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## Editorial

## What kind of research can be considered nursing research?



The purpose of publishing Asian Nursing Research is to support the excellence of Asian nursing researchers and to promote the advancement of nursing through the publication of high quality nursing research articles. What can be considered nursing research? Can all studies conducted by nurse researchers be considered nursing research? Is research conducted by researchers affiliated with nursing schools or research institutes nursing research? How does nursing research differ from other surrounding disciplines such as medicine, public health, psychology and social work research? In an era of interdisciplinary research and collaboration among researchers, how does nursing research ensure its own uniqueness and identity necessary for the advancement of the discipline? Finding answers to these questions is the current exploratory endeavor of the ANR.

Contemporary nursing began with the work of Florence Nightingale, who applied nursing's independent perspective of maximizing patients' self-healing power by improving environment and hygiene to wounded soldiers in the Crimean War, resulting in a revolutionary reduction in mortality. Before that, nurses were mostly apprenticed as female assistants to doctors in hospitals. However, the Civil War in the United States and the Crimean War in the United Kingdom led to the establishment of formal higher education for nurses. Nursing training institutions emerged in the mid-19th century, first in England and a decade later in the United States, and quickly grew into university education [1].

What is nursing education like in South Korea, where ANR is published? In the early 20th century, Western missionaries arrived at the end of the Joseon Dynasty and established nursing education institutions that became the forerunners of the current Ewha Womans University and Yonsei University in 1903 and 1906, respectively [2,3]. Public nursing education began in 1907 with the establishment of what is now the Seoul National University College of Nursing [4]. Although these pioneering institutions were established in the early 20th century, it was not until the mid-to-late 1950s that nursing education was reorganized into higher education institutions, similar to today's colleges.

The development of nursing colleges was followed by master's programs in the early 1960s and doctoral programs in the late 1970s and early 1980s, organizing the current system of nursing education. PhD nurse scientists have been produced in South Korea since the mid-1980s, so their involvement in academic activities is only about 40 years old. The history of nursing in other Asian countries is very similar in time. Meanwhile, health care in Korea and many other Asian countries has advanced dramatically, with mega-sized nursing organizations in several tertiary hospitals and a variety of systems to ensure efficient delivery of nursing care.

As a fledgling profession less than half a century old, how will nursing in Asian countries grow in the future, both independently

and in convergence with other disciplines? What are the core values of nursing that will enable the discipline to identify and develop its independence and prominence as a caring science beyond the scope of practice of nurses in health care settings? Not surprisingly, it is only through research that embodies these core values that the discipline of nursing will be able to move forward.

What constitutes quality nursing research? This is a question that all nurses, nurse researchers, and nurse educators need to answer together. Quality nursing research, which ANR aims to publish, should be informed by the history of nursing as the art and science of caring for the sick. Quality nursing research should have a message that carries forward the identity of human caring that so many nurses before us have created throughout history. Nursing did not begin as a theory created by language or text, but as a practice that began with compassion for the sick and a desire to care for human suffering. The willingness of women to volunteer to care for the wounded in war, one of the most painful moments in human history, constructed the phenomena from which the core values of nursing could be identified. Therefore, high quality nursing research takes into account the history of nursing, which should be practical enough to bring about change.

What is the scope of nursing research? Nursing is based on a meta-paradigm that is concerned with people, health, nursing, and the environment. More specifically, nursing research should be about "the protection, promotion, and optimization of health and human functioning" as defined by the American Nurses Association [5]. In addition, nursing research would be about preventing illness and injury, facilitating healing, and alleviating suffering in people [5]. Even big data research in nursing, which has recently become similar to that of other disciplines due to the increasing size of data, should also be interpreted qualitatively within the context of nursing.

Finally, in order to conduct high quality research that drives the development of nursing, nursing research must include the core essence of caring based on humanism. To conduct research that captures the essence of caring, the researcher's inquiry must be nursing-like. In the ANA's definition of nursing, compassionate presence is essential to caring, meaning that caring can only be embodied by being 'present' with those in need. This means that the nurse researcher needs to be close enough to be able to see those being researched as human beings. Research that objectifies and otherwise the research participants is a far cry from a nursing perspective of inquiry. Even when objectified, research findings should be reinterpreted from the perspective of compassionate presence.

In a rapidly changing modern society, changes in nurses' research perspectives, research methods, and the nature and amount of data are inevitable. Convergence research with surrounding disciplines and collaboration between researchers are

essential. After years of interdisciplinary research, if nursing research is to stand out as a human caring science that is both unique and universal, it must be carried out with an eye to the practical and the essential. The papers in this issue of ANR were selected using these principles.

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## Research Article

# Effects of a Remote Physical Activity Improvement Program on Male Office Workers with Metabolic Syndrome in Their 30s and 40s with Sedentary Behavior: A Randomized Controlled Trial

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## SUMMARY

**Purpose:** Sedentary office workers lack physical activity and have a high prevalence of metabolic syndrome (MetS). This study attempted to develop a remote physical activity improvement program for sedentary office workers and verify its effectiveness by applying it to male workers in their 30s and 40s with MetS.

**Methods:** This study used a randomized control group pretest–posttest design, and the study sample was 75 male workers recruited from an information and technology company. They were randomly assigned to either the intervention (n = 38) or control (n = 37) group. The remote physical activity improvement program was constructed based on the self-regulation theory emphasizing autonomy, and was conducted through non-face-to-face Zoom once a week for a total of 12 weeks. Health education, exercise training, small group meetings, and individual counseling were provided, and tailored text messages were sent to participants every day to encourage them to reflect on their lifestyle and practice exercise.

**Results:** The remote physical activity program significantly increased basic psychological needs (Z = -7.55, p < .001), intrinsic motivation (Z = -6.94, p < .001), health promotion behavior, (Z = -6.63, p < .001), and physical and physiological indicators (p < .05) in the intervention group compared to those in the control group.

**Conclusions:** In managing MetS among office workers, it was found that remote education using the Zoom platform was effective, even during the coronavirus pandemic. As a strategy for health education in the workplace, remote education content needs to be developed and applied.

**Trial registration:** Clinical Research Information Service, KCT0009322.

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## Introduction

Metabolic syndrome (MetS) is defined as the concurrence of mutually associated cardiovascular risk factors including abdominal obesity, impaired glucose tolerance, hypertriglyceridemia, decreased high-density lipoprotein (HDL) cholesterol, and/or hypertension [1]. It increases mortality from all causes by 1.35 times, and from cardiovascular diseases by 1.74 times [2]. In addition, it results in an increase in the relative risk of cancers, including liver

and rectal cancers [3]. In South Korea, owing to the influence of a westernized lifestyle, the prevalence of MetS reached 30.4% in 2020 [4], which is comparable to the prevalence of 33.3% in Finland [5]. Its prevalence has been steadily increasing over the past decade, especially in men in their 30s and 40s [6]. In addition, the prevalence of cardiovascular disease among men aged >50 years is increasing rapidly [4], probably because men in their 30s and 40s spend most of their time at work and are exposed to increased stress due to heavy workload, lack of exercise, and frequent alcohol consumption [7,8]. Therefore, it is important to improve the awareness and lifestyle of men with MetS in their 30s and 40s to prevent cardiovascular diseases later in life [9].

Workers engage in sedentary behavior most days because of advances in information technology (IT) [10]. Americans spend an average of 7.7 hours a day sitting [11], and Koreans, an average of 7.8 hours [12]. Adults in their 20s and 30s spend 8.5 hours sitting

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[13], and men in their 30s and 40s spend 8.4 hours sitting [14]. Office workers refer to people who sit at an office desk rather than at a factory or construction site and perform tasks such as using a computer [15], and usually sit for long periods of time during working hours [7]. Office workers have higher levels of sedentary behavior and lower levels of physical activity than technical or service workers [14,16]. In particular, male office workers have a higher risk of MetS than those in other occupational groups [17]; therefore, health behavior education is needed for male office workers with sedentary lifestyles.

The program for managing MetS in workers should aim to improve self-care skills, based on motivation, and encourage healthy lifestyles [8]. Lifestyle behaviors, such as smoking cessation, engaging in physical activity, weight loss, and diet management, along with education and counseling, lead to improvements in physical and physiological indicators [7,8,18]. According to self-determination theory, intrinsic motivation is necessary to change unhealthy lifestyles and adopt new healthy behaviors [19], and is promoted when basic psychological needs such as autonomy, competence, and relatedness are satisfied [20]. Many studies on office workers have shown that workers' psychological or physiological indicators improved as a result of as a result of participation in healthy behavior programs that help meet these basic psychological needs and intrinsic motivation [18,21].

In particular, remote education using information and communication technology such as the Internet has been reported to increase the intrinsic motivation of office workers in daily life and at work, leading to improved health conditions such as improved physiological indicators and increased physical activity [22]. Due to social distancing during the coronavirus infections disease (COVID-19) pandemic [23], many office workers have switched to working from home and use of sports facilities has been restricted. As a result, physical activity levels decreased by 58.0% and sitting time increased by 87.0%, resulting in physical health problems [24]. Therefore, in order to promote physical activity in early middle-aged workers with MetS, it is necessary to provide an intervention to practice physical activity every week at work or with colleagues based on strategies that can increase intrinsic motivation [20]. In addition, if a remote physical activity improvement program is developed and its effectiveness is verified by applying it for 12 weeks with proven effectiveness [18,25], it will contribute as an effective remote health management strategy in the workplace even after the COVID-19 pandemic.

