Acceptance Scale (BDAS) [12] in a Vietnamese sample.

Buddhist philosophy about death

In Buddhism, an individual is constituted by five factors or five aggregates. They are materials, feeling, perception, disposition, and consciousness. Death is the total dissolution of these five factors [5]. Buddhists' viewpoint toward death and death acceptance is greatly influenced by karma, nonself, impermanence, and suffering.

According to karma, all things result from antecedent causes. In turn, any single event that happens now will cause or provoke other events in the future. This means, life is a texture of causes and effects interacting in an endless process. Life itself is also an event in an endless cycle, and it is an antecedent of other events. Hence, Buddhists believe that the beliefs and practices surrounding death are important because they may influence their afterlife and rebirth [4,5].

Buddhists believe that there is no permanently existing self or soul within human beings. Indeed, the self is imaginary or a delusion, which leads to the sense of attachment, desire, selfishness, and so on. These feelings are sources of suffering. Therefore, an understanding of nonself can reduce suffering [5].

Impermanence means that life is transitory and insubstantial. It is constantly changing: rises and then falls, integrates and disintegrates, exists and disappears. In this sense, no existence or condition is stable, and things just happen out of our control. People suffer because they want life according to their own desires, while in fact, life often does not comply. Therefore, changing the mind to live with reality is one of the keys to living happily. Moreover, health and life are not permanent because nothing is stable and permanent. Acknowledging the impermanence and insubstantiality of life also suggests that one should not expect that his or her physical body, the connections with beloved ones, career achievements, and so on will remain forever. A Buddhist should accept that he or she may be healthy now but may not be so for long; the Buddhist view is that he or she could die and have to give up everything at any instant. Because life and death seem to be unpredictable, Buddhists treasure the "now" and "here" and try to live fruitfully in the now moment [4,5].

In Buddhism, suffering is a characteristic of life. The Sanskrit word for suffering is "dukkha", and sometimes this term is used in writing about suffering. Pain, grief, misery, or being dissatisfied all are forms of suffering and are undeniable to all human beings. Almost all things can make people suffer. Among them, death is one of the most important causes of suffering for both the dying one and his or her beloved persons [4,5].

Humans tend to ignore or refuse unpleasant experiences, including suffering [4,5]. However, none of those approaches resolves suffering, which is derived from the person's perceptions and is rooted in the mind of the sufferer. Buddhists, hence, try to accept the reality of suffering, search for the cause of suffering, seek for methods to end suffering, and follow the path to the cessation of suffering [5].

Unnecessary prolonging life during the dying process by medical interventions (or any other means) is indeed extending the time of suffering and hence is not accepted. Buddhists suppose that death should come naturally. In addition, during life, including the very last moments, awareness is important to Buddhists. Thus, Buddhists suppose that a calm, peaceful death occurs only if the mind of the dying person is clear and is not disturbed by sedatives or emotional expressions of others [5].

The development of the BDAS

The BDAS [12] was developed as part of a larger research study entitled, "The comparison of death acceptance between Thai and Vietnamese persons with cancer." It was initially constructed in Thai by a group of researchers, who are all active practicing Buddhists, for the purpose of cross-comparison of death acceptance in patients with cancer between Thai and Vietnamese people. Although most of the research groups are Thai, one is Vietnamese, fluent in Thai, allowing for a cross-cultural voice in the original BDAS development. The researchers all have extensive experience caring for dying patients and all have long-term Buddhist practices which were valuable in the development of the BDAS. However, specific items for the scale came from the literature and from in-depth interviews with patients with cancer.

The development of the original BDAS is mainly based on karma and the three characteristics of existence (suffering, impermanence, and nonself) [12]. It was found that Buddhism generally agrees that death is normal and life is likely full of suffering and sorrow. Moreover, Buddhist scripture advocates for the acceptance of death as an unavoidable event in an unending circle of death and life. In addition, accepting death is about not only acknowledging the reality of death but also preparing for it [12].

In particular, by accepting death, the person accepts the limitations of life and neither wishes to prolong the process of dying nor hastens death [4]. He or she will try to do his or her best for others, as well as for his or her current and next life. He or she is also able to leave behind the people and things that are loved in the final exit. All of such beliefs are driven by karma, impermanence, suffering, and nonself and are expressed in thoughts, verbalizations, and actions [12].

The original BDAS consisted of 13 items, which were formatted as statements about patients' thoughts, verbalizations, and actions toward their deaths. Respondents were asked to rate on a 4-point rating scale whether the statements were strongly untrue = 1, untrue = 2, true = 3, and strongly true = 4. Its psychometric properties were tested in Thai patients with cancer. Exploratory factor analysis (EFA) with a group of 300 patients found two domains, which were "acceptance of natural process of death" and "preparing for death," explaining 45.87% of the variation of the

construct. The Cronbach's α coefficient was .82. For subscales, the Cronbach's α coefficients of the two dimensions were .87 and .69, respectively. Confirmatory factor analysis conducted with a different sample of 230 patients showed that the two-domain construct of the scale fits with the empirical data (Chi-square = 68.19, df = 52, $p > .05$; AGFI = .96; CFI = .99, RMSEA = .04, and SRMSR = .05) [12].

Methods

The adaptation of the BDAS in Vietnamese consisted of two steps: (a) translation and content checking and (b) field testing.

Translation and content checking

The BDAS [12] was translated individually from its Thai original version to Vietnamese by two certified translators. The two translators then discussed any discrepancies together to finalize the single first draft of the scale in Vietnamese. The first translated version (in Vietnamese) was then reviewed, back translated and compared with the original one (in Thai), and finalized by a third certified translator.

