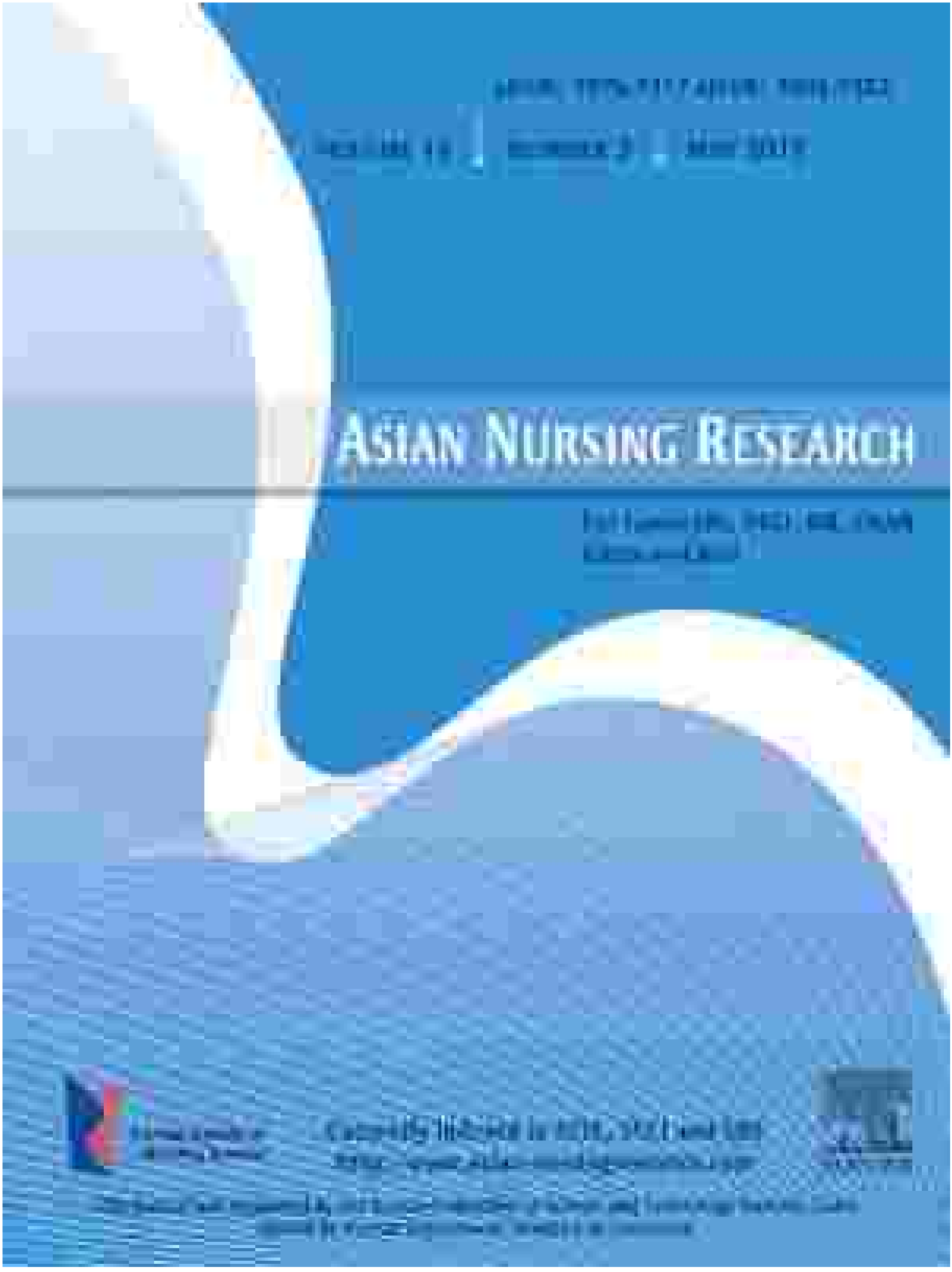
ASIAN NURSING RESEARCH

Asian Nursing Research 16 (2022) 197–207

Contents lists available at ScienceDirect

Asian Nursing Research

journal homepage: www.asian-nursingresearch.com

Research Article

Evaluating the Dimensionality and Reliability of the Thai Self-Care of Hypertension Inventory Version 2.0

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ARTICLE INFO

Article history:
Received 16 April 2022
Received in revised form
2 August 2022
Accepted 2 August 2022

Keywords:
hypertension
psychometrics
reliability
self-care
validity

SUMMARY

Purpose: Self-care is essential for hypertensive individuals to promote optimal health and illness treatment. We developed the Thai Self-Care of Hypertension Inventory (SC-HI) version 2.0 from the original US version using a multi-stage approach for cross-cultural adaptation. Scales previously studied outside a US context had different dimensions and factor solutions. Therefore, we examined the Thai SC-HI's factorial validity, construct validity, and internal reliability within a Thai context.
Methods: We administered a cross-sectional survey with hypertensive patients in 10 primary care settings, and conducted exploratory factor analysis (EFA) and confirmatory factor analysis (CFA) on two sets of separate samples from each of five sites to examine the model's factorial validity and construct validity. We estimated scale reliability with Cronbach's alpha and McDonald's omega coefficients.
Results: Participants were predominantly female, older adults, with mean age 66 years (SD = 11.94; range 36–97 years). The self-care maintenance scale had three factors and demonstrated good fit when the error covariances were respecified. The two-factor self-care management scale had different factorial solutions compared to previous models. The CFA result showed good fit indices for the Thai, original US, and Brazilian models. The self-care confidence scale was unidimensional, with partially supported fit indices that improved after we respecified the error covariances. Reliability coefficients estimated by difference methods were nearly equal: slightly lower than desired for self-care maintenance (.68–.70) and inadequate for self-care management (.62–.65); self-care confidence reliability was adequate (.89–.90).
Conclusion: The Thai SC-HI has good psychometric characteristics and reflects the original instrument's theoretical basis.

Introduction

High blood pressure is the primary cause of cardiovascular disease, and is showing increased global prevalence. In Thailand, one in four adults has hypertension [1]. Better self-care that leads to appropriate lifestyle modifications is essential for controlling high blood pressure and reducing heart disease and stroke [2–4]. As with other chronic illnesses, self-care is a surrogate hypertension health outcome, where a treatment regimen can promote and optimize overall health status [5]. Recommended hypertension self-care behaviors include: consuming optimal vegetable and fruit amounts, limiting sodium and fat, staying physically active, maintaining optimal body weight, reducing psychological stress, observing health condition changes, and managing high blood pressure symptoms [6]. Although self-care's core concepts are universal, self-care behaviors are culturally embedded [5]. Because self-care is important to clinical outcomes, it is essential to have an effective measurement of hypertension self-care in diverse cultures.

Self-care involves maintaining health and handling health condition changes through health promotion and illness

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https://doi.org/10.1016/j.anr.2022.08.002
p1976-1317 e2093-7482/

management behaviors. The self-care instrument named Self-care of Hypertension Inventory (SC–HI) version 2.0 was developed in the US [6]; therefore, cross-cultural adaptation was necessary to ensure its reliability and validity in a different cultural setting [7–10]. Two of three SC–HI scales (self-care maintenance and self-care management) measure self-care behaviors; the remaining self-care confidence scale measures self-care motivation [5,6]. The Thai SC–HI [7] was developed using a global framework for the instrument's cross-cultural adaptation. Initial tests demonstrated that the Thai SC–HI was valid and reliable. Good relevance, clarity, simplicity, and ambiguity were reflected by the larger content validity indices supporting the original version [7]. The Thai SC–HI's factorial validity, construct validity, and reliability required further testing because they are influenced by cultural context. Studies conducted outside the US that evaluated SC–HI versions showed that cross-cultural adaptations differed [8–10]. For example, the self-care maintenance scale had a multidimensional structure [8–10], different items were allocated to the self-care management scale's autonomous and consultative dimensions [9], and item correlations differed in the self-care confidence scale [9]. The cross-culturally developed SC–HI's dimensionality and psychometric properties showed that it is valid and reliable, has cultural diversity, and generally verified and re-conceptualized [8–10].

Few cross-cultural SC–HI's have been adapted within an Asian context [7,10], and these have only preliminary testing. Full psychometric property evaluation has not been conducted. The SC–HI is a theory-based instrument developed to assess naturalistic chronic illness self-care [5,6]. Hence, it measures the generic concept of self-care that reflects health-promoting and illness-related behaviors employed to maintain health, manage symptoms, and enhance confidence and efficacy. Each of the three scales includes items that measure specific self-care actions followed within a hypertension treatment regimen. Although self-care is a global concept and self-care behavior is disease specific (hypertension in this case), behavioral practices (e.g., dietary patterns, consumed foods, health care contacts, stress management) vary by cultural background [7,10]. Thus, a cross-cultural adaptation instrument is needed to test whether it is valid and reliable within the cultural context of where it is used. Previous validated and reliable hypertension self-care instruments were developed, tested, or used in Asia countries [11–13]. However, most were used to determine health maintenance behaviors that shared common self-care actions, and they were not comprehensive. A theory-based instrument is needed to evaluate overall self-care tasks that manage both stable illness stages and symptom changes in chronic illness, including hypertension [14].

This study tested the SC-HI's psychometric properties in Thai individuals with hypertension. First, we conducted an exploratory analysis (EFA) to assess the three scales' factorial validity. Next, validate the US and Brazilian versions of the self-care management scale with Thai data using confirmatory factor analysis (CFA) to test construct validity [15]. A modification model that fit the Thai data was respecified for all scales. We also evaluated discriminant and convergent validity. Cronbach's alpha coefficients and other criteria for multidimensional scales were used to test each scale's internal consistency reliability. We used composite reliability [16] or McDonald's omega [17] to evaluate multidimensional scales' reliability [14,18,19] because these methods were less biased [18]. We hypothesized that the SC–HI Thai version was valid and reliable, with adequate goodness of fit indices, discriminant validity, convergent validity, and the internal coherence.

Theoretical framework

The SC–HI is a theory based and disease specific measure of hypertension self-care that includes maintenance, management, and confidence components. It was derived from the middle-range self-care for chronic illness theory [5], and the situation-specific heart failure self-care theory [20]. The theories describe self-care as a realistic decision-making process that promotes health behavior and disease treatment. Self-care maintenance includes behaviors used to maintain physical and emotional stability. Self-care management involves responding to symptoms. Both self-care maintenance and management are motivated by self-confidence [5,6].

Methods

Study design

A multi-site, cross-sectional study design was conducted from May 2017 to April 2019 to evaluate the scales' psychometric properties. We investigated cardiometabolic risk factors, self-care, and hypertension outcomes as described in Identification of Complex Care Needed in Patients with Hypertension Treated at Primary Care (ICNHT) [7].

Ethical considerations

Approval was obtained from the University Ethics Board Committee (code number: 59/075). The study adhered to standards delineated in the Declaration of Helsinki.

Participants

Participants were recruited from ten health promotion hospitals (HPH) in one Southern Thailand province. Inclusion criteria: individuals with hypertension who are treated with any antihypertensive medication for at least six months. Pregnant women with hypertension and individuals who were unable to communicate were excluded. EFA was conducted with data from the first set of participants from five sites to test the dimensionality and factor loading on each of the scales' dimensions. CFA was conducted on a different set of samples from five other sites to evaluate validity (construct, discriminant, and convergent) and internal coherence. Generally, a sample size of 200 is required for psychometric testing [21]. However, for this analysis we enrolled the entire sample from the target settings to allow cross-validation [14].

HPHs are Thailand's first level health care facilities; they provide primary care in the subdistrict area and are covered by the district hospital. Our setting is among Thailand's largest provinces, reaching 1.6 million people, with four geographical areas: provincial or central district, hill-side, sea-side, and field or catchment basins. Each HPH treats 200 to 500 patients. Participants were recruited using a multi-stage cluster sampling method. Seven districts and one center were randomly selected based on geographical area. Two HPHs were chosen using simple random sampling, which yielded eight rural and two urban settings, with ten HPHs in total. Four rural and one urban setting were assigned to the EFA and CFA groups. Approximately 100 to 150 participants were selected by simple random sampling from each HPH. The target sample was

Table 1 *Sociodemographic and Clinical Characteristics of the Participants.*

Characteristics	Overall sample	EFA sample	CFA sample	*p*
Participant, n (%)	1,214 (100)	640 (52.7)	574 (47.3)	
Sociodemographic				
Women	889 (73.2)	477 (74.1)	412 (72.3)	.483
Age, mean (SD)	66.12 (11.94)	65.89 (11.46)	66.39 (12.47)	.466
Age, range in years	36–97	37–95	36–97	
Age ≥ 65 years old	672 (55.4)	345 (53.6)	327 (57.4)	.184
Living with spouse or family members	984 (81.1)	516 (80.1)	468 (82.1)	.379
Primary education	1,102 (90.8)	578 (89.8)	524 (91.9)	.191
Literate	1,120 (92.3)	616 (95.7)	504 (88.4)	<.001
Agriculture	1,117 (92.0)	593 (92.1)	524 (91.9)	.923
Working or employed	645 (53.1)	359 (55.7)	286 (50.2)	.052
Family income sufficiency	900 (74.1)	467 (72.5)	433 (76.0)	.171
Clinical characteristics				
Systolic blood pressure ≥ 140 mmHg	291 (24.0)	168 (26.1)	123 (21.6)	.066
Diastolic blood pressure ≥ 90 mmHg	98 (8.1)	56 (8.7)	72 (7.4)	.397
Known and treated diabetes	371 (30.6)	252 (39.1)	119 (20.9)	<.001
Known and treated dyslipidemia	639 (52.6)	405 (62.9)	234 (41.1)	<.001
Body mass index ≥ 25.0 kg/m^2	532 (43.8)	295 (45.8)	237 (41.6)	.128
Abdominal obesity	737 (60.7)	422 (65.5)	315 (55.3)	<.001
Currently smoking	132 (10.9)	74 (11.5)	58 (10.2)	.463
Currently drinking alcohol	83 (6.8)	46 (55.4)	37 (6.5)	.653
Number of hypertension medication use, median (IQR)	2 (1, 3)	2 (1, 3)	2 (1, 3)	.295
Duration of hypertension >2 years	989 (81.5)	524 (81.4)	465 (81.6)	.924
Self-care of hypertension				
Self-care maintenance scale	54.84 (14.51)	53.46 (13.90)	54.46 (15.03)	.367
Self-care management scale	52.19 (13.57)	51.70 (13.90)	52.69 (13.20)	.370
Self-care confidence scale	50.93 (19.38)	51.41 (19.66)	50.39 (19.06)	.358
Self-care of hypertension total	54.81 (11.33)	54.67 (11.27)	54.94 (11.41)	.770

Note. Values are n (%), mean (standard deviation [SD]), and median (interquartile rank [IQR]).
Abbreviation: CFA = confirmatory factor analysis; DBP = diastolic blood pressure; EFA = exploratory factor analysis.

stratified by 10-year age groups (i.e., <40; 40–49; … 80 and older). All men were recruited because of the small number of men across all age groups.

Thai SC–HI (version 2.0) instrument

The Thai SC–HI's content validity, face validity, test–retest reliability, and interobserver reliability was presented elsewhere [7]. In brief, following the original US version [6], we used a multi-stage approach for cross-cultural adaptation (https://self-care-measures.com). The SC–HI's 23 items comprise three scales: self-care maintenance (11 items: scmt 01–11 of the original version), self-care management (6 items: scmn 12–17 or items 13–18 of the original version), and self-care confidence (6 items: scc 18–23 or items 19–24 of the original version). The items are rated on Likert-type scales from 0 to 4 or 1 to 4. The

Table 2 *Self-care of Hypertension Item Descriptive Analysis.*

Items	Mean (SD)	Skewness	Kurtosis
Self-care maintenance scale			
Scmt 01. Check your blood pressure.	1.70 (0.85)	1.11	0.53
Scmt 02. Eat a variety of vegetables, fruits …	2.70 (0.79)	0.07	−0.66
Scmt 03. Exert on doing daily busy activity, …	2.84 (0.91)	−0.23	−0.89
Scmt 04. Attend hospital for routine follow-up …	3.77 (0.51)	−2.18	4.09
Scmt 05. Eat a less salty foodstuff.	2.67 (0.98)	−0.05	−1.07
Scmt 06. Exercise for at least a half-hour.	2.52 (1.01)	0.08	−1.11
Scmt 07. Take medicines as prescribed.	3.82 (0.45)	−2.52	6.13
Scmt 08. Selected less salty food choices …	2.22 (0.93)	0.45	−0.61
Scmt 09. Use a system to help you remember your medicines …	2.21 (1.28)	0.36	−1.44
Scmt 10. Avoiding high-fatty foodstuff.	2.39 (0.89)	0.22	−0.69
Scmt 11. Try to lower your weight …	2.27 (1.01)	0.28	−1.01
Self-care management scale			
Scmn 12. How quickly did you recognize that your blood pressure was up …	1.79 (0.72)	0.85	1.01
Scmn 13. Reduce the salt or salty recipes in your meal …	2.86 (0.78)	−0.35	−0.23
Scmn 14. Mindful relaxation, be aware of stress …	2.89 (0.71)	−0.37	0.13
Scmn 15. Be strict on taking your blood pressure-lowering medicines more regularly.	3.49 (0.67)	−1.04	0.30
Scmn 16. Contact your healthcare provider …	2.39 (1.06)	0.04	−1.26
Scmn 17. How sure were you that the action helped …	2.01 (0.69)	0.04	1.56
Self-care confidence scale			
Scc 18. Control your blood pressure.	2.49 (0.71)	0.22	−0.24
Scc 19. Follow your hypertension treatment regimen.	2.59 (0.73)	0.19	−0.39
Scc 20. Recognize when your health is out of the ordinary.	2.51 (0.71)	0.11	−0.26
Scc 21. Evaluate whether either your blood pressure was up …	2.49 (0.70)	0.03	−0.23
Scc 22. Take action that will control your blood pressure.	2.53 (0.71)	0.14	−0.27
Scc 23. Evaluate how well a self-care action works.	2.57 (0.70)	0.10	−0.29

Table 3 *Factors Loading Matrix, Communalities Values and Eigenvalue Values of the Rotated Model of Self-Care Maintenance, Self-Care Management, and Self-Care Confidence Scales.*

	One-factor		Two-factor			Three-factor			
	Factor 1	h^2	Factor 1	Factor 2	h^2	Factor 1	Factor 2	Factor 3	h^2
Self-care maintenance scale (N = 640)									
Scmt 01.	.203	.041	**.206**	.001	.043	.088	**.200**	.024	.048
Scmt 02.	.395	.156	**.409**	.090	.175	.229	**.335**	.051	.168
Scmt 03.	.425	.180	**.457**	.167	.237	.065	**.683**	.046	.473
Scmt 04.	.056	.003	.011	**.668**	.446	.029	.015	**.729**	.533
Scmt 05.	.387	.150	**.377**	.078	.148	**.471**	.049	.003	.224
Scmt 06.	.483	.233	**.515**	.150	.288	.102	**.768**	.024	.602
Scmt 07.	.076	.006	.034	**.723**	.525	.073	.029	**.734**	.545
Scmt 08.	.546	.299	**.535**	.067	.291	**.566**	.179	.002	.352
Scmt 09.	.445	.198	**.433**	.091	.196	**.484**	.105	.024	.246
Scmt 10.	.458	.210	**.443**	.155	.221	**.537**	.076	.074	.300
Scmt 11.	.592	.350	**.580**	.127	.352	**.508**	.274	.094	.342
Self-care management scale (N = 298)									
Scmn 12.			.108	**.336**	.124				
Scmn 13.			**.920**	.077	.853				
Scmn 14.			**.660**	.199	.476				
Scmn 15.			**.206**	.118	.056				
Scmn 16.			**.451**	.035	.205				
Scmn 17.			.025	**.904**	.817				
Self-care confidence scale (N = 640)									
Scc 18.	.830	.689							
Scc 19.	.789	.622							
Scc 20.	.810	.656							
Scc 21.	.794	.630							
Scc 22.	.837	.701							
Scc 23.	.823	.677							

Extraction Eigenvalues values and percentage (%) of variance by factors (Rotation sums of squared loading)

	Self-care maintenance			Self-care management		Self-care confidence
	Factor 1	Factor 2	Factor 3	Factor 1	Factor 2	Factor 1
Eigenvalues	2.59	1.63	1.31	2.04	1.27	3.97
% of variance	12.77	12.15	9.92	25.68	16.49	66.25
Cumulative %	12.77	24.92	34.84	25.68	42.17	66.25

Note. h^2 are the extraction communalities values.

self-care management scale is administered to individuals who experience hypertension-related symptoms or uncontrolled blood pressure within four weeks. Response choices for all items are standardized for scores from 0 to 100, where higher scores indicate better self-care. The Thai SC–HI's item-level and scale-level content validity index was 1.00. The item-level intraclass correlation coefficients (ICCs) ranged from .97 to 1.00 for interobserver agreement and .95 to 1.00 for test–retest. The overall scale and three distinct scales' interobserver ICCs were .99. The test–retest ICCs were .99 for the total scale, and ranged from .97 to .99 for the three individual scales [7].

In the original version, self-care management and self-care confidence were one-factor models, whereas self-care management was a two-factor model [6]. We found the following differences in the items allocated to self-care management components across the two existing models [6,9]: autonomous (US: scmn 14, 15, and 17; Brazilian: scmn 12, 15, and 17); and consultative (US: scmn 12, 13, and 16; Brazilian; scmn 13, 14, and 16). Thus, we conducted CFA on all Self-Care Management models where the Thai model EFA factorial differed from the previous models.

Data collection

Data were collected by five graduated nursing students. All attended the 72-hour clinical-based sessions on cardiometabolic risk and self-care assessment research protocols. The SC–HI data were collected during a face-to-face interview at the HPH or the participant's home, according to their preference. Participants were asked to complete the questionnaire by themselves or have the research assistant read it for them. Participants' sociodemographic and clinical data were obtained from electronic health records and physical examination, including: an average of two blood pressure measurements, body mass index, waist circumference, history of diabetes, history of dyslipidemia, self-reported daily or occasional smoking or alcohol consumption within the last six months. The sociodemographic and clinical data were record in a data collection form.

Data analysis

Descriptive statistics, EFA, and internal consistency reliability were analyzed with IBM SPSS Statistics, version 28.0; CFA was conducted with AMOS version 24.0. We checked for multivariate outliers using Mahalanobis distance and excluded them from all subsequent analyses [22]. Descriptive statistics included percentage (%), number, median (interquartile rank [IQR]) and mean (standard deviation [SD]), and assessed individual item skewness and kurtosis to identify the estimator [15,23]. Each scale's scores were standardized [6] on a scale of 0 to 100.

EFA was conducted before CFA, using the first data set to test the three separate scales' dimension structure. A Kaiser–Meyer–Olkin (KMO) measure of sampling adequacy of .60 or greater and a significant Bartlett's test of sphericity showed that the correlation matrix was suitable for factor analysis [24]. EFA was first performed unrotated, using principal axes factoring with non-normality data and maximum likelihood with multivariate normality [15]. Factors

with eigenvalues greater than 1.00 were retained [15]. We performed EFA with varimax rotation and enforced one-, two- and three-factor solutions to evaluate the scale's factorial validity.

CFA was conducted on the second data set to validate the three scales' construct validity. We used the robust maximum likelihood method to estimate the parameters because various non-normalized items and factor loadings above .30 were acceptable [14,25]. As done for the original version [6] and other self-care instruments [14,25], we used numerous goodness of fit indices to analyze the model fit: the Tucker–Lewis index (TLI), comparative fit index (CFI), standardized root mean square residual (SRMR), and root mean square error of approximation (RMSEA). CFI and TLI values above .95 indicate good model fit, and .90–.95 values indicate acceptable fit [26]. However, the TLI is a non-normed incremental fit index; therefore, the values can fall outside the 0–1.00 range [26]. We used these values to compare the desirable model with a null model. We used RMSEA to estimate model fit, where a value of .05 or less indicates good fit; .05–.08, moderate fit; .10 or above, poor fit [27]. We used SRMR to measure absolute fit, where a value of .08 or less indicates good fit, and .10 or above indicates poor fit [27]. The Chi-square likelihood ratio is sensitive to sample size; hence, we reported the traditional Chi-square test, but did not use it to interpret model fit.

We used the CFA data set to evaluate others characteristic of construct validity, discriminant validity and convergent validity [28]. Discriminant validity is the extent to which the factors are distinct and not highly correlated [29]. A new criterion for assessing discriminant validity, the heterotriat-monotrait (HTMT) ratio was used for the multidimensional scales, using a criterion of < .85 to indicate discriminant validity [30]. For the HTMT technique, the scale score correlation is converted to an error-adjusted correlation using parallel reliability [31]. Also, convergent validity provides supporting evidence for construct validity. We considered the correlation between factors within the scale to measure the same construct. We analyzed Pearson's coefficient correlation (r) by using the standardized scores of the multidimensional scales. A positive and significant correlation between two factors within the same scale was considered evidence of convergent validity [28].

Internal consistency was also tested using the CFA data set. We estimated scale reliability with Cronbach's alpha coefficients and composite reliability [16] or McDonald's omega coefficients [17], with .70 or above considered acceptable [32]. Similar to the alpha coefficient, the omega coefficient evaluates scale-level reliability. However, omega has an advantage with multidimensional scales [18]. We calculated omega from each scale's total items, similar to the relevant self-care instruments, because self-care interpretation is meaningful by the scale-level [6,14]. Item discrimination was estimated using item-total corrected correlation coefficients, with .30 or above considered acceptable [33].

Results

Participant characteristics

We enrolled 1,262 adults from ten primary care settings; the final sample included 1,214 individuals after excluding 48 outlier cases. Participants were predominantly female, older adults, with and mean age of 66 years (range 36–97 years), and were socioeconomically well off (Table 1). Rates of each clinical risk factor, including uncontrolled blood pressure, were 6.8%–60.7%, and 81.5% had been treated for hypertension for over two years. The standardized mean scores (± SD) of each scale were 54.84 (SD = 14.51), 52.19 (SD = 13.57), and 50.93 (SD = 19.38) for self-care maintenance, self-care management, and self-care confidence, respectively. EFA and CFA showed different rates in literacy, known and treated diabetes, known and treated dyslipidemia, and abdominal obesity, while the three scales' self-care scores and total SC–HI scores did not differ.

Item response

Table 2 shows item response means and distribution. All items had scores above the lowest, except one Self-Care Management scale item (scmt 01); two items had below average mean scores (items: scmt 01 and scmt 12); and two items had non-normal distributions (items: scmt 04 and scmt 07).

Factorial validity

The scale structure was evaluated based on EFA and the rotated factor loadings matrix in 640 samples, as shown in Table 3. The self-care maintenance, self-care management, and self-care confidence scales' KMO values were .68, .62, and .88, respectively. Bartlett's test of sphericity yielded $p < .001$ for all scales, indicating factor analysis suitability. We used a principal axes factor method [15] with no rotation and exacted three factors for self-care maintenance, and two factors for self-care management. We used the maximum likelihood method [15] with no rotation and exacted one-dimension for self-care confidence. Each scale's eigenvalues were: self-care maintenance (factor 1 = 2.59, factor 2 = 1.63, and factor 3 = 1.31); self-care management (factor 1 = 2.04 and factor 2 = 1.27); and self-care confidence (one-factor = 3.97). One-factor and two-factor models for self-care maintenance revealed eigenvalues as follows: one-factor (factor 1 = 1.82); and two-factor (factor 1 = 1.84 and factor 2 = 1.07).

Self-care maintenance scale

The principal axes factor method [15] with varimax rotation exacted three factors with the following total variance: Factor 1 comprised five items and explained 12.8% of the variance; Factor 2 comprised four items and explained 12.2% of the variance; and Factor 3 comprised two items and explained 9.9% of the variance. Factor loadings for each item in Factors 1, 2, and 3 ranged from .471 to .566, .200 to .768, and .729 to .734, respectively, explaining 34.8% of the total variance. The extraction communalities values were .048 to .602, and one item (scmt 01) with a rotated factor loading matrix was below .30. A two-factor model shows the factors' explanation power relative to the total variance: Factor 1 comprised nine items and explained 16.6% of the variance, and Factor 2

Table 4 *Model Fit Summary for the Thai Self-Care of Hypertension Inventory.*

	Chi-square	df	*p*	CFI	TLI	RMSEA (90% CI)	SRMR
Initial models							
Self-care maintenance scale							
One-factor	465.79	44	<.001	.594	.492	.129 (.119–.140)	.063
Two-factor	249.34	43	<.001	.801	.746	.092 (.081–.103)	.060
Three-factor	125.25	41	<.001	.919	.891	.060 (.048–.072)	.044
Self-care management scale							
Thai model	3.83	8	.872	1.000	1.037	.000 (.000–.034)	.010
US model	6.12	8	.634	1.000	1.016	.000 (.000–.056)	.012
Brazilian model	5.94	8	.654	1.000	1.018	.000 (.000–.055)	.012
Self-care confidence scale							
One-factor	96.14	9	<.001	.955	.925	.130 (.107–.154)	.019
Respecified models							
Self-care maintenance scale							
Two-factor	92.08	39	<.001	.950	.928	.049 (.036–.062)	.037
Three-factor	98.94	39	<.001	.942	.919	.052 (.039–.065)	.038
Self-care confidence scale							
One-factor	22.48	7	.002	.992	.983	.062 (.036–.093)	.008

comprised two items and explained 9.9% of the variance. Factor loadings for each item in factors 1 and 2 ranged from .206 to .580 and .668 to .723, respectively, explaining 26.6% of the total variance. The extraction communalities values were .043 to .525, and one item (scmt 01) with a rotated factor loading matrix was below .30. Finally, when we fixed the number of factor to a one-factor model as of the original US model, the factor loading was .056 to .592 and explained 16.6% of the total variance. The extraction communalities values were .003 to .350, and three items (scmt 01, scmt 04, and scmt 07) with a rotated factor loading matrix were below .30.

Self-care management scale

The principal axes factor method [15] with varimax rotation exacted two dimensions: Factor 1 comprised four items and explained 25.7% of the variance; Factor 2 comprised two items and explained 16.5% of the variance. Factor loadings of each item in Factors 1 and 2 ranged from .206 to .920 and .336 to .904, respectively, explaining 42.2% of the total variance. The extraction communalities values were .056 to .853, and one item (scmn 15) with a rotated factor loading matrix was below .30.

Self-care confidence scale

The maximum likelihood method [15] with varimax rotation exacted a one-factor model. The explanatory power of the factors relative to the total variance of 66.3% had factor loadings ranging from .789 to .837. The extraction communalities values were .622 to .701.

Construct validity

Table 4 and Figures 1–3 show the CFA results. We evaluated the initial model fit indices with 547 participants, and respecified models for self-care maintenance (Figure 1), self-care management (Figure 2A–C), and Self-Care Confidence (Figure 3).

Self-care maintenance scale

Three models of self-care management were analyzed. We first specified a one-factor confirmatory model per the original version [6]. The model's goodness of fit indices was unacceptable: χ^2/df (44, $N = 574$) = 465.79, $p < .001$, CFI = .594, TLI = .492, RMSEA = .129 (90% CI = .119–.140), SRMR = .063). Three items had factor loadings <.03 (items: scmt 04 "Attend hospital for routine follow-up"; scmt 07 "Take medicines as prescribed"; and scmt 09 "Use a system to help you remember your medicines." Second, since self-care maintenance includes health promoting behavior and illness related behavior dimensions as relevant self-care measures [14], we specified a two-factor model. The EFA results allocated nine items from health promoting behavior and two items from illness related behavior dimensions. The model's goodness of fit indices was

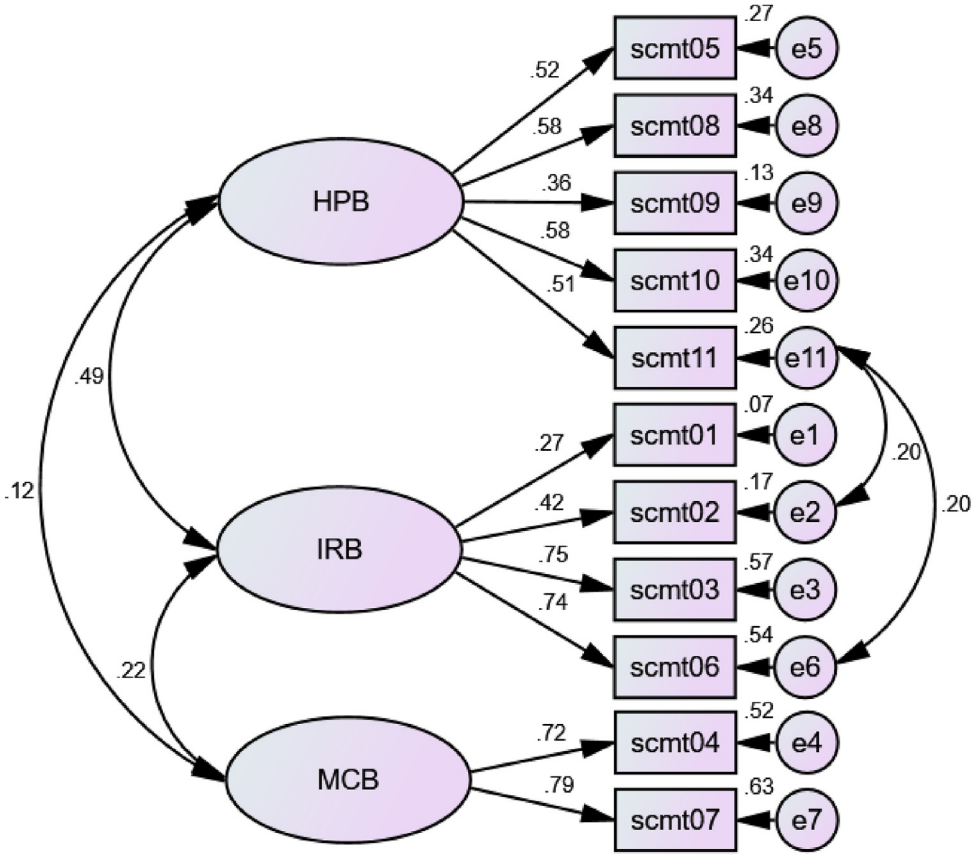

Figure 1. The standardized estimates of self-care maintenance scale with confirmatory factor analysis. *Note.* HPB = health promoting behaviors; IRB = illness related behaviors; MCB = medical care behaviors; scmt = self-care management; scmt 01 = item number 01. The numbers near the one headed arrows are factor loading coefficients; the numbers near the two-headed arrows are correlation coefficients.