The following research hypothesis was established by comparing the degree of difference in research variables before and after the remote educational intervention with the control group. Hypothesis 1, the intervention group will show different degrees of change in basic psychological needs and intrinsic motivation compared to the control group. Hypothesis 2, the intervention group will have different degrees of change in health promotion behaviors, physical activity, and sedentary behavior compared to the control group. Hypothesis 3, the intervention group will have different degrees of change in physical and physiological indicators compared to the control group.

## Methods

### Study design

This study is a randomized control group pretest–posttest design to develop a remote physical activity improvement program and verify its effectiveness.

### Setting and Samples

The participants included in this study were office workers in their 30s and 40s who had MetS and mainly used computers in an information and technology (IT) company with 3,400 employees. The purpose and content of this study were explained to the company's healthcare manager, and a research proposal was submitted to the manager to receive approval for recruitment of participants. From July to August 2021, a recruitment notice was posted on the internal bulletin board to recruit workers interested in the remote physical activity improvement program, and 82 workers expressed their intention to participate in this study. Among them, 78 workers who met the inclusion criteria were finally selected. To ensure the inclusion of workers with MetS, the results of the health checkups of workers in 2020 were reviewed with the consent of the participants and the health management manager. If necessary, the inclusion and exclusion criteria were confirmed through an interview.

The inclusion criteria were male, 30–49 years of age, and office workers who self-reported that they spent more than 70% (five hours) of their working hours in a sedentary position [26]. In addition, those who met three or more of the following five diagnostic criteria for MetS: 1) waist circumference of 90 cm or more [27]; 2) systolic blood pressure  $\geq 130$  mmHg or diastolic blood pressure  $\geq 85$  mmHg, or currently on medication for hypertension; 3) fasting blood glucose  $\geq 100$  mg/dL or currently on diabetes medication; 4) HDL cholesterol level  $< 40$  mg/dL or currently on HDL cholesterol medication; and 5) triglyceride level  $\geq 150$  mg/dL or currently on triglyceride medication [28].

Exclusion criteria include patients with a history of cardiovascular disease (angina pectoris, myocardial infarction, stroke, intracerebral hemorrhage, cerebral infarction, etc.), and those who engaged in at least 150 minutes per week of moderate-intensity physical activity or at least 90 minutes per week of vigorous-intensity physical activity [29] based on the Korean version [30] of the Global Physical Activity Questionnaire (GPAQ) [31].

The G\*Power 3.1 program was used to determine the sample size and for the t-tests, which tests the differences in the means between the two groups. The sample size was calculated at a significance level of .05, a power of .80, and an effect size of .73 [25]; 31 patients were required, assuming a dropout rate of 20.0% [25]. The 78 people who agreed to participate in the study were randomly assigned to an intervention group (IG) and a control group (CG) using Random Allocation Software 2.0, and participants were notified using sealed envelopes to conceal their allocation. The assistants who helped conduct the study were not informed of the participants' assignment results. By random assignment, 39 participants were assigned to the IG and the other 39 participants were assigned to the CG. However, one participant from IG and two participants from CG dropped out due to busy work, and in the end, 38 participants from IG and 37 from CG completed the 12-week program (Figure 1).

### Development of the remote physical activity improvement program

The physical activity improvement program in this study was developed through a literature review, needs analysis, and preliminary research. To learn about workers' needs in advance, data were collected through telephone interviews with seven workers who had MetS but were not research participants. It was confirmed that there was a lack of knowledge about MetS, an increase in sedentary work time due to COVID-19, a lack of time and motivation, and a lack of information and sports facilities. They wanted to

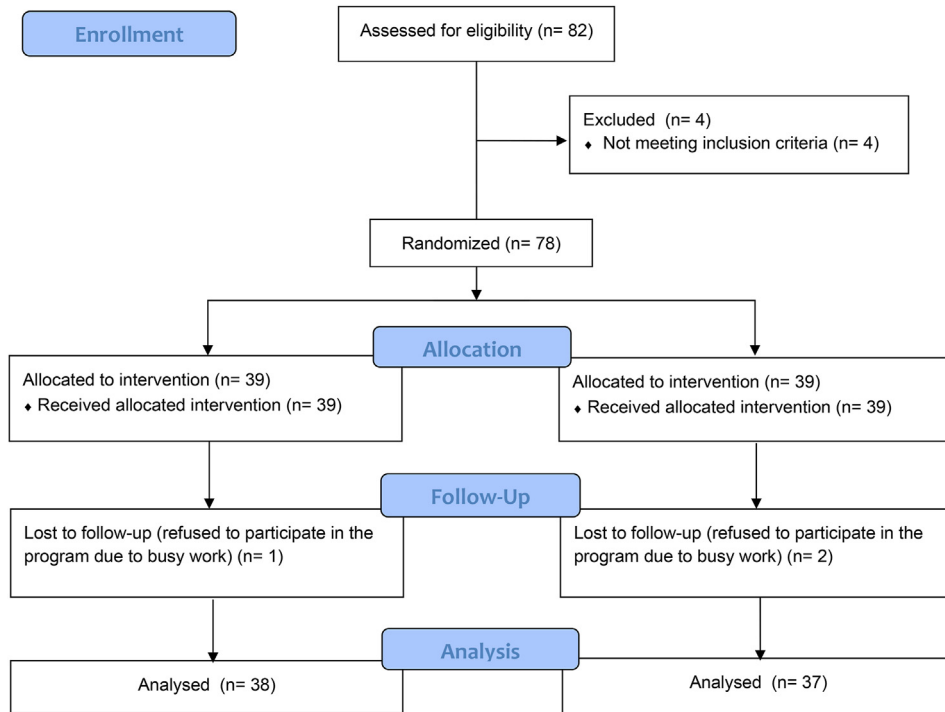


Figure 1. Research Participants Flow Diagram.

receive customized, professional health information and requested online education on weekend afternoons.

When designing the program, we decided to increase intrinsic motivation by satisfying basic psychological needs based on Ryan and Deci’s self-determination theory [20], and included not only group education but also interaction through small group activities with coworkers to ensure autonomy and relatedness (Figure 2). In particular, in the case of exercise training, which is the core of this program, videos and advice from actual exercise experts were provided. Additionally, the researcher provided individualized text messages for daily motivation so that the participants could self-monitor their lifestyle and maintain physical activity.

This program consisted of meetings once a week for 12 weeks in a virtual space through ZOOM. In odd-numbered weeks, health education and exercise training were conducted 6 times, and in even-numbered weeks, small group meetings using the ZOOM breakout room and tailored counseling were provided 6 times (Table 1). According to the attendance rates of the participants, 96.7% participated in health education, 98.3% participated in exercise training, 96.7% participated in small group meetings, 96.7% participated in tailored counseling, and 96.0% participated in self-monitoring their lifestyle.

The validity test for the program was conducted by seven experts, including two nursing professors, a nutritional epidemiology research professor, two cardiovascular nurses, an occupational health nurse, and one physical therapist. To verify the accuracy and suitability of the program, content validity was evaluated on a 4-point Likert scale. Evaluation data were received via e-mail and opinions on program modifications were collected through additional phone calls. Experts rated the programs on a scale from 1 (“the program is very inappropriate and must be deleted”) to 4 (“the program is very appropriate and must be retained”).

The average content validity index was 0.92. Based on expert opinions, we have revised and supplemented the contents of health education by adding easy-to-understand terms and visual materials. The revised and supplemented program underwent face validity testing and preliminary testing with three office workers. A preliminary test was conducted on three male office workers working at the same company and meeting the same selection conditions. They were satisfied that a remote physical activity improvement program conducted at home would motivate them, and preferred KakaoTalk rather than Google Form to record their lifestyle habits. The final program for this study was developed, including preferred meeting times and training completion times.

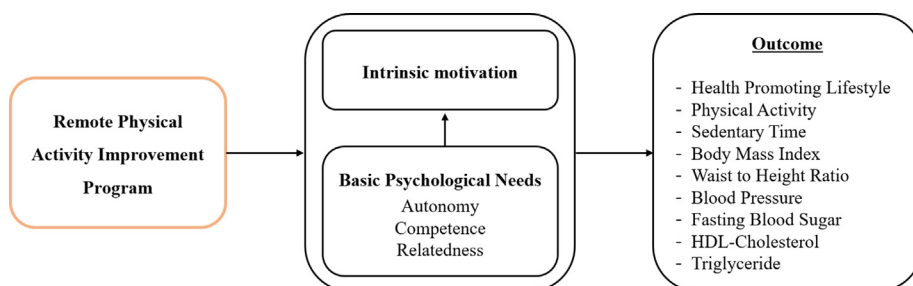


Figure 2. Conceptual Framework of the Intervention.