A meeting among five Vietnamese palliative care experts (3 nurses and 2 doctors) was organized to review the content of the BDAS Vietnamese version. The main purpose of the review was to check whether the items were appropriate and congruent with Vietnamese culture. In the meeting, during the discussion, the group of experts pointed out that three items among the thirteen items of the original BDAS were not a fit with Vietnamese culture in general or Vietnamese Buddhist perspectives.

In particular, item number # 9 of the original item pool was “The planning of my funeral decreases the burden on my family and others”. In Vietnamese culture, there are many traditional beliefs surrounding death that shape how the funeral is organized. Traditionally, the preparation for a funeral involves all family members, neighbors, friends, and relatives with many activities, which may last for at least 2 days. Hence, although one may accept his or her death, he or she still may not assume that the planning for the funeral is not a burden. In other words, considering the preparation of one's own funeral not a burden might not be convincing evidence of death acceptance in the Vietnamese population. Two other items about “having conversations and plans for managing property” and “talk about concerns before death” might be not applicable to Vietnamese respondents. In particular, Vietnamese people would not talk about property if his or her husband/wife is still alive or if he or she is not a decision maker in the family. Generally, the sick persons and the family also avoid talking about death or related concerns, unless the patients are at the very last days of their lives.

Therefore, 10 items of the BDAS Vietnamese version remained in the psychometric testing phase.

Field testing

Study design

The field testing was in the form of a cross-sectional study.

Setting and sample

This study was conducted in a large oncology center, which offered treatment for patients coming from 6 remote north provinces of Vietnam. A convenience sampling method was used. The sample consisting of 193 patients with cancer, who self-identified as Buddhists, received treatments at the Thai Nguyen Oncology Center at the time of data collection and voluntarily participated in the study. The data collection took place from August 2018 to January 2019.

Ethical consideration

This study was approved by the Institutional Review Board of the Ha Noi University (Approval no. 33/2018/YTCC-HD3).

Measurements

Two questionnaires were used. The demographic questionnaire designed by the authors was used to collect demographic information of the participants. The BDAS Vietnamese version was used to assess participants' death acceptance.

Data collection

Participants were approached at the hospital during their treatment. The researchers explained the purposes of the study and invited the patient to participate in the research. If the patient agreed to do so, signed consent forms were then obtained. The participant was offered the questionnaire to answer herself/himself afterward. The researchers collected the completed questionnaires and obtained other necessary information from the patients' medical records.

Data analysis

Descriptive statistics were used to depict demographic characteristics of the research sample, as presented in Table 1. Internal consistency reliability of the BDAS Vietnamese version was tested by Cronbach alpha coefficient. Its structure was examined by EFA. The adequacy of the sample to perform EFA was confirmed by the Kaiser–Meyer–Olkin test and the Bartlett's test of sphericity.

Results

The sample for the field study consisted of 193 patients with cancer. The mean age of the participants was 58.93 ± 12.71 years. The majority of the sample was married (78.2%). Farmer was the most common occupation (66.3%). The group of patients who had stomach, intestinal, or liver cancer accounted for the largest group of the sample (30.6%). Lung and breast cancers were also common (Table 1).

Exploratory factor analysis

The Kaiser–Meyer–Olkin test was significant with the KMO value of .67, and the Bartlett's test of sphericity was 679.57 with a p-value ($< .01$), indicating the adequacy of the sample for the factor analysis.

To determine the number of factors to retain in the EFA, the scree test was used. The bending point of the scree plot was three (Figure 1), suggesting that there would be two factors in the scale [13]. Hence, the EFA was run to extract 2 factors.

The two factors of the BDAS Vietnamese version are presented in Table 2. The sum squared loading of the first factor was 29.5% and that of the second factor was 21.6%. Cumulatively, the two factors of the scale explained 51.1% of variance of death acceptance.

The loading factors of items ranged from .53 to .84. No items were cross-loaded to both factors (loading factor higher than .40) [13].

Table 1 *Characteristics of the Sample (N = 193).*

Characteristics	Frequency	Percentage
Gender		
Women	97	50.3
Men	96	49.7
Marital status		
Single	9	4.7
Married	151	78.2
Divorced—widow/widower	33	17.1
Education		
Primary and secondary school	55	28.5
High school	87	45.1
Vocational school	34	17.6
University and above	17	8.8
Occupation		
Farmer	128	66.3
Government officer	25	12.9
Home business	12	6.2
Other	28	14.6
Tumor locations		
Stomach–Intestinal–Liver	59	30.6
Lung	34	17.6
Breast	29	15.0
Esophageal	10	5.2
Thyroid	25	13.0
Others (skin, pancreatic, larynx, ovarian, prostate, and so on)	36	18.6

Table 2 *Exploratory Factor Analysis of the BDAS Vietnamese version (N = 193).*

Items		Factors	
		1	2
1	**Acceptance of natural process of death**		
Q5	Life with pain but without suffering	.84	
Q6	Life with symptoms but without suffering	.84	
Q7	Verbalizing with others about my death	.73	
Q9	Releasing everything will help with a peaceful death	.71	
Q3	Not to use aggressive treatments to prolong life	.71	
2	**Preparing for death**		
Q8	Accept treatment results because nothing is certain in life		.72
Q2	Death is natural and happens to everybody		.70
Q4	My family can overcome grief after I die		.66
Q10	Death is unavoidable, so I want to be useful in the time left		.63
Q1	Death is certain for all people		.53

The scale was translated into English by the researchers only for the reader's understanding of the concepts presented.

Reliability

Table 3 presents the statistics related to the internal consistency testing. The Cronbach's α coefficient of the whole scale was .73. Those coefficients of the acceptance of natural process of death and preparing for death subscales were .82 and .63, respectively.