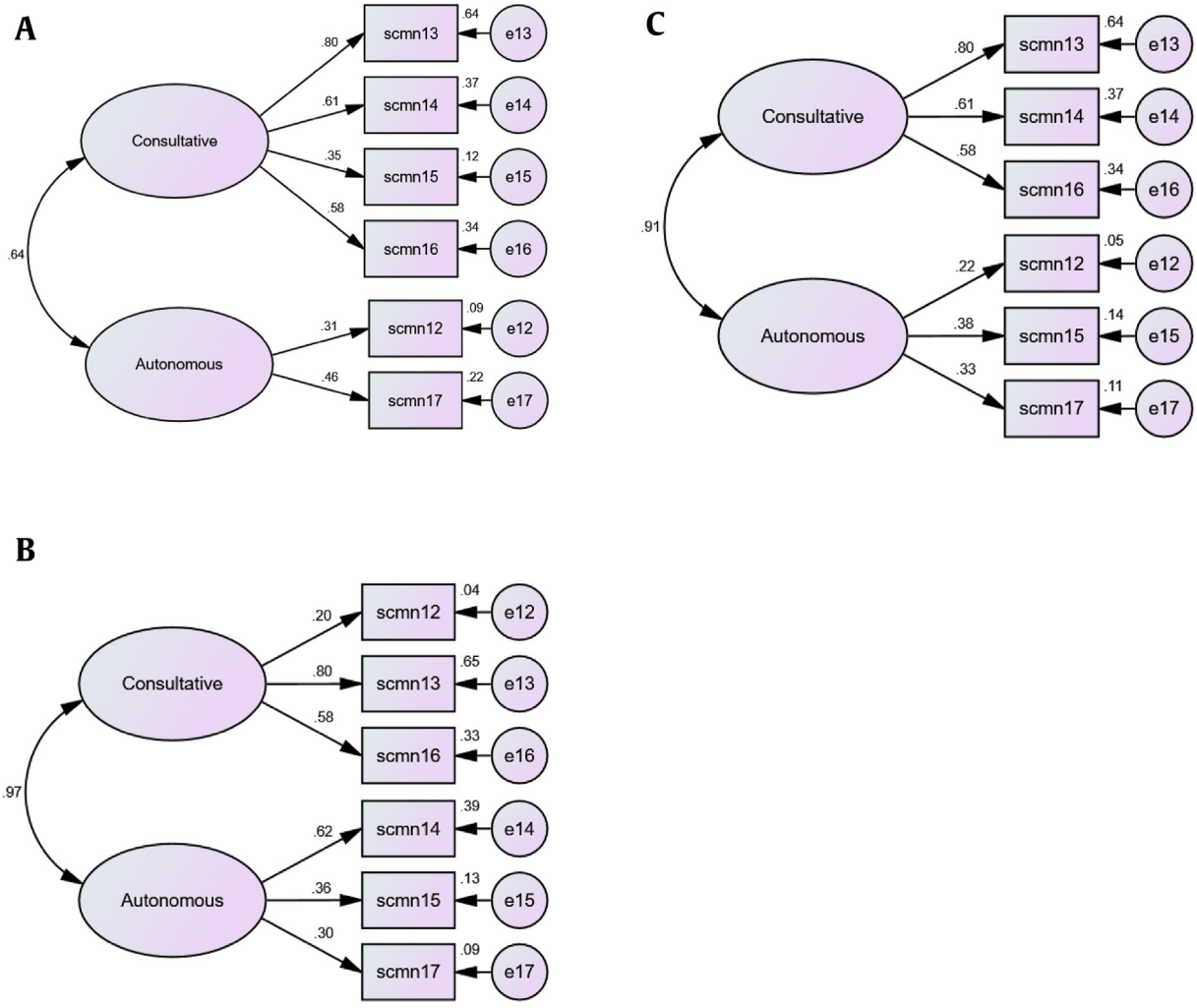

Figure 2. The standardized estimates of self-care management scale with confirmatory factor analysis. (A). Bidimensional self-care management Thai model. (B). Bidimensional self-care management US model. (C). Bidimensional self-care management Brazilian model. *Note.* scmn = self-care management; scmn 13 = item number 13. The numbers near the one headed arrows are factor loading coefficients.

partially supported: χ^2/df (43, N = 574) = 249.34, p < .001, CFI = .801, TLI = .746, RMSEA = .092 (90% CI = .081–.103), SRMR = .060). One item (scmt 09) had a factor loading <.03. We respecified a two-factor model and the modified indices estimated three error covariances. One variance was between items scmt 03 “exert on doing daily busy activity” and scmt 06 “exercise for at least a half-hour.” Items scmt 05 “eat less salty foodstuff” and scmt 08 “selected less salty food choices,” and scmt 10 “Avoiding high-fat foodstuff” covaried. Items scmt 08 and scmt 10 also covaried. Model fit was acceptable with partially supported goodness fit indices when respecified using these error covariances: χ^2/df (39, N = 574) = 92.08, p < .001, CFI = .950, TLI = .928, RMSEA = .049 (90% CI = .036–.062), SRMR = .037). All factor loadings were significantly positive. No items had factor loadings below .30. The two dimensions were positively correlated at .21.

Finally, we tested a three-factor model. Items allocated to each factor followed the EFA results. The model's goodness of fit indices was good: χ^2/df (41, N = 574) = 125.25, p < .001, CFI = .919, TLI = .891, RMSEA = .060 (90% CI = .048–.072), SRMR = .044). One item (scmt 01 “check your blood pressure”) had a factor loading <.03. We also respecified the three-factor model (Figure 1). The modification indices estimated two error covariances between items scmt 11 “try to lower your weight” and scmt 02 “eat a variety of vegetables, fruits, and grains,” and between scmt 11 and scmt 06 “exercise for at least a half-hour.” The final model's goodness of fit indices was improved: χ^2/df (39, N = 574) = 98.94, p < .001, CFI = .942, TLI = .919, RMSEA = .052 (90% CI = .039–.065), SRMR = .038). Still, one item, scmt 01 had a factor loading <.03. Two items (scmt 04 and scmt 07) allocated in the third factor reflected “medical care behaviors.” The health promoting behaviors and illness related behaviors dimensions comprised five and four items, respectively. A positive correlation among each pair's dimension was observed at .12 to .49.

Self-care management scale

The recent Thai, and the previous US [6] and Brazilian [9] self-care management models had different items belonging to autonomous and consultative dimensions. We conducted CFA on these three models. All models' goodness of fit indices suggested a perfect fit (Table 4, Figure 2A–C). Thai model: χ^2/df (8, N = 305) = 3.83, p = .872, CFI = 1.000, TLI = 1.037, RMSEA = .000 (90% CI = .000–.034), SRMR = .010); US model: χ^2/df (8, N = 305) = 6.12,

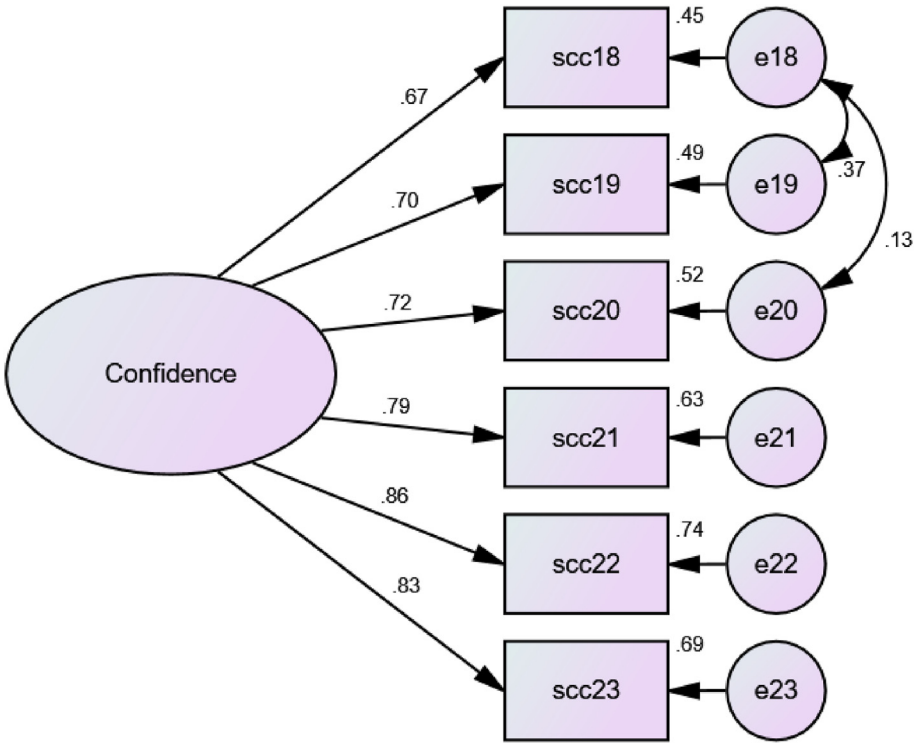

Figure 3. The standardized estimates self-care confidence scale with confirmatory factor analysis. *Note.* scc = self-care confidence; scc18 = item number 18. The numbers near the one headed arrows are factor loading coefficients; the numbers near the two-headed arrows are correlation coefficients.

p = .634, CFI = 1.000, TLI = 1.016, RMSEA = .000 (90% CI = .000–.056), SRMR = .012); and Brazilian model: χ^2/df (8, N = 305) = 5.94, p = .654, CFI = 1.000, TLI = 1.018, RMSEA = .000 (90% CI = .000–.055), SRMR = .012). All factor loadings for each model were positive and significant. Item scmn 12 from the US [6] and Brazilian [9] models had factor loading below .30. The two dimensions were positively correlated at .64, .97, and .91 for the Thai, US, and Brazilian models, respectively.

Self-care confidence scale

When we tested the one-factor CFA from the original model, the goodness of fit indices were adequate but only partially supportive (Table 4): χ^2/df (9, N = 574) = 96.14, p < .001, CFI = .955, TLI = .925, RMSEA = .130 (90% CI = .107–.154), SRMR = .019). The modification indices revealed three error covariances; one between items scc18 "control your blood pressure" and scc19 "follow your hypertension treatment regimen"; another between items scc 18 and scc 20 "recognize when your health is out of the ordinary." Model fit was good when the model was respecified with these error covariances (Table 4 and Figure 3): χ^2/df (7, N = 574) = 22.48, p = .002, CFI = .992, TLI = .983, RMSEA = .062 (90% CI = .036–.093), SRMR = .008). All factor loadings were positive and significant. No items had factor loadings below .30.

Discriminant validity

We examined discriminant validity in the self-care maintenance scale three-factor model by calculating HTMT ratios [30] among the three factors, which were less than .85, indicating acceptable discriminant validity. The HTMT ratios were .54 between health promoting behavior and medical care behavior, .12 between health promoting behavior and medical care behavior, and .23 between illness related behavior and medical care behavior. Self-care management discriminant validity was also supported by HTMT ratios [30] lower than .85. The HTMT ratio within the Thai two-factor model was .65 between consultative behavior and autonomous behavior.

Convergent validity

We evaluated convergent validity within the self-care maintenance scale three-factor model and found positive and significant correlations between pair dimensions [28]. Pearson correlation coefficients were 0.38 (p = .01) between health promoting behavior and illness related behavior, .11 (p < .05) between health promoting behavior and medical care behavior, and .15 (p = .01) between illness related behavior and medical care behavior. Also, we observed a positive and significant correlation [28] between consultative behavior and autonomous behavior (r = .24, p = .01) in the self-care management scale. This confirmed acceptable convergent validity for the two multidimensional scales.

Internal consistency and item analysis

Self-care maintenance scale

When the internal consistency of the self-care maintenance was calculated with all 11 items using the 574-CFA sample, the alpha coefficient was .70 and McDonald's omega coefficient was .69. If the items were deleted, the omega coefficient ranged from .64 to .69; no item was expected to significantly increase the coefficient if deleted. When the multidimensional scale's composite reliability was tested [16], the coefficient remained at .68, which is inadequate [33]. Most items presented adequate discrimination; the corrected

item-total correlation of all items was >.30, excluding one item (scmt 04).

Self-care management scale

The self-care management scale's internal consistency was calculated with all five items using the 305-sample CFA data from participants who had experienced hypertension-related symptom within the last four weeks. The alpha coefficient was .62 and McDonald's omega coefficient was .65. The coefficient if items were deleted ranged from .49 to .68, while one item (scmt 01) was expected to significantly increase the coefficient if deleted. The composite reliability test on this multidimensional scale [16] yielded a coefficient of .64, which was still inadequate [33]. Most items presented adequate discrimination, with the corrected item-total correlation of all items >.30, excluding one item (scmt 04).

Self-care confidence scale

The self-care maintenance scale's internal consistency was calculated with all six items using the 574-sample CFA dataset. The alpha coefficient was .90, and McDonald's omega coefficient was .89. The omega coefficient if items were deleted ranged from .87 to .88, with no item expected to significantly increase the coefficient if removed. All items presented adequate discrimination, with item to total corrected >.30.

Discussion

We evaluated the factorial validity, construct validity, and internal reliability of a Thai cross-cultural adaptation of the SC–HI (version 2.0). This is one of two recent studies outside the US to use EFA and CFA to evaluate the SC–HI. The dimensionality and psychometric properties we found partially supported the original model [6]. The self-care maintenance scale had a multidimensional construct. Factor loadings on the self-care management scale's autonomous and consultative dimensions differed from those of previous studies [6.9]. The relationship between the Thai self-care confidence scale items differed from those of the Brazilian model [9]. The respecified self-care management and self-care confidence scales improved the goodness of fit indices, supporting construct validity. The HTMT ratios and Pearson correlation coefficients confirmed acceptable discriminant validity and convergent validity of a three-factor self-care maintenance, and a two-factor self-care management scale. We used a new method to estimate discriminant validity because traditional methods, such as the Fornall–Larcker criterion and cross-loading method, had unacceptably low sensitivity compared to the HTMT ratios [30]. The self-care maintenance and self-care management scales' reliability coefficients were inadequate, whereas the self-care confidence reliability coefficient was acceptable. Overall, the study results illustrate that the cross-cultural adaptation of the Thai SC–HI is valid, but the reliability needs further testing.

Self-care of hypertension inventory

We used EFA to examine the dimensionality of the Thai SC–HI in this study, followed by CFA testing. We conducted EFA because it was already known that the scales characteristic of the US [6] and international SC–HI versions [8–10] differed. As expected, the Thai self-care maintenance and self-care management scales have a multidimensional structure, and the self-care confidence scale has a unidimensional structure. The multidimensional self-care maintenance scale in the Thai version does not support the previous models [6,9]; however, the multidimensional self-care maintenance scale has psychometric characteristics in Chinese [10], Arabic [8] and other relevant self-care measures [14,34,35]. Although the original self-care management scale was a two-factor model [6], items loaded on the autonomous and consultative dimensions in Thai model differ from those of the US and Brazilian models [6,9]. The self-care confidence items covariance matrix differed for the Thai and Brazilian models. The modified Thai SC–HI model had a moderate to high factor loading matrix for all items in the final three scales; one item (scmn 02) from the US and Brazilian self-care management models had poor factor loading. Our findings confirmed the Thai SC–HI model's construct validity is consistent with other international SC–HI models [6,8,9,36].

The Self-care maintenance and self-care management reliability coefficients were slightly lower, but the self-care confidence reliability coefficient was adequate. We used McDonald's omega and a composite reliability coefficient for the multidimensional scales instead of Cronbach's alpha alone. For multidimensional scales, the Cronbach's alpha coefficient overestimates reliability for the general common factor and underestimates the reliability of all model factors [18]. With Cronbach's alpha [36], the highest coefficient values were observed in the self-care confidence scale followed by the self-care maintenance and self-care management scales. However, in the Chinese version [10], the lowest Cronbach's alpha coefficients were found in the self-care maintenance scale. The Cronbach's alpha differences may depend on individuals' sociodemographic backgrounds, and the manner in which they perform self-care. The self-care maintenance and self-care management scales' lower internal consistency could be expected because self-care behaviors are largely independent of each other; they are controlled by various motivators, personal and cultural aspects, and change over time [25].

Self-care maintenance and self-care management items with lower corrected item-total correlation were expected to have high factor loading on other dimensions. The results were supported by both EFA and CFA. For example, we found that item scmt 01 “check your blood pressure” had the lowest score, because this self-care behavior is difficult to perform daily. Therefore, this finding supported deleting this item from the updated SC–HI version [37]. Although the CFA and EFA samples had different characteristics, the model was considered valid. Also, this finding may demonstrate the Thai SC–HI's external validity in patients with various sociodemographic and clinical characteristics.

Self-care maintenance

Thai self-care maintenance was multidimensional, as theorized. CFA indicated better fit indices with either a three-factor or two-factor model, but not with a unidimensional model. The multidimensional structure is consistent with the Chinese SC–HI [10], the Self-Care of Chronic Illness Inventory (SC–CII) [14], and the Caregiver Contribution to Self-Care of Chronic Illness Inventory (CC–SC–CII) [34,35], which were developed under similar theories [5]. We justified this scale's three-factor model based on KMO values and self-care actions' characteristics for each item and factor loading matrix. Items allocated to health promoting behaviors and illness related behaviors supported the self-care maintenance scale of the Self-Care of Chronic Illness Inventory [14]. Moreover, our findings revealed a third factor specific to medical care behaviors. The final three-factor model improved the fit indices and better explained the covariation effects in the two sets of three items. Each of the self-care behaviors correlated with the others. For example, patients trying to lose weight may eat a variety of vegetables, fruits, and grains (scmt02), and perform regular exercise (scmt 06).

Our findings support the conceptual basis [5] of daily self-care maintenance to promote health, coupled with specific treatment

to control hypertension. The Thai self-care maintenance dimensions supported the self-care of chronic illness theory and relevant self-care measurement in general [5,14,25]. Health promoting behaviors and illness related behaviors are two known dimensions [14,25]. Our study revealed another dimension, medical care behaviors. To control blood pressure and reduce cardiovascular risk, patients need to make lifestyle changes (e.g., diet, physical activity, weight control) and follow specific hypertension treatment protocols (e.g., medication, follow-up) [2–4].

Self-care management

Self-care management was bidimensional based on theory and in the original SC–HI [5,6]. Our analysis revealed autonomous and consultative dimension item numbers and factor loadings that differed from those of the US [6] and Brazilian [9] models. The factorial structure supported the Brazilian model and reflected cultural diversity. Autonomous dimension items focused on controlling symptoms, while consultative dimension items focused on daily self-care promoting behaviors. The controlling symptoms dimension in this study was similar to the self-care of heart failure index, which adequately addresses the theory of self-care, but it is not a self-care management subscale [25]. This finding supported a new revised SC–HI component [37] that separates items relevant to the self-care monitoring scale from the alternative self-care management scale.

Interestingly, CFA confirmed a good fit and supported all Thai, US, and Brazilian models. Our model had a better factor loading matrix with all items, specifically recognizing symptoms (item: scmn 12). The Self-Care Management process could be dissimilar but share commonality in one experience. Response to body changes may be related to emotion and illness. However, the response to change depends on physiological or disease/health related personal, psychological, sociological, and developmental factors [38]. Cross-cultural adaptations of the SC–HI must verify self-care management structures for the targeted population. Unlike other cardiovascular diseases, such as heart failure [25], hypertension has less severe symptoms. Common hypertension symptoms include headache, dizziness, and visual impairment; however, these symptoms are not disease specific and may occur in normotensive individuals. Therefore, hypertensive patients may not know when their blood pressure is elevated because they might not feel this change. Timely response to uncontrolled blood pressure and adequate behavioral change may depend on patient awareness, interpretation, and recognition of hypertensive conditions [38].

Self-care confidence

We found that self-care confidence was a unidimensional construct similar to the original model [6]. Despite the high factor loading matrix of all six items, the model partially supports most fit indices (CFI, TLI, and SRMR), except RMSEA. Unlike the Brazilian model [9], we found a high covariance between items scc 18 and scc 19 and scc 18 and scc 20. The final modified model improved all relevant fit indices and better explained the covariation effects among these items. This correlation was not present in the US [6], Chinese [10], or Polish [36] models; however, the Brazilian model [9] showed correlation between items scc 22 “evaluate changes in your blood pressure” and scc 23 “take action that will control your blood pressure.” Since the self-care confidence items scc 18, scc 19, and scc 20 measured different actions, our model demonstrated the relationship between confidence in blood pressure control, following a treatment regimen, and recognizing changes in health. Self-care confidence is a motivating factor for self-care maintenance and self-care management. The scale is a promising measure of self-efficacy within a health belief model; individuals' confidence facilitates specific self-care tasks [6]. Higher self-efficacy is associated with better hypertension self-care behaviors, including dietary changes, physical activity, and medical adherence [39].

Limitation and strengths

One limitation is that the self-care maintenance and self-care management scales' reliability coefficients were only partially accepted. This might be because factor loadings for the two items were lower than desired (items: scmt 01 “check your blood pressure,” scmn 15 “be strict on taking your blood pressure-lowering medicines”). However, because the indexes reliability in the population is unknown, we cannot know whether these conditions were met, hence further testing is needed to identify areas with compromised reliability in a national-level hypertension population. Also, we were unable to provide evidence for concurrent validity in this analysis because we lacked adequate data and an appropriate instrument. A third limitation is that the majority of the participants were recruited from rural primary care facilities, where lifestyle, behaviors, and environment may differ from those of urban or inner-city area. Study strengths include: participant enrollment from several settings; large sample sizes that were adequate for psychometric property testing; and participants (females, older adults, socioeconomic advantages, and various cardiometabolic risk factors) who were generally representative of Thailand's hypertensive population. We used two data sets: one to explore factorial validity using EFA, and the second to confirm construct validity. Thus, our analysis may reflect both hypothesis testing and generalizability. Implications for future research include testing those who may require hypertension self-care for complicated health conditions, such as older adults. Concurrent validity is also needed for full scale evaluation. Further research is needed to verify that the measure predicts hypertension results internationally.

Conclusion

The Thai SC–HI is a valid reflection of the theoretical concept on which it is based. This instrument is a useful clinical tool to assess and guide self-care development for promoting optimal health, hypertension treatment regimens, symptom management, and self-care confidence for Thai individuals with hypertension.

Ethical consideration

Approval was obtained from the Walailak Ethics Board Committee (code number: 59/075). The study adheres to standards delineated in the Declaration of Helsinki.

Funding

The research was financially supported by Walailak University under the National Research Council of Thailand (NRCT grant #WU60115), the Excellent Center of Community Health Promotion of Walailak University, and the new strategies research project (P2P) fiscal year 2022, Walailak University, Thailand.

Data statement

The original study is registered at Open Science Framework (https://osf.io/8j95k/).

Conflict of interest

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

Acknowledgment

We thank Professor Barbara Riegel, PhD, RN, FAHA, FHFSA, FAAN, for reviewing and approving Thai SC-HI, and also for encouraging us to conduct the psychometric test.

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Research Article

Psychometric Evaluation of the Korean Version of PROMIS Self-Efficacy for Managing Symptoms Item Bank: Item Response Theory

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ARTICLE INFO

Article history:
Received 29 March 2022
Received in revised form
22 August 2022
Accepted 23 August 2022

Keywords:
Patient reported outcome measures
psychometrics
self-efficacy
validity study

SUMMARY

Purpose: To evaluate the psychometric properties of the Patient-Reported Outcomes Measurement Information System (PROMIS) self-efficacy for managing symptoms of the version 1.0 item bank in Korea.
Methods: This study consisted of two phases: first, developing the Korean version of the item bank following the translation guidelines; and second, performing a cross-sectional study to evaluate its psychometric properties using the item response theory. This study enrolled 323 patients with type 2 diabetes mellitus between July and August 2020. Cronbach's α was used to assess the reliability of this item bank. Confirmatory factor analysis, using diagonally weighted least squares, was used to identify the assumptions of item response theory. Item parameter estimates including discrimination and thresholds were derived using the graded response model of the item response theory to reflect patient-reported outcomes as individualized responses.
Results: The Korean version of the item bank demonstrated good reliability (Cronbach's $\alpha = .98$) and its discrimination ranged from 1.82 to 4.93. The thresholds resulted in the establishment of a category response curve for each item. However, no overlap was observed among the category curves. Moreover, the differential item functioning was not significant for age, gender, and income variables.
Conclusion: The graded response model and differential item functioning provided qualitative evidence that demonstrated acceptable psychometric properties of symptom management self-efficacy among patients. This item bank is expected to provide adequate assessments of self-efficacy of symptom management for patients with a chronic disease, which can contribute to nursing research and intervention.

Introduction

The Patient-Reported Outcomes Measurement Information System (PROMIS) was established in 2004 to develop improved patient-reported outcomes (PRO) [1]. The multicenter collaborative PROMIS has produced more than 300 item banks within the physical, mental, and social domains. The PROMIS scales are advantageous for their high precision, which facilitates the assessment of a wide range of various aspects regarding patients' contexts. The information compiled by the PROMIS Health Organization has been translated into multiple languages and used worldwide [2]; thus, the study developed the PROMIS self-efficacy for managing symptoms item bank (version 1.0) in Korean, using the item response theory (IRT) and evaluated its psychometric properties.

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Abbreviations: CFA, Confirmatory Factor Analysis; CFI, Comparative Fit Index; COSMIN, Consensus-based Standards for the Selection of the Health Measurement Instruments; DIF, Differential Item Functioning; D-SMART, Diabetes Self-Management Assessment Report Tool; DWLS, Diagonally Weighted Least Squares; FACIT, Functional Assessment of Chronic Illness Therapy; GRM, Graded Response Model; HbA1c, hemoglobin A1c; IRT, Item Response Theory; PHO, PROMIS Health Organization; PRO, Patient-Reported Outcomes; PROMIS, Patient-Reported Outcomes Measurement Information System; RMSEA, Root Mean Square Error of Approximation; SDSCA, Summary of Diabetes Self-Care Activities Questionnaire; TLI, Tucker-Lewis Index.

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https://doi.org/10.1016/j.anr.2022.08.003
p1976-1317 e2093-7482/

The PRO is pertinent for establishing a scientific framework for patient experience in healthcare research [3,4]. The United States National Institutes of Health recognized the need for PRO measurement tools to ensure validity and reliability in high-quality care [1]. There has been a significant demand from patients for the expression and measurements of their "real" symptoms and experiences [5]. The PROMIS item banks from a physical category have been translated and validated more frequently than those in the psychosocial health categories [6,7].

The evaluation of self-care abilities among patients with chronic diseases is important for the maintenance, monitoring, and management of their medical information. According to the self-care of chronic illness theory, the improved management of chronic diseases results in positive self-care outcomes [8]. As shown by the health action process approach theory, initiating health-related behaviors, such as self-care, requires a *pre-intentional motivation process*. In a previous study, it was reported that self-efficacy had an effect on self-care in patients with chronic diseases such as heart failure, asthma, and hypertension [9–11]. Self-efficacy is relevant to this process, as it is the belief in one's own abilities to complete a task or achieve a goal [12,13]. Thus, self-efficacy for managing symptoms refers to a set of patients' beliefs about their ability to control their symptoms successfully.

The PROMIS self-efficacy scales for managing chronic conditions fall within the mental health category [14]. Patients are impacted by various needs and symptoms depending on their respective contexts; hence, evaluating patients can help to provide effective individualized care [15,16]. Standardized PRO measurements are necessary to evaluate the patients' cultural backgrounds, which are done during psychometric evaluations. Standardizing PRO measurements is crucial because multiple understandings could arise from different cultural backgrounds, even in the same given sentence [17].

According to the evidence, chronic diseases have consistent guidelines that include symptoms management and complication prevention. However, treatment goals and management processes vary among patients [18,19]. With an understanding of the patients' integrative context, nurses should be able to make sound clinical judgments [20]. For instance, a previous scoping review study emphasized the increasing need for cross-cultural studies that analyze indicators of Diabetes Mellitus (DM) in the context of the patients' life and experiences. Particularly, social factors can be considered in order to manage blood glucose levels [21]. Nurses' monitoring and intervention to manage chronic disease patients' symptoms make up a substantial axis of social factors. Thus, measuring self-efficacy for managing symptoms using the PROMIS self-efficacy scales is essential for patients with chronic disease.

Self-efficacy of patients with chronic disease for self-care and symptom management is a significant topic that has continuously piqued interest in healthcare [22–25], and instruments have been developed in response [26–28]. A systematic review of the self-efficacy instruments for patients with chronic diseases reported that most instruments had unclear purposes and measurement properties [29]. The widely used self-efficacy scale [30] is limited to general aspects of self-efficacy and not for assessment of patients' self-efficacy in managing symptoms. There is a need to assess patients' psychological readiness for the management of complications or acute exacerbations through the incorporation of voluntary self-care strategies. The PROMIS self-efficacy for managing symptoms item bank assesses self-efficacy in a variety of domains, ranging from daily symptom management activities to strategies for coping with unexpected changes.

The original PROMIS item banks were developed using the IRT model [31,32]. The IRT analysis highlighted the functions of each item and encompassed the characteristics of items in the whole measurement [33]. With regard to measuring, IRT is concerned with the item of measurement, whereas classical test theory depends on the entire measurement [34]. Using IRT, it is possible to determine how each item contributes to a total measurement and how each item performs on the measurement [35]. Each PROMIS item bank measures specific categories and domains and is considered a one-factor model [6,36]. The PROMIS seeks to expand the understanding of patients' experiences by using item banks in the global healthcare domain. Therefore, developing the PROMIS item bank in a different language through strict and systematic methods can help generate individualized PRO evidence.

This study aimed to develop the PROMIS self-efficacy to manage symptoms using the version 1.0 item bank that has been translated and adapted culturally to Korean. Furthermore, to investigate psychometrics using the IRT model for patients with type 2 DM.

Methods

Design

This is a methodological study designed to evaluate the validity and reliability of the Korean version of PROMIS self-efficacy for managing symptoms item bank (version 1.0) with original data from the survey.

The current study comprises two main phases. First, the Korean version of PROMIS self-efficacy for managing symptoms item bank was developed. The details of the first step are described in the following section, "Translation including cross-cultural context." Second, a cross-sectional study was conducted to evaluate the psychometric properties of the final version of the Korean item bank. After the survey, raw data was analyzed using the IRT model, in accordance with the reporting checklist for PROMIS [37]. Furthermore, this study adhered to the *Strengthening the Reporting of Observational Studies in Epidemiology* (STROBE) guidelines [38].

Translation process and validation

The license agreement to translate the PROMIS self-efficacy for managing symptoms item bank (version 1.0) into Korean was obtained from the PROMIS Health Organization (PHO). The PHO presented the guidelines for translation and development. Figure 1 presents an overview of the translation process. The translation process followed the PROMIS translation guidelines based on the Functional Assessment of Chronic Illness Therapy (FACIT) translation methodology [39,40]. One of two independent Korean speakers translated the first version of the item bank, and the other reviewed the first version. A Korean-English bilingual translator back-translated the version, and three Korean speakers reviewed the back-translation. All the translators used during this process were healthcare providers. The research team finalized the translated item bank and reached a consensus with the PROMIS center. Thereafter, five Korean patients with type 2 DM were enrolled in the cognitive testing and linguistic validation process. The study research team reported the cognitive interview results to the PROMIS center. The final version of the Korean version of PROMIS self-efficacy for managing symptoms item bank was completed based on the cognitive interview report and discussion.

Sample/Participants

A total of 354 patients with type 2 DM were recruited using convenience sampling from the DM center of a tertiary hospital in Seoul, South Korea. The study participants were adults aged 19 and above and had volunteered to participate in completing the questionnaires between July and August 2020. We chose type 2 DM

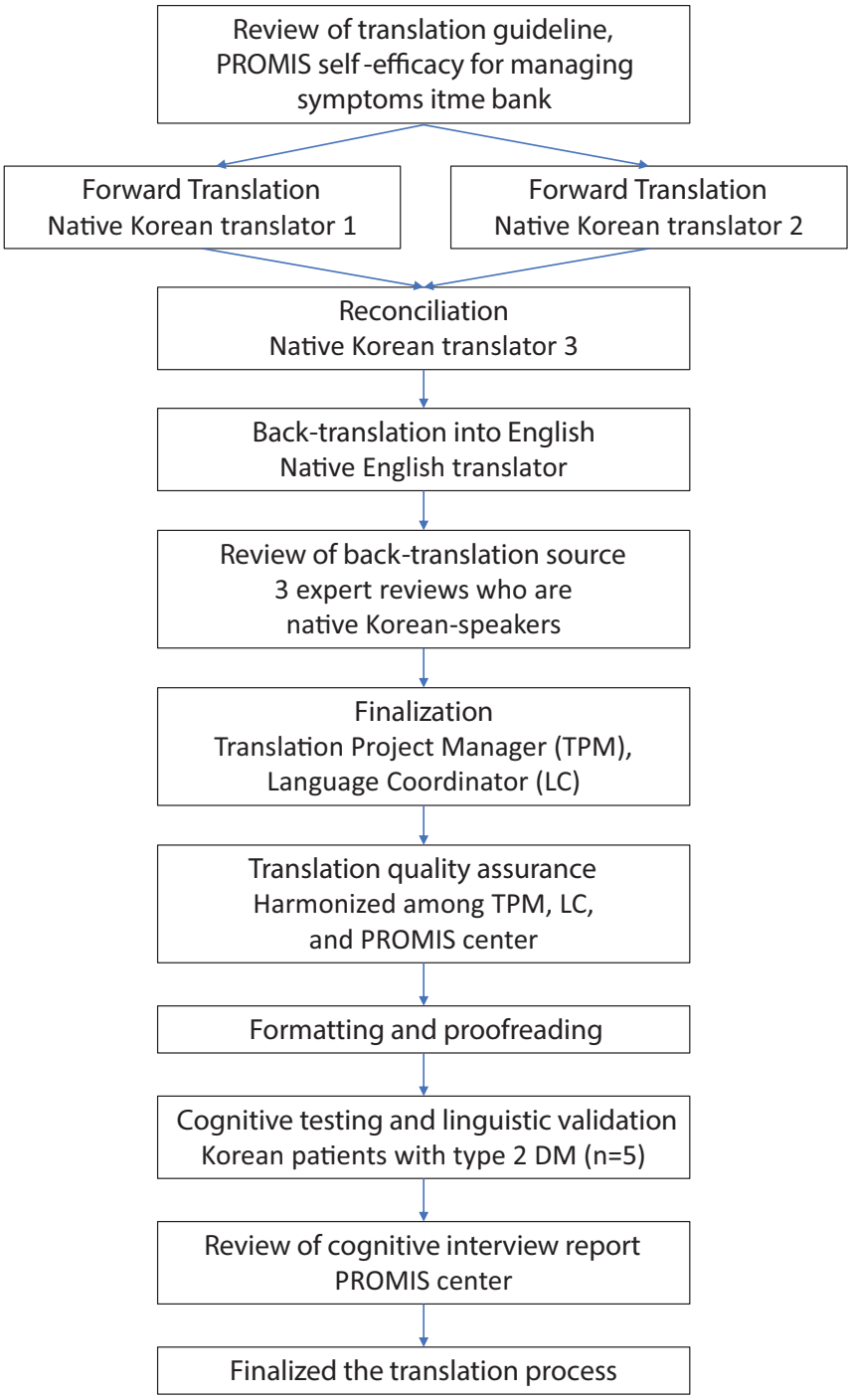

Figure 1. Translation Process of the Korean Version of PROMIS Self-efficacy for Managing Symptoms Item Bank. Note. PROMIS=Patient-Reported Outcomes Measurement Information System, DM = Diabetes Mellitus.

patients as the study population. The first reason is to reduce participant heterogeneity and to control exogenous variables for psychometric evaluation. Second, DM is one of the most common chronic diseases that can be treated and managed with regular evaluations and treatments such as diet, physical activity, and medication [41]. It thus becomes vital for patients with type 2 DM to manage symptoms through medication and treatment [42].