**Table 1** The Contents of Distance Physical Activity Improvement Program.

Classification	Contents	Strategies for satisfying basic needs	Time	Approach method
Health education	Knowing the MetS - Definition & diagnostic criteria - Relationship between MetS and CVD - Impacts of physical inactivity & sedentary lifestyle on MetS - Importance of MetS management	Autonomy	Every other week (in odd weeks) 6 times (1 h)	Group (ZOOM)
Exercise training	Stretching exercises (10 min), aerobic & strength training (20 min)			
Small group activity	Sharing lifestyle and goals - Participate in small groups using the breakout room function to share your lifestyle and your goals with colleagues	Relatedness	Every other week (in even weeks) 6 times (1 h)	Small group (ZOOM breakout room)
Individual counseling	Reflection and feedback - My physical activity and lifestyle - Encouraging family and friends to participate in the management of MetS	Autonomy Competence Relatedness		Individual (Phone/SNS)
Self-reflection & monitoring	Lifestyle self-monitoring - Steps per day, sedentary time, exercise time, smoking, and drinking	Competence	Daily	Individual (SNS)
Motivational text messages	Send individualized text messages to encourage physical activity	Autonomy		

Note. CVD = cardiovascular disease; MetS = metabolic syndrome; SNS = social networking service.

### Measurements

#### Basic psychological needs

Basic psychological needs were measured using the Korean Basic Psychological Needs Scale [32] adapted by Lee and Park from the Basic Psychological Needs Scale developed by Deci and Ryan [33]. Permission was obtained for the use of this questionnaire from the original author. This consists of 21 items including autonomy, competence, and relatedness [32]. Cronbach's  $\alpha$  was .90 in Deci and Ryan's study [33], .86 in Lee and Park's study [32], and 0.82 in this study.

#### Intrinsic motivation

Intrinsic motivation was measured using the Korean Intrinsic Motivation Tool [34] adapted by Kim and Kim from the Intrinsic Motivation Inventory developed by Deci and Ryan [34]. The original authors approved the use of this questionnaire. This tool consists of 20 items including interest/enjoyment, perceived competence, effort/importance, value/usefulness, pressure/tension, perceived choice, and relationship [34]. Cronbach's  $\alpha$  was .87 in Kim and Kim's study [34] and .93 in this study.

#### Health promotion behavior

Health promotion behavior was measured using the Korean Health Promotion Behavior Tool [35], translated by Hwang, Hong, and Rankin from the Health Promoting Lifestyle Profile II (HPLP II) developed by Walker, Sechrist, and Pender [36]. The original author approved the use of this questionnaire. This tool includes 52 items on health responsibility, physical activity, nutrition, spiritual growth, interpersonal relationships, and stress management [35]. Cronbach's  $\alpha$  was .94 in a previous study [36] and .95 in this study.

#### Physical activity and sedentary behavior indicators

Physical activity and sedentary behavior were measured using the Korean version [30] of the GPAQ [31]. The amount of physical activity was the sum of vigorous-intensity physical activity (8.0 metabolic equivalent of task (MET)  $\times$  min  $\times$  day), moderate physical activity (4.0 MET  $\times$  min  $\times$  day), and transport (4.0 MET  $\times$  min  $\times$  day) [31]. Sedentary behavior was determined by

asking questions about minutes spent sitting or reclining at work/home and getting to and from places, not including sleeping time [30]. The average sitting time per day was recorded separately for working days and holidays.

#### Physical and physiological indicators

Body mass index (BMI) was calculated by dividing the weight (kg) by the square of height (m<sup>2</sup>). Height measurements were taken from the participants' 2020 health checkup results, and a measuring tape was used to measure waist circumference. Then, the waist-to-height ratio (WHtR) was calculated. Blood pressure was measured in the participant's right arm in a sitting position after resting for 5 minutes. Using a portable blood analysis machine (LipidPro), the researcher collected 15–20  $\mu$ L of blood from the fingertips of all participants and performed the test. For measuring fasting blood sugar, HDL-cholesterol, and triglyceride levels, the participants fasted overnight and underwent blood tests in the morning before they had anything to eat.

#### Data collection and procedure

Data collection was carried out for three months, from August to November 2021. Pre-test and orientation meetings were conducted in the health service room at the workplace from August 4–7. The post-test was conducted from October 31 to November 3. To prevent contamination between the two groups, the pre- and post-test data collection periods for the IG and CG participants were different in the morning and afternoon, and no participant was assigned to the IG and CG in the same department. The purpose of the study and program procedure was explained to each participant, and written informed consent was obtained, followed by questionnaire surveys, physical measurements, and blood sampling. This researcher measured all physical and physiological indicators of the IG and CG participants in the workplace health room and collected all questionnaires. For the IG, the remote physical activity improvement program was delivered for 12 weeks, one time per week, for approximately 60 min/day.

The researcher provided health education using Zoom, a video communication platform. In addition, exercise information was provided to the IG participants every other week for approximately

one hour in each class. Exercise training was also provided via Zoom for approximately 30 minutes, where the group observed and followed the exercise specialist's demonstration. By sharing lifestyle records and goals through a small Zoom meeting, bonding and free communication among the study participants were encouraged. Participants received one-on-one counseling from researchers through phone and social networking services (SNS) and had time to explore and reflect on factors that hindered the improvement of their physical activity and lifestyle. The IG participants sent their daily lifestyle habits (number of steps per day, sedentary time, exercise time, smoking, and drinking) to the researcher via SNS. The researcher sent tailored text messages daily to the participants.

The CG participants provided written informed consent to participate in the study, followed by surveys, body measurements, and blood sampling. In addition, the definition of MetS, diagnostic criteria, and management method were briefly explained individually for approximately 10 min, and a health education brochure was provided.

#### Ethical consideration

This study complied with the principles of the Declaration of Helsinki. Participant recruitment was conducted after obtaining approval from the Institutional Review Board regarding the research purpose and methods, participants' rights and procedures (HYU-2021-071-2021-071), and approval of the study by the workplace and health managers. The benefits and risks of participating in the research, safety measures and risks, right to withdraw during the research process, and the right to refuse participation in the research were explained to the participants.

#### Statistical Analysis

The collected data were analyzed using SPSS/WIN 21.0 version (SPSS Inc., Chicago, IL, USA). Only cases with no missing values in the study variables and characteristics were included in the final analysis, and other than the three participants who refused, there was no data to be excluded as missing values. Descriptive statistics were used to analyze the demographic and MetS characteristics, research variables, and physical and physiological indicators of the participants to generate percentages, means, and standard deviations. The Chi-square test and Independent t-test were used to test for homogeneity between the IG and CG.

The normality test for the difference between pre and post in the IG and CG data was analyzed using the Shapiro-Wilk test. As a result, the  $p$  value for the triglyceride variable was greater than 0.05, so the null hypothesis of normal distribution was adopted. However, for all other variables, the  $p$  value was lower than 0.05, so normality was not satisfied. Therefore, to verify the research hypothesis, the parametric Mann–Whitney U test, and the independent t-test were used to compare the means of the two groups for the pre-post difference values of the study variables. The statistical significance level was set at  $p < .05$ .

## Results

#### Homogeneity test of participants' characteristics

The average age of the participants was  $39.3 \pm 3.8$  years in the IG and  $40.6 \pm 4.0$  years in the CG; 30.8% of the participants in the IG and 38.5% in the CG were smokers, and 61.5% each in the IG and CGs were drinkers. Regarding family history, 43.6% of the IG and 33.3% of the CG had hypertension, 30.8% of the IG and 17.9% of the CG had diabetes, 12.8% of the IG and 5.1% of the CG had ischemic heart

disease, and 5.1% of the CG had a history of stroke. There were no statistically significant differences between the two groups in terms of demographic characteristics, physiological indicators, and major research variables; thus, homogeneity was ensured (Table 2).

#### Verification of the effects of remote physical activity improvement program

The difference in the basic psychological needs scores before and after intervention was  $0.39 \pm 0.94$  points in the IG and  $0.01 \pm 0.12$  points in the CG; with a statistically significant difference between the two groups ( $p < .001$ ). The changes in autonomy ( $p < .001$ ), competence ( $p < .001$ ), and relatedness ( $p < .001$ ) were significantly different between the two groups. The change in intrinsic motivation level was significantly different between the two groups ( $p < .001$ ) (Table 3).

There was a statistically significant difference in the level of change in health promotion behavior between the two groups ( $p < .001$ ). The change in the level of physical activity was  $630.00 \pm 326.02$  MET-min/week in the IG, and  $34.60 \pm 130.01$  MET-min/week in the CG; with a significant difference ( $p < .001$ ). The change in the sitting time on a working day was  $-1.71 \pm 0.96$  hours in the IG, and  $-0.38 \pm 1.32$  hours in the CG; with a significant difference ( $p < .001$ ). The change in holiday sedentary time was  $-3.42 \pm 1.70$  hours in the IG, and  $-0.35 \pm 0.92$  hours in the CG; with a significant difference ( $p < .001$ ) (Table 3).

Changes in BMI and WHtR were significantly different between the IG and CG ( $p < .001$ ). The change in systolic blood pressure also showed a statistically significant difference between the IG and the CG ( $p < .001$ ). The change in fasting blood glucose level was  $-4.50 \pm 5.53$  mg/dL in the IG and  $1.22 \pm 3.12$  mg/dL in the CG, with a significant difference ( $p < .001$ ). The change in the level of HDL cholesterol was  $3.92 \pm 4.73$  mg/dL in the IG, and  $1.27 \pm 5.69$  mg/dL in the CG; with a significant difference ( $p < .001$ ) (Table 4).