Discussion

This study reports on the adaptation and validation of the BDAS in a Vietnamese sample. To our knowledge, the BDAS is the first measurement of death acceptance developed based on Buddhist philosophy, and the BDAS Vietnamese version is the first developed measurement for a Vietnamese Buddhist population. It is reported that one's religious beliefs influence his or her death acceptance [14]. The development of this scale could enable researchers to better understand death acceptance among one of the largest religious groups.

However, we found it is challenging to generate suitable items for the BDAS Vietnamese version. Firstly, Buddhist perspectives toward dying, death, and death acceptance are stated both explicitly and implicitly in various Buddhist teachings making the saturation of the item content hard to reach. Secondly, types of Buddhism vary, and the levels of comprehension and practice of the religion of Buddhists are quite diverse. The items, therefore, should be general enough to reflect common beliefs and practices related to death among the differing individual Buddhists. The preliminary analysis showed that the BDAS Vietnamese version psychometric quality was modest. The scale will need to be updated and revised further.

During the data analysis, the scree plot suggested that there were two factors in the scale. Hence, the EFA was run to extract two factors. Notably, using the threshold of .40 for the loading factors, no items of the BDAS Vietnamese version were cross-loaded across the two factors [13].

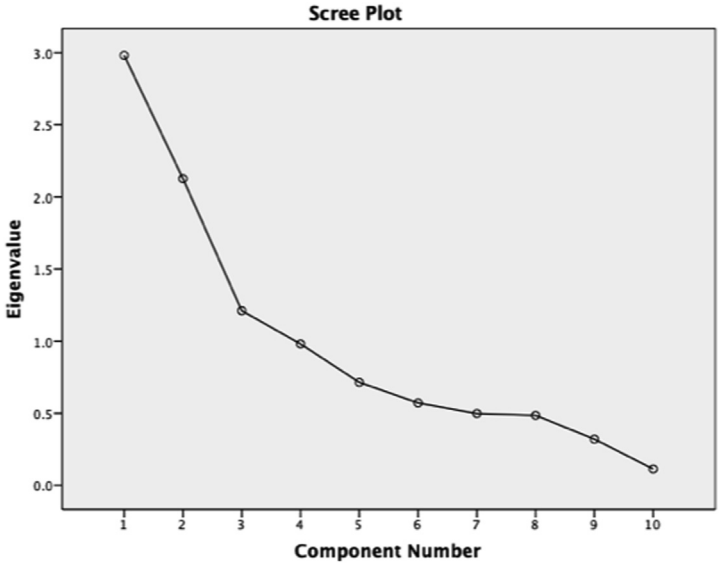

Figure 1. The scree plot.

Table 3 *Reliability Analysis of the BDAS Vietnamese version (N = 193).*

Item	Scale mean if item deleted	Scale variance if item deleted	Corrected item total correlation	Squared multiple correlation	Cronbach alpha if item deleted
Q1	18.58	29.49	.13	.26	.73
Q2	18.45	28.94	.17	.25	.73
Q3	16.91	21.58	.49	.44	.69
Q4	18.22	27.69	.19	.29	.73
Q5	16.61	21.09	.62	.79	.66
Q6	16.58	21.39	.60	.79	.67
Q7	17.33	21.04	.59	.39	.67
Q8	18.33	27.99	.17	.29	.73
Q9	17.28	21.41	.53	.49	.68
Q10	18.32	28.30	.16	.27	.73

The first factor of the BDAS Vietnamese version was “acceptance of natural process of death,” meaning the patient accepts his or her dying process. In Buddhism, one should experience a thing as it is. He or she may notice that there is pain or fatigue, but will just acknowledge them, and let them be as they are. The dying patient will not let pain or unpleasant symptoms provoke positive or negative thoughts or emotions [4,5,15]. By remaining nonattached, the dying person could be able to keep his or her mind clear during the last moments of life, which is believed to be the utmost thing for a better rebirth.

The second factor of the BDAS Vietnamese version was “preparing for death.” The factor reflects one's belief toward the nature of death and how he or she is prepared for the coming future. In Buddhism, all human beings are attached with their ego, physical body, beloved ones, their treasures, and pleasant experiences [5]. People tend to retain such attachments, and, thus, they are reluctant to prepare for the eternal leave. Accepting death in Buddhism, therefore, means that one accepts the separation to all the loved ones and things, wants to make the rest of his or her life meaningful, and is ready to go.

It should be noted that three items of the original BDAS were found unsuitable within the Vietnamese context so they are not included in the BDAS Vietnamese version. This suggests that the construct of death acceptance in Vietnamese and in Thai may be similar in some ways but not exactly the same. Such differences could be explained partially by the cultural and religious variation among Vietnamese and Thai. Particularly, while the school of Buddhism in Thai is Theravada, Buddhism in Vietnam is a harmonized mixture among Theravada, Mahayana, Vajrayana, and Zen. It is also highly influenced by local religious practices such as the Mother Goddess worship and Weather Gods (rain, wind, lighting, and thunder). The Mother Goddesses and Gods even have prestigious places in Vietnamese Buddhists’ pagodas. In addition, Vietnamese Buddhists have a strong connection with Taoism and Confucianism from the Chinese [16]. All of these factors may shape the unique perspectives and practices related to death in the Vietnamese, making them different from those of the Thai.

Importantly, although the same domains were found in the BDAS Vietnamese version, individual items did not load to the same domains as they do in the original BDAS. For example, item “death is unavoidable, so I want to be useful in the time left” loaded to the domain “preparing for death” in the BDAS Vietnamese version but was originally loaded to the domain “acceptance of natural process of death” in the BDAS. In contrast, the item “not to use aggressive treatments to prolong life” changed from the domain “preparing for death” in the original scale to the domain “acceptance of natural process of death” in the BDAS Vietnamese version. Again, these variations might be resulted from the cultural issues. Seemingly, a Thai patient asks “not to use aggressive treatments to prolong life” because he or she is preparing for the last moments of life. In contrast, when a Vietnamese patient asks “not to use aggressive treatments to prolong life,” he or she may be doing so with an acceptance to embrace the natural process of death. However, although both ways of thinking are plausible, this difference reinforces that the concept of death acceptance is not exactly the same cross-culturally. Hence, further conceptual and empirical works to refine the BDAS are strongly recommended.