A total sample of 323 patients (91.2%) completed the survey, and thus were included in the study utilized. Confirmatory factor analysis (CFA) was used to test the assumptions of the IRT model. The minimum sample size for CFA was 200 cases [43], with a previous study reporting that the IRT model can be applied to at least 200 patients depending on the model complexity in healthcare research [44]. Moreover, the sample size used in this study exceeded the minimum criterion for the IRT model.

Data Collection

Instrument

The main instrument used was the PROMIS self-efficacy for managing symptoms version 1.0 item bank for adults, which includes 28 items. A five-point Likert scale was used to assess the

responses, ranging from a scale of "1 = not at all confident" to "5 = very confident." A higher score implies an increased sense of self-efficacy in managing symptoms. This item bank measures patients' self-efficacy regarding the degree to which symptoms are controllable and the ability to prevent symptoms from worsening.

In addition, two measurements were used to analyze the convergent validity, namely the Diabetes Self-Management Assessment Report Tool (D-SMART) and the Korean version of the Summary of Diabetes Self-Care Activities Questionnaire (SDSCA), after approval from the original authors. These two instruments have established good validity and reliability in previous studies.

The original version of D-SMART was developed by the American Association of Diabetes Educators via Peyrot and colleagues to assess the self-management behavior of patients with DM [45]. The Korean version of D-SMART was used in previous studies [46,47]. Among the D-SMART questions, 23 items were used to evaluate the self-management skills confidence [45]. The evaluation of skills confidence for DM self-management behavior in seven categories, including exercise/activity, nutrition, medication, and monitoring, is conducted using a 4-point Likert scale, with higher scores indicating greater skills confidence. In this study, Cronbach's alpha value of scale was 0.91.

Toobert and colleagues revised SDSCA in 2000, which is used mainly in self-management activity studies for patients with DM and consists of 25 items, including six subscales: general and specific diet, exercise, blood sugar test, foot care, and smoking [48]. Chang and Song (2009) translated and modified the revised SDSCA in Korean and it has 17 items, excluding eight items that could not be scored [49], and five domains—diet, exercise, medication, blood sugar test, and foot care—were included [50]. This measurement asks participants to indicate on an 8-point scale ('0 day' to '7 days'), the number of days they engaged in self-care activities corresponding to each item during the previous week. Cronbach's alpha for the Korean version of this study was as follows: 0.58 for diet, 0.80 for diet, 0.36 for medication, 0.92 for blood sugar test, and 0.63 for foot care.

Assumptions of the IRT

The IRT model requires several robust assumptions, namely: *unidimensionality, invariance, local independence,* and *monotonicity* [43]. First, the CFA and coefficient omega (ω_h) were used to analyze *unidimensionality* and *invariance* [51,52]. The criteria of the CFA results of *unidimensionality* required the comparative fit index (CFI) or Tucker-Lewis Index (TLI) to exceed .95 or root mean square error of approximation (RMSEA) to be less than 0.06 [51]. In addition, the results of ω_h were used to assess *unidimensionality* [52]. The generally accepted criterion for ω_h is .70 [53]. Second, the chi-square (χ^2) value assessed whether the model was fit for *invariance*. When the *p*-value of χ^2 was not statistically significant, it was considered an appropriate model fit [51]. Confirming the assumption with χ^2 is a theoretical concept, and every case does not meet the χ^2 assumption. When χ^2 was not satisfied, it could be assumed that each subgroup has a varied differential item functioning (DIF) [35]; therefore, age, gender, and income were selected as the anchor variables to confirm the DIF in this study. Thirdly, using Yen's *Q*3, *local independence* was tested by residual correlations [54]. A study reported that *local independence* did not have a single critical value [55]. However, based on previous research and consensus-based standards for the selection of the health measurement instruments (COSMIN) manual for systematic reviews of PROMs, this study established criteria: <0.37 is suitable, and <0.7 is considered possible [51,56]. Finally, *monotonicity* was supported by an adequate graph of discrimination and thresholds [51,57].

Data analysis

The data was analyzed using SPSS (version 25.0; IBM, Armonk, NY, USA) and the *lavaan, psych, mirt,* and *lordif* packages in *R* version 4.1.2. A descriptive statistical test was performed for the demographic and clinical variables. Univariate normality was confirmed before analysis to identify the selection bias of the study. Cronbach's α coefficients were used to confirm the reliability of the measurements. This study applied diagonally weighted least squares (DWLS) to determine the CFA results using the *lavaan* package in *R,* because the item bank was an ordinal variable, and the ceiling effect was identified [58,59]. The ω_h were estimated using the *psych* package, and the residual correlation was tested using *mirt* package in *R*.

T-score

Following the PROMIS scoring guide, the standardized T-score was used in this study [21]. T-score is a standard score of reference samples including United States (U.S.) general population [31]. The underlying T-score of the self-efficacy for managing symptoms item bank was calibrated to reach an average of 50, with a standard deviation of ±10 for the U.S. clinical sample. The PROMIS center provides the PROMIS T-score maps on the website for some short-form item banks. The T-score was obtained using the website of the Health Measures Scoring Service (powered by the Assessment Center℠) that provides underlying item parameters and scoring for the U.S.

IRT model

This study used the graded response model (GRM) of the IRT model because the item bank has ordered categories, such as the Likert scale [43]. For the GRM, discrimination and thresholds were estimated, and category response curves were derived. The IRT model was implemented to reflect the patients' ability level for psychometric evaluation using the *mirt* package in *R* [43,60].

Differential item functioning

The DIF was analyzed to evaluate the validity of this item bank, which was constructed using a five-point Likert ordinal scale. Three group variables, including age, gender, and income, were used to analyze whether each question functions differently between groups. Among the group variables, the age group was divided into under 60 years [61] and above, with a male gender group as a reference. The income group was divided into less than four million South Korean won [62] and more.

The *lordif* package used the ordinal logistic regression model for DIF estimating methods [38]. The DIF analysis was conducted in two steps. First, the likelihood ratio χ^2 test was carried out without using the anchor item. Second, the DIF item was extracted from 28 items. The DIF can be categorized as either a uniform DIF (if the effect is constant) or a non-uniform DIF (if the effect varies depending on the trait level) [63,64]. The χ^2 difference test (df = 1) was conducted for each of the two types of DIF using logistic regression. The overall χ^2 difference test (d*f* = 2) for the total DIF was identified for the two inclusive types of DIF effect. A significance level of .01 was used as the criterion for each χ^2 test. Thereafter, the DIF was evaluated using the items that were not extracted during the first step as anchor items. In this step, at least 2.0% of the items within McFadden's pseudo R^2-change were extracted as a DIF [65].

Results

Demographics and clinical characteristics

The average age of the patients was 62.16 ± 10.54 years, with a DM period of 14.23 ± 10.33 years in this study. Male patients made up 68.4% of the participants, and the majority of the participants

were married (91.6%). Monthly income was reported as less than four million South Korean won by 52.3% of participants and as more than four million South Korean won by 47.7% of participants. The participants' average Body Mass Index (BMI) was 25.11 ± 3.57 kg/m^2, ranging from 16.60 to 42.82 kg/m^2. The average recent hemoglobin A1c (HbA1c), which measures the amount of glucose attached to hemoglobin, was 7.5 ± 1.5% according to patients' electronic health records. The majority of participants (90.1%) managed their DM through oral administration, 33.4% via insulin injection, and 26.9% through a combination of medication and insulin. Most of the participants did not receive DM group education (77.4%) and managed their DM through administering oral medications (90.1%).

Item analysis

In total, 28 items were analyzed using mean and standard deviation (Table 1). Considering the criteria that the average value should be between 1.5 and 4.5 on a five-point Likert scale, all items were within the range [66]. The patients in this study reported moderate self-efficacy for managing symptoms (T = 52.6, SD = 8.25). The T-Score differed merely by two points as compared to the T-score derived for the general U.S. population. Baseline self-efficacy for managing symptoms (T = 51.38, SD = 8.353) improved after two weeks of follow-up (T = 53.82, SD = 7.98).

Reliability and convergent validity

The Cronbach's α of this item bank was .98 (Table 1). All measures met the reliability criteria (>.70). In addition, if the items were deleted, lower levels of Cronbach's α would be observed as opposed to the total Cronbach's α (Table 1).

This study tested convergent validity using the D-SMART and the revised SDSCA. The correlation coefficients of the item bank and D-SMART was r = .59 ($p < .001$). However, there was no statistical significance between the item bank and each domain of revised SDSCA: diet 0.11 ($p = .054$), exercise 0.11 ($p = .059$), medication −0.02 ($p = .731$), blood sugar test 0.05 ($p = .420$), and foot care 0.03 ($p = .633$).

Table 1 *Item Analysis of the Korean Version of PROMIS Self-Efficacy for Managing Symptoms Item Bank (n = 323).*

Item	Mean ± SD	Cronbach's α if deleted
SEMSX001	3.53 ± 1.16	.98
SEMSX002	3.68 ± 1.07	.98
SEMSX003	3.17 ± 1.26	.98
SEMSX004	3.89 ± 1.05	.98
SEMSX005	3.74 ± 1.11	.98
SEMSX006	3.93 ± 1.05	.98
SEMSX007	4.18 ± 0.88	.98
SEMSX008	3.88 ± 1.01	.98
SEMSX009	3.72 ± 1.14	.98
SEMSX010	3.95 ± 1.01	.98
SEMSX011	3.89 ± 1.02	.98
SEMSX012	3.90 ± 1.05	.98
SEMSX013	3.77 ± 1.09	.98
SEMSX014	3.93 ± 1.01	.98
SEMSX015	3.84 ± 1.08	.98
SEMSX016	3.79 ± 1.05	.98
SEMSX017	3.85 ± 1.03	.98
SEMSX018	3.85 ± 1.07	.98
SEMSX019	3.73 ± 1.08	.98
SEMSX020	3.90 ± 1.03	.98
SEMSX021	3.73 ± 1.14	.98
SEMSX022	3.86 ± 1.02	.98
SEMSX023	2.85 ± 1.03	.98
SEMSX024	2.73 ± 1.08	.98
SEMSX025	2.73 ± 1.08	.98
SEMSX026	2.89 ± 1.03	.98
SEMSX027	2.73 ± 1.14	.98
SEMSX028	2.86 ± 1.02	.98
Total mean ± SD		105.13 ± 23.38
Minimum – Maximum		35 – 140
Coefficient α (Cronbach's α)		.98
Coefficient omega (ω_h)		.87
Total T-score Mean ± SD		52.6 ± 8.25
Baseline T-score Mean ± SD		51.38 ± 8.53
Follow-up T-score Mean ± SD		53.82 ± 7.98

Note. SD = standard deviation.

Assumptions and the expected scores curves for the IRT

First, *unidimensionality* was the primary assumption for IRT [43,67]. For this study, the CFA results were verified by applying the DWLS. As PROMIS item banks were developed as a unidimensional model [68,69], we determined the *unidimensionality* by conducting CFA to test the convergent validity without exploratory factor analysis [70]. The estimation result of χ^2 (df = 350) was 8809.65, and the model did not perfectly fit the data ($p < .001$). Both CFI and TLI of the Korean version of the item bank were 0.99 which met the criteria [51,71,72] but the RMSEA, 0.274, did not. As the COSMIN methodology for PRO measures [51] recommends that either CFI/TLI or RMSEA should be satisfied with the criteria for *unidimensionality*; thus, the *unidimensionality* of the Korean version of the item bank was identified. In addition, these results comply with the recommended value ω_h for this item bank, which was .87 (Table 1). Second, the p-value of $\chi^2 > .01$ provides an appropriate criterion for the *invariance* model fit. The χ^2 value of this item bank was 8809.649 ($p < .001$). Therefore, we determined the value of DIF to verify the *invariance* [35]. Using age, gender, and income as anchor items, a DIF analysis was conducted, and the results confirmed that this model showed *invariance*. Third, the results of residual correlation among the items as a unidimensional model using Yen's $Q3$ were less than 0.37, except for the residual correlation between items 1 (SEMSX001) and 2 (SEMSX002), which ranged from −0.24 to 0.33 [51]. The residual correlation between items 1 and 2 was estimated to be 0.51, and a previous study confirmed *local independence* [56]. Lastly, all category response curves indicated an adequate monotonic relationship between the item thresholds and participants' self-efficacy ability. These inform the *monotonicity* of the basic assumptions for IRT. Figure 2 displays the example of the category response curve for item 22.

Estimating graded response model

The GRM evaluated item discrimination (a) and thresholds (b) based on participants' response patterns regarding the IRT model (Table 2). Overall, the discrimination of this item bank was high, ranging from 1.82 to 4.93. The threshold values in the item bank were estimated in the order of low to high values according to the GRM (Table 2). For item 11, no patient selected the first category. Thus, the threshold of item 11 was analyzed using only four categories, from the initial two to five. When identifying the category response curve derived using the estimated item parameter, the category curve did not indicate complete overlap with another curve. The figures of the 28 items were interpreted to ensure that each item category had appropriate functions. An example of item 22 (SEMSX022) is shown in Figure 2.

Analyzing the DIF

This study used three group variables for DIF analysis: age, gender, and income.

First, as a result of conducting the likelihood ratio χ^2 test using the age group variable, items 1 (SEMSX001), 21 (SEMSX021), and 27 (SEMSX027) had DIF. Items 1 and 21 represented the non-

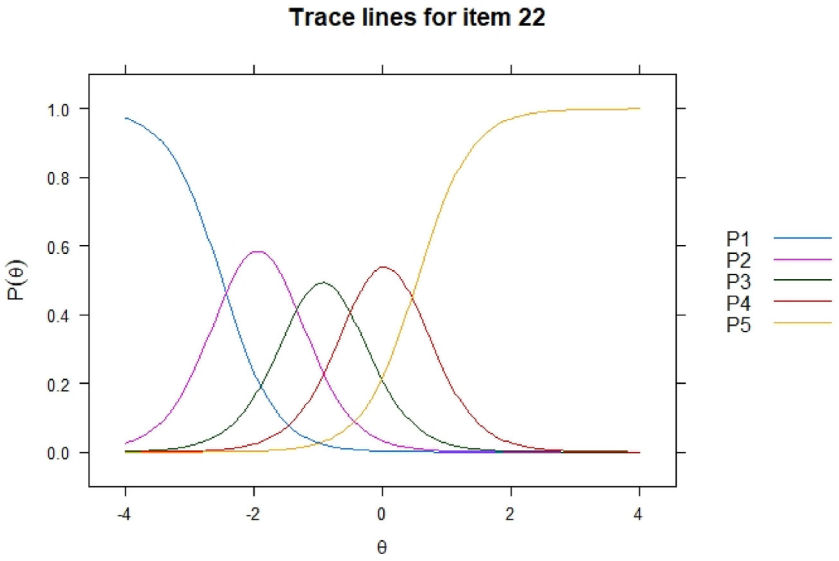

Figure 2. Category Response Curve of the Korean Version of PROMIS Self-Efficacy for Managing Symptoms Item Bank Item 22 (SEMSX022). The graphs of P1 to P5 are Likert scale scores, one to five, of the item 22.

Table 2 *Estimated Item Parameters for the Korean Version of PROMIS Self-Efficacy for Managing Symptoms Item Bank Using the Graded Response Model.*

Item	Discrimination *a* (SE)	Threshold			
		b_1 (SE)	b_2 (SE)	b_3 (SE)	b_4 (SE)
SEMSX001	2.34 (.22)	−2.43 (.24)	−1.18 (.12)	−0.08 (.09)	.73 (.10)
SEMSX002	1.99 (.19)	−2.18 (.21)	−0.84 (.11)	.27 (.09)	1.15 (.13)
SEMSX003	2.52 (.23)	−2.62 (.28)	−1.10 (.12)	−0.27 (.08)	.64 (.10)
SEMSX004	1.82 (.17)	−1.98 (.20)	−0.86 (.11)	.15 (.10)	1.08 (.13)
SEMSX005	2.55 (.23)	−1.84 (.17)	−1.08 (.11)	−0.19 (.08)	.76 (.10)
SEMSX006	2.42 (.23)	−2.19 (.21)	−1.38 (.13)	−0.33 (.09)	.67 (.10)
SEMSX007	1.93 (.18)	−1.73 (.17)	−0.67 (.10)	.20 (.09)	1.07 (.13)
SEMSX008	3.21 (.30)	−2.44 (.23)	−1.36 (.12)	−0.51 (.08)	.30 (.08)
SEMSX009	2.68 (.25)	−2.26 (.21)	−1.22 (.12)	−0.37 (.08)	.48 (.09)
SEMSX010	3.48 (.33)	−2.37 (.22)	−1.31 (.12)	−0.52 (.08)	.26 (.08)
SEMSX011	3.50 (.35)	N/A	−1.62 (.14)	−0.88 (.10)	.13 (.08)
SEMSX012	3.37 (.31)	−2.50 (.25)	−1.38 (.12)	−0.55 (.08)	.37 (.08)
SEMSX013	2.52 (.24)	−2.30 (.22)	−1.10 (.11)	−0.43 (.09)	.50 (.09)
SEMSX014	3.50 (.33)	−2.23 (.21)	−1.41 (.13)	−0.56 (.08)	.30 (.08)
SEMSX015	4.20 (.40)	−2.22 (.20)	−1.30 (.11)	−0.48 (.08)	.33 (.08)
SEMSX016	4.93 (.48)	−2.10 (.18)	−1.29 (.11)	−0.49 (.08)	.32 (.07)
SEMSX017	4.75 (.45)	−2.05 (.17)	−1.23 (.11)	−0.51 (.08)	.29 (.07)
SEMSX018	3.46 (.32)	−2.21 (.21)	−1.25 (.11)	−0.43 (.08)	.36 (.08)
SEMSX019	3.50 (.32)	−2.11 (.19)	−1.14 (.11)	−0.44 (.08)	.43 (.08)
SEMSX020	4.20 (.40)	−2.44 (.25)	−1.27 (.11)	−0.55 (.08)	.28 (.07)
SEMSX021	3.33 (.31)	−2.28 (.21)	−1.18 (.11)	−0.50 (.08)	.35 (.08)
SEMSX022	2.39 (.23)	−2.50 (.25)	−1.37 (.13)	−0.47 (.09)	.54 (.09)
SEMSX023	2.30 (.22)	−2.85 (.34)	−1.44 (.14)	−0.53 (.09)	.45 (.09)
SEMSX024	2.57 (.24)	−2.25 (.22)	−1.33 (.13)	−0.62 (.09)	.43 (.09)
SEMSX025	2.90 (.27)	−2.22 (.21)	−1.21 (.12)	−0.40 (.08)	.53 (.09)
SEMSX026	4.57 (.43)	−1.99 (.17)	−1.30 (11)	−0.52 (.08)	.34 (.07)
SEMSX027	2.08 (.20)	−2.32 (.23)	−1.27 (.13)	−0.50 (.09)	.53 (.10)
SEMSX028	3.70 (.34)	−2.20 (.20)	−1.28 (.12)	−0.48 (.08)	.42 (.08)
Range	1.82 to 4.93	−2.85 to −1.73	−1.62 to −0.67	−0.88 to .27	.13 to 1.15

Note. N/A = Not applicable, SE = standard error.

uniform DIF, and item 27 described the uniform DIF. All three DIF items (1, 21, and 27) had statistical significance in the total DIF effect ($p < .001$). Ordinal logistic regression was conducted again with other items, except these three, as the anchor item. Consequently, item 27 was identified with a McFaddens' pseudo R^2-change of over 2.0% or more; the R^2-change value of uniform DIF was 3.4%, and the total DIF was 3.9% ($p < .001$). Figure 3 shows the test characteristic curves (TCC) of item 27. The effect of item 27 on the expected score of the entire item bank was interpreted to be minimal.

Next, the χ^2 test results according to the gender group variable were described. Item 27 had a uniform DIF ($p < .008$); however, the total DIF effect was not statistically significant ($p = .211$). After the ordinal logistic regression was re-conducted with the remaining items, excluding item 27, there was no item with McFadden's

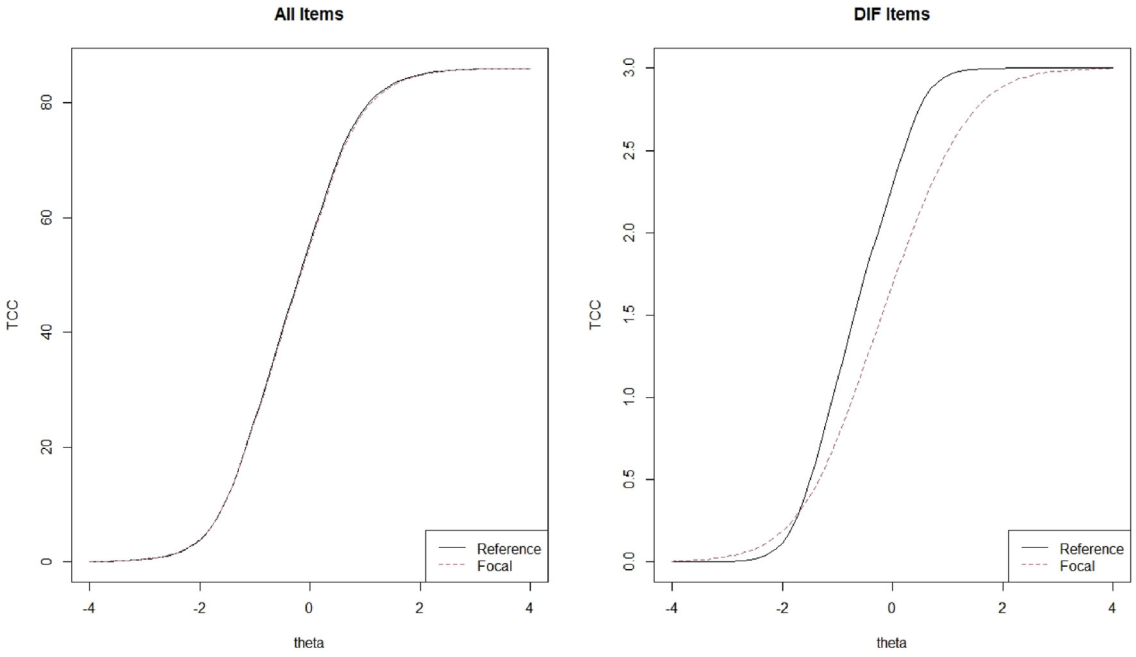

Figure 3. Test Characteristic Curves (TCC) for Age Differential Item Functioning (DIF) in the Korean Version of PROMIS Self-Efficacy for Managing Symptoms Item Bank. The TCC total consequence of DIF of all items is left graph; the TCC for item 27(SEMSX027) with negligible DIF is right graph. *Note*. DIF = differential item functioning.

pseudo R^2-change. Finally, the χ^2 test was conducted with the income group variable, and no item indicated the DIF.

Discussion

This study developed the Korean version of PROMIS self-efficacy for managing symptoms item bank. The PROMIS item banks are globally used instruments to assess self-reported patient outcomes, which include integrative factors that identify patients as individualized people [35]. Previous studies have translated psychometric evaluations into other languages using the IRT [73,74]. The IRT model underscores the functions of each item and outlines the item characteristics across the instrument [35,75]. Cleanthous and his colleagues verified that the IRT was suitable for PROMIS® measurement applications [76]. The IRT model was advantageous for measuring human abilities, attitudes, and other attributes using actual survey data.

Cronbach's α identified the reliability of this item bank as appropriate. This study used the D-SMART and the revised SDSCA to test convergent validity. The current item bank showed a significant correlation with D-SMART, which is evaluating the self-efficacy for self-management skills [70]. It indicates that the item bank was reliable and suited conceptually in terms of self-efficacy among participants of this study. On the contrary, none of the subdomains of the revised SDSCA, measuring self-care activities in the past week, showed statistical significance. A systematic review of measurements for self-care among DM patients reported that the revised SDSCA had low quality of comprehensiveness and comprehensibility [77]. This psychometric limitation of the revised SDSCA needs careful interpretation of the current result of convergent validity with the PROMIS item bank.

This study partially fulfilled the four basic IRT assumptions. The study adopted the COSMIN guidelines even though there was no absolute standard for the criteria of IRT assumptions. The CFA was conducted to validate the *unidimensionality* of the original PROMIS scale. Since the item bank comprised ordinal data, the DWLS was selected for the estimation method in this study [35]. A small sample of fewer than 200 participants may face an increased risk of an overestimated correlation using DWLS [58]. However, the number of participants in this study met this criterion (n = 326). The overall fit of this item bank fulfilled the requirements of the validity of CFA and supported the *unidimensionality* of CFI. The Root Mean Square Error of Approximation and Standard Root Mean Residual did not meet the inclusion criteria. These results implied the possibility that the Korean version of the PROMIS self-efficacy for managing symptoms item bank may possibly have a multiple factor structure. According to the original PROMIS item banks [31,32] as well as previous studies based on a psychometric evaluation of the PROMIS item banks, analyses were performed using a single factor model [2,52,76,78]. Since this study aimed to verify the results by applying PROMIS measurements to a Korean context, the IRT was performed without further modification of the items. Thus, further research is required to analyze the subcategories in the item bank across various settings and populations.

Data for this study was collected from the diabetes center at a tertiary hospital in Korea. The participants displayed effective outcomes with regard to DM control. For example, the HbA1c was 7.5 ± 1.5%, performing lower than that reported in previous studies [79,80]. In addition, over 90% of the participants controlled their glucose with oral medication. These results can result in the ceiling effect, indicating good control of their glucose levels. Ceiling effects negatively affect the CFA results [81]. This study was analyzed using the DWLS in consideration of the ceiling effect. Statistical calibration serves as one method to solve this problem; however, the flooring or ceiling effects need to be considered when developing psychological evaluation tools such as self-efficacy instruments.

As a result of the psychometric evaluation using the IRT model in this study, the Korean version of PROMIS self-efficacy for managing symptoms was a suitable instrument. The discrimination (a) range of the Korean version of this item bank was from 1.82 to 4.93. All the category response curves of the items were independent. The proper item showed discrimination that exceeded zero, indicating that the higher the values, the better the associated

discrimination [43]. In a previous study that analyzed the PROMIS self-efficacy for managing daily activities item bank through the IRT model, discrimination was scored between 1.90 and 4.03 [82]. This is similar to the present study. The independent category response curves derived from the threshold (*b*) values indicated that the scale of the item (five-point Likert scale) had its own traits [43]. The results of category response curves suggest that each item of the Korean version of this item bank did not need to be tuned or revised.

The major strength of this study was that it identified the global utility of the PROMIS item bank of self-efficacy for managing symptoms. The DIF results, comprising subgroups of age, gender, and income, suggested that specific general characteristics did not interfere with the total item bank. Psychological measurements generally target participants from various contexts. Each item should function similarly for the same ability of participants [83]. In this study, item 27 was identified as the DIF in the age group variable. The test characteristic curve of item 27 (*I can find the information I need to manage my symptoms*), showed a negligible difference between the total and item 27 graphs. The confidence or ability to obtain health-related information was affected by the use and access level of digital devices [84,85]. Although there was no significant difference observed from the graph, item 27 reflected the increased tendency of health literacy toward using smart devices to induce vulnerability among older adults [86,87]. This result suggests that nurses and nursing scientists should consider older adults' self-efficacy for information-seeking behavior.

Limitations

The Korean version of PROMIS self-efficacy for managing symptoms can be used to enhance healthcare providers' understanding of patients with chronic diseases and to individualize care plans according to a person's self-efficacy. In addition, it has become possible to benchmark the self-efficacy of chronic diseases on a global level. However, this study has some limitations. First, the study was conducted in a single tertiary hospital and recruited patients with type 2 DM. Therefore, its application to patients with other chronic diseases may be limited. Since the item bank is intended for patients with chronic diseases in general, it is suggested that future studies expand to include other chronic diseases. Second, we evaluated convergent validity using self-care instruments that are frequently used in patients with DM, as the self-efficacy instrument for symptom management can rarely be found; thus, consideration needs to be given to the interpretation of the convergent validity results of this study. Finally, the data had a ceiling effect and the probability of multi-dimensionality. The statistical results indicated that the ceiling effect affected the outcome. In future studies, the inclusion of various patient groups or situations is required to evaluate the psychometric properties of self-efficacy while considering the ceiling effect and multi-dimensionality.

Conclusions

For the Korean version of PROMIS self-efficacy for managing symptoms item bank, the IRT model for psychometric testing was used. The results indicated decent reliability and validity of the measurement. Increasing self-efficacy for managing symptoms in patients with chronic diseases can play a significant role in improving the capability of maintaining their health. Thus, this instrument can facilitate healthcare providers' evaluation of the degree of self-efficacy required to manage symptoms among patients as well as develop educational tools and interventions for their effective management.

Funding

This work was supported by funding [6-2018-0144] from Mo-Im Kim Nursing Research Institute and the Brain Korea 21 FOUR Project funded by National Research Foundation (NRF) of Korea, Yonsei University College of Nursing.

Conflict of interest

The authors declare no conflicts of interest.

This manuscript is not under consideration by another journal and has not been published or presented elsewhere in part or in its entirety except Research Square of a preprint.

Ethical approval

This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted from the Institutional Review Board of Severance Hospital (4-2019-0257) prior to the translation and survey. The purpose and process of this study were explained by the researchers to the participants. The study participants were guaranteed confidentiality and voluntary participation and provided their written informed consent.

Consent to participate

Informed consent was obtained from all individual participants included in the study.

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Asian Nursing Research 16 (2022) 231–240

Contents lists available at ScienceDirect

Asian Nursing Research

journal homepage: www.asian-nursingresearch.com

Review Article

Adaptive Behavior in Stroke Survivors: A Concept Analysis

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ARTICLE INFO

Article history:
Received 26 January 2022
Received in revised form
30 June 2022
Accepted 27 July 2022

Keywords:
adaptation
behavior
concept formation
stroke

SUMMARY

Purpose: This study aims to explore a clear and evidence-based definition of adaptive behavior in stroke survivors and establish the antecedents, attributes, consequences, and empirical referents of the concept.
Methods: The concept analysis was performed using the Walker and Avant method as a framework. Data from 90 publications were collected using various databases (PubMed, EMBASE, CINAHL, RISS, and KISS) and applied in the analysis.
Results: Adaptive behavior in stroke survivors was defined according to four attributes: realizing change, taking an optimistic view, restructuring daily activities to suit oneself, and carrying out one's own daily life. The conceptual structure of their adaptive behavior comprised stroke onset, functional changes, and emotional liability as antecedents and autonomy, family equilibrium, and quality of life as consequences.
Conclusions: Clarifying the concept of adaptive behavior in stroke survivors provides an understanding of the underlying attributes of this concept. Furthermore, it will facilitate the development of scales to measure the concept and the application of a theory-based intervention program that can improve adaptive behavior.

Introduction

In 2019, the World Health Organization declared stroke as the third leading cause of disability-adjusted life years [1], indicating that its disease burden is high. Stroke is a major cause of long-term disability and a leading diagnosis, accounting for approximately 70.0% of brain lesion disorder in Korea [2]. The prevalence of stroke in the population aged 30 or older remained at about 1.7% from 2014 to 2020 [3]; however, its mortality (per 100,000 people) has significantly decreased from 53.2 in 2010 to 42.6 in 2020 [4]. This means that as the number of stroke survivors increases, the population with acquired disabilities due to stroke is continuously increasing. This is a global trend, and the absolute number of stroke survivors is expected to continue to rise rapidly with the aging population [5]. Therefore, more attention should be paid to stroke survivors' health problems and adaptation.

Adaptation is a long and widely used term in nursing to capture the central concern of discipline, such as an individual's adaptation to a health problem, disease, or disability. Although adaptation was initially described in connection with evolutionary change, increasingly short-term and non-evolutionary changes have also been studied [6]. Even in the Roy adaptation model, adaptation is the process and outcome of making people think and feel, and conscious awareness and choice are used to create integration between human and the environment [7]. Behavior is described as a result of coping or response to coping [6]. Since stroke survivors experience sudden and shocking change, adaptive behavior should not appear as a result of adaptation, but should start from the process of realizing the change and re-establishing goals.

The term adaptive behavior has been used for a long time in the fields of psychology [8] and special education [9]. It has primarily been studied in children with congenital disabilities, such as autism spectrum disorder, intellectual disabilities, and developmental disabilities; it is a variable related to their quality of life [10].

Stroke causes sudden and profound changes in someone. They experience limited physical function due to hemiplegia [11]; limited roles at home and in the society [12]; economic difficulties due to job loss [13]; negative emotions, such as anxiety, anger, depression, and helplessness, due to a sudden onset of disease, an uncertain prognosis, and long-term rehabilitation [14]. Consequently, the quality of life of stroke survivors and their families

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https://doi.org/10.1016/j.anr.2022.07.002

declines [15]. Stroke survivors, regardless of its severity, refer to it as a turning point because it can make a profound difference in one's life. They must survive the uncertain consequences of the disease and their post-stroke future, as well as struggle to adapt to a new self; they find it challenging to manage the resultant changes [16,17]. Although the general clinical features of stroke survivors' recovery patterns have been described, there is not enough explanation for adaptive behavior, including the complexity of an individual's response to sudden and painful life events [18].