## Discussion

In this study, improvement of intrinsic motivation by satisfaction of basic psychological needs was used as a strategy to induce behavioral change in male office workers with MetS based on self-determination theory [20]. Reviewing the literature suggesting strategies to promote basic psychological needs [18,25] and studies showing that autonomy was not important [25], this study emphasized appropriate goal setting, lifestyle monitoring, and positive feedback. Referring to a previous research that found relationships were not important [18], strategies for improving relationships included utilizing ZOOM's small meeting room function and KakaoTalk to improve communication between managers and participants.

After completing the intervention, the scores for basic psychological needs in the IG showed significant improvements compared to those in the CG. The basic psychological needs of autonomy, competence, and relatedness scores also improved, supporting the results of previous research [18]. The improvement in relevance scores supports the results of a previous study that conducted group discussions to allow participants to share their feelings [25]. However, this result is contrary to the finding that physical activity alone, such as walking or jogging, does not have a significant effect on the improvement of relatedness with others [18], as this study was conducted when social distancing was reinforced and the outbreak of COVID-19 was the most severe. Although it was conducted in a virtual space, they shared their feelings and engaged in free communication about lifestyle problems in a small group

**Table 2** Homogeneity test of Participants' Characteristics (N = 78).

Characteristics/variables	Category	Intervention group (n = 39)	Control group (n = 39)	$\chi^2$ or t	p
		n (%) or M $\pm$ SD	n (%) or M $\pm$ SD		
Age (yr)		39.3 $\pm$ 3.8	40.6 $\pm$ 3.9	-1.46	.148
Education	$\leq$ High school	3(7.7)	4(10.3)	0.19	.711
	$\geq$ College	36(92.3)	35(89.7)		
Marital status	Married	21(53.9)	22(56.4)	0.13	.818
	Single	18(46.1)	17(43.6)		
Smoking	Never	16(41.0)	15(38.5)	0.39	.877
	Ex-smoker	11(28.2)	9(23.0)		
	Current smoker	12(30.8)	15(38.5)		
Drinking	Never	8(20.5)	6(15.4)	0.55	.769
	Ex-drinker	7(18.0)	9(23.1)		
	Current drinker	24(61.5)	24(61.5)		
Family history <sup>a</sup>	Hypertension	17(43.6)	13(33.3)	0.72	.482
	Diabetes mellitus	12(30.8)	7(17.9)	1.59	.289
	Ischemic heart disease	5(12.8)	2(5.1)	1.33	.430
	Cerebrovascular disease	0(0.0)	2(5.1)	2.11	.240
Basic psychological needs		2.81 $\pm$ 0.33	2.88 $\pm$ 0.37	-0.91	.364
Intrinsic motivation		4.08 $\pm$ 1.00	4.04 $\pm$ 0.94	0.2	.846
Health promoting lifestyle profile II		2.11 $\pm$ 0.40	2.15 $\pm$ 0.43	-0.35	.729
Body mass index (kg/m <sup>2</sup> )		28.15 $\pm$ 2.68	27.88 $\pm$ 3.02	0.41	.681
Waist-to-height ratio		0.54 $\pm$ 0.44	0.54 $\pm$ 0.35	-0.49	.623
Systolic blood pressure (mmHg)		129.11 $\pm$ 12.54	127.92 $\pm$ 9.88	0.45	.651
Diastolic blood pressure (mmHg)		89.16 $\pm$ 11.39	87.57 $\pm$ 8.59	0.68	.498
Fasting blood sugar (mg/dL)		100.87 $\pm$ 13.01	99.11 $\pm$ 8.60	0.69	.493
High density lipoprotein cholesterol (mg/dL)		38.84 $\pm$ 8.29	37.62 $\pm$ 8.85	0.62	.539
Triglycerides (mg/dL)		294.50 $\pm$ 139.69	290.59 $\pm$ 115.90	0.13	.896
Basic psychological needs		2.81 $\pm$ 0.33	2.88 $\pm$ 0.37	-0.91	.364
Intrinsic motivation		4.08 $\pm$ 1.00	4.04 $\pm$ 0.94	0.20	.846
Health promoting lifestyle profile II;		2.11 $\pm$ 0.40	2.15 $\pm$ 0.43	-0.35	.729

Note. M = mean; SD = standard deviation.

<sup>a</sup> Multiple response.

**Table 3** Differences in Changes of Study Variables at Pre-test and Post-test (N = 75).

Variables	Group	Pre-test	Post-test	Difference (Post-Pre)	Z	p <sup>a</sup>
		M $\pm$ SD	M $\pm$ SD	M $\pm$ SD		
Basic psychological needs	IG (n = 38)	2.81 $\pm$ 0.33	3.20 $\pm$ 0.29	0.39 $\pm$ 0.94	-7.55	<.001
	CG (n = 37)	2.88 $\pm$ 0.37	2.89 $\pm$ 0.36	0.01 $\pm$ 0.12		
Autonomy	IG (n = 38)	2.99 $\pm$ 0.37	3.42 $\pm$ 0.33	0.43 $\pm$ 0.21	-7.94	<.001
	CG (n = 37)	3.01 $\pm$ 0.44	3.00 $\pm$ 0.43	-0.01 $\pm$ 0.05		
Competence	IG (n = 38)	2.55 $\pm$ 0.35	2.93 $\pm$ 0.36	0.38 $\pm$ 0.17	-6.92	<.001
	CG (n = 37)	2.65 $\pm$ 0.34	2.67 $\pm$ 0.31	0.01 $\pm$ 0.25		
Relatedness	IG (n = 38)	2.85 $\pm$ 0.44	3.20 $\pm$ 0.46	0.35 $\pm$ 0.05	-6.20	<.001
	CG (n = 37)	2.95 $\pm$ 0.48	2.97 $\pm$ 0.47	0.02 $\pm$ 0.23		
Intrinsic motivation	IG (n = 38)	4.08 $\pm$ 1.00	4.79 $\pm$ 0.65	0.71 $\pm$ 0.59	-6.94	<.001
	CG (n = 37)	4.04 $\pm$ 0.94	4.02 $\pm$ 0.96	-0.02 $\pm$ 0.14		
Health promotion behavior	IG (n = 38)	2.11 $\pm$ 0.40	2.35 $\pm$ 0.35	0.24 $\pm$ 0.89	-6.63	<.001
	CG (n = 37)	2.15 $\pm$ 0.43	2.17 $\pm$ 0.39	0.02 $\pm$ 0.80		
Physical activity (MET-min/wk)	IG (n = 38)	533.16 $\pm$ 230.73	1163.16 $\pm$ 417.50	630.00 $\pm$ 326.02	-7.41	<.001
	CG (n = 37)	506.49 $\pm$ 206.99	541.08 $\pm$ 225.88	34.60 $\pm$ 130.01		
Sedentary behavior/workday (hr/day)	IG (n = 38)	12.39 $\pm$ 1.22	10.68 $\pm$ 1.51	-1.71 $\pm$ 0.96	-4.25	<.001
	CG (n = 37)	11.89 $\pm$ 1.29	11.51 $\pm$ 1.88	-0.38 $\pm$ 1.32		
Sedentary behavior/holiday (hr/day)	IG (n = 38)	13.89 $\pm$ 2.26	10.47 $\pm$ 2.22	-3.42 $\pm$ 1.70	-6.66	<.001
	CG (n = 37)	13.95 $\pm$ 1.20	13.59 $\pm$ 1.44	-0.35 $\pm$ 0.92		

Note. CG = control; IG = intervention; M = mean; MET = metabolic equivalent; SD = standard deviation.

<sup>a</sup> Mann-Whitney U test.

meeting. It is believed that this increased their sense of belonging and relationship.

The level of intrinsic motivation also increased significantly in the IG group compared with that in the CG. Since intrinsic motivation is promoted when basic psychological needs are satisfied [20], it appears that intrinsic motivation was improved through this program by satisfying the participants' basic psychological needs. This result was consistent with the results of a smartphone game-based study [37] and a web-based intervention study [34].

The health promotion behavior score was significantly higher in the IG than that in the CG. This result is in line with the results of a study that found an improvement in health-promotion behavior

after the application of an in-person education and aerobic exercise program [38]. To continue health-promoting behaviors, intrinsic motivation is required [20]. The program in this study included strategies to satisfy basic psychological needs and strengthen the intrinsic motivation of the participants. Counseling, self-monitoring, and behavioral goal setting eventually helped the subjects to continue their healthy behavior [18].