Study limitations

This study is a preliminary effort to adapt a religion-based measurement of death acceptance to the Vietnamese Buddhist population. Participants were recruited from a single oncology center. Consequently, the representativeness of the sample may be somehow limited. Perspectives about death acceptance are culturally bound to some degree. Hence, the study findings would have been stronger if participants with more diverse ethnic and demographic backgrounds had been recruited.

Items of the BDAS are derived from Buddhist perspectives toward life and death by a small group of scholars. Because such viewpoints are expressed both explicitly and implicitly in various Buddha's teachings, the initial item pool might not be able to capture all aspects of death acceptance in Buddhism. Hence, further refinement of the current items or the development of additional items may be needed. Additional items, which are more relevant to Vietnamese culture, would help to improve both validity and reliability of the BDAS Vietnamese version. Finally, once the further refinements of items are completed, confirmatory factor analysis should be conducted with a Vietnamese Buddhist population of patients to confirm the scale validity.

Clinical implications

The availability of the BDAS Vietnamese version will facilitate clinicians' evaluation of patients’ death acceptance. As it is a brief scale (10 items), it can be used as the initial assessment to provide preliminary understandings about the patients. With such baseline information, clinicians would be better prepared before implementing any further discussions or interventions with their patients.

For clinical studies, the BDAS Vietnamese version would allow researchers to measure death acceptance among the Buddhist population. It would facilitate research in this area, which, to date, is still in its infancy. More importantly, because the BDAS Vietnamese version is comparable with the original scale in Thai, it would permit cross-cultural studies on death and death acceptance between the two countries.

Conclusion

In conclusion, the BDAS Vietnamese version was adapted from the original Thai BDAS scale, which was developed based on Buddhist philosophy to measure patients’ death acceptance. Being tested with a sample of 193 Vietnamese patients with cancer, the BDAS Vietnamese version showed acceptable internal consistency coefficient. There were two factors, which were acceptance of natural process of death and preparing for death. The two factors explicitly reflect Buddhist perspectives toward death acceptance. However, the BDAS Vietnamese version requires further development and testing.

Ethical approval statement

The proposal of this study was approved by Institutional Review Board of the Ha Noi School of Public Health (Approval no. 33/2018/

YTCC-HD3). The participants signed informed consent before data collection.

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Conflicts of interest

The authors declare no conflicts of interest.

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Research Article

Comparison of Bleeding, Hematoma, Pain, and Discomfort After Bone Marrow Examination With or Without Sandbag Compression

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SUMMARY

Purpose: A safe and effective hemostatic care is necessary after bone marrow examination to minimize bleeding, pain, and discomfort. However, a standardized hemostatic care protocol following bone marrow examination has not been established. The purpose of this study was to investigate the differences in bleeding, hematoma, pain, and discomfort by the hemostatic method used following bone marrow examination.

Methods: This study was carried out with a pre-test/post-test nonequivalent control group design. Sixty-four patients undergoing bone marrow examination at the hemato-oncology ward in a tertiary hospital in South Korea were assigned to an intervention ($n = 30$) and comparison group ($n = 34$). The intervention group was treated using a compression dressing alone, while the comparison group received a compression dressing followed by sandbag compression. Both groups received two hours of bedrest. Bleeding, hematoma, pain, and discomfort were measured at one and two hours after the biopsy.

Results: No significant differences in the occurrence of bleeding between the groups at one and two hours after bone marrow examination were observed, and no participant developed hematoma. The intervention group had significantly lower pain than the comparison group two hours after the bone marrow examination as well as lower discomfort one hour and two hours after the bone marrow examination ($p < .05$).

Conclusion: Applying only compression dressing after a bone marrow examination is effective in reducing pain and discomfort without measurable differences in bleeding and hematoma, suggesting that compression dressings alone could be effective in lowering pain and discomfort following bone marrow examination.

Introduction

Patients with hematologic disorders often undergo bone marrow aspiration or bone marrow aspiration and biopsy to obtain an accurate diagnosis and to identify the etiology of the disease [1–3]. Owing to population aging, changes in dietary patterns, and environmental changes, blood disorders have increased in recent years [4], and bone marrow biopsy is becoming increasingly common in South Korea. From 2010 to 2017, there was a 21.0% increase from 17,349 to 21,003 biopsies [5], suggesting that better management of patients undergoing bone marrow biopsy may be required.

Bone marrow examination is an invasive procedure in which bone marrow samples are typically obtained from the iliac crest,

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anterior iliac crest, or sternum using a needle. Hence, bleeding prevention at the puncture site is important [1]. Because the incidence of bleeding two hours following a bone marrow examination is 16.0% and four hours after the bone marrow examination is 5.3% [6], appropriate hemostasis is crucial. Discomfort around the puncture site has been reported to have an average rating of 3.12 (out of 10) two hours after the bone marrow examination and 5.90 four hours after the bone marrow examination, suggesting that patient discomfort rose with increased periods of bedrest [6]. Fifty-nine percent of patients during the procedure of bone marrow examination reported experiencing moderate discomfort [7]. Furthermore, 17.0% of the patients after 10 minutes and 64.0% after 1 day following bone marrow examination reported experiencing moderate pain [7]. The pain level after bone marrow examination was 1.98 on a 0–5 scale [8], which also showed moderate pain after bone marrow examination. Given these findings, safe and effective hemostatic care is needed after bone marrow examination both to minimize bleeding and to promote the patient's comfort.