Clarifying the concept of adaptive behavior in stroke survivors can provide a basic understanding of the nature of adaptation in this demographic and ensure consistency in use and application. It can also enable theorists and researchers to construct statements or hypotheses that clearly reflect the relationships between related concepts and facilitate the development of scales for assessing the adaptive behaviors of stroke survivors. Additionally, healthcare professionals caring for stroke survivors may be able to apply interventions that can improve adaptive behavior. Therefore, this study aimed to explore a clear and evidence-based definition of adaptive behavior in people who have suffered a stroke and establish its antecedents, attributes, consequences, and empirical referents.

Methods

Literature search and data collection were conducted using several databases (PubMed, EMBASE, CINAHL, RISS, and KISS) from November 28, 2020 to January 12, 2021 to confirm the basic elements of the concept. The keywords employed were “stroke”, “cerebrovascular accident”, “adaptive behavior”, “adaptive AND behavior”, and “adaptation”, and the search terms were used individually or in combination with each other. Each PubMed, CINAHL, and RISS database was searched from their inception to November 28, 2020, the KISS database from their inception to November 30, 2020, and the EMBASE database from their inception to January 12, 2021. The initial exploration identified 1,798 papers and the duplicate (n = 151) were excluded. After reviewing the titles and abstracts of the remaining articles, 1,340 literatures were removed, the full texts of 307 studies were evaluated, and 1 paper was added through manual search. The inclusion criteria were qualitative, quantitative, and mixed method research that can confirm the concept of adaptive behavior using stroke survivors as samples; additionally, only the literature written in English or Korean was selected. Of the 308 documents whose full texts were evaluated, 218 papers were removed for the following reasons; studies in which the subject is a caregiver (n = 35) or healthcare provider (n = 15), studies that do not deal of adaptive behavior (n = 49), biomedical measurement papers after stroke (n = 46), case studies (n = 38), studies of instrument evaluation (n = 23), literatures with conference article abstracts only (n = 9), studies that are not written in English or Korean (n = 3). Overall, 90 publications were included in this study (Figure 1). The search process followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) search strategy guidelines [19].

Concept analysis was conducted according to the method suggested by Walker and Avant [20]. Concept analysis is that analyzes words or phrases and their meaning and usage and is the basis of theory development. Similarities or differentiations among the disciplines of a concept can be distinguished through the concept analysis process. The Walker and Avant's method provides a precise definition that reflects concept's theoretical base and, by its very nature, has construct validity. It can help clarify concepts that are used vaguely [20]. Through this, concepts can be clarified and theoretical definitions are derived, which are the basis for developing measurement tools [20]. The development of measurement tools can further enable practical application. The eight steps of this concept analysis are as follows: (i) select a concept, (ii) determine the aims or purposes of analysis, (iii) identify all the uses of the concept that you can discover, (iv) determine the defining attributes, (v) identify a model case, (vi) identify borderline, related, contrary, invented, and illegitimate cases, (vii) identify antecedents and consequences, and (viii) define empirical referents.

Results

Dictionary definition

There is no dictionary that defines adaptive behavior in one word. However, the dictionary well defines adaptation and behavior, respectively. To define the adaptive behavior, the existing literatures related to the adaptive behavior of stroke survivors were searched.

The American Psychological Association (APA) Dictionary describes adaptive behavior as the level of everyday performance of tasks that is required for a person to fulfill typical roles in a society; this includes maintaining independence and meeting cultural expectations regarding personal and social responsibilities. Categories that are usually assessed comprise self-help, mobility, health care, communication, domestic abilities, consumer skills, community use, practical academic skills, and vocational capabilities [21]. Adaptive behavior is an action that enables people to survive in their environment with the greatest success and least conflict with others. Similar to the term ‘life skills,’ it relates to the everyday skills or tasks that the average person is able to complete; moreover, it reflects an individual's social and practical competence to meet the demands of daily life [22]. Thus, adaptive behavior is a skill that enables individuals to maintain their independence from their environment and perform the tasks required in daily life and by society.

In a longitudinal qualitative study (A75) interviewed 6, 12, 24, and 36 months after stroke, the process of adaptation was described as an ongoing process of shock, confusion, and fear, understanding what happened, adapting to what was provided, finding what suits oneself and developing new standards, and managing life's ups and downs. In addition, in a phenomenological qualitative study of survivors who first suffered a stroke 5 years ago (A58), stroke survivors are in an unstabilized process of continuous change, dealing with disability, self-identity, and lifestyle changes, and they dealt with continuous processes, including resignation and personal growth. According to previous studies, the adaptive behavior in stroke survivors should be defined as a comprehensive concept that appears simultaneously.

Use of the concept

In 1900, adaptive behavior was used as a criterion for the informal evaluation of intellectual disabilities. In 1936, the Vineland Social Maturity Scale was developed, which can be considered the first assessment of the adaptive behavior constructs. It measures individual's abilities and growth in relation to everyday situations; it consists of three categories: self-help, locomotion, and socialization [9]. In 1959, maturation, learning, and social adjustment were added to the diagnostic criteria for intellectual disabilities [8], and the American Association on Intellectual and Developmental Disabilities formally included adaptive behavior deficits as an integral part of the definition of intellectual disability [9]. Furthermore, the concept of adaptive behavior has been developed both

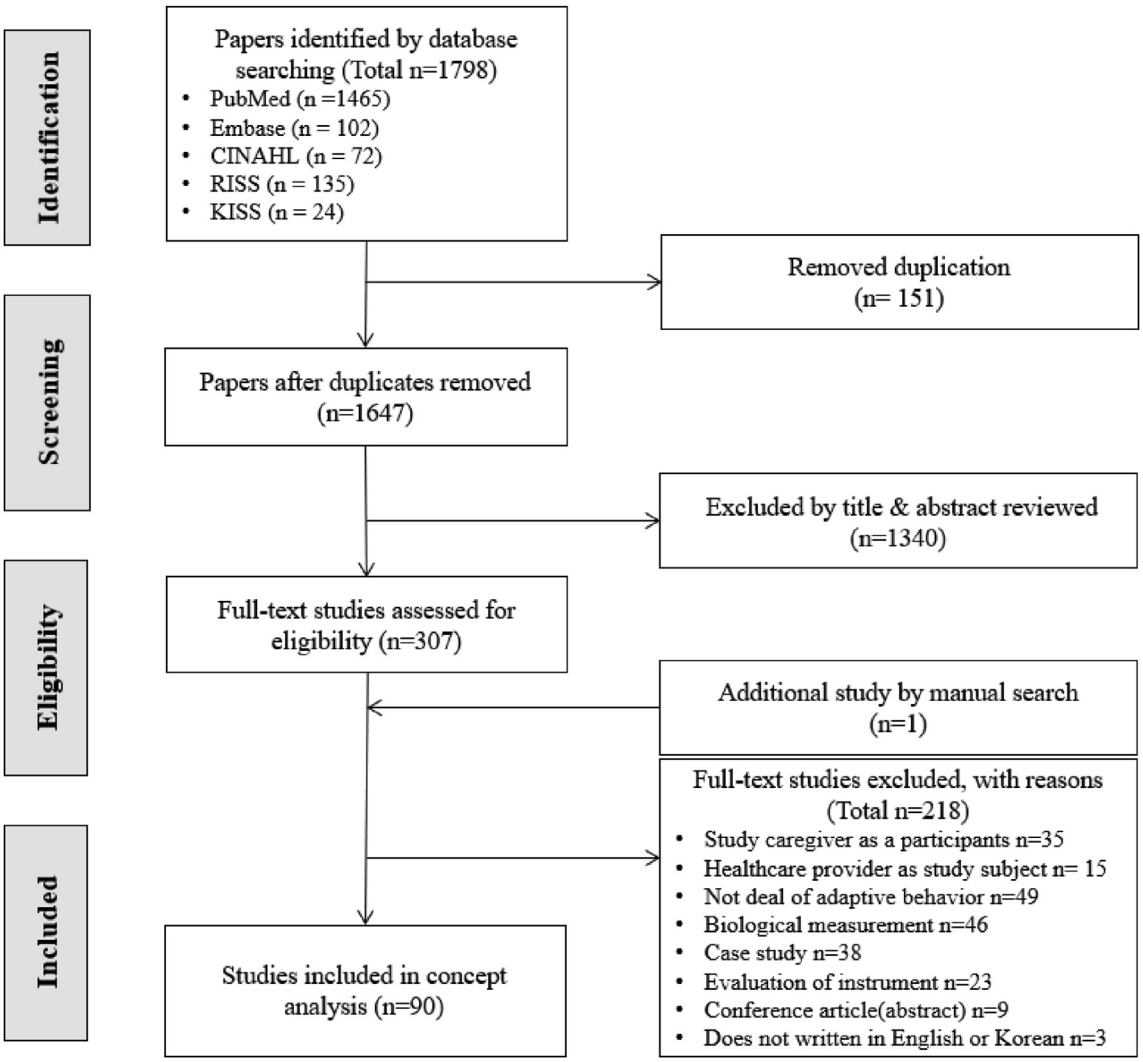

Figure 1. Flow Diagram of the Study Selection.

socially and theoretically. The Diagnostic Adaptive Behavior Scale measures it by assessing the conceptual (literacy; self-direction; and concepts of number, money, and time), social (interpersonal skills, social responsibility, self-esteem, naïveté [i.e., wariness], social problem solving, following rules, obeying laws, and avoiding being victimized), and practical skills (activities of daily living [personal care], occupational skills, use of money, safety, health care, travel/transportation, schedules/routines, and use a the telephone) [23]. It evaluates the skills that average people naturally acquire through experiences in everyday life. The concept of adaptive behavior has been mainly used in people with congenital disabilities. It was initially used only as a tool for diagnosis, but it is moving toward a multidimensional approach by discussions that focus on individual functionality rather than fixed deficits.

Studies addressing concepts similar to adaptive behavior in stroke survivors have been found in the fields of nursing, medicine, psychology, clinical speech and language, physiology, occupational therapy, social sciences, and social work. Most of these are exploratory qualitative studies regarding life, experience, adaptation, and solution strategies after stroke (A75): communication difficulties (A88), pain (A44), dysphagia (A51), urinary incontinence (A30), visual impairment (A68), sexual problems (A54), and movement changes (A72). And several quantitative studies explored the association between adaptive behavior and psychosocial factors such as acceptance and social support (A10).

Attributes of adaptive behavior in stroke survivor

The adaptive behavior in stroke survivors were found to be realizing change, taking an optimistic view, restructuring daily activities to suit oneself, and carrying out one's own daily life. Details of each attribute are described below.

Realizing change: This means knowing and accepting the physical, psychological, and social changes caused by stroke. Knowing and accepting what has happened subsequent to a stroke reduces maladaptive behaviors and emotions, creates a balance between independence and receiving help from others, helps in the struggle with the belief that 'I must return to normal,' leading to the rebuilding of a routine and a new normal (A75).

Taking an optimistic view: This means that stroke survivors have a positive meaning in life by hoping for recovery, gaining self-efficacy, maintaining meaningful relationships, and securing self-worth in situations where they experience sudden changes in physical functioning and social relationships. Having an optimistic view of life after a stroke promotes goal-oriented action, which in turn promotes the restructuring of identity, learning about

individual abilities and limitations, and continued acquisition of new adaptive skills (A58).

Restructuring daily activities to suit oneself: This refers to modifying and negotiating activities to suit oneself so that one can safely and smoothly carry out daily life in their new, stroke-altered physical, psychological, and social situations. They develop customized strategies to manage difficulties in communication (A2, A88), dysphagia (A51), fatigue (A76), pain (A44), urination problems (A30), and vision impairment (A68) that occur after stroke. In addition, they have to modify and redefine their roles in the home or society due to functional disturbances, such as physical or psychological problems (A39). Stroke survivors structure a new routine by tailoring their daily activities to suit them [17].

Carrying out one's own daily life: This means actually performing daily activities that are modified and negotiated to suit oneself. Stroke survivors have established their own new normal and living their daily lives. They perform functional activities to their fullest potential, perform healthy behaviors, including taking medications or rehabilitating exercises, and participate in family or community activities to reintegrate (A50, A73). They have clear expectations of themselves and are well aware of what others expect of them (A75).

Model case

A model case is an example that contains all the defining attributes of the concept [20].

Mrs. A is 68 years old and was usually healthy. One day she suddenly had a stroke and was paralyzed on her right side. She was shocked, but did not want to spend her life lying in bed. She also believed that she would be able to withstand crises on her own. After being discharged from the hospital, she made plans to keep her routine under the changed situation. She woke up at 5 am, did the exercises she learned at the hospital, and walked around her house with the help of a cane and her husband. Their meals were mainly prepared by her husband; she sat down to do the laundry or mop with one hand. When she needed help, she turned to her daughters for help. She found solace in interacting with other people with stroke when she visited a physical therapy center near her home. Besides, she got information on how to manage shoulder pain, go to the bathroom, and change clothes. She also faced challenges and tried to be more active in her daily life. She felt her potential as she heard her family and neighbors say her movement and strength improved. She said she lives a meaningful life. She hopes to be able to travel alone someday.

Mrs. A's case contains all the previously discussed defining attributes of adaptive behavior in stroke survivors.

Borderline case

Borderline cases are those that contain most of the defining attributes, but differ significantly in time or intensity in one of them. These help to identify inconsistencies in the concept under study and to define their attributes clearly [20].

Mr. B is 76 years old and has left hemiplegia. After the death of his wife, he had a stroke while living alone. He knows that a stroke involves a slow recovery and that hemiplegia makes it difficult to live independently. Thus, when his son suggested that they live together, he agreed. However, he feels like a burden on his son and does not want to show his daughter-in-law or grandchildren his changed circumstance; hence, he says he would rather die. He believes that his grandchildren ignore him; therefore, he avoids talking to them and hates them. He attaches a great importance to exercising as he believes that if his illness becomes more severe or he is unable to move, he will become a greater burden on his son and the balance of his son's family will be disrupted. He learned how to wash and change clothes by himself. Furthermore, he took a taxi to the community or the public health center to see if there were any services that could help him. He walks around the house with his cane and talks and plays chess with the locals. He tries to perform his daily life activities by himself as much as possible. However, he has no hope that things will get better and [feels that] this situation that has no end in sight is hard to bear.

Mr. B's case contains the attributes of realizing change, restructuring daily activities to suit oneself, and carrying out one's own daily life, but he did not take an optimistic view. He does not have a meaningful relationship with his family and is unable to find hope and meaning in life.

Related case

Related cases are instances that are in some way related to the concept being examined but do not include all the defining attributes. These help us understand how the concept under study fits into the network of concepts surrounding it [20].

Mr. C is 47 years old and has left hemiplegia. He is embarrassed by the physical changes caused by [his] stroke. However, if he works hard on rehabilitation, he will be better than now and hopes to return to work as soon as possible. He spends too much time exercising. Excessive exercise can cause shoulder and leg pain, but [he] does not control the level of exercise. He also strives to carry out daily activities alone. However, he sometimes falls while walking alone without using a cane or a walker and bruises his face and body. He also had a car accident while driving his own car.

Mr. C's case contains the attributes of realizing change and taking an optimistic view. However, he does not understand the characteristics of a stroke with a long-term rehabilitation. In addition, he has not modified his activities to suit him and is unable to perform his daily activities safely.

Contrary case

Contrary cases are clear examples of not following the concept [20] as the one described below.

Mrs. D is 58 years old and has right hemiplegia. She is divorced and lives with her unmarried daughter. She is outraged about her stroke "… and now it is all over," she says. She makes no effort to carry out her daily life activities by herself and depends on her daughter for everything. One day, her daughter invited her mother's friends to the house. Mrs. D spilled food while eating and salivated when talking; thus, her friends wiped her with napkins. Subsequently, she decided that she did not want other people to look at her pitifully. [Now] She stays alone in her house and weeps.

The case of Mrs. D does not include any attributes of adaptive behavior. She is angry and frustrated without accepting the changes caused by the stroke. She does not make any effort to reconstruct and carry out her own new daily life.

Antecedents and Consequences

Antecedents

Antecedents are incidents or events that must exist or occur prior to the concept's occurrence [20]. It is not synonymous with causation, and may contribute to the occurrence of a concept, relate to its occurrence, or may have to exist in order for the concept to exist [24]. Those events that occur before the adaptive behavior in stroke survivors include stroke onset, functional changes, and emotional lability. A stroke occurs, and survivors experience changes in physical and social functions, such as movement limitations (A72), communication difficulties (A88), dysphagia (A51),

urinary incontinence (A30), visual impairment (A68), and sexual problems (A54). They also experience grief and anger due to the destructive diagnosis, and the shock and confusion of relapses, disability, and worries about the future tend to be profound and long-lasting (A75). Approximately 20.0% of stroke survivors are at risk of clinically significant depression [14].

Consequences

Consequences are incidents that happen due to the occurrence of the concept. Specifically, they are the outcomes of a concept [20]. The results of the occurrence of adaptive behavior in stroke survivors include autonomy, family equilibrium, and quality of life. The adaptive behavior of stroke survivors helps them regain autonomy by acting according to norms and gaining a sense of competence in them (A30, A72). When individuals recover capacity for daily activities, the burden on spouse and children is minimized and family equilibrium can be maintained (A39). Furthermore, it reduces maladaptive behaviors and emotions and has a positive effect on quality of life (A80).

The conceptual structure of the adaptive behavior in stroke survivors, including the relationships between antecedents, attributes, and consequences is shown in Figure 2.

Empirical referents

Empirical referents are the categories of real phenomena that prove the occurrence of the concept itself. In the final step of concept analysis, the question arises: How can I measure this concept or verify its existence in the real world? Empirical referents are not tools for measuring concepts, they are means by which defining attributes can be recognized or measured, not the whole concept itself [20].

The attributes of adaptive behavior in stroke survivors are examined using the tools for evaluating post-stroke status. The Stroke Impact Scale 3.0 [25] is a 59-item scale that consists of the domains of strength, memory and thinking, emotion, communication, ADL, mobility, hand function, and social participation. The items in this tool are similar to taking an optimistic view and carrying out one's own daily life among the attributes of adaptive behavior in stroke survivors. The Preference-Based Stroke Index [26] consisted of 10 items to measure walking, climbing stairs, physical activities, recreational activities, work/activity, driving, memory, speech, coping, and self-esteem. Its items are similar to taking an optimistic view and carrying out one's own daily life attributes among the findings of this study. The Post-Stroke Checklist [27] consists of 14 items to evaluate secondary prevention, ADL, mobility, pain, stiffness, incontinence, communication, mood, cognition, relationships with family, fatigue, intimate relationships, work, and social activities. Its items are similar to carrying out one's own daily life attribute of adaptive behavior in stroke survivors. In addition, some studies have suggested that realizing change is an important factor for the rehabilitation of stroke survivors. Failure to acceptance stroke and its changes have been reported to be associated with anxiety and depression after stroke and behaviors that lowered the risk of complications and accelerated recovery (A10).

Discussion

As a result of concept analysis through rigorous literature review, four attributes were derived: realizing change, taking an optimistic view, restructuring daily activities to suit oneself, and carrying out one's own daily life. We discuss the meaning and characteristics of each attribute.

Stroke onset might be a turning point in the lives of individuals who experience it. This is because, for them, the stroke and its effects were not present from the beginning (birth) but rather come as a sudden change. They have to know and accept their new physical, psychological, and social statuses (classified as 'realizing change' in this analysis). An interview described in a qualitative study by Wottrich et al. (A87): "*I have to walk with a crutch and my balance is poor; further, my hand does not quite follow when I pick something up.*" supports this attribute. People who have suffered a stroke are often unable to accept these changes, resulting in physical and psychosocial dissonance or unrealistic expectations regarding recovery (A87), which negatively affects their adaptation and rehabilitation processes (A10). Understanding and accepting illness is related to physical, emotional, and social adaptation and plays a pivotal role in determining life satisfaction (A10, A80). In this situation, healthcare professionals should support patients adjust to real life by balancing realistic views and expectations about the prognosis (A87).

The second attribute, 'taking an optimistic view,' can appear based on the 'realizing change' attribute. Stroke onset leads to disturbing life changes but taking an optimistic perspective has shown to be an indicator of reinforcing limitations and a force that drives survivors to do their best to gain new normalcy (A3, A86). The interviews described in the study by Kitzmüller et al. (A38) and Price et al. (A63): *"We are closer to each other. Nowadays, we talk more about our problems, we are more open with each other."*, *"I can be innovative when challenged."* support this attribute. People who take an optimistic view are characterized by having hope for recovery, gaining self-efficacy, maintaining meaningful relationships, and securing self-worth. Consciously seeking and positively experiencing the benefits of their changes can enhance survivors' self-care confidence and hope for rehabilitation, and can reduce negative emotions such as anger, depression, and sadness (A63). Studies have reported that these characteristics play an important role in adaptive behavior that requires various learning through rehabilitation. For example, psychological constructs such as self-efficacy have been shown to predict disability, quality of life, and functional independence after stroke [18,28,29]. All processes of

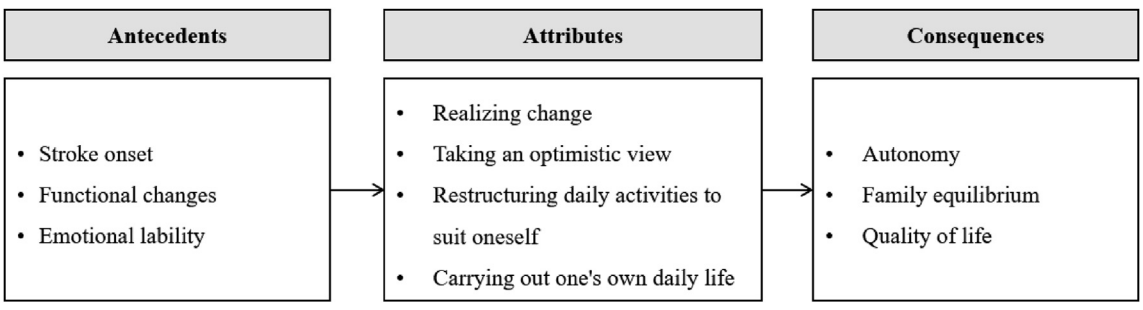

Figure 2. Conceptual Structure of the Adaptive Behavior in Stroke Survivors.

learning survival skills such as eating (A51), voiding (A30), communicating (A88), connecting with society, and maintaining identity and role (A2, A21), require an optimistic view.

They also develop strategies to modify their activities and negotiate with themselves to accommodate their stroke-induced functional changes. This appeared as the third attribute, 'restructuring daily activities to suit oneself.' Stroke survivors may restructure their daily life activities to ensure a smoother way of living. In an interview described in a study by Williams and Murray (A86), *"When I was discharged from the hospital I had to rethink how to do things. They told me how to shower, they taught me how to dress; thus, I was not extremely bad [at] them."* supports this attribute. Such restructuring has been reported not only in the physical but also in the psychosocial aspect in several studies. For example, communication restructuring strategies include slowing speech or breaking long words into syllables (A88). Other strategies include modifying food and drinks to avoid aspiration (A51), adopting time voiding decisions to manage incontinence (A30), distracting attention to manage fatigue and pain (A44, A76), managing sexual problems (A54), and re-establishing one's role in the home or society (A38, A39). These strategies are quantitatively and qualitatively diverse and creative depending on the individual. The timeframe for re-establishment may also vary. Healthcare providers should support survivors by advocating these various strategies and assisting them with the strategies they have failed or missed.

The last attribute of adaptive behavior in stroke survivors was 'carrying out one's own daily life.' They carry out their own routines, individually coordinated and negotiated with themselves. They can perform daily activities to their full potential and utilize human, social, and physical resources according to negotiations. Many stroke survivors look forward to participating in social activities again; they do not hesitate to walk, use public transportation, or drive and utilize appropriate means of transportation to travel (A6). The interviews described in studies by Williams and Murray (A86) and Taule et al. (A73): *"Initially, I was similar to a trapped animal, and then I thought 'slow down, do not panic.' Thus, I bought a scooter … it gets me around the area", "To have something to do and someone to mingle with, I have many nice co-workers who I like to talk to and socialize with. Just to get out of bed, catch the bus, get to work, and be where you were previously"* support this attribute. Studies have reported that carrying out everyday activities and participating in social activities help to secure independence, minimize burden on family members, and affect depression and quality of life (A39, A50, A73).

The significance, limitation, and implication of this concept should be discussed as to how it relates to existing adaptation-related theories and whether it can be applied to adaptive behavior in other situations such as chronic or congenital condition.

First, similar to various theories explaining adaptation to chronic diseases, it was confirmed through concept analysis that the adaptive behavior of stroke survivors is a complex, multidimensional, and dynamic process. There are already several theories that have contributed to the concept of adaptation. For example, in Roy's adaptation model, the 'adaptation level' defines the state of the multidimensional life process [7] and individual coping process, situational background, and personal resources affect the characteristics of adaptation process in theory of stress, coping, and adaptation by Lazarus and Folkman [30]. Stroke survivors experience disability, identity, and life changes amidst shock and grief, developing new standards for themselves and managing their lives. This is not a linear process, it is an unstable process that is constantly changing and renegotiation continues in the process (A58, A75).

Second, there is a question as to whether a phenomenon similar to the results of this study also exists in other chronic diseases such as diabetes or hypertension. Since the derivation of these attributes are for stroke survivors (somewhat limitation), it is necessary to study whether there is similarity or differentiation in other situations. However, existing theories explain that disease should be considered when understanding or interpreting the adaptation process due to have disease-specific task such as symptom management. Situational attributes from the disease experience shape the individual characteristics of adaptive process in theories [31]. Considering this point, many researchers are studying how the adaptations of subjects with various situational contexts are different and similar. In the same context, it is necessary to research whether similarity or differentiation is seen in various chronic disease situations through future tool development.

Nevertheless, a third implication is that the attributes of adaptive behavior in stroke survival can be distinguished from congenital disorders. Adaptive behaviors in people with a congenitally disabilities, such as developmental disability, include conceptual (concepts of number, money, and time, etc.), social (obeying laws, avoiding being victimized, etc.), and practical (use of money, use of the telephone, etc.) skills [32]. It is the intentional education and training of skills that average people, from birth, learn and perform naturally through experience in their daily lives. However, the adaptive behaviors in stroke survivors are self-directed behaviors including acceptance, perspective, and negotiation. Self-directed behavior leads to adaptive behaviors in stroke survivors, such as realizing change, taking an optimistic view, and restructuring daily activities to suit oneself.

This concept analysis is useful to provide a fundamental understanding of adaptive behavior in stroke survivors. Furthermore, it will contribute to constructing scale items or clinically validating by reflecting the attributes defined according to the researcher's aims. However, there are some considerations. Specifically, we only referenced published papers focusing on "stroke," "cerebrovascular accident," "adaptive behavior," "adaptive AND behavior," and "adaptation" and analyzed limited the languages to English and Korean. In addition, since there are methodological limitations, further study that sufficiently reflects the actual field is needed, and a study of the evolutionary method to confirm whether the conceptual structure presented in this result is consistent with other disciplines will also be meaningful.

Conclusion

This study explored the evidence-based definition of adaptive behavior in stroke survivors and its antecedents, attributes, consequences, and empirical referents. In conclusion, adaptive behavior in stroke survivors was defined as realizing the physical, psychological, and social changes caused by stroke, taking an optimistic view, restructuring daily activities to suit oneself, and carrying out one's own daily life. These results provide a basic understanding of the nature of adaptive behavior in stroke survivors. It can facilitate the development of scales for assessing the adaptive behaviors in stroke survivors and the application of theory-based intervention programs that can improve adaptive behavior.

Author contributions

Study design: Choi H, Lim A, Song Y, Data collection: Choi H, Lim A, Data analysis: Choi H, Lim A, Song Y, Manuscript writing: Choi H, Lim A, Song Y.

Conflict of interest

No conflict of interest has been declared by the authors.

Acknowledgments

This study was supported by the National Research Foundation (NRF) of Korea grant funded by the Korea government (Ministry of Science and Information and Communication Technologies: MSIT) (No NRF-2019R1A2C1006016).

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.anr.2022.07.002.

Appendix. List of literatures included in the concept analysis

No.	Literature included in the concept analysis
A1	Anderson S, Whitfield K. Social identity and stroke: 'they don't make me feel like, there's something wrong with me'. Scand J Caring Sci. 2013; 27(4):820-30. http://doi.org/10.1111/j.1471-6712.2012.01086.x
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Asian Nursing Research 16 (2022) 208–214

Contents lists available at ScienceDirect

Asian Nursing Research

journal homepage: www.asian-nursingresearch.com

Research Article

Relationships among Type-D Personality, Fatigue, and Quality of Life in Infertile Women

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ARTICLE INFO

Article history:
Received 7 January 2022
Received in revised form
26 July 2022
Accepted 2 August 2022

Keywords:
fatigue
infertility
personality
quality of life
women's health

SUMMARY

Purpose: The objective of the present study was to investigate the prevalence of the type-D personality and identify the relationship between type-D personality, fatigue, and quality of life (QoL) in infertile women.

Methods: A total of 149 infertile women were recruited between October 2020 and January 2021. The participants were assessed through self-administered questionnaires using the type- D personality scale-14, fatigue severity scale, and fertility QoL instrumental questionnaire. Data were analyzed using the independent t-test, chi-square test, Pearson's correlation coefficients, and multiple regression analysis using the SPSS/WIN 25.0 program for Windows.

Results: Approximately 40.9% of infertile women were classified into the type-D personality group, which showed significantly higher fatigue and lower QoL than the non-type-D personality group. Fatigue was the most influential factor on the QoL of infertile women ($\beta = -.23$, $p = .003$), followed by the duration of infertility treatment ($\beta = -.22$, $p = .003$), type-D personality ($\beta = -.18$, $p = .025$), and relationship with spouse ($\beta = -.17$, $p = .024$). These variables account for approximately 22% of the variance.

Conclusions: Intervention programs that consider fatigue, type-D personality, relationship with spouses, and treatment duration may be useful for improving QoL in infertile women.

Introduction

In general, infertility is defined as the inability to conceive after 1 year or longer of unprotected sexual intercourse [1]. About 19% of married women aged 15–49 years in the United States report being unable to conceive even after one year of trying [1]. Among 1,289 married women aged 15–49 years in South Korea, 52.1% experienced infertility [2]. Despite the increased cost of treating infertility, the domestic fertility rate remains low [3]. Among the Organization for Economic Cooperation and Development (OECD) member countries, South Korea has the lowest fertility rate (.84 in 2020, compared to 1.64 in the United States, 1.70 in China, 1.33 in Japan, and 1.24 in Italy) [4].

Infertility is a global public health problem, and the proportion of infertile couples worldwide is increasing [5]. Infertility can easily act as a chronic stressor [6] and is a low-control stressor [7]; even if the cause of infertility is in men, women are more affected than men [8]. Recently, infertility has been increasing due to frequent miscarriages, age, long-term use of contraceptives, social stress, changes in eating habits and lifestyle, increases in women's social activities, and delays in marriage [1]. Therefore, in situations where the number of infertile women is increasing and various health problems caused by infertility are related [9], it is necessary to investigate the factors related to the QoL of infertile women.

The QoL of infertile women is generally low [10]. According to previous research, infertile Italian women perceive QoL as very low [11], and infertile women in China also report lower QoL [12]. Compared with women of childbearing age, infertile women experience lower QoL [13]. Moreover, women undergoing in vitro fertilization (IVF) for infertility have a lower QoL than other women

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https://doi.org/10.1016/j.anr.2022.08.001

of childbearing age [14,15], which affects not only infertile women but also the QoL of their spouse [16].

Various factors have been reported to affect the QoL of infertile women. Infertile women experience various physical, psychological, and relational problems that affect their QoL [17]. Among these are demographic factors such as the duration of marriage and burden of the cost of infertility testing, burden of infertility, age [18], education level, duration of infertility treatment [19], relationship with spouse [10,20], physical factors such as fatigue [17,21], psychological factors such as stress [10], uncertainty [18], depression [17,22], and type-D personality [22].

Fatigue is a symptom of physical problems that occur when attempting to conceive through fertility procedures [17]. In a study of 140 infertile women, approximately 37% complained of fatigue, and the higher the fatigue of infertile women, the lower the QoL [17].

Type-D personality refers to a personality that is vulnerable to negative emotions, such as depression, anxiety, and stress, and tends to consciously suppress self-expression in social interactions [23,24]. Negative affectivity refers to a persistent negative emotional state regardless of time and place, and social inhibition means suppressing the expression of emotions and behaviors to avoid the potential fear of being rejected in social relationships with others [23,24]. According to previous studies, people with a type-D personality are more likely to experience lower QoL than people with a non-type-D personality [25]. According to a study on infertile women with type-D personality, depression and type-D personality were higher in the infertility group, and type-D personality had a significant correlation with infertility. In particular, it was confirmed that there was a negative correlation with young infertile women (<35 years old) [22]; therefore, it is necessary to investigate the QoL of infertile women according to their type-D personality.

Despite social changes, in which the number of subjects diagnosed with infertility is increasing, research so far has been limited to the fragmentary evaluation of each variable, and considering the classification according to the type-D personality of infertile women, it is difficult to find studies that affect QoL according to type-D personality. Therefore, researchers have identified factors affecting QoL in infertile women and investigated the correlation between fatigue and QoL according to the type-D personality. The specific purposes were as follows: i) to identify general characteristics, fatigue, and QoL related to infertility according to type-D personality of infertile women, ii) investigate QoL according to participant characteristics, iii) investigate the correlation between variables, and iv) identify factors affecting infertility-related QoL in infertile women.

Methods

Design

This study used a descriptive correlational research design to identify factors affecting fertility-related QoL in infertile women through a cross-sectional survey.

Setting and study participants

The present study was conducted on 150 infertile women who did not have children naturally, even after more than one year of marriage. All women with infertility problems, including primary and secondary infertility, were targeted, and the specific criteria were as follows. In the present study, convenience was extracted from women who were diagnosed with infertility at a fertility hospital located in the J province. As for the sample size, multiple regression analysis with a significance level of .05, power of .8, and effect size of .15 median based on a previous study [26], was performed using G*Power 3.1.9.7 (Universität Düsseldorf, Düsseldorf, Germany). When 11 predictors (women' age, spouse's age, religion, occupation, education level, monthly income, duration of infertility treatment, experienced infertility treatment methods, relationship with the spouse, fatigue, type-D personality) were input, 123 was the minimum sample size. A total of 150 questionnaires were distributed and collected considering the omission of responses. After excluding one questionnaire owing to insincere responses and errors in filling out, 149 subjects participated in the study (response rate: 99.3%). Data were collected from October 30, 2020, to January 8, 2021. Data were collected from two obstetrics and gynecology clinics and two public health centers. After obtaining permission from the heads of the institutions, a poster was attached to the centers to guide the recruitment of research participants. After obtaining voluntary consent, participants filled out the self-administered questionnaires in offices at centers with quiet, comfortable, and private places. The questionnaire took approximately 20 minutes and was sealed and collected thereafter. The inclusion criteria were as follows: i) infertile women older than 19 years and ii) diagnosed with infertility at a hospital. The exclusion criteria were as follows: i) those with diseases other than infertility, and ii) those who had been diagnosed with depression or had a disease that may affect fatigue.