The amount of physical activity in the IG increased from 533 to 1163 MET-min/week, showing a significant improvement compared to that in the CG. This result is in line with the results of previous studies, where the number of daily steps and moderate-to-vigorous physical activity levels in a group of workers



**Table 4** Differences in Changes of Physical and Physiological Variables at Pre-test and Post-test (N = 75).

Characteristics	Group	Pre-test	Post-test	Difference (Post-Pre)	Z or t	p
		M ± SD	M ± SD	M ± SD		
Body mass index (kg/m <sup>2</sup> )	IG (n = 38)	28.15 ± 2.68	26.74 ± 2.60	-1.42 ± 1.15	-6.67	<.001 <sup>a</sup>
	CG (n = 37)	27.88 ± 3.02	27.84 ± 2.81	-0.04 ± 0.42		
Waist-to-height ratio	IG (n = 38)	0.54 ± 0.44	0.52 ± 0.36	-0.01 ± 0.01	-5.63	<.001 <sup>a</sup>
	CG (n = 37)	0.54 ± 0.35	0.54 ± 0.36	-0.00 ± 0.01		
Systolic blood pressure (mmHg)	IG (n = 38)	129.11 ± 12.54	123.87 ± 6.52	-5.24 ± 7.41	-4.04	<.001 <sup>a</sup>
	CG (n = 37)	127.92 ± 9.88	129.70 ± 9.66	1.78 ± 3.04		
Diastolic blood pressure (mmHg)	IG (n = 38)	89.16 ± 11.39	88.29 ± 6.66	-0.87 ± 8.23	-0.59	0.558 <sup>a</sup>
	CG (n = 37)	87.57 ± 8.59	88.57 ± 8.25	1.00 ± 3.67		
Fasting blood sugar (mg/dL)	IG (n = 38)	100.87 ± 13.01	96.37 ± 9.18	-4.50 ± 5.53	-5.47	<.001 <sup>a</sup>
	CG (n = 37)	99.11 ± 8.60	100.32 ± 8.65	1.22 ± 3.12		
High density lipoprotein cholesterol (mg/dL)	IG (n = 38)	38.84 ± 8.29	42.76 ± 5.58	3.92 ± 4.73	-3.40	<.001 <sup>a</sup>
	CG (n = 37)	37.62 ± 8.85	38.89 ± 8.71	1.27 ± 5.69		
Triglycerides (mg/dL)	IG (n = 38)	294.50 ± 139.69	246.47 ± 123.48	-48.03 ± 68.81	-1.87	.067 <sup>b</sup>
	CG (n = 37)	290.59 ± 115.90	298.22 ± 124.64	7.62 ± 167.59		

Note. CG = control; IG = intervention; M = mean; SD = standard deviation.

<sup>a</sup> Mann–Whitney U test.

<sup>b</sup> Independent t-test.

increased [18], as did the amount of physical activity [39] after the completion of a physical activity improvement program. It is necessary to verify the effectiveness of the remote physical activity improvement program developed in this study as an intervention for workers in various occupational groups who cannot exercise because of time and location constraints. In the IG, the daily sedentary time on working days decreased from 12.4 hours to 10.7 hours, and the daily sitting time on holidays decreased from 13.9 hours to 10.5 hours. This result supports the results of a Cochrane review [40] in which sedentary working time was reduced by approximately 100 minutes when an integrated intervention for reducing sedentary behavior was applied. In our study, health education and personalized texting helped reduce sedentary time by facilitating intrinsic motivation and helping participants to understand the risks of sedentary behavior when working from home during the coronavirus pandemic.

Regarding physical indicators, there were significant changes in BMI and WHtR in the IG compared to those in the CG. Similarly, in a study by Lin et al [21], the weight and waist circumference of the IG were significantly reduced. In contrast, in Kang and Hwang's study, neither BMI nor abdominal circumference showed a significant change [41]. The study by Lin et al included office workers who sat for more than six hours a day [21], while the present study included office workers who sat for more than five hours a day, demonstrating similarity in the study participants. The participants in Kang and Hwang's study were office workers with one or more cardiovascular risk factors [41]; however, in the present study, the participants were office workers with MetS. Therefore, even if the same 12-week intervention were applied, the results would be different because of the different baseline characteristics of the study participants.

There were significant changes in systolic blood pressure, fasting blood sugar, and HDL cholesterol levels, but not in diastolic blood pressure and triglyceride levels, between the groups. This is similar to the findings of Mouodi et al, in which significant changes in physiological parameters were observed after the application of an email intervention recommending stair climbing for ten weeks [38]. However, this is contrary to a previous study that found no significant change in systolic or diastolic blood pressure after 16 weeks of education and aerobic exercise face-to-face [22].

The strength of this study is that by applying a remote physical activity improvement program without time and space constraints in the COVID-19 situation, subjective and objective indicators were improved through satisfying the psychological needs and intrinsic motivation of office workers with MetS who had sedentary

lifestyles. Confirming the effectiveness of remote education in promoting cardiovascular disease prevention awareness and physical activity among office workers with MetS provided the basis for remote education as an educational intervention strategy for workplace healthcare providers to manage MetS. In the future, we propose a follow-up study that extends the research period to verify the effectiveness of remote education and compares the effectiveness with on-site education.

#### Limitations of This Study

First, the results of this study cannot be generalized to all male office workers because it targeted workers in one IT workplace with a high academic background. Second, because the researcher directly applied the intervention to the IG, double-blinding was not ensured, and the possibility of Hawthorne's effect could not be excluded. Third, sedentary time and physical activity were not objective indicators, and we collected data using self-reporting questionnaires. Fourth, since the intervention was performed in the context of COVID-19, it is possible that the participants improved their physical activity and sedentary lifestyle by focusing more on remote health education. Hence, there are limitations in the generalizability of the results of this study.

#### Conclusions

In this study, health education and counseling provided remotely via ZOOM for 12 weeks increased the amount of physical activity through satisfaction of basic psychological needs and intrinsic motivation of sedentary workers with MetS in their 30s and 40s, which improved physical and physiological indicators. This study has significance in improving clinical indicators at a younger age and in the MetS stage for the prevention of cardiovascular disease, which is highly prevalent in middle-aged men. In addition, by confirming the effectiveness of remote health education without time and space constraints, it provided grounds for use as a non-face-to-face health education program in the workplace. In order to establish a strong evidence for the use of non-face-to-face programs, further research is needed to verify their effectiveness after the COVID-19 pandemic.

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## Conflict of interest

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

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## Research Article

# Relationship Between Mindfulness and Affiliate Stigma in Parents of Children with Autism Spectrum Disorder in China: The Mediating Role of Coping Styles

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## ABSTRACT

**Purpose:** This study aims to investigate the current status of affiliate stigma among parents of autistic children, analyze the influencing factors, explore the relationship among mindfulness, coping styles, and affiliate stigma, and verify the mediating role of coping styles between mindfulness and affiliate stigma in parents of children with autism in China.

**Method:** Between February and April 2023, the Child Development Behaviour Centre of a public hospital in China recruited 345 parents of children with autism. These parents completed the general information questionnaire, the Mindful Attention Awareness Scale, the Affiliate Stigma Scale, and the Simple Coping Style Questionnaire. We then adapted the Hayes Process Macro and Bootstrap methods to examine the mediating effects of coping styles between mindfulness and affiliate stigma.

**Results:** (1) The total affiliate stigma score of parents of children with autism was 48.53 (standard deviation: 10.74). Parents' age, monthly family income, duration of care, mindfulness, and coping styles were the influencing factors of parental affiliate stigma. (2) Mindfulness was positively correlated with positive coping style ( $r = 0.33, p < .01$ ) and negatively correlated with negative coping style, affiliate stigma ( $r = -0.38, -0.39, p < .01$ ), whereas affiliate stigma was negatively correlated with positive coping style ( $r = -0.34, p < .01$ ) and positively correlated with negative coping style ( $r = 0.41, p < .01$ ). (3) Positive coping style and negative coping style play a parallel mediating role between mindfulness and affiliate stigma of parents of autistic children.

**Conclusions:** Parents of children with autism experience significant levels of affiliate stigma. Mindfulness has a direct impact on associated stigma in parents of children with autism and also indirectly predicts associated stigma through the intermediary influence of positive and negative coping styles. Healthcare professionals could perform mindfulness interventions from an optimistic psychology viewpoint to boost parents' mindfulness and coping abilities, thereby accomplishing the objective of mitigating affiliate stigma.

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## Introduction

The neurodevelopmental disease known as autism spectrum disorder (ASD) is a set of conditions that start in early childhood and are typified by repeated stereotyped behaviors, limited interests, and difficulties with social communication [1]. About 1.0% to 2.0% of people have autism, and the lifelong disability rate is between 58.0% and 78.0% [2,3], with the percentage rising [4]. These statistics make autism a public health issue of international

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significance. Children with autism require lifelong rehabilitation training due to the unidentified etiology of the condition and the absence of efficacious treatment medications. Families are under pressure about energy and financial resources, as well as the psychological effects on parents. Parents should not be ignored as the foremost bearers of the child's daily life care tasks because their healthy physical and mental conditions and positive coping styles can effectively promote the child's recovery process [5].