However, the lack of a standardized hemostatic care protocol following bone marrow examination, such as the lack of recommendations of a hemostatic method (whether sandbag is applied or not) and absolute bedrest time, has led hospitals in South Korea and abroad develop and implement their own protocols [9–22]. Existing hemostasis protocols of other countries after bone marrow examination have recommended applying pressure for two minutes until bleeding stops, compressing with gauze and Elastoplast [12], applying pressure to the biopsy site with the patient lying on their back for 10–60 minutes until the bleeding stops, and then adhering a bandage [10,13–18]. Bedrest should be taken within an hour after compression on the biopsy site following a bone marrow examination in the USA, Japan, Vietnam, Singapore, and Canada. While it is the current practice not to use sandbags in other countries, some Korean nurses still practice applying sandbags after the bone marrow examination for 1 to 6 hours.

In South Korea, the guidelines for hemostatic care following a bone marrow examination, such as duration of absolute bedrest and the use of a sandbag, have shown variations by academic society, nursing associations, and hospitals. South Korean hospitals and the Korean Nurses Association guidelines currently instruct patients to place a sterile gauze and sandbag on the biopsy site while the patient lies in the supine position for 1–2 hours [19] or 4–6 hours [20,21]; applying manual pressure to the biopsy site for 5–10 minutes, applying a dressing, and having the patient lie on his or her back for 90 minutes [11]; applying pressure with a sterile bandage over it and having the patient lie down quietly until their vital signs are normalized [22]. One notable difference between the South Korean and international guidelines is that existing South Korean guidelines suggest bedrest with a sandbag lasting from several minutes to several hours.

Particularly, patients who have received a hemostatic method involving a sandbag after a bone marrow examination have reported that pain and physical discomfort from the bedrest in a fixed position for a prescribed length of time are greater than the discomfort from the biopsy [6]. If there is no increase of bleeding complication without a sandbag and the bedrest time is shortened, patients' pain, discomfort, complaint, and toileting self-care deficit from the sandbag and immobility will be reduced [6]. Needs for nursing care for those patients' problems will be reduced furthermore. With consensus from evidence-based nursing practice, educating a revised protocol and applying it to nursing practice are necessary to increase the satisfaction of patients and the nursing efficiency. Exploring nursing interventions that effectively prevent bleeding while minimizing pain and discomfort in patients who undergo a bone marrow examination is needed to improve patient care. Therefore, we explored if the bedrest time can be reduced to 1 or 2 hours, even without sandbag application.

Objectives

The purpose of this study was to compare the effects of hemostatic methods with and without a sandbag on the incidence of bleeding and hematoma, pain, and discomfort following a bone marrow examination. First, we hypothesized that there would be no difference in the occurrence of bleeding between the intervention group that used a compression dressing alone and the comparison group that used both a compression dressing and sandbag (Hypothesis 1). Second, we hypothesized that there would be no difference in the incidence of hematoma between the intervention group that used a compression dressing alone and the comparison group that used both a compression dressing and sandbag (Hypothesis 2). Third, we hypothesized that the intervention group that used a compression dressing alone would report less pain than the comparison group that used both a compression dressing and sandbag (Hypothesis 3). Fourth, the intervention group that used a compression dressing alone would have less discomfort than the comparison group that used both a compression dressing and sandbag (Hypothesis 4).

Methods

Study Design

The study used a pre-test/post-test nonequivalent control group design to examine the effects of hemostatic methods using a sandbag on bone marrow examination complications.

Participants and Setting

Patients who were admitted to a single tertiary hospital in Cheongju, South Korea for a bone marrow examination were identified for potential enrollment in this study. We recruited participants of the outpatient department who were scheduled to undergo bone marrow examination. We explained the study to the patients prior to their consent. To be eligible for participation, the inclusion criteria included the following: being aged 19 or older; having a diagnosed blood disease; being hospitalized for a bone marrow examination; no current spinal disease with low back pain; a platelet count $\geq 10 \times 10^3/\mu L$; intact cognition; alert consciousness; ability to communicate; ability to understand and respond to the survey; and being willing to sign an informed consent to participate in the study. The exclusion criteria were those who were unable to stop antithrombotic and anticoagulant agents, were cognitively impaired, or had a mental illness that would hinder study participation [23].

The sample size was computed using the G*Power program (Heinrich Heine University Dusseldorf, German). For an independent *t*-test with a power of .80, a significance of .05, and an effect size of .80 [24], the minimum sample size per group was found to be 26. Anticipating a 30.0% attrition rate, we attempted to recruit 34 participants for each group. Four patients in the intervention group were dropped because of their refusal to complete the questionnaire; the final analysis included data from 34 patients in the comparison group and 30 patients from the intervention group.

Instruments

Demographic and Clinical Characteristics

The survey included the demographic characteristics of participants' gender, age, education level, religion, marital status, and

occupation. Diagnosis, history of bone marrow examination, underlying disease, bleeding in the past month, and blood test results (platelet count and prothrombin time) were collected as clinical characteristics.

Bleeding and Hematoma

The amount of bleeding was measured based on the area (length × width) of blood on one 10 × 10 cm gauze after one hour and two hours of biopsy. Bleeding after two hours was measured by including the area of bleeding measured at one hour without replacing the compression dressing [25]. Hematoma refers to a collection of blood, and its presence was determined based on visual inspection and palpation [26]. Hematoma was categorized dichotomously as “present” or “absent” [27].

Pain

Pain is defined by the International Association for the Study of Pain [28] as an unpleasant sensory and emotional experience related to tissue damage. Pain associated with bone marrow examination was assessed with a numerical rating scale (NRS) [29]. We assessed pain using the one-item NRS for pain presented by Korea's National Cancer Information Center [3]. The ratings ranged from 0–10 with a higher score indicating more severe pain. The scores were categorized as *mild pain* for 0–3, *moderate pain* for 4–6, and *severe pain* for 7–10.