Ethical considerations

This study was approved by the Institutional Review Board of Jeonbuk National University (no. 2020-08-008-001). In accordance with the Helsinki Declaration, voluntary written consent was obtained after explaining the privacy guarantee, research content, purpose, anonymity, and possibility of opting out.

Measures

Type-D personality

The type-D personality measured by the type-D scale-14 (DS14) [24] consists of seven items each for the “negative affectivity” (NA) and “social inhibition” (SI) domains. Each item is measured on a five-point Likert scale and composed of 0–4 points. The NA and SI scales range from 0 to 28 points, respectively. The cutoff on both subdomains is 10 points; a score of 10 or more in each domain is classified as a type-D personality (i.e., NA $\geq$ 10 and SI $\geq$ 10), and others are classified as non-type-D personality [24]. The Cronbach's α of original version of the DS 14 was .88 for the NA and .82 for the SI [24], and the those of Korean version was .88 for the NA and .86 for the SI [27]. In this study, Cronbach's α was .87 for the NA and .85 for the SI. It was used after receiving approval from the copyright holder (Copyright Clearance Center) of original version [24] and translator's Korean version.

Fatigue

The fatigue was measured The Fatigue Severity Scale (FSS) [28] The FSS consists of a total of nine questions, “not at all” 1 to “strongly agree” 7 points. The total score was calculated as the average of the scores for each item and ranged from 1 to 7, with a higher average value indicating more severe fatigue. If the average score was 4 or higher, it was interpreted as the fatigue group, and if it was less than 4, it was classified as the non-fatigue group. Cronbach's α of the original version of the FSS was .89 [28] and that of the Korean version of the FSS was .94 [29]. In this study, the Cronbach's α was .91. It was used after the receiving approval from the translator's Korean version and

Table 1 *General Characteristics of the Type-D and Non-Type-D Personality Groups (N = 149).*

Variables	Categories	Total (n = 149)	Type-D (n = 61)	Non-type-D (n = 88)	t or χ^2 or F	*p*	Range
		M ± SD, n (%)					
Demographic characteristics							
Age (year)	Women	35.61 ± 4.62	35.75 ± 4.26	35.51 ± 4.88	.31	.754	25–46
	<35	64 (43.0)	22 (36.1)	42 (47.7)	2.00	.180	
	≥35	85 (57.0)	39 (63.9)	46 (52.3)			
	Husband	37.57 ± 5.00	37.49 ± 4.99	37.63 ± 5.04	−.16	.874	27–55
	<35	43 (28.9)	18 (29.5)	25 (28.4)	.02	.884	
	≥35	106 (71.1)	43 (70.5)	63 (71.6)			
Religion	Yes	75 (50.3)	30 (49.2)	45 (51.1)	.06	.868	
	No	74 (49.7)	31 (50.8)	43 (48.9)			
Occupation	Yes	95 (63.8)	41 (43.2)	54 (56.8)	.53	.465	
	No	54 (36.2)	20 (37.0)	34 (63.0)			
Education	≤High school	29 (19.5)	9 (14.8)	20 (22.7)	1.46	.294	
	≥University	120 (80.5)	52 (85.2)	68 (77.3)			
Monthly income (thousand won)	<3,000	45 (30.2)	18 (29.5)	27 (30.7)	2.92	.231	
	3,000–4,000	49 (32.9)	16 (26.2)	33 (37.5)			
	≥4,000	55 (36.9)	27 (44.3)	28 (31.8)			
Fertility-related characteristics							
Duration of infertility treatment (in months)		24.24 ± 18.61	29.26 ± 21.20	20.76 ± 15.78	−2.66	.009	
	<36	115 (77.2)	42 (68.9)	73 (83.0)	4.07	.044	
	≥36	34 (22.8)	19 (31.1)	15 (17.0)			
Experienced treatment (double choice)	OI (yes)	88 (59.1)	40 (65.6)	48 (54.5)	1.81	.178	
	(no)	61 (40.9)	21 (34.4)	40 (45.5)			
	IUI (yes)	74 (49.7)	32 (52.5)	42 (47.7)	.32	.570	
	(no)	75 (50.3)	29 (47.5)	46 (52.3)			
	IVF (yes)	81 (54.4)	35 (57.4)	46 (52.3)	.38	.538	
	(no)	68 (45.6)	26 (42.6)	42 (47.7)			
	Others (yes)	16 (10.7)	5 (8.2)	11 (12.5)	.70	.404	
	(no)	133 (89.3)	56 (91.8)	77 (87.5)			
Relationship with spouse	Good	128 (85.9)	48 (78.7)	80 (90.9)	4.44	.035	
	Bad	21 (14.1)	13 (21.3)	8 (9.1)			
Fatigue	Total	3.48 ± 1.24	3.97 ± .97	3.13 ± 1.29	4.52	<.001[a]	1.11–6.11
	Yes (≥4)	51 (34.2)	31 (50.8)	20 (22.7)	12.63	<.001	
	No (<4)	98 (65.8)	30 (49.2)	68 (77.3)			
Fertility-related Quality of Life	Total	58.98 ± 11.99	54.46 ± 12.93	62.11 ± 10.25	−3.86	<.001[a]	28.65–88.02
	Overall physical health	2.27 ± .71	2.21 ± .76	2.31 ± .68	−.79	.432[a]	1–4
	QoL Life satisfaction	2.50 ± .71	2.28 ± .66	2.66 ± .71	−3.31	.001[a]	0–4
	Core Ferti QoL	62.86 ± 14.94	57.55 ± 16.39	66.55 ± 12.69	−3.61	<.001[a]	21.88–92.71
	Emotional	61.86 ± 18.37	56.15 ± 21.06	65.81 ± 15.14	−3.08	.003[a]	12.50–100.0
	Mind-body	61.88 ± 19.19	57.04 ± 19.80	65.25 ± 18.11	−2.62	.010[a]	12.67–100.0
	Relational	65.41 ± 17.06	59.77 ± 17.49	69.32 ± 15.69	−3.48	.001[a]	20.83–100.0
	Social	62.30 ± 16.65	57.24 ± 17.64	65.81 ± 15.05	−3.19	.002[a]	12.50–95.83
	Treatment Ferti QoL	55.09 ± 11.56	51.37 ± 11.63	57.67 ± 10.85	−3.39	.001[a]	30.21–85.42
	Environment	51.96 ± 11.96	49.45 ± 12.21	53.69 ± 11.54	−2.15	.033[a]	25.00–87.50
	Tolerability	58.22 ± 18.47	53.28 ± 18.99	61.65 ± 17.40	−2.78	.006[a]	18.75–100.0

Note, IUI = intrauterine insemination; IVF = in vitro fertilization; OI = ovulation induction.
[a] ANCOVA adjusted relationship with spouse.

Quality of life

The Fertility QoL tool (FertiQoL) was used to measure the QoL of infertile women [30]. This scale was developed to measure the QoL of people with infertility problems, as presented by Boivin and Schmidt in collaboration with the European Association for Reproductive Embryology and the American Society of Reproductive Medicine [30]. The Korean version of the FertiQoL, translated into 45 languages, was used, and its validity was confirmed in Korean infertile women [31]. It has 34 items, and the higher the total score, the higher the QoL related to infertility. The Cronbach's α of the original version of the FertiQoL was .92 [30]. In this study, the Cronbach's α was .92.

General characteristics

General factors such as age (women with infertility, spouse), religion, occupation, education level, average monthly income, and fertility-related characteristics, including the duration of infertility treatment, experience of infertility treatment methods, and relationship with the spouse during infertility treatment.

Statistical analysis

The collected data were statistically analyzed using SPSS (version 25.0; IBM SPSS Statistics for Windows, IBM Corp., Armonk, NY, USA). An independent t-test and chi-square test were conducted to compare the differences in infertility-related QoL according to participants' demographic characteristics. Pearson's correlation analysis was performed to investigate the correlation between age, fatigue, and QoL. Hierarchical multiple regression analysis was used to identify the factors affecting the QoL of infertile women according to their type-D personality.

Results

General characteristics, fatigue, and QoL according to type-D personality

The mean age of the participants and spouses was 35.61 ± 4.62 years (range 25-46) and 37.57 ± 5.00 years (range 27–55), respectively. Of

Table 2 *Quality of Life According to General Characteristics (N = 149).*

Variables		Categories	Quality of life M ± SD	t or F	p
Women's age (in years)		<35	59.37 ± 9.95	.36	.721
		≥35	58.68 ± 13.38		
Husband's age (in years)		<35	58.36 ± 11.64	−.41	.523
		≥35	59.23 ± 12.18		
Religion		Yes	57.83 ± 10.34	−1.17	.244
		No	60.14 ± 13.43		
Occupation		Yes	58.99 ± 12.44	.01	.990
		No	58.96 ± 11.28		
Education		≤High school	60.52 ± 12.59	.77	.440
		≥University	58.60 ± 11.87		
Monthly income (thousand won)		<3,000	58.60 ± 11.02	.37	.690
		3,000–4,000	60.17 ± 10.92		
		≥4,000	58.22 ± 13.69		
Duration of infertility treatment (month)		<36	61.11 ± 10.91	4.20	<.001
		≥36	51.78 ± 12.84		
Experienced treatment (double choice)	OI	Yes	57.64 ± 12.50	−1.64	.103
		No	60.90 ± 11.04		
	IUI	Yes	57.24 ± 12.54	−1.77	.080
		No	60.69 ± 11.25		
	IVF	Yes	57.36 ± 13.53	−1.86	.065
		No	60.90 ± 9.61		
	Others	Yes	62.21 ± 11.91	1.14	.255
		No	58.59 ± 11.99		
Relationship with spouse		Good	60.10 ± 11.53	2.90	.004
		Bad	52.11 ± 12.73		

Note, IUI = intrauterine insemination; IVF = in vitro fertilization; OI = Ovulation induction.

those who had undergone infertility treatment for >36 months, 22.8%. Among the participants, 40.9% belonged to the type-D personality group. Participants with and without type-D personality showed significant differences in their relationship with their spouses ($\chi^2 = 4.44$, $p = .035$) (Table 1). The group with type-D personality had significantly higher fatigue than the group with non-type-D personality ($t = 17.38$, $p < .001$), including prevalence of fatigue ($\chi^2 = 12.75$, $p < .001$). In addition, the group with type-D personality had significantly lower QoL than the group with non-type-D personality ($t = 16.71$, $p < .001$) in all QoL subscales except for overall physical health and environment (Table 1 and Figure 1).

QoL according to general characteristics

Women who had undergone over 36 months' duration of infertility treatment ($t = 4.20$, $p < .001$) and had a good relationship with their spouse ($t = 2.90$, $p = .004$) had higher QoL scores than those with less than 36 months' duration of infertility treatment and poor relationship with spouse (Table 2).

Correlation between variables in infertile women

Fatigue in infertile women was negatively correlated with QoL ($r = -.35$, $p < .001$). Women's age showed a positive correlation with husband's age ($r = .69$, $p < .001$) (Table 3).

Factors affecting QoL in infertile women

A hierarchical regression analysis was performed to investigate the factors that affected QoL in women who were infertile. Based on previous studies [32–34], the main variables entered were general characteristics that showed differences in QoL (duration of infertility treatment and relationship with spouse) in the first model and fatigue and type-D personality as physical and psychological factors in the second model, respectively. To confirm the assumption of linear regression, the linearity of all variables and normality were examined. The Durbin–Watson value was close to 2 (1.87), which indicated no problem of autocorrelation. The tolerance ranged from .86 to .97, which was greater than .10, and the variation inflation factor showed that values of all variables were not greater than 10 (1.03 to 1.16), which indicated no issue of multicollinearity. The residual histogram and residual normal probability and homoscedasticity graphs were examined to confirm the normality of residuals. The results were deemed satisfactory. Cook's distance was less than 1.0, at .00 to .06, which implied that no cases needed to be deleted.

In model 1, duration of infertility treatment [>36 months] ($\beta = -.29$, $p < .001$) and relationship with spouse [bad] ($\beta = -.22$, $p = .006$) were demonstrated to be statistically significant. This model was statistically significant ($F = 11.75$, $p < .001$) and explained 13.0% of the variance in QoL in infertile women. In model 2, fatigue and type-D personality were added to the regression model, and

Table 3 *Correlation of Fatigue and Quality of Life (N = 149).*

Variables	Women's age r (p)	Husband's age r (p)	Fatigue r (p)
Husband's age	.69 (<.001)		
Fatigue	−.01 (.920)	−.04 (.620)	
QoL	.04 (.658)	.02 (.806)	−.35 (<.001)

Note, QoL = quality of life.

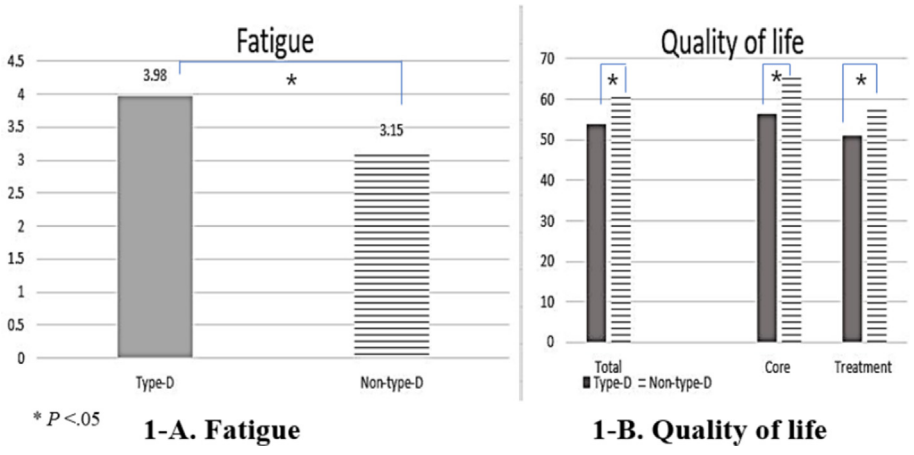

Figure 1. Fatigue and Quality of Life according to Type-D Personality.

Table 4 *Factors Affecting Quality of Life in Infertility Women (N = 149).*

Variable (constant)	Step 1					Step 2				
	B	SE	β	t	*p*	B	SE	β	t	*p*
	62.38	1.16		53.80	<.001	71.19	2.59		27.45	<.001
Duration of infertility treatment[a]	−7.49	1.98	−.29	−3.78	<.001	−5.71	1.91	−.22	−2.99	.003
Relationship with spouse[b]	−7.42	2.64	−.22	−2.81	.006	−5.77	2.53	−.17	−2.28	.024
Fatigue						−2.25	.75	−.23	−2.99	.003
Type-D personality[c]						−4.30	1.90	−.18	−2.27	.025
Adjusted R^2	.13					.22				
Adjusted R^2 change	.13					.09				
F	11.75					11.64				
F change	11.75					10.07				
p	<.001					<.001				

Note, Dummy variable references [a]Duration of infertility treatment (≤36 month), [b]Relationship with spouse (good), [c]Type-D personality (no).
Durbin–Watson 1.87; tolerance: .86–.97; variable inflation factors: 1.03–1.16.

type-D personality was treated as a dummy variable. Fatigue (β = −.23, p = .003) was the most significant factor, followed by duration of infertility treatment [>36 months] (β = −.22, p = .003), type-D personality [yes] (β = −.18, p = .025), and relationship with spouse [bad] (β = −.17, p = .024). Model 2 was also statistically significant (F = 11.64, p < .001), and the explanatory power of model 2 was 22.0%, an increase of 9% from model 1 (Table 4).

Discussion

This study attempted to identify the factors affecting the QoL of infertile women and discuss the factors that have the greatest influence on QoL. The duration of treatment among the general characteristics had the greatest influence on the QoL. Fatigue had the greatest influence on the QoL of infertile women in this study. Infertility treatment causes physical and psychological fatigue during examinations [22]. Physical fatigue due to frequent hospital visits and invasive procedures (ovulation induction, intrauterine insemination, and in vitro fertilization) can cause anxiety and tension, making it difficult to treat infertility [35]. Therefore, considering that the fatigue of infertile women may be aggravated after the failure of the infertility treatment procedure, it is necessary for healthcare providers to understand the patient through information regarding their individual coping style checked in advance and induce them to use the active coping style and music therapy to reduce fatigue during treatment [36]; Therefore, various active nursing interventions or strategies are needed to reduce the fatigue of infertile women and improve their QoL in the future.

The second factor was the duration of treatment among the general characteristics. QoL was found to be low when the infertility treatment period was long, which was similar to the results of previous studies [37]. Thus, to improve the QoL related to infertility, an educational program can help infertile women recognize infertility early and actively treat it through education or promotion as a policy for infertile women.

The third factor influencing QoL was type-D personality. The type-D personality of infertile women also affects QoL. In this study, 40.9% of the participants had a type-D personality; 22.4% to 36.2% of foreign university students [25,38], 30.8% of college students in Korea [39], 34.5% of middle-aged women [40], and 56% of ovarian cancer patients receiving chemotherapy [41] had type-D personality. Considering that hemodialysis patients account for 42.9% of hemodialysis patients [42], the type-D personality of infertile women is higher than that of general college students and middle-aged women, showing a similar aspect to the type-D prevalence of subjects with disease, indicating that active management of infertile women with type-D personality is urgently needed. Considering that the type-D personality is vulnerable to negative affectivity, people belonging to this group experience many negative emotions regardless of time and place and have a tendency to isolate themselves due to social inhibition [24,43]. It is thought that the special situation of infertile women and the phenomenon of infertility treatment increase their negative affectivity and social inhibition. One reason for this improvement is that infertile women express their feelings and negative emotions to those close to them, such as their spouses and family [44]. It seems that interventions that allow people to express their emotions are necessary. As social inhibition intensifies social alienation, it is necessary to find ways to alleviate social inhibition and strengthen social belonging by encouraging not only infertile women, but also their spouses to participate in social activities such as infertility-related lectures and self-help groups. As lifestyle interventions, including physical activity and stress reduction, were effective in reducing type-D personality traits in middle-aged women [45]. Further studies are needed to confirm the effect of applying a lifestyle intervention program for infertile women during the treatment process.

In the present study, participants with type-D personality had higher fatigue and lower QoL than those in the non-type-D group. Type-D personality has a direct impact on QoL [39], and people with type-D personality have been reported to have a lower QoL [46]. These personality traits are said to have a significant correlation with infertility. Therefore, there is a need for interest in and support for the QoL of infertile women with this type-D personality, and efforts are needed to actively cope with infertility problems, such as developing interventions including education, music therapy, lifestyle intervention, spousal cooperation, and active management to improve the type-D personality and QoL of infertile women. In this study, the type-D personality group had a negative relationship with the spouse. These results suggest that social isolation may have a relationship with one's spouse. Therefore, it is necessary to assess the type-D personality of women with infertility because those with a type-D personality have a worse relationship with their spouse.

The fourth factor was the relationship with the spouse, which influenced the QoL of infertile women. When the relationship with the spouse was poor, QoL related to infertility in infertile women was low. This is in line with a study [17] that shows that the spouse's attitude has an effect on QoL, and that QoL is higher when the spouse's attitude is active than when it is passive. Therefore, during the infertility treatment period, spouses' active cooperation with the treatment and support for infertile women is necessary. Infertility is not solely a woman's problem—couples must face it together, as there are limits to individual coping strategies [6]. Thus, it is necessary to develop and apply nursing education and related programs for infertile couples who value relationships with their spouses during infertility treatment.

This study had some limitations. First, there are various infertility treatment methods experienced by women, which may lead

to differences in fatigue and QoL. Second, this study used a cross-sectional design; thus, we did not demonstrate the longitudinal impact of type-D personality on QoL. Nevertheless, this study identified the influence of fatigue, type-D personality, and demographic characteristics on QoL in infertile women.

Conclusion

The present study is significant as it is the first to be conducted in South Korea on infertile women according to type-D personality type. To improve the QoL of infertile women, it is necessary to develop and apply various nursing interventions such as education, lifestyle interventions, music therapy, and stress management programs in which the spouse participates in consideration of the infertility treatment period.

Funding

This work was supported by the National Research Foundation of Korea (NRF) grant funded by the Korea government (No. NRF-2020R1F1A1050767).

Authorship

All authors listed meet the authorship criteria according to the latest guidelines of the international Committee of Medical Journal Editors, and all authors are in agreement with the article.

Conflicts of interest

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

Data availability statement

The data that support the findings of this study are available on request from the corresponding author.

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Asian Nursing Research 16 (2022) 215–223

Contents lists available at ScienceDirect

Asian Nursing Research

journal homepage: www.asian-nursingresearch.com

Research Article

Effects of On-Campus and Off-Campus Smartphone Overdependence Prevention Programs Among University Students

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ARTICLE INFO

Article history:
Received 10 September 2021
Received in revised form
26 July 2022
Accepted 31 July 2022

Keywords:
Personal autonomy
Smartphone overdependence/addiction
University students

SUMMARY

Purpose: The purpose of this article is to evaluate effects of self-determination theory-based on-campus and off-campus prevention programs on smartphone overdependence among university students.
Methods: This was a pre-posttest quasi-experimental study with a nonequivalent control group (CG). Seventy-eight students were recruited as participants. They were allowed to choose either an experiment group (EG) or a CG. On-campus smartphone overdependence prevention program was provided to participants in experimental group 1 (EG1), while on-campus program combined with off-campus prevention camp was provided to those in experimental group 2 (EG2). Instruments used in this study included a smartphone overdependence self-diagnosis scale, a basic psychological needs scale, and a self-regulation ability scale. Data collection was performed at baseline, immediately after intervention, at 1 month and 3 months after intervention. Data were analyzed using mixed analysis of covariance. Focus group interview was performed for qualitative evaluation.
Results: After the intervention, smartphone overdependence and basic psychological needs exhibited significant interactions between group and time. Smartphone overdependence scores decreased in EG1 and EG2 but increased in CG ($F = 4.56$, $p = .001$). Basic psychological needs improved in EG1 and EG2 but deteriorated in CG ($F = 5.04$, $p = .009$). Focus group interviews revealed that participants strived to control their smartphone usage through individual efforts and by interacting with new friends in college even after completing the program.
Conclusion: In this study, on-campus only program and combined intervention of on- and off-campus programs were both effective in maintaining and managing smartphone use. However, participants perceived that the off-campus program provided an opportunity to apply the theory learned in on-campus to the real world.

Introduction

Smartphone overdependence or addiction is characterized by excessive smartphone use or unable to control smartphone use. It can interfere with daily lives such as work, school, and social activities [1]. Currently, the rate of smartphone usage in the Korean population is 93.6% [2]. About 99.8% of Korean university students have a smartphone, of them 25.0% are at risk of being dependent on smartphones [2]. Smartphone overdependence is associated with poor academic achievement, stress, and difficulty in adapting to college life [3,4]. It has been reported that smartphone addiction is positively associated with anxiety, depression, and obsessive–compulsive disorder [5].

In particular, college freshman year is a time when students network with others and focus on their studies in order to build a foundation for a successful college life and career after graduation [4,6]. Therefore, interventions are needed to modify smartphone overdependence behavior among college freshmen. A previous study has reported that self-regulation is negatively associated with dependence on smartphone use [7]. Accordingly, it is

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https://doi.org/10.1016/j.anr.2022.07.004
p1976-1317 e2093-7482/

necessary to improve students' self-regulatory ability associated with smartphone use.

The self-determination theory (SDT) emphasizes the satisfaction of universal psychological needs and internalization of motivation based on a growth-oriented view of humans [8]. It posits that human behavior is induced, maintained, and continued by intrinsic motivation. In addition, behavior change is viewed as a process of using one's volitional control with an emphasis on self-regulation [8].

According to the SDT, an individual's behavior is motivated and determined by oneself. Basic psychological needs such as autonomy, competence, and relatedness are important promoters of individual growth and satisfaction that can increase intrinsic motivation [9]. Therefore, interventions to facilitate satisfaction with basic psychological needs and increase self-regulation using strategies to promote intrinsic motivation might be effective in overcoming smartphone overdependence based on the SDT [9,10].

Most former intervention studies about smartphone users have focused on psychosocial symptom relief or cognitive behavior changes targeting overdependent smartphone users [11,12]. SDT-based intervention studies have also been performed to modify self-management behaviors of those who suffer from chronic diseases [13,14] or to promote smoking cessation [10]. However, studies on SDT-based intervention for preventing smartphone overdependence among college students who have not yet developed smartphone overdependence are scarce. Thus, the aim of this study was to evaluate effects of SDT-based on-campus and off-campus prevention programs on smartphone overdependence among university students. Specifically, this study has the following objectives: (1) to examine effects of on-campus and off-campus interventions for preventing smartphone overdependence and determine whether such interventions could influence basic psychological needs and self-regulatory ability of college students and (2) to assess changes in feelings and perceptions of smartphone use as results of participating in the program and individual efforts to prevent smartphone overdependence.

Methods

Design

This was a pre-posttest quasi-experimental study with a nonequivalent control group (CG) to determine effects of an on-campus smartphone overdependence prevention program (SOPP) alone and in combination with an off-campus prevention camp. In addition, two focus group interviews (FGIs) were performed to explore subjective perceptions of these programs.

Participants

Participants of this study were freshmen from H University in C city through a convenience sampling. Potential participants were recruited using a poster on campus bulletin board. Inclusion criteria were freshmen who were enrolled in the H University at the time of recruitment, those who could understand Korean language, and those who agreed to participate in this study. Freshmen who are interested in the program were allowed to participate regardless of their degree of smartphone overdependence. Exclusion criteria were those who had addiction problems other than smartphone overdependence.

Potential participants were allowed to choose group allocation (either in an experiment group [EG] or a CG). Participants were divided into three groups: (1) experimental group I (EG1), an on-campus program; (2) experimental group II (EG2), on-campus program + off-campus prevention camp; and (3) CG. FGIs were conducted for participants in EG1 and EG2.

The sample size required for this study was calculated using the G*Power 3.1 program. With a large effect size ($f = .40$) and 80.0% power ($\alpha = .05$), at least 42 subjects were required for mixed analysis of covariance (ANCOVA) at four time points for three groups. The effect size was calculated based on research results of Park and Kim [15]. They tested the effect of self-determination by applying the internet addiction group counseling program for high school students, which yielded a large effect ($d = .86$).

Considering potential withdrawals from the study, 30 participants were required for each group. A total of 84 students (28 in EG1, 26 in EG2, and 30 in the CG) were enrolled. Of them, two from EG1, three from EG2, and one from the CG withdrew from this study after completing the baseline survey due to their academic schedules. Thus, a total of 78 (92.9%) participants (EG1, $n = 26$; EG2, $n = 23$; and CG, $n = 29$) completed posttests. Among those who completed the intervention, 14 students (seven students from EG1 and seven students from EG2) voluntarily participated in FGIs (Figure 1).

Measurements

Smartphone overdependence

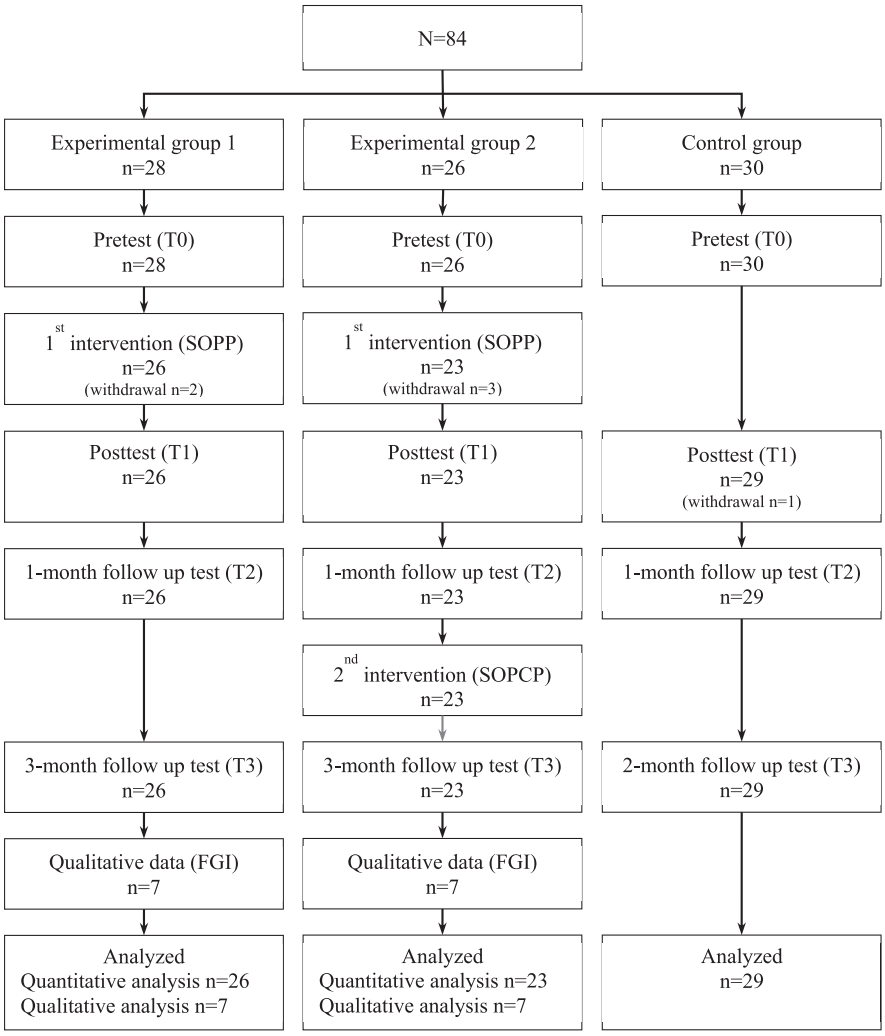
Smartphone overdependence was measured using the smartphone overdependence self-diagnosis scale developed by the National Information Society Agency of Korea [16] with permission from the agency. This 10-item scale comprised three subscales: self-control failure (three items), salience (three items), and serious consequences (four items). Each item was rated on a 4-point Likert scale ranging from 1 (strongly disagree) to 4 (strongly agree), with a higher score indicating a higher risk of smartphone overdependence. The total score ranged from 10 to 40. Based on total scores, individuals were divided into three user groups based on smartphone usage: general users (score: 10–22), potential-risk users (score: 23–30), and high-risk users (score: 31–40) [16]. Cronbach's alpha was .84 in the former study [16]. It was .83 in the current study.

Basic psychological needs

The basic psychological needs scale developed by Lee and Kim [17] was used with permission from the developers. This 18-item tool comprised six items for autonomy, six items for competence, and six items for relatedness. Each item was rated on a 6-point Likert scale ranging from 1 (strongly disagree) to 6 (strongly agree), with a higher score indicating a greater basic psychological need. In the study by Lee and Kim [17], Cronbach's α was .87 for the whole scale, .70 for autonomy, .75 for competence, and .79 for relatedness. In this study, Cronbach's α was .86 for the whole scale, .68 for autonomy, .78 for competence, and .83 for relatedness.

Self-regulatory ability

The short form of the Volitional Components Inventory developed by Kuhl and Fuhrmann [18] and modified for Koreans by Yoon [19] was used with permission from the developers. This self-regulatory ability scale consisted of 10 items for self-regulation mode and 11 items for volitional inhibition mode. Cronbach's α was .76 for self-regulation mode and .75 for volitional inhibition mode [19]. Each item was rated on a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). The total score ranged from 21 to 105, with a higher score indicating a greater self-regulatory ability. Cronbach's α of this scale was .82 in the present study. It was .76 for the self-regulation mode and .80 for the volitional inhibition mode.



Note. SOPP=Smartphone overdependence[오전1 prevention program; SOPCP=Smartphone overdependence prevention camp program

Figure 1. Flow Chart of the Study.

Intervention

Two interventions were used in this study. EG1 was provided with an on-campus program (SOPP), while EG2 was provided with both an on-campus program and an off-campus camp program. First, an on-campus, eight-session SDT-based SOPP was provided to EG1 and EG2 to improve autonomy, competence, and relatedness of participants. SOPP was a modified version of the former program developed by Kwon and Yu [20]. The eight-session program consisted of two 90-minute sessions per week for 4 weeks between April 22, 2019, and May 16, 2019. Contents of the SOPP included building intimate relationship with participants, promoting motivation and reinforcement for control of smartphone use by identifying strengths and weaknesses, and exploring and practicing alternative activities to control smartphone use. The program also included reassessment of modified behaviors and commitment to action for further behavior changes [20]. Second, a three-day/two-night off-campus smartphone overdependence prevention camp program (SOPCP) was offered to EG2 in an environment with limited internet access from June 14, 2019, to June 16, 2019. The camp program was operated on weekends, avoiding midterm and final exam periods. SOPCP was focused on planning and practicing appropriate use of smartphones (Table 1). In the current study, sequences of on-campus program activities were modified, and off-campus program was added to the intervention of the former study [20].

EG2 was also provided SOPP at the same period as EG1. In other words, EG1 participated only in an SOPP, while EG2 additionally participated in a SOPCP within 1–3 months after the SOPP to maintain intervention effects. Both programs were conducted by a counselor, an expert in the field of smartphone addiction prevention. The counselor also participated in the development of the program used in the current study.

Procedure

Data were collected via self-report questionnaire from April 15, 2019, to September 11, 2019. Data were collected at four points: baseline, immediately after, 1 month after, and 3 months after the intervention. Participants were informed that confidentiality would be maintained throughout the study. Pretest and posttest data were collected by two research assistants.

Table 1 *Contents of Smartphone Overdependence Prevention Camp Program.*

Day	Objective	Activities	BPN	Operating time
1st day	Orientation	• Program orientation • Group activity by art	R	2 hours
2nd day	Explore and plan alternative activities	• Explore and running alternative activities • Presenting and sharing alternative activities.	A, C, R	2 hours
	Implementation and restructuring of alternative activities	• Readjustment of alternative activities • UCC shooting about alternative activities	A, C, R	2.5 hours
	Creating UCC	• Sharing practice of alternative activities • Making UCC for correct use of smartphone or enjoying alternative activities	A, C, R	2.5 hours
3rd day	Wrap-up	• Presentation produced UCC • Make a commitment to control your smartphone use.	A, C, R	1.5 hours

Note. BPN=basic psychological needs; A=autonomy; C=competence; R=relatedness.