The term "stigma" was initially used to describe the stigmatization of criminals, enslaved individuals, and other groups that resulted in their social exclusion or isolation [6]. "Stigma" is defined by Goffman as "a characteristic that greatly tarnishes someone's reputation." Because of their intimate social ties to the patient, family caregivers frequently face prejudice and discrimination, according to Goffman [7], who labeled this stigma as "Affiliate stigma." Parental affiliate stigma in children with autism refers to the negative emotional experiences and cognitive biases that arise when parents do not suffer from the disease themselves and their social functioning is relatively intact. However, in the course of their interactions with their child, they internalize the discrimination and prejudice from the outside world with which they psychologically identify. The absence of physical disability and distinct phenotypic features make autism an invisible form of disability, abnormal behaviors are seen as the result of poor parenting, and adverse reactions and attitudes from others make parents feel socially isolated and excluded [8]. Parents of children with ASD experience higher levels of affiliate stigma than parents of children with other physical or mental health disorders [9]. This can lead to a decrease in healthcare-seeking behaviors, which delays the diagnosis and treatment of ASD children [10], reduces the children's involvement in community activities and social interactions [11], and causes parents to experience a range of negative emotions [12] and even suicidal thoughts [13], all of which can worsen the functioning and environment of the family and make it even less favorable for the child's recovery. Strategies to assist parents in developing resistance to stigma are essential, given the negative consequences of affiliate stigma on parental self-perception and emotional well-being, as well as on the rehabilitation of affected children. According to Chan's theoretical model of stigma resistance [14], one potential way to protect stigmatized individuals from stigma-related harm is to cultivate mindfulness. Mindfulness has been linked to fewer emotional symptoms and mental health issues, according to earlier cross-sectional correlational research [15]. Further evidence from intervention research has shown that mindfulness improves coping strategies and stigma resistance across various stigmatized populations [16]. It is unclear, nevertheless, exactly how mindfulness impacts parental affiliate stigma in children with autism.

As "awareness that arises from intentional, non-judgmental attention to the present moment," mindfulness is defined as follows [17]. Through particular techniques, people can increase their degree of mindfulness. Positive adjustments in a person's self-emotional regulation, value restructuring, cognitive-behavioral flexibility, and self-expression are referred to as the psychological mechanisms of mindfulness. People can deal with unpleasant life experiences openly and in an acceptable manner by "decentering" and concentrating on the here and now without passing judgment [18]. By revealing negative emotions or changing the original thinking mode, individuals can re-examine the existing values from a more open perspective, and then choose a more flexible cognitive behavior way to cope with external challenges and improve the adverse stress response [19]. Situational elements, the external environment, and individual cognitive characteristics impact coping styles when dealing with stressful circumstances [20]. Previous studies have demonstrated that an individual's choice of positive

coping style is influenced by their mindfulness level [21]. Additionally, there might be a relationship between parental coping styles and the level of mindfulness that parents of autistic children exhibit throughout their child's diagnosis, course of treatment, and long-term recovery. The term "coping style" refers to an adaptive mechanism that describes how people think and act under stress or frustration [22]. Research indicates that parents of children with ASD are less likely to use positive coping styles "solving problems and asking for help" and more likely to use negative coping styles "fantasizing, avoiding, and blaming" when it comes to their children with ASD [23]. Coping styles are intermediate factors between life events and stress reactions that affect patients' psychological stress response and well-being [24]. Previous studies have shown that negative coping styles are significantly negatively correlated with parental affiliate stigma in children with autism [25]. Negative coping styles have the potential to lessen stress-related discomfort momentarily. However, it can also heighten the chance of mental symptoms such as interpersonal sensitivity and obsessive-compulsive states, as well as enhance affiliate stigma and hinder parents' ability to think clearly and act appropriately [26].

Stress and coping theory suggests that the ability to produce stress after a stressor has acted on an individual depends on two main processes: cognitive appraisal and coping [22]. Mindfulness moderates cognition, which can reconfigure cognitive appraisal and help parents adopt more positive coping styles to deal with problems, thereby reducing the production of affiliate stigma [27]. Stress and coping theory classify relevant variables into antecedent, moderating, and outcome variables. Individual characteristics and environmental factors serve as variables that influence outcomes through the mediating role of cognitive appraisals and coping styles. Outcome measures represent the final level of adaptation to stress. Based on the aforementioned theoretical and practical implications, the present study investigated the relationship between mindfulness, coping styles, and affiliate stigma among parents of children with autism, using mindfulness as the prevariable, coping styles as the moderating variables, and affiliate stigma as the outcome variable of stress and coping theory (Supplementary Figure 1). We propose two hypotheses.

- H1: Mindfulness is negatively associated with affiliate stigma.
- H2: Coping styles mediate the correlation between mindfulness and affiliate stigma.

## Methods

### Study design

A correlational and cross-sectional study design was used to explore the mediating role of parental coping styles in the relationship between mindfulness and affiliate stigma in children with autism.

### Participants and data collection

We recruited 345 parents of children diagnosed with ASD from February to April 2023 at the Child Developmental Behavior Center of a prominent public hospital in Zhengzhou, Henan Province, China. The hospital manager initially conveyed the questionnaire to the assigned survey leader at the Child Developmental Behavior Center, who directed, guided, and oversaw the parents of children with ASD in the department, completing the online questionnaire in person.

Inclusion criteria: (1) a precise diagnosis of ASD consistent with the American Diagnostic and Statistical Manual of Mental Disorders

(5th Edition) was required [28]; (2) the parents had to have no history of major physical diseases, cognitive disorders, or mental illnesses and be able to complete the questionnaire survey; (3) parents had to have lived with the child for at least one year, undertaken the main care tasks, and provided care for the child for a minimum of eight hours per day; and (4) informed consent and voluntary participation.

Exclusion criteria: (1) Children with other malignant tumors, organic diseases, or those in unstable or critical condition, are excluded. (2) Patients with significant physical or mental illnesses in their family, such as dementia or cancer, are also excluded. (3) Other significant adverse events occurred within the family over the past six months.

**Ethical considerations:** This study was approved by the Ethics Committee of the Zhengzhou university (Approval number: ZZUIRB2023-22). All parents gave written informed consent before taking part in the study. In accordance with the principles of voluntary participation, anonymity, and confidentiality, our research will ensure the protection of participants' privacy.

## Measures

### Demographics

A comprehensive data questionnaire was administered to collect demographic and clinical characteristics of ASD children and their parents, including age, duration of disease, and duration of treatment/rehabilitation training. Additionally, the questionnaire also gathered information on how long the parents had cared for them and whether they had received psychotherapy.

### Mindfulness

Mindfulness was measured using the Mindful Attention Awareness Scale developed by Brown and Ryan [29], with a total of 15 items, involving the cognitive, emotional, physiological, and other aspects of the individual in daily life. Likert 6 scale was used, and the total score was 15–90 points, with 66–90 points indicating a high level, 41–65 points indicating a medium level, and 15–40 points indicating a low level. The higher the score, the lower the frequency of the situation described by the item, reflecting that the individual has a higher awareness and attention to the present in daily life. The Cronbach's  $\alpha$  coefficient of the original scale was .89. The total Mindful Attention Awareness Scale was also found to be at an acceptable level of reliability in our study (Cronbach's  $\alpha = .94$ ).

### Coping style

Based on a coping style questionnaire compiled by Folkman and Lazarus [30], Jie Yaning designed the Simplified Coping Style Questionnaire in combination with the characteristics of Chinese culture [31], including 20 items in 2 dimensions of positive coping (12 items) and negative coping (8 items), and used Liker grade 4 scale. The total score of positive coping was 0–36. The total score of negative coping style ranged from 0 to 24, and the difference between the scores of positive and negative coping dimensions determined the individual's coping tendency in the face of setbacks. If the result was more significant than zero, the individual tended to have a positive coping style, and vice versa, otherwise, the individual tended to have a negative coping style. The Cronbach's  $\alpha$  coefficients of positive and negative coping dimensions were .89 and .78, respectively; in our research, they were .92 and .89, respectively.

### Affiliate stigma

Mak et al. developed the Affiliate Stigma Scale (ASS) to measure affiliate stigma in caregivers of individuals with mental illness and validated it for caregivers of autistic children [32]. Yin Qunming

et al. [33]culturally adapted the ASS to 1625 parents of children with ASD in mainland China in 2021. The revised Chinese version of the ASS contained 18 entries in 4 dimensions, namely, negative emotional perceptions (8 entries), social worry avoidance (5 entries), alienation from stigmatized persons (3 entries), and discrimination experiences (2 entries). The revised Chinese version of the ASS consists of 18 items in 4 dimensions (8 items), with a total score of 18–72 on a Likert 4 scale. The mean score of the items is the scale score, with higher scores indicating higher levels of affiliate stigma. The Cronbach's  $\alpha$  coefficient of the original scale was .88; in our study, it was .91.

## Statistical analysis

All statistical analyses were performed using the Statistical Package for Social Sciences (IBM SPSS Statistics) for Windows version 25.0 (IBM Corporation, Armonk, NY, USA). We used frequency and percentage to analyze participants' categorical demographic characteristics; we used mean and standard deviation (SD) to characterize the interval/ratio demographic characteristics and main variables. The study used the independent sample t-test, one-way ANOVA, and multivariate analysis to investigate the variations in affiliate stigma scores across parents with varying demographic characteristics. Pearson correlation analysis examined the bivariate relationships among mindfulness, coping styles, and affiliate stigma. Hayes Process 4.1 Macro Program with SPSS and the Bootstrap method was used to test the mediating role of coping styles between mindfulness and affiliate stigma [34]. The statistical significance of the correlation and effects was evaluated by generating a 95% bias-corrected confidence interval from 5000 resamples using the bias-corrected bootstrapping method. After bias correction, we determined a significant mediation effect when excluding zero in the 95% bootstrap confidence intervals. The value of 0.05 was accepted as a statistical significance level.