Discomfort

Ashkenazy and DeKeyser Ganz defined discomfort as an unpleasant feeling resulting in a natural avoidance or reduction of the source of the feeling [30]. Discomfort related to applying a sandbag after the procedure was measured with a self-reported questionnaire developed by Park et al. [25,31]. We assessed discomfort using the discomfort scale developed by Lee [32] and modified and adapted by Park et al. [33] The scale consists of 16 items rating psychological (3 items), environmental (1 item), and physical discomfort (12 items). For this study, we selected seven relevant items from the 12 items assessing physical discomfort, and the content validity was verified by three hemato-oncology nurses, one oncology nurse specialist, and one hematologist-oncologist. All seven items had a CVI of .80 or higher, so all were selected. The discomfort scale was rated on a four-point Likert scale (1 = *No*; 2 = *Mild*, 3 = *Moderate*, and 4 = *Severe*). The total score ranged from 7–28, where a higher score indicated a higher level of discomfort. The Cronbach's α of physical discomfort was reported to be .71 by Park et al. [33] and .84 in this study.

Study Intervention

In this study, for hemostasis, a sandbag was applied following the use of a compression dressing for the comparison group, while a compression dressing alone was applied for the intervention group. To prevent the diffusion effect, participants were initially assigned to the comparison group first, and then participants were assigned to the intervention group.

The bone marrow examination took about 30 minutes. An analgesic (meperidine 25 mg) was intravenously injected 5 minutes prior to the biopsy for both groups. There was no adverse effect from the medication. A bone marrow examination needle of 11 gauge (TrokaBone, PAJUNK GmbH Medizintechnologie; thickness 3 mm, length 100 mm) was used. After removing the biopsy needle, the compression dressing and sandbag were applied for the comparison group and the compression dressing alone was applied for the intervention group for hemostasis.

Hemostasis following a bone marrow examination was performed as follows with the reference to the hemostasis protocols after a bone marrow examination used in hospitals [10,13–19]. Countries except Korea apply less than 1-hour bedrest [10,13–18], and at least two hospitals including the one in this research were applying the 2-hour bedrest method [19].

First, for the compression dressing, manual compression was performed for 2–3 minutes until bleeding from the puncture site stopped, with an additional 2–3 minutes of compression if the bleeding did not stop. Next, a 10 × 10 cm gauze was folded into one-fourth size and placed over the puncture site with some pressure, and the patient was instructed to lie on a bed for two hours. For sandbag compression, a 1.8 kg sandbag (25 cm × 16 cm × 2.5 cm) was fixed over the iliac crest (puncture site) such that it did not drop to one side following the compression dressing, after which the patient was prescribed bedrest for two hours. For both groups, another hour of bedrest was ordered after two hours of bedrest when the blood on the gauze did not turn brown and pinkish blood was still observed. Two patients in the intervention group had another hour of bedrest after two hours of bedrest.

Data Collection

Data were collected from April 20, 2017 to December 20, 2017, for the comparison group, and from December 22, 2017 to September 2, 2018, for the intervention group. Two oncology nurse specialists participated in data collection: one for the questionnaire survey and medical record collection and the other for measuring bleeding, pain, and discomfort at the patient's bedside. All the measurements were done by one specialist, intermeasurer variability was not a concern. Baseline data were collected by an oncology nurse specialist in the education and counseling room in the hemato-oncology ward. The oncology nurse specialist distributed a structured questionnaire to the patients prior to the bone marrow examination, and patients completed the questionnaire containing items about their demographic and clinical characteristics. The questionnaire took about 2–3 minutes. Information about prothrombin time and platelet count, which may affect bleeding, was collected by an oncology specialist nurse from the patients' medical records after they completed the survey. Another oncology specialist nurse measured post-procedural bleeding, hematoma, pain, and discomfort at the patient's bedside one hour and two hours after the bone marrow examination. Hematoma was examined during an additional outpatient follow-up visit one week after the bone marrow examination.

Data Analysis

The collected data were analyzed using the SPSS 24.0 software (IBM Corp., Armonk, NY, USA). Demographic and clinical characteristics were analyzed with the frequency and percentage or mean and standard deviation, and the baseline differences between the two groups were examined using an independent *t*-test, Chi-square test, and Fisher's exact test. The effects after treatment in both groups were analyzed with independent *t*-tests and Chi-square tests.

Ethical Consideration

This study was approved by the institutional review board at the study hospital (Approval No. 2017-03-018-002), and written consent was obtained from the participants after informing them of the purpose and procedure of the study.

Results

Homogeneity Among Participants

Demographic Characteristics

There were no significant differences between the two groups with regards to gender, age, education, religion, marital status, and occupation (Table 1). Of the 64 participants (30 in the intervention group and 34 in the comparison group), 40 (62.5%) were men and 24 (37.5%) were women. The mean age of participants was 57.63 years ($SD = 14.58$) in the intervention group and 61.27 years ($SD = 17.02$) in the comparison group.

Clinical Characteristics

The most common diagnosis was acute leukemia, with 12 in the intervention group (40.0%) and 13 in the comparison group (38.2%) having this diagnosis. There were no significant differences in past bone marrow exam history, underlying disease, bleeding history, and blood test results (platelet count and prothrombin time; Table 2).

Group Comparisons

Amount of Bleeding

There were no significant differences in the occurrence of bleeding between the intervention group and the comparison group one hour ($t = 0.84$, $p = .403$) and two hours ($t = 0.69$, $p = .491$) after the bone marrow examination, supporting Hypothesis 1 regarding the lack of differences in the occurrence of bleeding between the two groups. The mean values of bleeding at one hour and two hours after a bone marrow examination were 0.86 cm^2 ($SD = 1.12$) and 1.41 cm^2 ($SD = 1.65$), respectively, in the intervention group and 1.14 cm^2 ($SD = 1.53$) and 1.75 cm^2 ($SD = 2.22$), respectively, in the comparison group (Table 3).