Two rounds of FGIs were performed from November 26, 2019, to November 28, 2019, after data were collected from the 3-month follow-up. FGIs were conducted in a quiet and soundproof lecture room within the H University. Seven volunteers from EG1 and seven volunteers from EG2 participated in FGIs. The interview lasted for 60–90 minutes. The audio was recorded after obtaining permission from participants. Open and semistructured questions were used to allow participants to freely describe their experiences. Interview questions were developed with advice from an expert panel (four counseling experts, one psychiatrist, one psychiatric nursing professor, one community nursing professor, and one advertising and public relations professor). Questions for EG1 and EG2 were: "What has changed after participating in the program?" "What are you currently doing to prevent smartphone overdependence?" and "What content or activities should be added to the SOPP?" An additional question was asked for EG2 as follows: "How were the SOPP and SOPCP different?" These FGIs were conducted on different dates for each group. Three researchers participated in the interview. These researchers listened to recordings repeatedly immediately after the interviews to transcribe ad verbatim. Personally identifiable information was deleted from the transcript.

Data analysis

All data were analyzed using SPSS WIN 25.0 software. Shapiro–Wilk test for normality revealed that all dependent variables were normally distributed (W = .92-.97, p = .053-.655). Sociodemographic characteristics were analyzed using descriptive statistics. Homogeneity of sociodemographic characteristics and dependent variables was analyzed using the χ^2 test, Fisher's exact test, and analysis of variance. To test the effectiveness of the program, a mixed ANCOVA was conducted with main effects of group (three groups) and time (four time in points) and interaction effect of group*time. If the assumption of Mauchly's sphericity was not met, a Greenhouse–Geisser correction was applied. In the mixed ANCOVA, gender was included as a covariate, which showed a significant difference among groups. ANCOVAs were performed to examine differences among groups at four time points. Post hoc tests were performed to examine differences between groups and within groups using the Scheffé test and the Games–Howell test, respectively.

FGI data were analyzed using content analysis. First, three researchers (one counseling expert, one nursing professor with experience in qualitative study, and one nursing PhD student with experience in developing and implementing a program) read the transcripts to gain an overall understanding of the raw data. They read the transcripts repeatedly to identify key statements for each question. The validity of the data was further examined by two nursing professors with experience in student counseling and qualitative methodology.

Ethical considerations

This study was approved by the Institutional Review Board of H University (approval number: HIRB-2017-024-3-CRM). The first IRB approval was obtained in 2017. IRB extension was approved twice in 2018 and 2019. Participants signed a consent form after being informed of the purpose and procedure of this study, their freedom to participate and withdraw from the study, the use of collected data for research purposes only, and audio-recording of interviews. Participants were also informed that no extra point would be awarded for grade or test and that there would be no penalty for nonattendance or withdrawal. This study excluded students who were taking classes instructed by the principal investigator. Participants were provided a copy of the information sheet and consent form. Benefits of participation were communicated. Each participant was given a small gift (10 USD per participation) upon completion of the study.

Results

Homogeneity test of participant characteristics and measured variables

A total of 78 subjects were enrolled in this study: 26 in EG1, 23 in EG2, and 29 in CG. The mean age of participants was 19.04 ± 0.33 years. Female students accounted for 82.1% and biomedical students constituted 59.0% of participants.

Among the three groups (EG1, EG2, and CG), gender ($x^2 = 7.78$, p = .017) and smartphone overdependence (F = 5.77, p = .005) differed significantly at baseline. EG1 had the highest proportion (96.2%) of female participants, and EG2 had the highest proportion (34.8%) of male participants. Mean score for smartphone overdependence was the highest in EG2 (25.09 ± 5.24) but the lowest in CG (20.83 ± 4.31). Other dependent variables such as basic psychological needs (F = 1.93, p = .152) and self-regulatory ability (F = 0.39, p = .675) were not significantly different among groups at baseline (Table 2).

Effects of program

For mixed ANCOVA results of smartphone overdependence, the interaction between group and time was found to be statistically significant (Wilks' lambda = 0.80, F (4.91, 181.49) = 4.56, p = .001, η^2_p = 0.13). However, the main effect of group (F (2, 74) = 2.37, p = .100, η^2_p = 0.06) and the main effect of time (Wilks' lambda = 0.97, F (2.45, 181.49) = 0.87, p = .441, η^2_p = 0.03) were not significant. Group comparison by each time point using a simple ANCOVA indicated that differences among groups in smartphone overdependence were not statistically significant at T1, T2, or T3 (all p > .05). Similarly, within-group differences by time point were not statistically significant in EG1 or CG (p > .05). However, smartphone

Table 2 *Homogeneity Test of General Characteristics and Measured Variables in Groups (N = 78).*

Characteristics	Categories	EG1[a](n = 26)	EG2[b](n = 23)	CG[c](n = 29)	x^2/F	p
		n (%)/M±SD	n (%)/M±SD	n (%)/M±SD		
Gender	Men	1 (3.8)	8 (34.8)	5 (17.2)	7.78	.017[d]
	Women	25 (96.2)	15 (65.2)	24 (82.8)		
Age		19.12 ± 0.33	19.09 ± 0.29	18.93 ± 0.38	1.97	.147
Department	Social science and humanities	5 (19.2)	4 (17.4)	5 (17.2)	1.40	.844
	Nature science	6 (23.1)	7 (30.4)	5 (17.2)		
	Biomedical science	15 (57.7)	12 (52.2)	19 (65.5)		
Satisfaction with college life	Satisfied	21 (80.8)	14 (60.9)	20 (69.0)	2.38	.305
	Unsatisfied	5 (19.2)	9 (39.1)	9 (31.0)		
Satisfaction with family life	Satisfied	20 (76.9)	19 (82.6)	26 (89.7)	1.64	.479[d]
	Unsatisfied	6 (23.1)	4 (17.4)	3 (10.3)		
Usage motivation	Latest trend	9 (34.6)	9 (39.1)	11 (27.9)	9.75	.112
	Information searching	1 (3.8)	1 (4.3)	(4 (13.8)		
	Relation with people	16 (61.5)	8 (34.8)	11 (37.9)		
	Others	0 (0.0)	5 (21.7)	3 (10.3)		
Mainly used function of smartphone[e]	Voice call and SMS	4 (15.4)	1 (4.3)	4 (13.8)	1.70	.450[d]
	Entertainment function (gaming, hobby etc.)	2 (7.7)	3 (13.0)	1 (3.4)	1.68	.429[d]
	Web searching	6 (23.1)	9 (39.1)	12 (41.4)	2.32	.364
	Playing music, movie and YouTube	11 (42.3)	15 (65.2)	11 (37.9)	4.24	.127
	SNS (kakao talk etc.)	24 (92.3)	17 (73.9)	22 (75.9)	5.03	.077
Daily smartphone using time (hours)	1≤~<3	4 (15.4)	6 (26.1)	5 (17.2)	1.82	.769
	3≤~<6	15 (57.7)	13 (56.5)	19 (65.5)		
	≥6	7 (26.9)	4 (17.4)	5 (17.2)		
Satisfaction of smartphone usage[e]	Information searching	16 (61.5)	18 (78.3)	23 (79.3)	0.18	.835
	Networking through SNS	18 (69.2)	10 (43.5)	19 (65.5)	1.12	.333
	Relieve stress	9 (34.6)	8 (34.8)	4 (13.8)	1.16	.320
	Others (Financial effect, use for learning)	7 (26.9)	7 (30.4)	8 (27.6)	0.03	.971
Dissatisfaction of smartphone usage[e]	High smartphone bill	5 (19.2)	4 (17.4)	4 (13.8)	0.41	.929[d]
	Decreased health	11 (42.2)	10 (43.5)	13 (44.8)	0.04	.982
	Decreased academic achievement	13 (50.0)	16 (69.6)	16 (55.2)	2.03	.362
	Others (including conflict with parents)	8 (47.1)	9 (39.1)	12 (41.4)	0.71	.700
Health status[e]	Sleep deprived.	4 (15.4)	5 (21.8)	9 (31.0)	1.92	.382
	Loss of vision/dry eye	6 (23.1)	9 (39.1)	9 (31.0)	1.48	.478
	Headache/memory loss	2 (7.7)	2 (8.7)	2 (6.9)	0.29	>.999[d]
	Etc. (including decreased physical condition)	4 (15.4)	0 (0.0)	2 (6.9)	3.70	.151[d]
Smartphone overdependence		22.58 ± 3.95	25.09 ± 5.24	20.83 ± 4.31	5.77	.005
Basic psychological needs	Total	86.88 ± 6.28	82.39 ± 9.38	84.21 ± 8.41	1.93	.152
	Autonomy	30.73 ± 2.51	29.13 ± 3.57	29.66 ± 1.91	2.30	.107
	Competence	25.77 ± 3.70	25.52 ± 3.94	25.52 ± 3.97	0.04	.965
	Relatedness	30.38 ± 2.06	27.74 ± 4.78	29.03 ± 3.90	3.11	.051
Self-regulatory Ability		65.96 ± 9.79	63.57 ± 13.97	63.62 ± 9.46	0.39	.675

[a] EG1 = experimental group 1.
[b] EG2 = experimental group 2.
[c] CG=control group.
[d] Fisher's exact test.
[e] Multiple response.

overdependence was significantly decreased in EG2 after the intervention ($p = .027$) (Table 3). Smartphone overdependence scores trended consistently decreased in EG1 and EG2 but increased in CG (Figure 2).

Considering basic psychological needs, the main effect of the group was statistically significant ($F(2, 74) = 5.04$, $p = .009$, $\eta^2_p = 0.12$). The mean score of basic psychological needs was higher in EG1 (88.29 ± 1.52) than in EG2 (82.48 ± 1.63) and CG (82.22 ± 1.40). Scores of basic psychological needs increased in EG1 and EG2 but decreased in CG. However, the main effect of time (Wilks' lambda = 0.96, $F(3, 222) = 0.39$, $p = .759$, $\eta^2_p = 0.01$) and the interaction between group and time (Wilks' lambda = 0.85, $F(3, 222) = 1.82$, $p = .097$, $\eta^2_p = 0.05$) were not statistically significant (Table 3).

Among subfactors of basic psychological needs, the main effect of the group on autonomy was statistically significant ($F(2, 74) = 6.39$, $p = .003$, $\eta2_p = 0.15$), where the autonomy score was higher in EG1 (30.55 ± 0.53) than in EG2 (28.16 ± 0.56) and CG (28.26 ± 0.49). However, the main effect of time (Wilks' lambda = 0.84, $F(5.39, 199.23) = 0.10$, $p = .949$, $\eta^2_p = 0.00$) and the interaction between group and time (Wilks' lambda = 0.72, $F(2.49, 184.29) = 0.52$, $p = .634$, $\eta^2_p = 0.01$) were not statistically significant (Table 3).

Considering competence, the main effect of group ($F(2, 74) = 2.47$, $p = .091$, $\eta^2_p = 0.06$), the main effect of time (Wilks' lambda = 0.91, $F(2.44, 180.66) = 0.03$, $p = .982$, $\eta^2_p = 0.00$), and the interaction between group and time (Wilks' lambda = 0.72, $F(2.49, 184.29) = 1.80$, $p = 0.117$, $\eta^2_p = 0.01$) were not statistically significant (Table 3). Competence scores trended to increase in EG1 and EG2 but decrease in CG (Figure 2).

Considering relatedness, the interaction between group and time (Wilks' lambda = 0.78, $F(2.49, 184.29) = 4.21$, $p = .001$, $\eta^2_p = 0.10$) and the main effect of group ($F(2, 74) = 8.87$, $p < .001$, $\eta^2_p = 0.19$) were statistically significant. However, the main effect of time (Wilks' lambda = 0.72, $F(2.49, 184.29) = 0.52$, $p = .634$, $\eta^2_p = 0.01$) was not statistically significant (Table 3). Relatedness score maintained or improved over the follow-up period among participants in EG1 and EG2, while it fluctuated among those in CG (Figure 2). Group comparison by each time point using a simple ANCOVA indicated that differences among groups in relatedness were statistically significant at T1 only ($p < .001$), with CG showing the lowest mean score (24.69 ± 3.01). However, neither group showed significant within-group differences by time point ($p > .05$) (Table 3).

Considering self-regulatory ability, the main effect of group ($F(2, 74) = 1.53$, $p = .224$, $\eta^2_p = 0.04$), main effect of time (Wilks'

Table 3 *ANCOVA for the Effects of Smartphone Overdependence Prevent Program (N = 78).*

Variables	Groups	T0	T1	T2	T3	Source	F (*p*)	η^2_p
		M±SD	M±SD	M±SD	M±SD			
Smartphone overdependence	EG1[a] (n = 26)	22.58 ± 3.95	20.85 ± 2.77	19.65 ± 4.66	19.12 ± 4.12	T	0.87 (.441)	0.01
	EG2[b] (n = 23)	25.09 ± 5.24	22.48 ± 4.72	21.65 ± 5.04	20.13 ± 4.49	G	2.37 (.100)	0.06
	CG[c] (n = 29)	20.83 ± 4.31	21.34 ± 4.58	22.31 ± 5.22	20.41 ± 4.26	T*G	4.56 (.001)	0.11
Basic psychological needs	EG1[a] (n = 26)	86.88 ± 6.28	88.69 ± 8.95	88.15 ± 8.20	88.62 ± 6.94	T	0.39 (.759)	0.01
	EG2[b] (n = 23)	82.39 ± 9.38	81.30 ± 9.06	83.17 ± 9.27	84.04 ± 9.56	G	5.04 (.009)	0.12
	CG[c] (n = 29)	84.21 ± 8.41	81.48 ± 10.52	80.31 ± 9.54	82.83 ± 7.75	T*G	1.82 (.097)	0.05
Autonomy	EG1[a] (n = 26)	30.73 ± 2.51	30.50 ± 3.58	30.08 ± 3.64	30.42 ± 3.21	T	0.01 (.949)	0.00
	EG2[b] (n = 23)	29.13 ± 3.57	27.57 ± 3.88	28.30 ± 3.77	28.22 ± 3.41	G	6.39 (.003)	0.15
	CG[c] (n = 29)	29.66 ± 1.91	27.93 ± 4.40	27.38 ± 3.62	28.03 ± 2.91	T*G	0.99 (.431)	0.03
Competence	EG1[a] (n = 26)	25.77 ± 3.70	27.69 ± 5.18	27.31 ± 3.81	27.27 ± 3.75	T	0.03 (.982)	0.00
	EG2[b] (n = 23)	25.52 ± 3.94	25.48 ± 4.33	25.83 ± 5.04	26.52 ± 4.82	G	2.47 (.091)	0.06
	CG[c] (n = 29)	25.52 ± 3.97	25.00 ± 4.25	24.14 ± 4.49	25.93 ± 3.23	T*G	1.80 (.117)	0.05
Relatedness	EG1[a] (n = 26)	30.38 ± 2.06	30.19 ± 2.28	30.77 ± 2.72	30.92 ± 2.12	T	0.52 (.634)	0.01
	EG2[b] (n = 23)	27.74 ± 4.78	26.87 ± 2.14	29.04 ± 4.05	29.30 ± 2.70	G	8.87 (<.001)	0.19
	CG[c] (n = 29)	29.03 ± 3.90	24.69 ± 3.01	28.79 ± 3.63	28.86 ± 4.22	T*G	4.21 (.001)	0.10
Self-regulatory ability	EG1[a] (n = 26)	65.96 ± 9.79	66.69 ± 7.55	68.65 ± 9.94	69.19 ± 11.30	T	2.30 (.087)	0.03
	EG2[b] (n = 23)	63.57 ± 13.97	61.61 ± 12.40	62.48 ± 14.59	64.09 ± 13.03	G	1.53 (.224)	0.04
	CG[c] (n = 29)	63.62 ± 9.46	62.62 ± 9.64	64.69 ± 8.12	64.55 ± 8.02	T*G	0.97 (.438)	0.03
Group comparisons by time-point and time-point comparisons by groups								
Smartphone overdependence	EG1[a] (n = 26)	22.58 ± 3.95	20.85 ± 2.77	19.65 ± 4.66	19.12 ± 4.12		0.21 (.892)	
	EG2[b] (n = 23)	25.09 ± 5.24	22.48 ± 4.72	21.65 ± 5.04	20.13 ± 4.49		3.28 (.027)	
	CG[c] (n = 29)	20.83 ± 4.31	21.34 ± 4.58	22.31 ± 5.22	20.41 ± 4.26		0.44 (.660).	
	F(*p*)	5.77 (.005) (b>c)[d]	1.47 (.237)	2.83 (.065)	1.11 (.336)			
Relatedness	EG1[a] (n = 26)	30.38 ± 2.06	30.19 ± 2.28	30.77 ± 2.72	30.92 ± 2.12		0.16 (.845)	
	EG2[b] (n = 23)	27.74 ± 4.78	26.87 ± 2.14	29.04 ± 4.05	29.30 ± 2.70		2.24 (.113)	
	CG[c] (n = 29)	29.03 ± 3.90	24.69 ± 3.01	28.79 ± 3.63	28.86 ± 4.22		2.15 (.127)	
	F(*p*)	3.11 (.051)	30.89 (<.001) (a>b>c)[d]	1.83 (.168)	2.78 (.068)			

Note. T0=Prestst; T1=Posttest; T2=1 month follow up; T3=3 month follow up; T=Time; G=Group; T*G=Time*Group.
[a] Experimental group 1.
[b] Experimental group 2.
[c] Control group.
[d] Scheffe test.

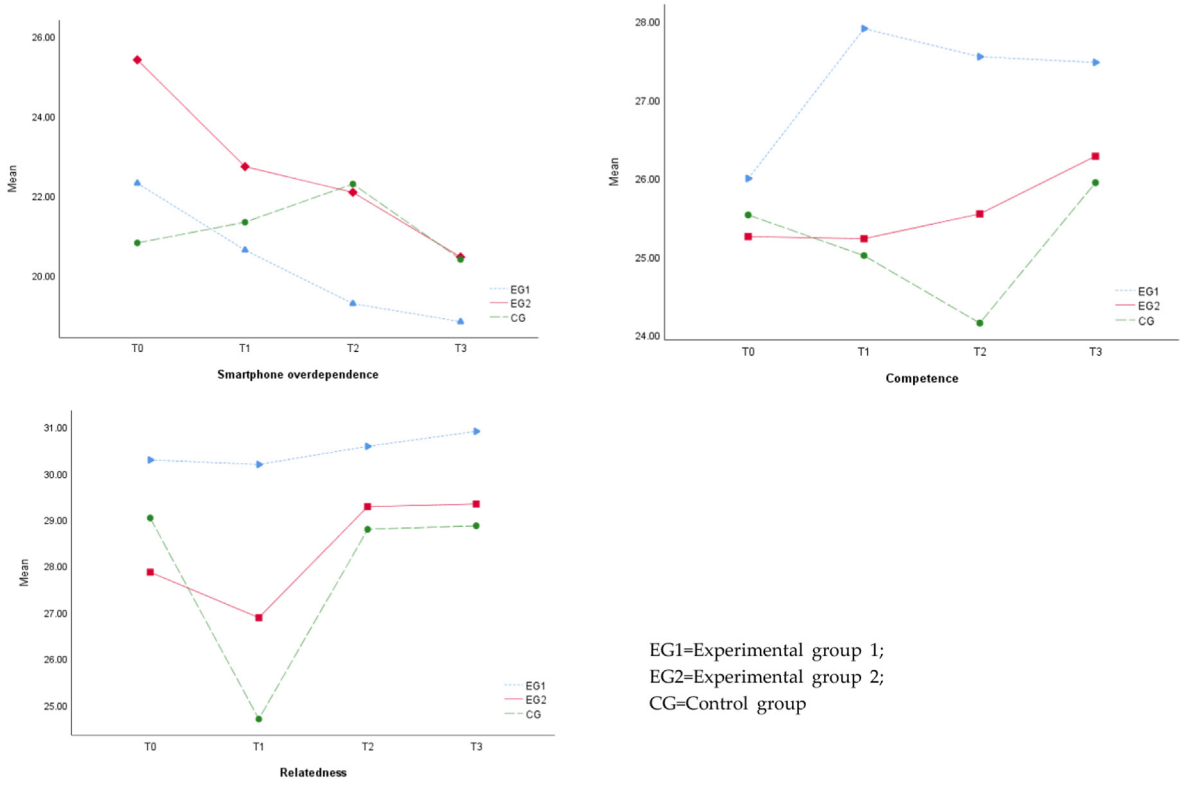


Figure 2. Average trend of the groups.

lambda = 0.92, F (2.63, 194.80) = 1.53, $p = .224$, $\eta^2_p = 0.04$), and the interaction between group and time (Wilks' lambda = 0.92, F (2.63, 194.80) = 0.97, $p = .438$, $\eta^2_p = 0.03$) were not statistically significant (Table 3).

Subjective effects on program experience

The interview was focused on the following: changes after program participation, personal effort to prevent smartphone overdependence, things to be corrected or added for future programs, and benefits of the off-campus camp program.

Changes after program participation

Participants reported improved confidence, autonomy, determination, and self-control, which are components of basic psychological needs. Regarding competence, participants realized how much they used their smartphones and expressed an improvement in self-esteem. Regarding relatedness, participants looked forward to meeting friends from varying backgrounds and stated that they observed improvements in their health such as better sleep, recovery from fatigue, and reduced headache.

> "The program wasn't simply a lecture but more like a group activity, where you have to keep expressing your opinions. I think my self-confidence and autonomy have improved compared to before." (1A, F/19)

> "Through this program, I was able to check the amount of time I spent on it on my own and I realized that I really did use my smartphone a lot. I tried to control that." (2A, F/19)

Personal effort to prevent smartphone overdependence

Applying three engineering control mechanisms (substitution, isolation, and ventilation) [21], participants substituted smartphone use with other activities such as talking to family or friends, watching a movie, or exercising. They were isolated from their smartphones by turning on the "do not disturb" mode or using the smartphone screen time feature. Using the ventilation mechanism, they read letters they had written to themselves or looked at the certificate they had received during the program.

> "How should I spend my leisure time?… I will take a walk or go on a trip. I am trying to go out every weekend with my family except during midterms or finals." (2A, F/19)

> "I think it was the letter that I wrote … when I feel like I am kind of becoming addicted to my smartphone again, I read the letter and motivate myself again." (3A, F/19)

Strengths of the camp program

The SOPP was theoretical. However, the SOPCP allowed participants to engage in various alternatives to smartphones while staying at the camp without a smartphone. The camp provided students an opportunity to pay attention to others and realize they could spend time without their smartphones. They also grew confident and explored new hobbies.

> "… like the camp better because the campus activity was more theoretical and the camp was real world stuff …" (4B, M/19)

> "There's no Wi-Fi, and I can't make calls. I think I discovered new hobbies through this camp." (1B, F/19)

Suggestions for the program

Suggestions made by participants are summarized as follows: (1) lengthening the program duration; (2) forming social support groups by networking with friends or providing continuous monitoring; (3) providing advanced education for smartphone overdependence; (4) analyzing the relationship between health and smartphone overdependence; and (5) providing an undergraduate-specific education program that could reflect the latest trends.

> "Reducing smartphone usage cannot be achieved in a short period of time … I think if you want to see changes in the long-term, it would be better to extend the program to the second semester …" (6A, F/19)

> "This is for smartphone prevention … I thought it would be better if the program was more advanced … then I think people would realize how serious the issue is." (1B, F/19)

Discussion

This study aims to apply an SDT-based SOPP to college students and to determine the program's effects. We developed two types of interventions and tested them on two experimental groups. Participants in EG1 received SOPP, while those in EG2 received SOPCP in combination with SOPP. Effects of these interventions were assessed using self-report surveys, while FGIs were performed as a supplementary process to obtain qualitative evaluations. Accordingly, the discussion was conducted focusing on quantitative research results. FGI results were also provided as backup data to help us understand quantitative results and to provide in-depth information for the study phenomenon.

Interventions based on the SDT were intended to promote basic psychological needs (autonomy, competence, and relatedness) in the current study. To promote autonomy, students were asked to set specific goals for controlling smartphone use. To enhance competence, the program focused on the strengths of students and explored alternative activities over smartphone use. Relatedness was supported through collaborative activities. Combined effects of these activities might have produced significant changes in basic psychological needs, which in turn influenced the self-regulatory ability of participants about smartphone use.

In this study, the level of smartphone overdependence significantly changed in all groups, consistent with a previous study [13]. During the follow-up period, smartphone overdependence scores continued to decrease in EG1 and EG2, but increased in CG. Further analysis by time point revealed that within-group differences were statistically significant in EG2 only, indicating that combined intervention of SOPP and SOPCP was more effective in modifying behavior regarding smartphone overdependence than SOPP or SOPCP alone. In the current study, participants strived to prevent smartphone overdependence using substitution, isolation, and ventilation methods described in a previous study [21]. Example strategies included substituting smartphones with other activities, isolating themselves from the smartphone, and covering the screen so that they could use the smartphone less often. Findings of the current study are in line with previous results showing that smartphone overdependence is reduced even after completion of the program when participants learn how to use smartphones appropriately [12]. EG2 participants who received SOPCP (off-campus camp) showed a greater change in the score for smartphone overdependence across four time points than EG1 participants although such difference was not statistically significant between the two groups. FGIs revealed that EG2 participants

perceived the on-campus program as a theoretical process. However, they recognized SOPCP as an experiential learning program where they could learn how to actually use a variety of alternative activities during the camp. This study introduced alternative activities to participants and provided them with an opportunity to explore alternatives that they could practice on their own. Alternative activities such as art, meditation, and physical activities have been suggested as effective methods to alleviate smartphone overdependence [11,22,23]. Therefore, continuous encouragement and support are needed so that students can apply various measures they have learned during the camp to prevent smartphone addiction. However, in the current study, we did not consider the level of smartphone overdependence for study participants recruited. General users were included in the study. Therefore, future intervention studies should recruit potential- or high-risk users for smartphone overdependence.

In this study, there were significant differences in basic psychological needs among groups after the intervention. EG1 and EG2 showed an increase in basic psychological needs at 3 months after the intervention compared to baseline, whereas basic psychological needs decreased in CG participants during the same period. This is similar to the results of a previous study on internet addiction counseling programs [15]. Among the three basic psychological needs, autonomy significantly differed among groups, similar to the results of previous studies on internet addiction in high school students [15] and smoking cessation in adults [10]. Interventions in the current study might have promoted autonomy among experimental group participants by providing clear evidence for the negative impact of smartphone overreliance. The intervention also included various alternatives to replace smartphone overuse so that participants could choose their own control methods [24]. FGI participants reported that group discussions and hands-on experience improved their confidence and motivated them to control their smartphone usage, which in turn increased their autonomy. Autonomy encompasses a property in which an individual acknowledges and accepts a problem and is willing to maintain healthy behaviors as an agent of change [24]. This calls for various tailored strategies to promote autonomy. Meanwhile, although competence scores were not statistically significant, EG1 showed a decrease in competence score at 3-month follow-up, while EG2 showed an increasing trend. These results suggest that the off-campus camp program could facilitate an effective interaction with the social environment and that the positive feedback might have contributed to the improvement in competence [25]. Additionally, it was speculated that overcoming the environment with limited smartphone access and engaging in new activities might have motivated participants to reduce smartphone use even after the program ended. Relatedness significantly differed among the three groups. EG1 and EG2 showed a significant increase in relatedness compared to CG immediately after the intervention. In particular, college freshmen have the burden of adapting to the changing external environment and building interpersonal relationships [24]. The sense of belonging formed through group activities with common interests at the beginning of the semester can have a positive effect on improving relatedness [8,15]. Considering that participants of this program were college freshmen, positive relationships built by the program and group efforts to control smartphone use might have contributed to enhanced relatedness [20]. Since intimate relationships have a positive effect on the control of smartphone use [25], social support is needed to maintain relationships formed through the program.

In the present study, the self-regulatory ability showed an increase during the follow-up period in EG1 and EG2 although such increase was statistically insignificant. This result was similar to results of a previous study on smartphone overdependence among college students [20]. We speculate that with the support of peers, participants could recognize their problematic behavior regarding smartphone use. Additionally, development of their own action plans to control smartphone use [20] might have contributed to the improvement of their self-regulatory ability. Failure to self-regulate can increase media use [26] and the risk for smartphone addiction [27]. College students who have experienced smartphone overuse want to change this problem behavior. However, they find it difficult to self-regulate their smartphone use [24]. Thus, it is necessary for them to recognize, pay attention, and correct wrong behaviors by observing themselves [25]. In particular, feedback from close family or friends offers a stronger motivation for individuals to evaluate themselves. Such relationships as a social support resource and increased motivation by competition have positive effects [25]. Therefore, it is necessary to create an environment where they can receive continuous monitoring from colleagues through the formation of social network relationships.

However, participants of this study were exposed to external influence because they participated in the program while performing their daily activities. Therefore, tension and academic stress due to their regular exam schedules might have impacted study results. The lack of control for external influences was a limitation of this study. Nevertheless, the camp program (SOPCP) helped students clearly recognize their problems and provided a stronger motivation for them to change their behaviors with their external environment being controlled. Contrary to most theories, it has been reported that the SDT may help sustain behavioral changes when basic psychological needs are met [10]. Therefore, by using various social networks, interventions such as support, encouragement, and monitoring are required to maintain modified behaviors [25]. However, pressure and influence from external environments should be minimized to maintain personal autonomy [10]. Some participants mentioned that long-term programs that could span for more than one year and social support groups are needed to ensure control of smartphone usage in the long term. As part of the program, participants wrote letters to themselves during the intervention period and sent these letters to themselves at 3 months after the intervention was finished. It provided an opportunity to check their current smartphone usage behavior among study participants after the program ended. Long-term quantitative evaluation was not performed for more than 3 months in the current study. However, FGI participants stated that the letter motivated them to continue controlling their smartphone usage and to maintain their changes. Long-term support for college students who have the motivation to control smartphone use is required. A previous study reported that maintenance of tobacco abstinence was achieved when the 6-month smoking cessation program was extended to 12 months based on the needs of participants [10]. If the period for maintaining behavioral changes is considered 6 months to 5 years [28], a short-term intervention cannot produce long-term outcomes. Thus, subsequent studies should provide extended interventions with long-term evaluations of at least 6 months to 1 year to maintain long-term behavioral changes.

Study limitations

This study has some limitations. Since participants were recruited during the semester, it was difficult to control for exogenous variables such as midterms and finals, which might have influenced participants' intention to participate in the program, increasing the possibility of withdrawal. In addition, this study did not employ random sampling methods. Participants were allowed to choose their group assignments, which might have caused a systematic selection bias. Indeed, some study variables differed

significantly at pretest among the three groups, which might have influenced results of this study. Therefore, care should be taken when interpreting research results of this study.

Conclusion

This study implemented and evaluated effects of a program developed based on strategies to improve components of basic psychological needs (autonomy, competence, and relatedness) of college students by applying the SDT. Results of this study confirmed the effectiveness of the program in reducing smartphone overdependence by improving basic psychological needs. This study was significant as it verified the effectiveness of on-campus and off-campus interventions for smartphone overdependence prevention based on SDT and provided a comprehensive evaluation of the research phenomenon by exploring practical experiences of smartphone use through a qualitative approach. In conclusion, results of this study revealed that on-campus only program and combined intervention of on- and off-campus programs were both effective in maintaining and managing smartphone use. However, the off-campus program has the advantage of providing an opportunity to apply the theory learned from the on-campus program to practice. Therefore, combined intervention of theory and practice would be a practical strategy to induce and improve behavior modification of university students for smartphone use. Incorporating these programs into university curricula and extracurricular activities will encourage students to have an appropriate use of smartphones.

Funding sources

This work was supported by the National Research Foundation of Korea (NRF) grant funded by the Korea government (MSIT) (NRF-2017R1A2B4007087 and NRF-2018S1A3A2074932).

Declaration of interest

The authors declare no conflict of interest.

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Asian Nursing Research 16 (2022) 224–230

Contents lists available at ScienceDirect

Asian Nursing Research

journal homepage: www.asian-nursingresearch.com

Research Article

Sex-Based Differences in Outcomes of Coronavirus Disease 2019 (COVID-19) in Korea

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ARTICLE INFO

Article history:
Received 4 November 2021
Received in revised form
5 July 2022
Accepted 31 July 2022

Keywords:
COVID-19
death
risk factors
sex

SUMMARY

Purpose: This study examined the factors affecting mortality and clinical severity score (CSS) of male and female patients with Coronavirus Disease 2019 (COVID-19) using clinical epidemiological information provided by the Korea Disease Control and Prevention Agency.
Methods: This is a retrospective, observational cohort study. From January 21 to April 30, 2020, a total of 5624 patients who were released from quarantine or died were analyzed.
Results: The factors influencing release or death that differed by sex were high heart rate and malignancy in males and chronic kidney disease in females. In addition, the factors influencing progression to severe CSS were high BMI (severe obesity) and rheumatic disease in males and high temperature, sputum production, absence of sore throat and headache, chronic kidney disease, malignancy, and chronic liver disease in females. Older age, low lymphocyte count and platelets, dyspnea, diabetes mellitus, dementia, and intensive care unit (ICU) admission affected mortality in all the patients, and older age, low lymphocyte count and platelets, fever, dyspnea, diabetes mellitus, dementia, and ICU admission affected progression to severe stage of CSS.
Conclusions: This study is expected to contribute to the general results by analyzing nationally representative data. The results of this study present an important basis for development of differentiated nursing and medical management strategies in consideration of factors that influence treatment effects and outcomes according to sex of patients with COVID-19.

Introduction

The World Health Organization (WHO) declared the Coronavirus Disease 2019 (COVID-19) was a pandemic on March 11, 2020 [1]. As of July 4, 2022, a total of 546,357,444 patients were reported to have COVID-19, and 6,336,415 were reported to have died from the disease [2]. In comparison, severe acute respiratory syndrome (SARS) was identified first on November 16, 2002 and confirmed in 8096 patients, causing 774 deaths in 29 countries through July 2003, but was not judged to be a global pandemic. COVID-19 is believed to be one of the most serious health crises ever.