## Results

### Common method biases

Harman's single-factor test was conducted on all measurement items in this study before data analysis, extracting seven common factors with eigenvalues  $>1$ . The first common factor had an extraction variance of 26.2%, 40.0% lower than the critical value, indicating the absence of any common method bias within the research data.

### Description variables, including mindfulness, coping styles, and affiliate stigma

Parents of autistic children have a total score of mindfulness level 51.11 (SD: 20.05), and the average score of items was 3.41 (SD: 1.34). The total score of positive coping style was 14.94 (SD: 9.38), negative coping styles was 15.62 (SD: 5.77). The total score of affiliate stigma was 48.53 (SD: 10.74), the average score of items was 2.70 (SD: 0.60), the dimension of the negative emotion cognitive, the social anxiety avoidance, the alienate the stigmatized and the discriminatory experience was respectively 23.17 (SD: 5.11), 13.34 (SD: 3.93), 7.22 (SD: 3.10), and 4.81 (SD: 1.68).

### Sociodemographic characteristics and their influence on affiliate stigma

Independent samples t-test or one-way ANOVA was conducted with the general information of parents of children with autism as the independent variable and the affiliate stigma score as the

dependent variable. The results showed statistically significant differences between parents' age, monthly family income, and length of caregiving in the affiliate stigma score ( $p < .05$ ). Details are shown in Table 1.

**Table 1** Sociodemographic Characteristics and their Influence on Affiliate Stigma (N = 345).

Variables	n (%)	ASS		
		Mean ± SD	F or t	p
Gender of child			-1.79	.074
Men	174 (50.4)	2.75 ± 0.60		
Women	171 (49.6)	2.64 ± 0.59		
Child age (years)			0.15	.857
≤3	133 (38.5)	2.68 ± 0.55		
3 ~ 6	114 (33.0)	2.72 ± 0.66		
7 ~ 14	98 (28.5)	2.68 ± 0.59		
Duration of disease (years)			0.21	.809
≤1	203 (58.8)	2.68 ± 0.61		
1–3	64 (18.6)	2.69 ± 0.58		
>3	78 (22.6)	2.74 ± 0.59		
Duration of treatment/rehabilitation training			0.12	.947
0 to 6 months	143 (41.5)	2.72 ± 0.62		
7 months to less than 1 year	116 (33.6)	2.68 ± 0.58		
1 year to less than 2 years	36 (10.4)	2.68 ± 0.60		
At least 2 years	50 (14.5)	2.68 ± 0.59		
Attendance			0.82	.443
Ordinary school	72 (20.9)	2.78 ± 0.62		
Special schools/rehabilitation institutions	223 (64.6)	2.67 ± 0.60		
Homeschooling	50 (14.5)	2.69 ± 0.58		
Whether they are only children or not			-1.32	.189
Yes	95 (27.5)	2.77 ± 0.63		
No	250 (72.5)	2.67 ± 0.58		
Age of parents (years)			4.22	.016*
≤30	115 (33.3)	2.83 ± 0.64		
31 ~ 40	201 (58.3)	2.64 ± 0.48		
≥41	29 (8.4)	2.61 ± 0.96		
Relationship with child			-1.24	.217
Mother	173 (50.2)	2.66 ± 0.62		
Father	172 (49.8)	2.74 ± 0.57		
Nation			0.42	.672
The Han nationality	302 (87.5)	2.70 ± 0.59		
Minority nationality	43 (12.5)	2.66 ± 0.62		
Religious belief			-1.56	.12
Yes	82 (23.8)	2.79 ± 0.53		
No	263 (76.2)	2.67 ± 0.61		
Parents' level of education			0.25	.862
Junior high school and below	87 (25.2)	2.72 ± 0.60		
High school and technical secondary school	137 (39.7)	2.66 ± 0.61		
College and undergraduate	115 (33.3)	2.72 ± 0.58		
Master's degree or above	6 (1.8)	2.78 ± 0.51		
Marital status			-0.38	.702
Married	336 (97.4)	2.69 ± 0.60		
Divorced/widowed/other	9 (2.6)	2.77 ± 0.48		
Monthly household income (yuan)			5.84	<.001**
≤2999	62 (18.0)	2.96 ± 0.65		
3000 ~ 4999	86 (24.9)	2.57 ± 0.53		
5000 ~ 6999	121 (35.1)	2.69 ± 0.57		
≥7000	76 (22.0)	2.64 ± 0.61		
Duration of care			14.35	<.001**
Less than 1 year	58 (16.8)	2.56 ± 0.59		
1 year to less than 2 years	145 (42.1)	2.60 ± 0.56		
2 years to less than 3 years	66 (19.1)	2.67 ± 0.52		
3 years and above	76 (22.0)	3.06 ± 0.56		
Whether received psychotherapy			-0.48	.635
Yes	154 (44.6)	2.68 ± 0.63		
No	191 (55.4)	2.71 ± 0.57		

Note. ASS= The Affiliate Stigma Scale; SD = standard deviation; \* $p < .05$ , \*\* $p < .001$ .

*Pearson correlation between mindfulness, coping style and affiliate stigma*

Table 2 illustrates that mindfulness was positively correlated with positive coping style ( $r = .33, p < .01$ ) and negatively correlated with negative coping style, affiliate stigma ( $r = -.38, -.39, p < .01$ ), whereas affiliate stigma was negatively correlated with positive coping style ( $r = -.34, p < .01$ ) and positively correlated with negative coping style( $r = .41, p < .01$ ).

*Multiple stepwise regression analysis of affiliate stigma*

Multiple linear regression analyses were conducted using variables with statistically significant differences in univariate analyses, the scores of mindfulness and coping styles as independent variables, and the scores of parental affiliate stigma of children with autism as dependent variables. The results showed that parental age, monthly family income, caregiving hours, mindfulness, and coping styles were the factors influencing parental affiliate stigma in children with autism in Table 3.

*Mediating role of coping styles in the relationship between mindfulness and affiliate stigma*

The mediating effect of coping styles between mindfulness and affiliate stigma in children with autism was tested, controlling for parental age, monthly household income, and length of care. The results showed that the predictive effect of mindfulness on affiliate stigma was significant ( $\beta = -0.35, t = -7.18, p < .01$ ), and when the mediating variables (positive and negative coping styles) were introduced, the direct predictive effect of mindfulness on affiliate stigma remained significant ( $\beta = -0.20, t = -3.97, p < .01$ ), and the positive predictive effect of mindfulness on positive coping style was effect was significant ( $\beta = 0.33, t = 6.48, p < .01$ ), the negative predictive effect of mindfulness on negative coping style was significant ( $\beta = -0.37, t = -7.39, p < .01$ ), the negative predictive effect of positive coping style on affiliate stigma was significant ( $\beta = -0.15, t = -3.08, p < .01$ ), and the negative predictive effect of negative coping style on positive prediction of affiliate stigma was significant ( $\beta = 0.25, t = 5.03, p < .01$ ), thus coping styles may be a mediating variable between mindfulness and affiliate stigma.

Bootstrap's method was used to test the significance of the paths further. The results showed that the mediating effect of the variables of positive coping style and negative coping style was significant ( $Z = -0.08, p < .05$ ) and that the direct effect of mindfulness on affiliate stigma was significant ( $Z = -0.09, p < .05$ ), and the total effect was significant ( $Z = -0.17, p < .01$ ), and the direct effect and mediating effect accounted for 54.5% and 45.5% of the total effect, respectively. Thus, positive coping style and negative coping style played parallel partial mediating roles between mindfulness and affiliate stigma in children with autism (Tables 4 and 5, Supplementary Figure 2).

**Table 2** Pearson Correlation Between Mindfulness, Coping style and Affiliate Stigma.

Variables	1	2	3	4
1. Mindfulness	1			
2. Positive coping style	0.33**	1		
3. Negative coping style	-0.38**	-0.28**	1	
4. Affiliate stigma	-0.39**	-0.34**	0.41**	1

Note. \* $p < .05$ , \*\* $p < .01$ .



**Table 3** Multiple Stepwise Regression Analysis of Affiliate Stigma (N = 345).

Independent variable	$\beta$	Standard error	$\beta'$	t value	p	VIF
Constant	2.87	0.19		15.37	<.001**	
Age of parents	-0.11	0.05	-0.11	-2.32	.021*	1.02
Monthly household income	-0.06	0.02	-0.09	-2.02	.044*	1.05
Duration of care	0.09	0.02	0.18	3.91	<.001**	1.07
Mindfulness	-0.09	0.02	-0.21	-4.07	<.001**	1.28
Positive coping style	-0.11	0.04	-0.14	-2.81	.005**	1.23
Negative coping style	0.21	0.04	0.25	4.95	<.001**	1.23

Note.  $R^2 = 0.31$ , Adjusted  $R^2 = 0.30$ ,  $F = 25.38$ ,  $p < .001$ , \* $p < .05$ , \*\* $p < .01$ . VIF = Variance Inflation Factor.