Incidence of Hematoma

None of the participants in both groups developed a hematoma one hour, two hours, and one week after the bone marrow examination, supporting Hypothesis 2 regarding the lack of difference between the two groups in the incidence of hematoma (Table 3).

Level of Pain

There was no significant difference in pain one hour ($t = 1.58$, $p = .120$) after a bone marrow examination, but there was a statistically significant difference in pain two hours ($t = 2.90$, $p = .006$) after a bone marrow examination between the two groups. Hypothesis 3 regarding decreased pain in the intervention group compared to the comparison group was partially supported. The mean pain scores at one hour in the intervention and comparison groups were 0.33 ($SD = 0.76$) and 0.79 ($SD = 1.49$), respectively, and those at two hours were 0.33 ($SD = 0.66$) and 1.32 ($SD = 1.87$), respectively, showing lower pain scores in the intervention group (Table 3).

Level of Discomfort

There were significant differences in discomfort between the two groups at one hour ($t = 2.00$, $p = .049$) and two hours ($t = 3.09$, $p = .003$) after a bone marrow examination, which supported Hypothesis 4 which predicted that the intervention group would have lower levels of discomfort compared to the comparison group. The discomfort scores at one hour in the intervention and comparison groups were 1.32 ($SD = 0.36$) and 1.51 ($SD = 0.41$), respectively, and those at two hours were 1.43 ($SD = 0.41$) and 1.79 ($SD = 0.49$), respectively, showing lower discomfort scores in the intervention group (Table 3).

Table 1 *Comparison of Demographic Characteristics (N = 64).*

Variables	Categories	Intervention Group ($n = 30$)	Control Group ($n = 34$)	χ^2 or t (p)
		n (%) or M (SD)	n (%) or M (SD)	
Gender	Men	21 (70.0)	19 (55.9)	1.16 (.249)
	Women	9 (30.0)	15 (44.1)	
Age (years)		57.63 (14.58)	61.27 (17.02)	0.91 (.366)
Level of Education	≤ Middle School	12 (40.0)	15 (44.1)	−0.04 (.968)
	High School	11 (36.7)	9 (26.5)	
	≥ College	7 (23.3)	10 (29.4)	
Religion	No	15 (50.0)	18 (52.9)	−0.23 (.818)
	Yes	15 (50.0)	16 (47.1)	
Marital Status	Married	26 (86.7)	31 (91.2)	1.54 (.553)[a]
	Single	4 (13.3)	3 (8.8)	
Occupation	No	15 (50.0)	18 (52.9)	−0.23 (.818)
	Yes	15 (50.0)	16 (47.1)	

[a] Fisher's exact test.

Discussion

Although bedrest and restricted movement following a bone marrow examination is viewed as being essential for the prevention of bleeding complications, the exact extent of allowable movement has not been clearly defined, and discomfort and pain, owing to remaining in a fixed, supine position for a prolonged period, pose a challenge for patients [31,34]. This study examined differences in the incidence of bleeding and hematoma as well as pain and discomfort levels by a hemostatic method following a bone marrow examination.

One of the major adverse events following a bone marrow examination is hemorrhage resulting from injuries to surrounding organs from the insertion of a biopsy needle [35]. Our results showed that there were no differences in the incidence of bleeding and hematoma between the comparison group that used a sandbag and compression dressing and the intervention group that used compression dressing only. This finding is consistent with a previous study that showed the lack of significant differences in the incidence of complications following cardiac catheterization between the group that used a sandbag and the group that did not [36]. Furthermore, these findings are consistent with results demonstrating that patients who did not use a sandbag after coronary angiography showed no increased incidence of hemorrhagic complications [37]. Accordingly, it appears that compression dressing alone without the use of a sandbag for hemostasis is effective.

In our study, the comparison group that used a sandbag showed significantly higher pain scores two hours after a bone marrow examination compared to the intervention group that only received a compression dressing. While the pain score one hour after a bone marrow examination was not different between the two groups, the intervention group showed a little change in pain scores over time, unlike the comparison group that showed a higher pain score at two hours compared to one hour. Similar results were found in previous research where the patients' pain scores increased with more weight of the sandbag or over time in patients who underwent transcatheter arterial chemoembolization [38]. Overall, these results indicate that prolonged bedrest with a sandbag increases pain.

As patients need to lie down in a fixed posture with their knees straight for a prolonged time following a bone marrow examination [39], 70.0% of patients who underwent a bone marrow examination experienced moderate to severe (VAS ≥ 30 mm) pain due to immobilization and bedrest [7]. To mitigate such pain, analgesics and sedatives can be administered [40]. In our study, an opioid

Table 2 *Comparison of Clinical Characteristics (N = 64).*

Variables	Category	Intervention Group (n = 30)	Control Group (n = 34)	χ^2 (p)
		n (%)	n (%)	
Diagnosis	Acute leukemia	12 (40.0)	13 (38.2)	11.23 (.245)[a]
	Chronic leukemia	4 (13.3)	1 (2.9)	
	Lymphoma	5 (16.7)	3 (8.8)	
	Multiple myeloma	1 (3.3)	3 (8.8)	
	MDS	1 (3.3)	4 (11.8)	
	MPN	5 (16.7)	3 (8.8)	
	AA	0 (0.0)	2 (5.9)	
	ITP	0 (0.0)	1 (2.9)	
	PRCA	1 (3.3)	0 (0.0)	
	Unknown Origin Cytopenia	1 (3.3)	4 (11.8)	
History of Bone Marrow Biopsy	No	21 (70.0)	29 (85.3)	−1.46 (.151)
	Yes	9 (30.0)	5 (14.7)	
History of Bleeding	No	25 (83.3)	30 (88.2)	0.32 (.723)[a]
	Yes	5 (16.7)	4 (11.8)	
		M (SD)	M (SD)	t (p)
PLT ($\times 10^3/\mu L$)		334.33 (397.64)	181.25 (243.57)	−1.83 (.074)
PT (INR)		1.12 (0.14)	1.43 (1.63)	1.05 (.296)
Count of Comorbidity		1.20 (.48)	1.26 (.51)	0.52 (.606)