Detecting the causative agent of COVID-19 and providing appropriate isolation and treatment by sharing information is a top priority. Therefore, several studies have analyzed clinical epidemiological data. Studies based on early epidemiological data found that males were more likely to be infected than females [3,4]. A study of severely ill patients with COVID-19 identified a larger proportion of males than females, indicating that COVID-19 varies by sex, and that male patients are more susceptible to severe COVID-19 [5,6]. In particular, severity and complications were more severe in male patients, and this was premised on pathophysiological evidence that the potential functional regulation of angiotensin-converting enzyme 2 (ACE2) by estrogen results in sex differences between morbidity and mortality [7–11]. Conversely, androgens can be a predisposing factor to greater severity of COVID-19 in males [12]. Additionally, although the mechanism of these sex differences is not fully understood, factors such as

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https://doi.org/10.1016/j.anr.2022.07.003
p1976-1317 e2093-7482/

socioeconomic status, lifestyle habits (e.g., smoking and drinking rates), personal hygiene patterns (e.g., hand washing), healthcare-seeking behavior, and access to healthcare might partially explain the sex-based differences [5,13,14]. The mortality and severity of patients with COVID-19 differ according to sex, indicating it is an important variable in prevention and treatment of COVID-19. However, most studies have generally reported differences in incidence, mortality, and severity according to epidemiological characteristics [5,6,15,16]. A meta-analysis of 4420 patients with SARS-CoV-2/COVID-19 by Brady et al. [17] found that sex/gender was included as an analytical variable in only 178 (4%). In other words, there have been no reports on systematic analysis of specific and various factors for effective medical management, such as clinical findings, comorbid diseases, and blood tests, according to sex. A study of patients with COVID-19 in Korea identified risk factors for progression to severe stage [18] using models that predicted clinical severity and duration of hospitalization [19] but failed to account for sex differences. A study using data from the Korea Disease Control and Prevention Agency (KDCA) daily reports also analyzed dynamic patterns among age and sex groups and found that epidemics among young adults resulted in the epidemic spreading across the entire population, whereas overall sex differences in the COVID-19 epidemic were moderate; however, other related factors could not be analyzed [20]. In light of the current results, researchers of SARS-CoV2 and COVID-19 are urged to systematically apply sex-specific methodologies [17]. This should include performance of sex-specific analyses and reporting of sex-disaggregated results for identification of differences in treatment effects [21].

Therefore, this study uses clinical epidemiological information recorded by the KDCA from patients confirmed to have COVID-19 to identify and compare factors that affect mortality and clinical severity score (CSS) of male and female patients. The predictive variables selected in this study (age, body mass index [BMI], clinical findings at hospitalization, comorbidities, etc.) were found to be related to COVID-19 outcomes in previous studies [18–20]. In addition, as much information as can be obtained from the early clinical process, it could be very useful in identifying the risk of mortality and CSS in male and female patients before or at the early stage of diagnosis of COVID-19. Therefore, the results of this study will provide data for planning evidence-based nursing and medical management strategies by sex for the prevention and treatment of COVID-19.

Methods

Study design and samples

This is a retrospective observational cohort study using patient clinical epidemiological information provided by the KDCA (http://www.kdca.go.kr/). The clinical epidemiological information was collected for COVID-19 patients with confirmed COVID-19 who were con-firmed to be released from quarantine or died as of April 30, 2020. Confirmed cases include those who have been confirmed as infected with the infectious disease pathogen according to the diagnostic testing standard, regardless of clinical manifestations [22]. The raw data included 5628 patients; each variable did not have many missing values and patients with missing values were excluded from the analysis. A total of 5624 patients (2317 males, 3307 females) were included in the final analysis.

Measurements

Epidemiological and clinical characteristic data were obtained by healthcare providers at admission. Patients were followed until the end of hospitalization. During hospitalization, patients were monitored by the KDCA of the National Medical Center.

Epidemiological and clinical characteristics

The age, BMI, initial examination findings (heart rate, temperature), clinical findings at hospitalization (fever, cough, sputum production, sore throat, rhinorrhea, dyspnea, headache, confusion), comorbid diseases (diabetes mellitus, hypertension, chronic kidney disease, malignancy, chronic liver disease, rheumatic disease, dementia), intensive care unit (ICU) admission, and complete blood count (lymphocytes and platelets) of the patients were analyzed.

Definition of outcome

The first treatment effect was mortality according to the following criteria. Confirmed cases who display symptoms are discharged if they meet the clinical and testing criteria. (1) According to the clinical criteria, a person should not exhibit a fever without taking fever reducers and show improvements in clinical symptoms for at least 72 hours after 10 days on onset. (2) For the testing criteria, a person should not exhibit a fever without taking fever reducers and show improvements in clinical symptoms after 7 days on onset. Thereafter, the person should test negative on PCR tests twice in a row with at least a 24-hour interval. Confirmed cases who do not display symptoms are discharged if they do not exhibit any clinical symptoms for 10 days on confirmation. According to the testing criteria, they should test negative on PCR tests twice in a row with at least a 24-hour interval after 7 days on confirmation [22]. Death was defined as in-hospital mortality.

The second treatment effect was CSS. The CSS represents clinical severity of patients with COVID-19. The original CSS provided by the KDCA is scored from 1 to 8, with the lowest stage 1 indicating no disruption of daily life and the highest stage 8 indicating death. In this study, appropriate treatment was determined by reclassifying severity into four stages from the original 8 stages according to patient condition. These CSS stages (Stage 1: No disruption to daily life; Stage 2: Hindrance to daily life but no oxygen required; Stage 3: Oxygen treatment, multi-organ damage, and extracorporeal membrane oxygenation (ECMO); Stage 4: Death) were classified and analyzed.

Data analysis

Data were analyzed using SAS 9.4 program [23]. Epidemiological and clinical characteristics of the patients were analyzed as the frequency, percentage, mean, and standard deviation, and Chi-square test was used to examine the differences in epidemiological and clinical characteristics between male and female patients. Pearson's correlation coefficient analysis was used to identify the associations between CSS and age, heart rate, temperature, lymphocytes, platelets variables in male and female patients. Multiple binary/ordinal stepwise logistic regression was performed to investigate the major factors affecting treatment effect and outcomes (mortality, CSS) in male and female patients, considering the useable major factors such as age, BMI, rhinorrhea, dyspnea, confusion, diabetes mellitus, chronic kidney disease, malignancy, dementia, ICU admission, lymphocytes, platelets, and so on. The stepwise logistic regression was used to remove variables that were not required to explain the dependent variable. The variance inflation factors (VIF) of all selected independent variables are below 3, which means multicollinearity does not exist in these regression models. The threshold for statistical significance for this study was $p < .05$.

Ethical considerations

This study was approved for information disclosure by the KDCA. The research was approved by the Institutional Review Board of the associated institute (IRB No. SMUIRB, ex-2020-005). To ensure the anonymity and confidentiality of participants, personal information was provided and used through a secured closed system.

Results

Participants' characteristics

A total of 5624 participants was in the final analysis, including 2317 males (41.2%) and 3307 females (58.8%). Of the 5624 confirmed patients with COVID-19, 5383 (95.7%) were released from quarantine and 241 (4.3%) died. The mortality rate for males was 5.5%, higher than that for females (3.5%). There were significant differences between male and female patients according to release or death, CSS, age, BMI, temperature, cough, sputum production, sore throat, headache, diabetes mellitus, chronic liver disease, dementia, ICU admission, lymphocyte, and platelets (Table 1).

Correlation coefficients for variables

To identify bivariate correlations, Pearson's correlation coefficient analyses were performed and confirmed that predictor variables had an association with CSS (Table 2).

Multiple binary logistic regression for mortality

To identify factors affecting mortality, multiple binary logistic regression was conducted by dividing all patients into quarantine

Table 1 *Epidemiological and Clinical Characteristics.*

Variables	Categories	Men (n = 2317)	Women (n = 3307)	Total	X^2	p
		n (%) or M ± SD	n (%) or M ± SD	n (%) or M ± SD		
Release or death[a]	Release	2190 (97.5)	3193 (96.6)	5383 (95.7)	13.74	<.001
	Death	127 (5.5)	114 (3.5)	241 (4.3)		
Clinical severity score (CSS)[a]	No disruption to daily life	1804 (78.2)	2647 (80.5)	4451 (79.5)	18.53	<.001
	Hindrance to daily life but no oxygen required	118 (5.1)	212 (6.4)	330 (5.9)		
	Oxygen treatment, multi-organ damage, and extracorporeal membrane oxygenation (ECMO)	201 (11.2)	317 (9.6)	575 (10.3)		
	Death	127 (5.5)	114 (3.5)	241 (4.3)		
Age (years)[a]	60<	1604 (69.2)	2235 (67.6)	3839 (68.3)	12.04	0.007
	60–69	377 (16.3)	539 (16.3)	916 (16.3)		
	70–79	232 (10.0)	313 (9.5)	545 (9.7)		
	≥80	104 (4.5)	220 (6.7)	324 (5.8)		
BMI[a]	<18.5	87 (4.7)	173 (6.8)	260 (5.9)	154.52	<.001
	18.5–22.9	614 (33.0)	1253 (48.9)	1867 (42.2)		
	23.0–24.9	487 (26.1)	551 (21.5)	1038 (23.5)		
	25.0–29.9	576 (30.1)	476 (18.6)	1052 (23.8)		
	≥30	99 (5.3)	109 (4.3)	208 (4.7)		
HR		86.17 ± 15.40	85.58 ± 14.82	85.82 ± 15.06	1.56	0.459
	<60	48 (2.3)	59 (1.9)	107 (2.0)		
	60–100	1762 (82.9)	2615 (84.0)	4377 (83.6)		
	≥100	316 (14.9)	438 (14.1)	754 (14.4)		
Temperature[a]		36.90 ± 0.57	36.98 ± 0.54	36.94 ± 0.56	41.48	<.001
	<36.1	68 (3.2)	66 (2.1)	134 (2.6)		
	36.1–37.2	1602 (74.4)	2191 (69.3)	3793 (71.4)		
	37.3–38.2	416 (19.3)	835 (26.4)	1251 (23.5)		
	38.3–40.4	66 (3.1)	70 (2.2)	136 (2.6)		
Fever	Yes	521 (22.5)	784 (23.7)	1305 (23.2)	1.14	0.286
Cough[a]	Yes	918 (39.6)	1423 (43.0)	2341 (41.6)	6.52	0.011
Sputum production[a]	Yes	592 (25.6)	1027 (31.1)	1619 (28.8)	20.14	<.001
Sore throat[a]	Yes	290 (12.5)	591 (17.9)	881 (15.7)	29.57	<.001
Rhinorrhea	Yes	239 (10.3)	382 (11.6)	621 (11.0)	2.12	0.145
Dyspnea	Yes	263 (11.4)	403 (12.2)	666 (11.8)	0.91	0.340
Headache[a]	Yes	299 (12.9)	668 (20.2)	967 (17.2)	50.92	<.001
Confusion	Yes	16 (0.7)	19 (0.6)	35 (0.6)	0.30	0.586
DM[a]	Yes	325 (14.0)	366 (11.1)	691 (12.3)	11.07	0.001
Hypertension	Yes	506 (21.8)	695 (21.0)	1201 (21.4)	0.55	0.459
CKD	Yes	26 (1.1)	29 (0.9)	55 (1.0)	0.85	0.358
Malignancy	Yes	49 (2.1)	96 (2.9)	145 (2.6)	3.37	0.066
CLD[a]	Yes	48 (2.2)	35 (1.1)	83 (1.6)	9.62	0.002
Rheumatoid disease	Yes	12 (0.6)	26 (0.8)	38 (0.7)	1.46	0.227
Dementia[a]	Yes	71 (3.2)	153 (4.9)	224 (4.2)	8.70	0.003
ICU admission[a]	Yes	115 (5.0)	74 (2.3)	189 (3.4)	31.11	<.001
Lymphocytes (%)[a]		27.60 ± 12.28	30.12 ± 11.14	29.15 ± 11.66	46.27	<.001
	<20	428 (27.2)	455 (18.3)	883 (21.8)		
	20–39	913 (58.0)	1579 (63.3)	2492 (61.4)		
	≥40	232 (14.8)	450 (18.0)	682 (16.8)		
PLT ($10^3/\mu L$)[a]	<150	263 (16.6)	237 (25.5)	500 (12.2)	44.99	<.001
	150–399	1298 (81.7)	2212 (88.7)	3510 (86.0)		
	≥400	27 (1.7)	45 (1.8)	72 (1.8)		

Note. BMI = body mass index; CKD = chronic kidney disease; CLD = chronic liver disease; DM = diabetes mellitus; HR = heart rate; ICU = intensive care unit; PLT = platelets.
[a] Indicates that the proportions of male and female are significantly different at significance level 0.05 by Chi-square test.

Table 2 *Correlation Coefficients for Variables in Males and Females.*

Variables	Men			Women		
	Clinical severity score (CSS)			CSS		
	r	95% CI		r	95% CI	
		Low	High		Low	High
Age[a]	0.43***	0.40	0.47	0.38***	0.35	0.40
HR[a]	0.11***	0.07	0.15	−0.00	−0.04	0.03
Temperature	0.16***	0.12	0.20	0.11***	0.07	0.14
Lymphocytes[a]	−0.41***	−0.44	−0.38	−0.34***	−0.37	−0.31
PLT	−0.20***	−0.23	−0.16	−0.17***	−0.20	−0.14

*$p < .05$, **$p < .01$, ***$p < .001$.
Note. HR = heart rate; PLT = platelets.
[a] Indicates that the correlation coefficients of male and female are significantly different at significance level 0.05 by Fisher's z-test.

release or death (Table 3). Older age, high heart rate, low lymphocyte count and platelets, rhinorrhea, dyspnea, confusion, diabetes mellitus, malignancy, dementia, and ICU admission were factors influencing mortality among all patients.

Older age, high heart rate, low lymphocyte count and platelets, dyspnea, diabetes mellitus, malignancy, dementia, and ICU admission affected mortality among male patients. When other variables were controlled, the odds ratio of release was 25.22 times lower in the younger than 60-year-old group, 7.73 times lower in the 60-69-year-old group, and 5.23 times lower in the 70-79-year-old group compared with patients 80 years or older. When heart rate increased by 1 beat per min, the odds ratio of release was 0.97 times higher than that of death; when the number of lymphocytes increased by 1%, the odds ratio of release was 1.10 times higher than that of death. In clinical findings, the odds ratio of release in the absence of dyspnea was 2.62 times (1/0.38) higher than in the presence of dyspnea. For comorbid diseases, the odds ratio of release was 2.16 times (1/0.46), 5.78 times (1/0.17), and 9.71 times (1/0.10) higher in the absence of diabetes mellitus, malignancy, or dementia, respectively. In addition, the odds ratio of release was 10.64 times (1/0.09) higher in cases not admitted to the ICU.

Older age, low lymphocyte count and platelets, dyspnea, diabetes mellitus, chronic kidney disease, dementia, and ICU admission affected mortality of female patients. The odds ratio of release was 67.1 times lower in the younger than 60-year-old group, 35.7 times lower in the 60-69-year-old group, and 4.64 times lower in the 70-79-year-old group compared with death in patients 80 years or older. When the number of lymphocytes increased by 1%, the odds ratio of release was 1.11 times higher than that of death. In clinical findings, the odds ratio of release in the absence of dyspnea symptoms was 5.88 times (1/0.17) greater than that in patients with symptoms. For comorbid diseases, the odds ratio of release was 2.96 times (1/0.34), 9.43 times (1/0.11), and 2.80 times (1/0.36) higher in the absence of diabetes mellitus, chronic kidney disease, and dementia, respectively. In addition, the odds ratio of release was 17.24 times (1/0.06) higher in cases not admitted to the ICU.

Multiple ordinal logistic regression for clinical severity score

For testing the proportional odds assumption, *p* values of score Chi-squares are .607 (for male), .512 (for female), and .538 (for total), which indicate that the proportional odds assumption is reasonable.

Multiple ordinal logistic regression was performed to identify the factors affecting CSS (Table 4). Older age, high BMI (severe obesity), low lymphocyte count and platelets, fever, sputum production, absence of sore throat and headache, rhinorrhea, dyspnea, confusion, diabetes mellitus, malignancy, dementia, and ICU admission affected progression to severe CSS in all patients.

Older age, high BMI (severe obesity), low lymphocyte count and platelets, fever, dyspnea, diabetes mellitus, rheumatic disease, dementia, and ICU admission were found to affect progression to severe CSS in male patients. When the coefficients were increased and other variables were controlled, the odds ratio of stage 1 CSS (No disruption to daily life) in the under 60-, 60-69-, and 70-79-

Table 3 *Multiple Binary Logistic Regression for Mortality.*

Variables		Men			Women			Total		
		OR	95% CI		OR	95% CI		OR	95% CI	
			Low	High		Low	High		Low	High
Age	60<	25.22***	7.45	85.44	67.15***	12.52	360.27	33.43***	12.76	87.56
	60–69	7.73***	2.87	20.85	35.73***	4.88	261.57	10.72***	4.66	24.67
	70–79	5.23**	1.96	13.95	4.63**	1.66	12.96	4.88***	2.39	9.94
	≥80	Ref.			Ref.			Ref.		
BMI	<18.5				0.15	0.02	1.18	0.79	0.18	3.43
	18.5–22.9				0.81	0.12	5.40	1.80	0.48	6.66
	23.0–24.9				1.66	0.18	15.00	3.98	1.00	15.80
	25.0–29.9				0.63	0.09	4.25	1.39	0.38	5.08
	≥30				Ref.			Ref.		
HR		0.97*	0.95	1.00				0.98*	0.97	1.00
Rhinorrhea								6.93*	1.28	37.48
Dyspnea		0.38*	0.18	0.83	0.17***	0.07	0.43	0.34***	0.19	0.61
Confusion								0.13*	0.02	0.84
DM		0.46*	0.22	0.96	0.34*	0.14	0.85	0.38**	0.21	0.67
CKD					0.11*	0.02	0.61			
Malignancy		0.17**	0.05	0.61				0.20**	0.07	0.55
Dementia		0.10***	0.03	0.33	0.36*	0.13	0.98	0.21***	0.10	0.44
ICU admission		0.09***	0.04	0.21	0.06***	0.02	0.17	0.08***	0.04	0.15
Lymphocytes (%)		1.10***	1.05	1.15	1.11***	1.06	1.16	1.11***	1.08	1.15
PLT ($10^3/\mu L$)		1.00**	1.00	1.00	1.00*	1.00	1.00	1.00***	1.00	1.00
χ^2/df		290.08/11***			304.60/14***			606.37/17***		

*$p < .05$, **$p < .01$, ***$p < .001$.
Note. BMI = body mass index; 95% CI = 95% confidence interval; CKD = chronic kidney disease; DM = diabetes mellitus; HR = heart rate; ICU = intensive care unit; OR = odds ratio; PLT = platelets; Ref = reference group.
Excluded predictors are temperature, fever, cough, sputum production, sore throat, headache, hypertension, chronic liver disease, and rheumatoid disease.

Table 4 *Multiple Ordinal Logistic Regression for Clinical Severity Score (CSS).*

Variables		Men			Women			Total		
		B	95% CI		B	95% CI		B	95% CI	
			Low	High		Low	High		Low	High
Age	60<	2.73***	8.31	28.53	2.03***	4.64	12.55	2.16***	5.90	12.62
	60–69	1.96***	3.81	13.14	1.68***	3.12	9.26	1.66***	3.52	7.83
	70–79	1.55***	2.49	8.95	0.90**	1.46	4.11	1.13***	2.07	4.59
	≥80	Ref.			Ref.			Ref.		
BMI	<18.5	0.57	0.66	4.76				0.33	0.75	2.56
	18.5–22.9	1.24**	1.61	7.35				0.55*	1.07	2.79
	23.0–24.9	1.07**	1.37	6.19				0.58*	1.09	2.92
	25.0–29.9	0.64	0.91	3.91				0.16	0.73	1.91
	≥30	Ref.						Ref.		
Temperature					−0.32*	0.55	0.96			
Fever		−0.97***	0.27	0.53	−0.60**	0.38	0.80	−0.89***	0.33	0.51
Sputum production					−0.39**	0.51	0.90	−0.32**	0.58	0.90
Sore throat					0.50*	1.09	2.48	0.40*	1.08	2.06
Rhinorrhea								0.45*	1.04	2.38
Dyspnea		−1.29***	0.19	0.41	−1.48***	0.17	0.32	−1.37***	0.20	0.33
Headache					0.52**	1.15	2.47	0.38*	1.08	1.97
Confusion								−1.33*	0.080	0.88
DM		−0.50**	0.42	0.88	−0.67***	0.36	0.73	−0.62***	0.42	0.70
CKD					−1.42**	0.09	0.66			
Malignancy					−0.87**	0.23	0.78	−0.85**	0.27	0.69
CLD					−1.03*	0.14	0.94			
Rheumatoid disease		−2.12**	0.03	0.53						
Dementia		−1.78***	0.08	0.37	−1.20***	0.17	0.53	−1.30***	0.17	0.43
ICU admission		−2.24***	0.06	0.18	−2.08***	0.07	0.23	−2.19***	0.08	0.17
Lymphocytes (%)		0.06***	1.05	1.09	0.05***	1.04	1.07	0.06***	1.05	1.07
PLT (10^3/μL)		0.00**	1.00	1.00	0.00***	1.00	1.00	0.00***	1.00	1.00
χ^2/df		625.09/15***			661.02/17***			1282.53/20***		

*$p < .05$, **$p < .01$, ***$p < .001$.
Note. BMI = body mass index; 95% CI = 95% confidence interval; CKD = chronic kidney disease; CLD = chronic liver disease; DM = diabetes mellitus; ICU = intensive care unit; PLT = platelets; Ref = reference group.
Excluded predictors are heart rate, cough, and hypertension.

years age groups increased compared with that of the 80-year-old group. In BMI, the odds ratio of stage 1 CSS was increased in the normal and overweight groups compared with the group of severe obesity.

Older age, high temperature, low lymphocyte count and platelets, fever, sputum production, absence of sore throat and headache, dyspnea, diabetes mellitus, chronic kidney disease, malignancy, chronic liver disease, dementia, and ICU admission were found to affect progression to severe CSS in female patients. When the coefficients were increased and other variables were controlled, the odds ratio of having stage 1 CSS in the under 60-, 60-69-, and 70-79-years age groups increased compared with those of the 80-year-old group.

Discussion

This study used clinical epidemiological information of COVID-19 patients to determine the factors affecting mortality and CSS of male and female patients in 5624 confirmed cases of COVID-19. The results showed differences according to sex.

In this study, male and female patients showed a significant difference according to mortality and CSS. In this retrospective observational cohort study among COVID-19 patients in Korea, the mortality rate was 5.4% for males and 3.45% for females. In CSS, there were 11.2% male and 9.6% female patients with stage 3 (oxygen treatment, multi-organ damage, and ECMO). In addition, 5.0% of males and 2.3% of females used the ICU during the hospitalization period. In a study of patients hospitalized for COVID-19 at Wuhan Hospital in China [16], among 168 severely ill patients (86 males and 82 females), the mortality rate was 12.8% for males and 7.3% for females. As a result of examining the odds ratio of intensive treatment unit (ITU) admission through a meta-analysis of 3,111,714 cases reported worldwide, it was found that male patients were more than three times more likely to die than females [6]. The results of this study were similar to the difference in prognosis according to sex in other COVID-19-related studies.

Factors that influenced mortality in all patients included older age, low lymphocyte count and platelets, dyspnea, diabetes mellitus, dementia, and ICU admission. In a study of patients with confirmed COVID-19 in China [24], the risk factors for severe pneumonia or death were age over 60, hypertension, diabetes mellitus, cardiovascular disease, chronic lung disease, and cancer. In a meta-analysis study, it was shown that comorbid diseases such as hypertension, diabetes mellitus, cardiovascular disease, and respiratory diseases can have a significant effect on the prognosis of COVID-19 [15]. Moon et al. [25] reported that elderly age can influence the clinical course of COVID-19 and COVID-19-related mortality through immune aging or high prevalence of comorbid diseases. A study of adult patients with COVID-19 in England and Wales [26] showed that hypertension, dementia, chronic lung disease, and diabetes mellitus were associated with death. The results of this study were similar to the results of domestic and foreign studies that showed a high mortality rate among the elderly with comorbid diseases. Among complete blood counts, lymphocytes are important for immunological responses such as cytokines and chemokines [27,28]. When abnormal lymphocytes and abnormal platelets enter the immune system, patients were believed to be vulnerable and COVID-19 symptoms could be exacerbated [18,27,28]. In terms of the biological mechanisms and in viral-associated hyperinflammatory syndromes, mediators (which primarily kill viral infected cells by stimulating CD8 + cells) are secreted during eradication of the virus, which inadvertently inhibits bone marrow function and activates platelets, resulting in thrombocytopenia [29]. In addition, COVID-19 starts with systemic

symptoms such as muscle pain, chills, fatigue, with a dry cough and dyspnea occurring from several days to one week after infection [30]. Among the systemic symptoms, dyspnea was a factor affecting mortality in both male and female patients.

In this study, the initial examination findings and comorbid diseases showed differences according to sex. Heart rate and malignancy were associated with mortality in men, whereas chronic kidney disease was associated with mortality in women. Although heart rate was a significant factor in these results, most participants had normal heart rates and showed no significant change in practice. These results must be interpreted with caution and verified in a larger number of patients. New COVID-19 vaccines and treatments are being developed [31], but the prolonged pandemic is causing major socioeconomic and medical concerns in limited nursing and medical resource settings. Taking this into account, it is thought that the risk of death related to COVID-19 and the related nursing and medical system burden can be reduced if appropriate prevention and treatment are provided according to comorbid diseases of male and female patients.

The factors affecting progression to severe CSS in all patients were older age, low lymphocyte count and platelets, fever, dyspnea, diabetes mellitus, dementia, and ICU admission. As a result of analyzing the characteristics of COVID-19 pneumonia according to severity at a hospital in Wuhan, 36 of 138 pneumonia patients needed intensive treatment, and the average age of these 36 people was 66 years, with underlying diseases such as hypertension and diabetes mellitus [32]. The most common symptom of COVID-19 is fever [29]. Previous studies have shown that high body temperature increases the risk of progressing to the severe stage of COVID-19 [33]. The present study showed a similar trend in the relationship between comorbid diseases, clinical findings, and CSS. The results of this study can be used for early assessment of patients to identify those that might require intensive care from those who will experience mild disease.

The factors influencing progression to severe CSS that differed according to sex were high BMI (severe obesity) and rheumatic disease in men and high temperature, sputum production, absence of sore throat and/or headache, chronic kidney disease, malignancy, and chronic liver disease in women. Several studies have shown that high BMI increases the risk of progressing to the severe stage of COVID-19 [34,35]. In the context of metabolic syndrome, obesity has been shown to provide an inflammatory environment by rapidly increasing the cytokine storm associated with COVID-19 severity [36]. In the present study, BMI and CSS in women were not related, but in men, the odds ratio of stage 1 CSS was higher in the normal and overweight groups than in the group with a BMI of 30 or higher. Nurses caring for patients with COVID-19 should educate male patients on obesity management as a means of reducing the risk of progression to severe CSS. In Italy, analysis of the sex-related clinical predictors of ICU hospitalization through a cross-sectional observation multicenter national survey revealed that obesity was more frequent in both males and females admitted to the ICU [37]. As such, sex-based differences in the relationship between BMI and CSS were not consistent. Further studies on sex-based differences are needed. In addition, symptoms of upper respiratory tract infection such as sore throat were rare in COVID-19 patients [30], and absence of sore throat was found to affect progression to severe CSS in female patients. Based on the results of the present study, sex differences in CSS might also be caused by comorbid diseases. In addition, more influencing factors such as rheumatic disease and chronic liver disease were identified in COVID-19 CSS in male and female patients, respectively, which has implications for prevention and treatment.

This study is a comprehensive comparative analysis of factors influencing mortality and CSS of male and female patients using the clinical epidemiological information of COVID-19 patients provided by the KDCA. The results of this study will be used as important information to develop nurses' infection expertise. Nursing management strategies for new infectious diseases such as COVID-19 should be based on evidence, and it is important to develop strategies for preemptive and tailored nursing care to vulnerable populations. Therefore, nurses should provide differentiated nursing management for each patient by identifying various factors that affect treatment effects and outcomes according to sex, thereby reducing the risk of developing into severe COVID-19 or mortality. However, the present study has some limitations. It is not clear whether the results of this study can be generalized to other regions of the world, so a study that specifically analyzes various factors related to sex differences in COVID-19 patients in various countries is necessary. In this study, we did not report gender differences in the statistical significance of each predictor, and evaluated based on the results of previous studies. In the future, specific studies are needed to investigate the difference in the predictors presented in this study. Currently, since the validity verification was not performed while modifying the CSS scale in the study, the validity verification should be performed by accumulating related data for the precision of the study. In addition, it was not possible to collect and analyze data on various diagnostic tests, medications, and lifestyle factors by male and female patients as a retrospective study. Research should take into account not only biological differences, but also social and behavioral differences (lifestyle habits, health care seeking behavior, etc.). Lastly, the strain of coronavirus, the type of vaccine, the number of inoculations, and treatment information are not reflected in these data. In the future, repeated studies including various factors are needed, and prospective studies are needed to confirm mechanisms between symptoms, comorbidities, mortality, and CSS.

Conclusions

This study is expected to contribute to the general results by analyzing nationally representative data using the clinical epidemiological information of COVID-19 patients provided by the KDCA. It is significant in that it identifies factors affecting mortality and the CSS of COVID-19 male and female patients and identified differences according to sex. In this study, factors influencing mortality that differed according to sex were high heart rate and malignancy in men and chronic kidney disease in women. In addition, factors influencing CSS that differed by sex were high BMI and rheumatic disease in men and high temperature, sputum production, absence of sore throat and/or headache, chronic kidney disease, malignancy, and chronic liver disease in women. Therefore, classifying patients as at high risk of mortality and severe CSS according to sex and managing patients considering risk factors as such clinical findings at hospitalization and comorbid diseases can lead to effective management of COVID-19 patients. Understanding the specific factors that affect COVID-19 treatment effects and outcomes by sex is important for nursing and medical management, including prevention and treatment. As COVID-19 continues to spread, it is important to be aware of vulnerable populations, and there is a need to tailor ongoing and planned prevention and treatment according to sex. Ultimately, the results of this study can be used to efficiently allocate nursing and medical resources by identifying the factors affecting mortality and CSS according to sex. Understanding sex differences in COVID-19 outcomes is expected to contribute to the development of individualized nursing and

medical management strategies for COVID-19 and new infectious diseases.

Data statement

The data in this study were obtained from the Korea Disease Control and Prevention Agency (KDCA). All data generated or analyzed during this study are included in this published article.

Funding

This research received no external funding.

Conflict of interest

The authors declare no conflict of interest.

Acknowledgments

The authors thank Korea Disease Control and Prevention Agency for offering and using COVID-19 patients clinical epidemiological information as a research source.

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Asian Nursing Research 16 (2022) 241–248

Contents lists available at ScienceDirect

Asian Nursing Research

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Research Article

Profile of non-communicable Disease Risk Factors Among Nurses in a Tertiary Care Hospital in South India

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ARTICLE INFO

Article history:
Received 18 February 2022
Received in revised form
19 July 2022
Accepted 27 July 2022

Keywords:
Cardiometabolic risk factors
Health promotion
Noncommunicable diseases

SUMMARY

Purpose: The work nature of nurses and the associated lifestyle changes put them at high risk of developing noncommunicable diseases (NCDs). This study was conducted to estimate the prevalence of NCD risk factors among nurses working in a tertiary care hospital in Puducherry and to determine the associated factors among nurses.

Methods: We conducted a cross-sectional study among all nurses (N = 1217) in the tertiary care hospital aged between 21 and 60 from May 2019 to April 2020. We assessed NCDs behavioral, physical, and biochemical risk factors using a self-administered questionnaire. The adjusted prevalence ratio was calculated using a generalized linear regression model to determine factors associated with NCD risk factors.

Results: The response rate was 99.0% (1217/1229), and 77.5% of the participants were women. Current tobacco use and alcohol consumption were 1.5% (95% CI: 0.8–2.2) and 2.9% (95% CI: 2–3.9), respectively, with significantly higher prevalence among men. Overweight or obesity (body mass index ≥ 23 kg/m^2) was 77.7%, with a significantly higher prevalence among those aged ≥30 and married. Prevalence of hypertension was 14.4% (95% CI: 12.5–16.4), and diabetes mellitus was 11.5% (95% CI: 9.7–13.6). Both were significantly higher among those aged ≥50 years. One-third of nurses, 34.3% (95% CI: 31.6–37.1), had hypercholesterolemia, significantly higher among men.

Conclusion: We found a high prevalence of various NCD risk factors among the nurses. We highlight the urgent need for initiating health promotion interventions, especially to improve intake of healthy diet and physical activity among nurses aged ≥30 years.

Introduction

Noncommunicable diseases (NCDs) have emerged as major threats to socioeconomic development in low- and middle-income countries. Worldwide, NCDs account for 71.0% of all deaths, of which four of the five occur among those aged between 30 and 69 years [1].

Globally, only about half of the countries have worker's health profiles, of which NCDs and other lifestyle risks were the least covered [2]. A step toward addressing the rising burden of NCDs among employees is implementing setting-based health promotion [3]. India has 1.7 nurses per thousand, which is less than 43.0% of the World Health Organization (WHO) norm of 3 per 1000 [4]. Indian medical services heavily depend on nurses to cater to the health services of a large population but falling short of the prescribed strength of nurses causes hardship among health professionals.

Nurses play a pivotal role in combating the NCD burden in the country by promoting optimal health among patients and the population. NCD risk factors among nurses are expected to be lower than in other professionals. But, emerging shreds of evidence present poor health status among nurses. For instance, a recent meta-analysis reported the pooled prevalence of tobacco use among

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https://doi.org/10.1016/j.anr.2022.07.001
p1976-1317 e2093-7482/

nurses worldwide to be 24.0% across regions [5]. Alcohol dependency among nurses was 5.3%, whereas obesity and central obesity were present among more than 80.0% of nurses in Delhi [6,7]. Another study reported inadequate intake of fruits and vegetables (85.4%) and inadequate physical activity (39.7%) among employees in a tertiary care hospital in Delhi [8]. Among nurses, shift work, especially the night shift, is linked to dyslipidemia due to a lack of time to prepare healthy meals and resort to fast foods that put them at risk of developing NCDs [9]. Additionally, stressful work puts added strain on health, particularly among government nurses who experience higher emotional exhaustion and depersonalization due to high patient turnover [10,11].

Few studies have assessed NCD risk factors among healthcare workers, particularly nurses in India. There is a lack of data on NCD risk factors among nurses, which is essential to facilitate the employee wellness program for NCD prevention. Hence, we conducted this study to estimate the prevalence of NCD risk factors and determine the associated factors among nurses.