Note. AA = aplastic anemia; ITP = immune thrombocytopenic purpura; M = mean; MDS = myelodysplastic syndrome; MPN = myeloproliferative neoplasm; PLT = platelet; PT = prothrombin time; SD = standard deviaiton.
[a] Fisher's exact test.

analgesic was administered immediately prior to the biopsy, and the participants showed low levels of pain (0.33 in the intervention group and 0.79–1.32 in the comparison group). In a previous study, applying acupressure after a bone marrow examination reduced the pain score from 7.9 out of 10 to 4.9 out of 10 [41], while applying massage therapy reduced the pain scores from 5.75 out of 10 to 4.00 out of 10 [42]. Furthermore, the intervention group that was treated using a classical Turkish Music intervention showed a significantly lower pain score (1.55 out of 10) compared to the control group (3.36 out of 10) [43]. In our study, administering an opioid analgesic and abstaining from the use of a sandbag led to the lowest pain score among patients.

In our study, the comparison group that used a sandbag showed significantly higher discomfort scores one hour and two hours after a bone marrow examination compared to the intervention group that was only treated with a compression dressing. Although we cannot compare our results directly with previous findings due to a lack of studies examining discomfort after a bone marrow examination, our results are consistent with previous findings that suggest that patients who used a sandbag had greater discomfort six hours after a cardiac catheterization than patients who did not use a sandbag [36]. Furthermore, whereas the discomfort score increased by 0.11 over time in the intervention group, it increased by 0.28 in the comparison group. This is like previous results that reported decreased discomfort in patients whose duration of bedrest with a sandbag was shortened from 4 to 2 hours following cerebral angiography [44].

Applying sandbag for the hemostatic method following a bone marrow examination is not used in other countries. However, some Korean nurses have used a sandbag for 1–6 hours to prevent bleeding from bone marrow examination. This appears to be just a convention passed on from generation to generation. In this study, there was no bleeding complication in the intervention group with less bedrest time and without a sandbag alongside a reduction of patients' pain and discomfort. The satisfaction and safety of patients will be increased if nurses do not apply sandbag compression with shorter bedrest. Without sandbag application and with the reduction of immobility, nursing care for the discomfort, toileting, and transferring patients to the examination room will be reduced. No additional staff will be necessary for another medical examination during the bedrest [6]. In addition, nursing activity, such as changing the sterile drape of sandbags to prevent infection, will be no more necessary. Revision of the nursing protocol based on the evidence will increase productivity and satisfaction of nursing. Therefore, empirical evidence suggests that omitting the use of a sandbag and minimizing bedrest after a bone marrow examination

Table 3 *Comparison of Bleeding, Pain, and Discomfort by the Method of Compression (N = 64).*

Variables	Categories		Intervention Group (n = 30)	Control Group (n = 34)	t (p)
			M (SD)	M (SD)	
Bleeding	One hour later		0.86 (1.12)	1.14 (1.53)	0.84 (.403)
	Two hours later		1.41 (1.65)	1.75 (2.22)	0.69 (.491)
Pain	One hour later		0.33 (0.76)	0.79 (1.49)	1.58 (.120)
	Two hours later		0.33 (0.66)	1.32 (1.87)	2.89 (**.006**)
Discomfort	One hour later		1.32 (0.36)	1.51 (0.41)	2.00 (**.049**)
	Two hours later		1.43 (0.41)	1.79 (0.49)	3.09 (**.003**)
			n (%)	n (%)	χ^2 (p)
Hematoma	One hour later	Present	0 (0%)	0 (0%)	0.00(1.000)
		Absent	30 (100%)	34 (100%)	
	Two hours later	Present	0 (0%)	0 (0%)	0.00 (1.000)
		Absent	30 (100%)	34 (100%)	
	One week later	Present	0 (0%)	0 (0%)	0.00 (1.000)
		Absent	30 (100%)	34 (100%)	

Note. M = mean; SD = standard deviation.

could effectively improve the quality of nursing care on bone marrow examination.

Limitations

This study was a single-center study that could not completely control exogenous variables owing to the nonrandomized assignment to prevent the diffusion of intervention. Measurement on bleeding and hematoma was done by a nurse. It will be better if bleeding and hematoma were measured by two nurses independently and their measurements were averaged. Moreover, we could not control the potential impact of the clinician on the outcomes of the procedure. Hence, we recommend that future research includes a randomized controlled experimental design to adjust confounding factors. In order to find out whether the bedrest time can be reduced, the study on the comparison of bleeding and discomfort according to 30, 60, 90, and 120 minutes is necessary.

Conclusions

Bone marrow examination is an invasive procedure needed to diagnose a blood disease and determine a patient's prognosis. We found no differences in bleeding and the presence of hematomas between the group that used both compression dressing and sandbag and the group that had compression dressing alone for hemostasis after a bone marrow examination. The intervention group showed significantly lower pain and discomfort compared to the comparison group. In conclusion, applying compression dressing with a two-hour bedrest could be an appropriate hemostatic intervention following a bone marrow examination.

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Conflict of interest

The authors declare no conflict of interest to disclose.

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