Methods

Study design and setting

We conducted a hospital-based cross-sectional study among permanent nursing employees aged between 21 and 60 from May 2019 to April 2020 in a tertiary care hospital, Puducherry. The hospital has an inpatient bed capacity of 2143 (210 beds in ICU) and caters to outpatient services to about 8000 patients per day. The department of nursing services constitutes 1350 nursing employees providing patient care with a nurse–patient ratio of 0.63 nurses per bed. The hospital has been running an employee wellness program through an in-house quality council since 2012 that encourages employees to undergo annual health check-ups on their birthdays.

Sample size calculation and sampling technique

We calculated the sample size using Open Epi Version 3.01 by considering the prevalence of hypertension among nurses as 13.7% [12], relative precision of 15.0%, power of 80.0%, and confidence interval of 95.0%. The final sample size of 1216 was obtained by considering 10.0% of the nonresponse rate. However, we included all 1350 nursing employees. One hundred twenty-one employees were not available at the beginning of the study, and the final sample size was reduced to 1229.

Data collection tools

We used the “NCD work lite” questionnaire, a simplified, validated, locally adapted, and pilot-tested tool to assess the NCD risk factors of study participants. In this study, the “NCD work lite” questionnaire was adopted after conducting a face and content validity assessment through a group of experts through Delphi, followed by pilot testing of the questionnaire in the field. Studies that have assessed NCD risk factors have also used this questionnaire [13,14]. In this study, data were collected in three steps. Sociodemographic information and NCD behavioral risk factors (Step 1) were collected using self-administered performa. The investigator collected physical measurements to estimate overweight, obesity, and abdominal obesity and a blood sample to estimate blood glucose and lipid profile in Steps 2 and 3. All the risk factors were assessed by following the WHO-recommended STEPS (stepwise) guidelines for NCD risk factors assessment. The WHO STEPS guideline prescribes a standardized methodology for evaluating key behavioral risk factors such as alcohol use, tobacco use, physical inactivity, and unhealthy diet and biological risk factors such as abnormal blood lipids, overweight and obesity, raised blood pressure (BP), and raised blood glucose (RBG) [15]. As STEPS guidelines follow standardized methodology, it facilitates monitoring the prevalence of various risk factors over time in a single study setting and in making comparisons across other settings.

Data collection procedure

We obtained a list of all eligible nursing employees from the Nursing department. The investigator contacted the employees in their area of posting in person after obtaining written consent for participation. When the approached individual was unavailable at the time of visit for their participation, revisits were made up to three times at timings suitable to participants, beyond which they were considered nonrespondent.

Behavioral risk factors (Step 1): Initially, sociodemographic information such as age, gender, residence, experience, marital status, and designation was collected. Information on tobacco use (smoke and smokeless forms), alcohol use (frequency), intake of fruits and vegetables, and physical activity was collected. Before handing over the questionnaire, we used show cards to describe the types of physical activity and servings of fruits and vegetables.

Physical measurements (Step 2): Height, weight, waist circumference, and BP were measured as prescribed by WHO STEPS guidelines [15]. The participant's height was measured in standing posture with barefoot and light clothing using a portable stadiometer. Weight was measured using an electronic weighing scale at the nearest 100gm. SECA constant tension tape (SECA 201) was used for waist measurement at the nearest 0.1 cm. BP was measured on OMRON, HEM 7120 (Fully automatic digital BP monitor). Three BP readings were taken with a resting interval of 3 minutes between each measurement, and the mean of the last two measurements was used to assess the BP. All equipment was calibrated regularly before and during data collection.

Biochemical Measurements (Step 3): Overnight fasting (10–12 hours) of 5 ml venous sample was drawn from each participant in a sitting position and transferred to the central lab of the Biochemistry Department of our Institute under the cold chain. Samples were collected in fluoride containers for fasting blood glucose and serum container for lipid profile, and they were estimated by glucose oxidase peroxide and cholesterol oxidase peroxide methods, respectively. The process was carried out in spectrophotometry at 520 nm (Beckman Coulter Inc., Brea, California, USA) through commercially available kits. All information was recorded in the performa after getting lab reports on the same day.

Operation definitions

The use of tobacco (smoke/smokeless forms) and alcohol consumption in the last 30 days and 1 year was considered current use of tobacco and alcohol. Inadequate intake of fruits and vegetables was defined as consuming less than five servings of fruits and vegetables on an average per day [15]. Inadequate physical activity was defined as spending at least 150 minutes per week for physical activity apart from work. Overweight (23.0 –24.9 kg/m^2) and obesity ($\geq$25 kg/m^2) were determined based on Asian cut-offs of body mass index (BMI) classification. Waist circumference $\geq$ 90 cm for men and $\geq$80 cm for women were considered abdominal obesity [16].

RBG was defined at fasting plasma glucose of $\geq$126 mg/dl or currently on antidiabetic medications [17]. Systolic BP of $\geq$140 mm Hg or diastolic BP of $\geq$90 mm Hg or currently on hypertension lowering drugs was defined as raised BP [18].

Hypercholesterolemia was described as having a total cholesterol level of ≥200 mg/dl or currently on lipid-lowering drugs. Raised triglycerides were defined as triglycerides levels of ≥150 mg/dl, and a low-density lipoprotein (LDL) level of ≥130 mg/dl was regarded as triglyceridemia and raised LDL, respectively. Low high-density lipoprotein (HDL) was defined as those having HDL levels of ≤50 mg/dl among women and ≤40 mg/dl among men [19].

Statistical analysis

Data collected in a paper-based questionnaire were entered in the EpiCollect5 app, and the final data were extracted in Microsoft Excel (version 2011) sheet. Data analysis was carried out in STATA14.0 (StataCorp LP, College Station, TX, USA). Continuous variables such as age and experience, and categorical variables such as the prevalence of various risk factors (tobacco and alcohol use, low physical exercise, raised BP, and RBG) were summarized using mean (SD) and proportions, respectively. The differences in risk factors prevalence between subgroups of independent variables were determined by comparing 95.0% confidence interval. The adjusted prevalence ratio for each independent variable was estimated using weighted forward stepwise generalized linear modeling with Gaussian regression. The sample size was not adequate as per assumptions in a particular stratum for binomial regression (In multivariate analysis, the sample size should be at least 20 in each stratum). Hence, we have opted for Gaussian regression analysis. The models were developed for each risk factor by keeping the risk factor as the dependent variable and socio-demographic characteristics (gender, age group, marital status, residence) as independent variables. Independent variables were chosen based on evidence from the literature. In regression models, $p < .05$ was considered statistically significant.

Ethical considerations

The ethical committee approved this study of the institute (JIP/IEC/2018/307) dated October 3, 2018. We had undertaken several measures to promote the voluntary participation of the nurses in the study. The study investigators conducted several rounds of sensitization programs for different cadres of nurses in the hospital as a part of the ongoing nursing education program throughout the study's data collection period to propagate the study. Further, at the time of data collection, the study investigator visited each nurse in person in their working area and described the need, risks, and benefits, voluntary nature of the study, and the option to withdraw from the study at any time during the study. These measures played a crucial role in their participation in the study. Informed written consent was obtained from each participant before enrolling in the study. Confidentiality of data was maintained by generating a unique ID.

Results

The response rate for Steps 1, 2, and 3 were 99.0% (1217/1229) and 90.3 (1100/1217), respectively.

Table 1 shows sociodemographic characteristics. In the study, more than three-fourths were women (77.5%), and the mean age (SD) of participants was 36.6 (8.6) years. About nine-tenth of the participants (90.9%) were residing in urban areas, and three-fifth (60.6%) had less than 10 years of experience.

Table 2 shows the mean and standard deviation of NCD risk factors**.** Mean (SD) body mass index and mean (SD) fasting blood glucose were higher among women and those aged >50 years. Mean (SD) of total cholesterol and mean (SD) of triglycerides were higher among men. Mean (SD) HDL was high among women and those aged >50 years.

Table 3 shows the prevalence of behavioral risk factors for NCDs. Among the behavioral risk factors, current tobacco use (1.5%) and alcohol use (2.9%) were higher among men, whereas inadequate fruits and vegetable intake (76.1%) and low physical exercise (74.6%) were higher among women.

Table 4 shows the prevalence of biological risk factors for NCDs. Among biological risk factors, more than two-thirds had abdominal obesity (71.6%), more than half were obese (57.2%), and one-fifth were overweight (20.5%), which was higher among women and those aged ≥40 years. About one-tenth of nurses had raised BP (14.4%) and RBG (11.5%). More than one-third of nurses had hypercholesterolemia (34.3%) and raised LDL (41.9%), and two third had low HDL (65.3%).

Table 5 shows determinants of various risk factors for NCDs. Prevalence of current tobacco and alcohol use was significantly ($p < .001$) higher among men by 5.0% and 12.0% compared to women. Inadequate physical activity (74.6%) and inadequate intake of fruit and vegetables were significantly higher among men ($p < .001$) and those aged ≥50 years ($p < .001$), respectively. Among biological risk factors, obesity was significantly higher among married and urban residents and those aged above 30 years ($p < .035$). Abdominal obesity was significantly higher among women ($p < .001$) and married ($p < .001$), and those aged above 40 years ($p < .001$). The prevalence of raised BP was significantly higher among men and those aged ≥40 years ($p < .001$). The prevalence of RBG was significantly higher among married nurses and those aged ≥40 years ($p < .001$). Hypercholesterolemia was significantly higher among men ($p < .001$). Triglyceridemia was significantly higher among men ($p < .001$) and those married ($p < .001$). Raised LDL was significantly higher among men ($p < .001$) and those aged ≥50 years ($p < .033$), whereas low HDL was significantly higher among women ($p < .001$) and aged 30–39 years ($p < .023$).

Discussion

In this study, current tobacco use among nurses was 1.5%, significantly higher among men than women. This prevalence was substantially low compared to studies conducted worldwide

Table 1 *Sociodemographic Characteristics of the Study Participants (N = 1217).*

Variables	Men (n = 274) n (%)	Women (n = 943) n (%)	Total (N = 1217) n (%)
Age (years)			
20–29	66 (24.1)	148 (15.7)	214 (17.6)
30–39	193 (70.4)	448 (47.5)	641 (52.7)
40–49	14 (5.1)	209 (22.2)	223 (18.3)
≥50	1 (0.4)	138 (14.6)	139 (11.4)
Experience (years)			
1–9	238 (86.9)	499 (52.9)	737 (60.6)
10–19	29 (10.6)	226 (24.0)	255 (21.0)
≥20	7 (2.6)	218 (23.1)	225 (18.5)
Residence			
Rural	38 (13.9)	73 (7.7)	111 (9.1)
Urban	236 (86.1)	870 (92.3)	1106 (90.9)
Marital status			
Married	231 (84.3)	862 (91.4)	1093 (89.8)
Unmarried	42 (15.3)	69 (7.3)	111 (9.1)
Others	1 (0.4)	12 (1.3)	13 (1.1)
Designation			
Nursing officer	258 (94.2)	576 (61.1)	834 (68.5)
SNO and PHN	16 (5.8)	301 (31.9)	317 (26.0)
ANS and above	0 (0.0)	66 (7.0)	66 (5.4)

SNO = senior nursing officer; PHN = public health nurse; ANS = assistant nursing superintendent.

Table 2 *Mean and Standard Deviation of Noncommunicable Disease (NCD) Risk Factors by Age and Gender Among the Study Participants (N = 1217).*

Mean and standard deviation of NCD risk factors						
Variables	N = 1217 n (%)	F and V intake (servings)	BMI kg/m^2	Waist circumference (cm)	Systolic BP (mmHg)	Diastolic BP (mmHg)
Age (in yrs.)						
20–29	214 (17.6)	3.85 (1.94)	24.10 (3.55)	86.08 (9.20)	107.41 (11.57)	72.75 (9.26)
30–39	641 (52.7)	3.90 (2.19)	25.82 (3.94)	89.43 (10.49)	110.81 (12.67)	73.87 (9.03)
40–49	223 (18.3)	3.83 (2.32)	27.30 (4.24)	92.25 (10.50)	112.39 (13.26)	75.01 (9.06)
≥50	139 (11.4)	4.30 (2.25)	28.98 (4.43)	94.77 (9.49)	117.16 (14.35)	75.89 (9.52)
Gender						
Men	274 (22.5)	4.18 (2.70)	25.31 (3.39)	88.42 (9.88)	117.87 (12.54)	77.88 (8.91)
Women	943 (77.5)	3.85 (2.01)	26.40 (4.41)	90.42 (10.59)	109.29 (12.56)	73.01 (8.95)
Overall		3.92 (2.18)	26.15 (4.22)	89.97 (10.46)	111.23 (13.05)	74.11 (9.17)
Variables	n = 1100 n (%)	Fasting blood sugar (mg/dl)	Total cholesterol (mg/dl)	Triglycerides (mg/dl)	LDL (mg/dl)	HDL (mg/dl)
Age (in yrs.)						
20–29	166 (15.0)	84.18 (22.75)	183.30 (39.29)	118.14 (59.12)	119.21 (34.04)	46.47 (14.14)
30–39	591 (53.7)	87.38 (24.17)	186.47 (37.41)	118.18 (64.41)	125.47 (31.97)	44.25 (12.44)
40–49	215 (19.5)	95.47 (31.11)	186.84 (33.53)	115.23 (48.97)	123.64 (30.60)	45.88 (10.12)
≥50	128 (11.6)	107.01 (36.98)	186.79 (39.44)	127.13 (54.27)	124.98 (31.19)	47.41 (17.21)
Gender						
Men	237 (21.5)	88.49 (29.91)	196.19 (37.95)	148.83 (71.74)	136.77 (34.69)	40.3 (12.00)
Women	863 (78.5)	91.38 (27.48)	183.33 (36.52)	110.35 (53.14)	120.63 (30.29)	46.6 (12.90)
Overall		90.76 (28.00)	186.10 (37.19)	118.64 (59.75)	124.11 (31.97)	45.27 (12.99)

F and V = fruits and vegetables; BMI = body mass index; HDL = high-density lipoprotein; LDL = low-density lipoprotein.

Table 3 *Prevalence of Behavioral Risk Factors of Noncommunicable Diseases Among Study Participants (N = 1217).*

Variables	Current tobacco use % (95% CI)	Current alcohol use % (95% CI)	Inadequate physical activity % (95% CI)	Inadequate intake of F and V % (95% CI)
Age (years)				
20–29	0.9 (0–2.3)	1.4 (0–3.3)	75.9 (68.7–81.9)	77.6 (71.5–82.7)
30–39	2.2 (1.1–3.3)	4.5 (3–6.1)	77.5 (74.1–80.9)	77.5 (74.3–80.8)
40–49	0.9 (0–2.2)	1.3 (0–3.1)	76.3 (70.7–81.9)	75.8 (70–81.6)
≥50	0 (0)	0 (0)	57 .0(47.7–65.6)	67.6 (59–75.5)
Gender				
Men	5.8 (3.3–8.8)	12 (8.4–16.1)	60.8 (54.4–67.1)	70.1 (65–75.5)
Women	0.2 (0–.5)	0.2 (0–.5)	78.4 (75.7–81.1)	77.8 (75.1–80.5)
Residence				
Rural	0.9 (0–2.7)	2.7 (0–6.3)	68.5 (59.5–76.6)	81.9 (73.4–89.4)
Urban	1.5 (0.8–2.3)	2.9 (1.9–3.9)	75 (72.3–77.6)	75.8 (73.2–78.5)
Marital status				
Married	1.3 (0.6–1.9)	2.8 (1.9–3.8)	75 (72.5–77.7)	77 (74.6–79.4)
Unmarried and others	3.2 (0.8–7.2)	3.2 (0.8–6.5)	68.5 (60.5–76.6)	72.6 (64.5–80.6)
Overall	1.5 (.8–2.2)	2.9 (2–3.9)	74.6 (71.8–77.2)	76.1 (73.7–78.6)

F and V = fruits and vegetables; CI = confidence interval.

among nurses and other healthcare professionals, where the pooled prevalence was 22.0–26.0% and 21.0–28.0%, respectively [5]. Similarly, current alcohol use among nurses was 2.9%, significantly higher among men ($p = .001$). This prevalence was less when compared to other studies on nurses that reported the prevalence of alcohol use between 3.8% and 77.4% [7,20–22]. Comparatively, lower prevalence of alcohol use and tobacco use observed in the study could be attributed to the majority of study participants being women (77.5%) and higher cultural inhibition on tobacco and alcohol use attached to women in India [23,24]. In particular, the lower prevalence of tobacco and alcohol use among nurses, particularly women, could be attributed to strict adherence to antitobacco and alcohol policies implemented in the study hospital. There is strict implementation of the COTPA (The Cigarettes and Other Tobacco Products Act), 2003 that prohibits the use of tobacco within the hospital premises, and the employee's service rules prohibit the use of alcohol at the workplace, which could be attributed as the key determinants of the lesser prevalence of alcohol and tobacco use observed in the study. Further, the study hospital, one of the WHO-recognized health-promoting hospitals, has implemented several preventive and health promotive services that are proven to promote health and wellness of hospital employees, including preventing tobacco and alcohol use in the workplace [14]. Other factors such as lesser social gathering due to shift duties, health consciousness about ill effects, and concern for professional dignity could have led to less prevalence in the study. To drive down the prevalence of tobacco and alcohol further, the hospital shall consider integrating mental health screening with the current annual medical check-up activity to help identify and treat the tobacco and alcohol use problems among the nurses [25].

In this study, the prevalence of overweight or obesity was 77.9%, with a significantly higher prevalence among those aged ≥30 years and those married and urban residents. This prevalence was substantially higher when compared to studies conducted in India that used a BMI classification of ≥23 kg/m^2 for the Asian population (16.1%) and was lower when compared to studies (80.0%) that used the WHO classification of BMI (≥25 kg/m^2) [6,12]. Studies conducted in the United States (48.6–54.0%) had a lesser prevalence that used BMI of ≥25 kg/m^2, and a study from Iran which used BMI of ≥23 kg/m^2 had a higher prevalence (82.4%) than the current study [22,26,27]. Studies also indicate that among healthcare professionals, nurses and unregistered care workers have a higher

Table 4 *Prevalence of Biological Risk Factors of Noncommunicable Diseases Among Study Participants (N = 1217).*

Variables	Abdominal obesity % (95% CI)	Obesity % (95% CI)	Raised BP % (95% CI)	[#]Raised blood glucose % (95% CI)
Age (years)				
20–29	54.7 (48.1–61.2)	34.6 (28–41.1)	6.1 (2.8–9.3)	4.2 (1.2–7.8)
30–39	66.9 (63.2–70.4)	56.3 (52.1–60.1)	10.5 (8.1–12.8)	6.9 (4.7–9.1)
40–49	85.2 (80.3–89.7)	67.3 (61.4–73.1)	18.8 (13.9–23.8)	17.7 (12.6–22.8)
≥50	97.1 (94.2–99.3)	79.9 (73.4–86.3)	38.1 (30.2–46.8)	32 (23.5–40.6)
Gender				
Men	35.4 (29.9–40.9)	48.9 (43.1–55.1)	15.3 (10.9–19.3)	8.9 (5.5–12.2)
Women	82.1 (79.4–84.6)	59.6 (56.3–62.7)	14.1 (12.1–16.2)	12.3 (10.2–14.4)
Residence				
Rural	64.9 (55.9–73)	39.6 (30.6–48.6)	14.4 (8.1–21.6)	9.6 (4.3–16)
Urban	72.2 (69.6–74.9)	59.0 (56.1–61.8)	14.4 (12.3–16.5)	11.7 (9.7–13.8)
Marital status				
Married	74.3 (71.6–76.9)	60.1 (57.1–63.3)	14.9 (12.8–16.9)	12.4 (10.4–14.4)
Unmarried and others	47.6 (38.7–56.5)	31.5 (24.2–39.5)	9.7 (4.8–15.3)	2.2 (0–5.6)
Overall	71.6 (68.9–74.1)	57.2 (54.4–59.9)	14.4 (12.5–16.4)	11.5 (9.7–13.6)
	[#]Hypercholesterolemia % (95% CI)	[#]Low HDL % (95% CI)	[#]Raised LDL % (95% CI)	[#]Triglyceridemia % (95% CI)
Age (years)				
20–29	31.3 (24.7–37.3)	57.8 (50.6–65.7)	33.7 (26.5–41)	25.3 (18.7–31.9)
30–39	34.5 (31–38.6)	66.8 (62.9–70.7)	43.7 (39.3–47.5)	25.4 (22–28.8)
40–49	34.4 (27.5–40.9)	66.5 (60.9–73)	42.8 (36.3–49.8)	20.9 (15.8–26.5)
≥50	36.7 (28.1–45.3)	65.6 (57.8–73.4)	43.0 (35.2–51.6)	24.2 (17.2–32)
Gender				
Men	45.6 (38.8–51.9)	51.5 (45.6–58.2)	57.8 (50.6–64.1)	44.7 (38.4–51.1)
Women	31.2 (28.3–34.2)	69.1 (65.8–72)	37.5 (34.4–40.9)	18.8 (16.2–21.4)
Residence				
Rural	35.1 (25.5–45.7)	72.3 (62.8–81.9)	42.6 (33–53.2)	29.8 (20.2–39.4)
Urban	34.2 (31–37.4)	64.6 (61.8–67.4)	41.8 (38.3–44.7)	23.9 (21.1–26.6)
Marital status				
Married	35.0 (32.2–38.1)	65.4 (62.4–68.3)	42.9 (39.8–45.8)	25.1 (22.5–27.8)
Unmarried and others	25.6 (16.7–35.6)	63.3 (52.2–73.3)	31.1 (21.1–40)	15.6 (8.9–23.3)
Overall	34.3 (31.6–37.1)	65.3 (62.2–68.2)	41.9 (38.7–45)	24.4 (21.9–27.1)

BP = blood pressure; CI = confidence interval; HDL = high-density lipoprotein; LDL = low-density lipoprotein; [#]n = 1100.
[#] The n=1100 refers to the variables Raised blood glucose, Hypercholesterolemia, Low HDL, Raised LDL and Triglyceridemia.

prevalence of obesity [28]. Studies also documented that nurses who had married and resided in urban places had a higher prevalence of obesity [29,30]. The high prevalence observed in the study, and its variation compared to other studies could be attributed to the variations in the definition of overweight/obesity used across studies (Asian BMI classification in this study). A significantly higher prevalence of overweight/obesity among those aged ≥30 years observed in this study could be due to a progressive reduction in work-related physical activity among the nurses as they move to the next levels in job positions, which involves more managerial work than physical. The higher prevalence of obesity among nurses who were married and residing in urban in this study could be due to the high prevalence of unhealthy lifestyle practices especially inadequate physical activity, inadequate intake of fruits and vegetables, and easy access to processed food, especially in the urban areas.

Similarly, more than two-thirds of nurses had abdominal obesity (71.6%), significantly higher among women and married and those aged ≥40 years. This prevalence was lower among nurses (82.0%) from a tertiary care hospital in New Delhi and south Indian nurses (94.3%). [6,12] Research evidence also suggests that the nurses who were women and over 30 years had a significantly higher prevalence of abdominal obesity [31]. The higher prevalence in this study could be due to inadequate physical activity (74.6%) and unhealthy dietary practices, which can be addressed by suitable workplace health policies toward promoting a healthy lifestyle and weight reduction among the nurses [31].

Around three-fourths of participants had inadequate physical activity (74.6%), which was significantly higher among men and those aged above ≥50 years. This prevalence was higher than tertiary hospital administrative employees in Delhi (39.7%) and lower than Bangladeshi nurses (92.0%) [8,32]. Evidence suggests shift work hinders nurses from meeting required physical activity levels (150 minutes per week). The higher prevalence of physical inactivity in this study could be due to the shift work nature of the nursing profession, which prevents nurses from adopting a routine physical activity. This could be addressed by providing facilities for physical activities and behavior change to integrate physical activity into their daily routine [33].

About three-fourths of participants had inadequate intake of fruits and vegetables (76.1%), which was significantly higher among men. This was slightly lower than the prevalence among administrative staff in a tertiary care hospital (85.4%) but higher when compared to a study among nurses from Bangladesh (56.3%) [8,32]. Evidence also suggests that physical inactivity and dietary habits, especially skipping meals, contribute to overweight and obesity among nurses [10]. Considering the higher prevalence of physical inactivity (74.6%) and unhealthy diet (76.1%) in the current study, the hospital administrators shall consider implementing initiatives to promote healthy foods and physical activity among the nurses [34]. Innovative campaigns that improve fruits and vegetable intake in workplace settings, such as “5-a day” and “just add F and V in your diet,” shall also be considered for implementation [35].

Roughly 15.0% of participants had raised BP significantly higher among men aged ≥40 years. This was slightly higher than studies conducted among hospital nurses in south India (13.7%) and north India (10.0%), whereas lower than studies done in north India (16.8%) [12,22,36]. This difference could be attributed to the regional differences in the prevalence of hypertension across India [37]. The prevalence of raised BP in Iran and the United States was

Table 5 *Determinants of Various Risk Factors of Noncommunicable Diseases (N = 1217).*

Variables	Current tobacco use	Current alcohol use	Inadequate intake of F and V	Inadequate physical activity	Abdominal obesity
	aPR (95% CI)	aPR (95% CI)	aPR (95% CI)	aPR (95% CI)	aPR (95% CI)
Age (years)					
20–29	1	1	1	1	1
30–39	1.01 (0.99–1.04)	1.03 (1.0–1.05)	1.01 (0.94–1.08)	1.0 (0.93–1.07)	1.07 (1.0–1.15)
40–49	1.01 (0.99–1.04)	1.02 (1.0–1.05)	1.05 (0.97–1.15)	1.07 (0.98–1.16)	*1.16 (1.07–1.26)
≥50	1.01 (0.99–1.03)	1.02 (1.0–1.04)	*1.15 (1.04–1.27)	*1.32 (1.19–1.47)	*1.29 (1.19–1.38)
Gender					
Men	*1.05 (1.02–1.08)	*1.12 (1.08–1.17)	*1.1 (1.04–1.18)	*1.25 (1.17–1.33)	1
Women	1	1	1	1	*1.50 (1.41–1.60)
Residence					
Rural	1	1	1	1.05 (0.97–1.14)	1.01 (0.94–1.09)
Urban	1.01 (0.99–1.03)	1.01 (0.98–1.04)	1.0 (0.99–1.15)	1	1
Marital status					
Married	1	1	1	1	*1.16 (1.06–1.27)
Unmarried and others	1.02 (0.98–1.05)	1.0 (0.96–1.03)	1.06 (0.96–1.15)	1.06 (0.98–1.16)	

*Significant – $p < .05$.
aPR = adjusted prevalence ratio; BP = blood pressure; CI = confidence interval; F and V = fruits and vegetables; HDL = high-density lipoprotein; LDL = low-density lipoprotein; 1 = reference category.

15.1% and 17.0%, respectively [22,27]. In the current study, RBG prevalence was 11.5% and was significantly higher among those aged ≥40 years and married nurses. This was higher than the studies conducted among clinical nurses in public hospitals in south India (5.6%) and north India (5.0%), whereas this was lower when compared to the tertiary hospital in north India (13.5%) [12,21,36]. The higher prevalence of RBG in this study could be attributed to a substantially higher prevalence of overweight or obesity, involvement of shift work and low levels of physical activity among married nurses, and family responsibilities.

Evidence on biological risk factors among nurses from Indian settings is scarce. In the current study, more than one-third of participants had hypercholesterolemia (34.3%) which was significantly higher among men. This was higher when compared to studies among nurses from Iran (5.0%), the United States (23.0%), and Indian healthcare professionals (7.0%) [21,22,27]. Further, almost one-fourth of nurses had triglyceridemia (24.4%), significantly higher among men and those married. This prevalence was higher than among Iranian nurses (6.0%) [27]. The higher prevalence of hypercholesterolemia and triglyceridemia among men was possibly due to a higher intake of unhealthy foods, particularly a diet rich in saturated fats and a lack of physical activity, whereas in the case of married nurses, the possible reason could be inadequate physical activity and intake of fruits and vegetables, as evidenced by this study. Another reason could be these study participants were a considerable proportion of mid-level adults who were married nurses and had more responsibility toward caring for young children without caring for them in modifying unhealthy lifestyle choices. Indian studies have shown that married nurses and men had significantly higher hypercholesterolemia [38]. The prevalence of raised LDL (41.9%) was significantly higher among men and those aged above ≥50 years, which was higher when compared to studies from Iranian nurses (6.0%), US nurses (10.0%), and Indian health professionals (4.0%) [21,22,27]. The higher prevalence could be attributed to consuming junk food among men and the sedentary job nature of those above 50 years old. Similarly, the prevalence of low HDL (65.3%) was significantly higher among women aged between 30 and 39. This prevalence was higher than in studies conducted on Iranian nurses (51.0%), US nurses (39.2%), and Indian health professionals (59.0%) [21,22,27]. The higher prevalence of low HDL in this study could be attributed to parents of child-rearing age (30–39 years) who neglect their self-prioritization of health. In the case of women, they have less time for physical activity due to higher family responsibilities. Various studies documented that gender, obesity, age, marital status, sedentary lifestyle, and fruit diet habits were associated with dyslipidemia [39,40]. Adequate physical exercise and proper diet are prerequisites for addressing metabolic risk factors at both individual and population level [41]. Complementary medicine principles and lifestyle and diet modifications effectively counter cardiovascular disease risks [42]. There is a need for a comprehensive approach to identify gaps in existing workplace wellness programs and identify target groups to achieve the wellness goals [43].

We compared the prevalence of various behavioral and biological risk factors obtained in the study with the general population. Among behavioral risk factors, the prevalence of physical inactivity obtained in the study (74.6%) was substantially higher when compared to the prevalence obtained in the district of Puducherry (45.8%) and nationally (41.3%) by the National NCD Monitoring Survey [44,45]. The prevalence of other behavioral risk factors obtained in this study was lesser when compared to the prevalence obtained from the Puducherry district and the national estimates for tobacco use (12.3% and 32.8%), alcohol use (18.5% and 15.9%), and inadequate intake of fruits and vegetables (86.8% and 98.4%) [44,45]. Similarly, among biological risk factors, the prevalence of obesity in this study (57.1%) was higher when compared to the prevalence in the Puducherry district (46.1%) [44]. The prevalence of RBG in this study (11.5%) was marginally higher than the national estimate (9.3%) but lower than in the Puducherry district (26.7%) [44,45]. Similarly, the prevalence of hypercholesterolemia obtained in the present study (34.3%) was comparable to the general population in the Puducherry district (34.8%) [44]. The prevalence of raised BP in this study (14.3%) was lesser than the prevalence obtained from the Puducherry district and national estimate (33.6% and 28.5%, respectively) [44,45].

This comparison with the general population points out that the prevalence of inadequate physical activity and obesity is comparatively higher among nurses than the general population, highlighting the target groups that need to be targeted with health promotion interventions through the existing workplace wellness programs in the hospital. The differences in the prevalence of these NCD risk factors in the general population could be attributed to the differences in the health-seeking behavior, health knowledge, affordability, and nature of work among the compared population groups.

This study included all nursing employees in the hospital, with an overall response rate of 99.0%. Therefore, the chance of selection bias is minimal. The study also presents a scientific approach to setting up surveillance on NCD risk factors among nurses working in a tertiary care center. There are some limitations to the study. The data were collected through self-administrated performa. This could have affected the accuracy of behavioral risk factors elicited

Obesity	Raised BP	Raised blood glucose	Hypercholesterolemia	Triglyceridemia	Raised LDL	Low HDL
aPR (95% CI)	aPR (95% CI)	aPR (95% CI)	aPR (95% CI)	aPR (95% CI)	aPR (95% CI)	aPR (95% CI)
Age (years)						
1	1	1	1	1	1	1
*1.16 (1.07–1.26)	1.03 (0.99–1.08)	1.0 (0.96–1.05)	1.0 (0.92–1.09)	0.96 (0.88–1.04)	1.07 (0.98–1.17)	*1.10 (1.01–1.21)
*1.28 (1.16–1.41)	*1.14 (1.07–1.22)	*1.12 (1.05–1.2)	1.04 (0.94–1.15)	0.98 (0.89–0.92)	1.11 (1.01–1.24)	1.05 (0.95–1.17)
*1.45 (1.31–1.61)	*1.40 (1.27–1.53)	*1.30 (1.19–1.42)	1.07 (0.95–1.20)	1.03 (0.92–1.14)	*1.13 (1.01–1.28)	1.04 (0.92–1.16)
Gender						
1	*1.08 (1.03–1.13)	1.02 (0.98–1.07)	*1.18 (1.09–1.26)	*1.31 (1.22–1.41)	*1.25 (1.16–1.35)	1
1.02 (0.95–1.09)	1	1	1	1	1	*1.21 (1.12–1.30)
Residence						
1	1.01 (0.95–1.08)	1.0 (0.94–1.06)	1.0 (0.90–1.1)	1.04 (0.95–1.14)	1.0 (0.90–1.10)	1.09 (0.99–1.20)
*1.14 (1.04–1.25)	1	1	1	1	1	1
Marital status						
*1.18 (1.08–1.30)	1.02 (0.97–1.09)	*1.07 (1.02–1.12)	1.1 (0.99–1.23)	*1.15 (1.05–1.25)	1.10 (0.99–1.35)	1
1	1	1	1	1	1	1.03 (0.92–1.15)

due to recall bias. The low prevalence of tobacco and alcohol use evidenced in the study could be due to social desirability bias. This study's cross-sectional nature and variations in the prevalence of various NCD risk factors in an individual over time could not be captured. To address the variation, future longitudinal studies shall be planned. As this study was conducted in a single tertiary care hospital, the results obtained may not be generalizable to other tertiary care hospitals in the country.

Conclusion

We found a high prevalence of major risk factors of NCDs such as obesity, abdominal obesity, inadequate intake of fruits and vegetables, inadequate physical activity, and low HDL among women, whereas hypercholesterolemia and raised LDL were higher among men. The higher prevalence of these risk factors indicates an urgent need to address this burden among the target groups identified in the study through workplace wellness programs such as periodic surveillance of NCD risk factors, wellness clinics, and multifactorial lifestyle intervention in preventing premature NCD mortality and morbidity.

Financial support and sponsorship

Dr. Sitanshu Sekhar Kar received the Intramural grant for this study. This research work was funded by Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Puducherry, India. Grant no: JIP/Dean(R)/Intramural/Phs1/2019-20. The funder did not have any role in preparing, conducting, writing, and submitting the manuscript.

Conflict of interest

Nil.

Acknowledgments

Nil

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