**Discussion**

*Affiliate stigma and related factors*

According to the research findings, parents of autistic children experience upper-medium levels of stigma, which is in line with Mayyu et al.'s research findings [35], which reveal that the negative-emotion cognitive and social anxiety avoidance dimensions have the highest scores. Parental age, monthly family income, and duration of care were found to be significant determinants of affiliate stigma among parents of children with autism. Young parents may be highly stigmatized due to their inexperience in providing care and the demands of juggling jobs, social obligations, and family ties at the same time. It is challenging to self-regulate due to the influence of stigma, resulting in a high affiliate stigma.

The financial burden of providing lifetime rehabilitation training for autistic children is significant because of the disorder's unclear origin and dearth of viable therapeutic medications. In order to better care for their children, 61.15% of families quit their work [36], and the current medical security and social welfare systems for autism are not flawless [37]. Low-monthly family income families are less equipped to cope with the process of seeking therapy, which can result in a high level of affiliate stigma and an inability to cope with it [38]. Autism is an unseen form of disability since it lacks phenotypic characteristics and physical impairment [9]. The inconsistency of symptoms, such as self-beating and abrupt crying, is a significant challenge in the rehabilitation of children with autism, particularly as they get older. Specific symptoms are hard to fully recover from, making the difference between autistic children and typically developing children of the same age more pronounced. Parents will become more perceptive as well. Parents feel ostracized and socially isolated as a result of public stereotypes and unfavorable opinions. Parents may be barred from social events, and the longer they provide care, the more frequently they feel stigma in any form and at a higher level [39]. Therefore, it is

**Table 5** Specific Direct and Indirect Pathways.

Type of effect	Estimate	Boot SE	Bootstrap 95% CI		Ratio (%)
			Lower	Upper	
Direct effect	-0.09	0.02	-0.14	-0.05	54.4
Indirect effect 1	-0.03	0.00	-0.05	-0.01	17.2
Indirect effect 2	-0.05	0.01	-0.07	-0.03	28.4
Total indirect effect	-0.08	0.01	-0.11	-0.05	45.6
Total effect	-0.17	0.02	-0.21	-0.13	100

Note. CI = confidence interval; SE = standard error; N = 345; Bootstrap sample = 5000. Indirect effect 1 = Mindfulness → Positive coping style → Affiliate stigma. Indirect effect 2 = Mindfulness → Negative coping style → Affiliate stigma. Total indirect effect = Indirect effect 1 + Indirect effect 2.

essential for medical staff to pay attention to the psychological problems of parents and their affiliate stigma in clinical work, and it is imperative to explore systematic intervention strategies.

*Mindfulness exerts a direct negative effect on affiliate stigma*

In the present study, there was a negative correlation between the level of mindfulness and affiliate stigma in parents of autistic children. According to regression analysis, the direct effect of mindfulness on affiliate stigma was -0.09, indicating that a high level of mindfulness could alleviate the affiliate stigma of parents of autistic children. The results of this study show that the mindfulness level of parents of autistic children is at a medium level and needs to be improved and that there is a high level of affiliate stigma. The degree of mindfulness is correlated with an individual's capacity for emotion management and cognitive response [40]. Low mindfulness causes parents of ASD children to become overly involved in a string of unfavorable occurrences following their child's sickness, which exacerbates affiliate stigma by causing negative thoughts and feelings. Stigmatization has an impact on parents' conduct and mental health, which in turn affects how well autistic children rehabilitate [11]. Conversely, parents with higher levels of mindfulness can better deal with their child's internalization of negative stereotypes, view the emotional experience at hand with a "decentralized" attitude, and let go of their internal fixed coping mode, mobilizing available positive resources to cope with the internalization of negative stereotypes and improve adverse stress responses. The most obvious and valuable outcome of mindfulness training is an increase in an individual's level of mindfulness, as numerous studies have demonstrated [41]. Longer mindfulness training sessions increase people's capacity to instinctively suppress negative thoughts and demonstrate more suitable and objective emotional reactions in various contexts [15].

**Table 4** Mediating Role of Coping style in the Relationship Between Mindfulness and Affiliate Stigma.

Variables	Model 1		Model 2		Model 3		Model 4	
	Positive coping style		Negative coping style		Affiliate stigma		Affiliate stigma	
	$\beta$	t	$\beta$	t	$\beta$	t	$\beta$	t
Control variables								
Age of parents	0.08	1.66	-0.04	-0.74	-0.13	-2.70**	-0.11	-2.35*
Monthly household income	0.19	3.74**	-0.09	-1.80	-0.14	-2.85**	-0.09	-1.83
Duration of care	-0.07	-1.42	0.10	1.94	0.22	4.47**	0.18	3.91**
Independent variable								
Mindfulness	0.33	6.48**	-0.37	-7.39**	-0.35	-7.18**	-0.20	-3.97**
Mediating variable								
Positive coping style							-0.15	-3.08**
Negative coping style							0.25	5.03**
F	16.03		17.05		25.21		25.38	
R <sup>2</sup>	0.16		0.17		0.23		0.31	

Note.\* $p < .05$ , \*\* $p < .01$ .

Medical practitioners should, therefore, focus on the assessment, treatment, and stigma reduction of parents of autistic children. Research could be attempted with parents of children with ASD to explore mindfulness interventions tailored to the characteristics of this special population. Examples of such programs include mindful stress reduction and cognitive behavioral intervention. By linking cognition and behavior, parents can be guided to consciously increase positive meditation and establish a new cognitive behavior model to improve the level of mindfulness and reduce affiliate stigma.

#### *Coping styles exert direct effects on affiliate stigma*

Our findings also showed that positive coping styles were negatively associated with affiliate stigma and that negative coping styles were positively associated with affiliate stigma. An individual's chosen coping strategy dictates their emotional reaction under pressure [26]. The findings of this study contradict the results of Liu et al. [42] by demonstrating that parents are more likely to use negative coping styles. Parents of children with ASD must work harder to modify their psychological state when handling stressful situations in order to meet their children's requirements and manage daily and yearly stressors in their lives as caregivers. It is simple for them to get sucked into bad feelings. Negative coping styles have the potential to lessen stress-related discomfort momentarily. However, it can also heighten the chance of mental symptoms such as interpersonal sensitivity and obsessive-compulsive states, as well as enhance affiliate stigma and hinder parents' ability to think clearly and act appropriately [26]. Positive coping styles, on the other hand, can serve as a catalyst for parents of children with ASD to regulate their psychological and emotional states. This can help parents lessen the affiliate stigma, lessen the effects of stressful events, and preserve their physical and mental well-being. Examples of these strategies include asking for support from family members and utilizing professional counseling services. Medical professionals should pay attention to the psychological counseling of parents of children with ASD, advise parents on how to respond appropriately, and assist parents in learning effective rehabilitation training skills for children's behavioral problems to improve their ability to cope.

#### *Mindfulness exerts an indirect negative effect on affiliate stigma*

The results of the Bootstrap test revealed that positive coping styles and negative coping styles acted as parallel mediators between mindfulness and affiliate stigma in parents of autistic children. Mindfulness could indirectly influence affiliate stigma through coping styles. The parallel mediators accounted for 45.6% of the total effect, with positive coping styles contributing 17.2% and negative coping styles contributing 28.4%. The low level of mindfulness significantly influences patients' propensity to adopt negative coping styles, resulting in elevated levels of affiliate stigma. Positive coping styles, on the other hand, had the opposite effects. In the results of this study, negative-emotion cognitive and social anxiety avoidance were the dimensions with the highest scores of affiliate stigma in parents of children with ASD, indicating that parents have been rejected by society, lack of psychological flexibility, and are prone to fall into negative emotions, self-cognition bias, and then behavioral change [11]. Parents engage in the entire process of disease diagnosis and treatment, rehabilitation training, day-to-day care, and future life planning for their children with ASD during their periodic rehabilitation sessions. Children with ASD live in a state of "ignorance" about their illness and the world around them as a result of cognitive development impairments. Because parents and children have such a tight

relationship, parents are the ones who are most likely to receive negative attitudes from the public and medical professionals. Their relationship with children will have an impact on their social role, family dynamics, physical and mental health, and financial status. The family environment for rehabilitation and adherence to treatment will be directly influenced by the parents' physical and mental health and coping styles. According to the stress and coping theory [22], parents of autistic children have increased negative emotions toward their children's diseases. Parents with lower levels of mindfulness lack positive adaptation and cognitive processing; their negative emotional experience is internalized, and cognitive bias is present. In addition, limited access to social resources and support causes them to change their behavior and tend to adopt negative coping styles. Finally, it leads to a high level of affiliate stigma. According to studies, combining mindfulness intervention with traditional mindfulness practice techniques such as mindful eating, three-step breathing training, and mindfulness stretching can not only increase one's level of mindfulness directly [41] but also focus on developing one's own cognitive and attention skills, strengthen one's metacognitive abilities, help people make realistic assessments of stressors, and lessen the tendency for cognitive behavior to become habitual [43], gain a positive perspective on the world, increase the impact of the good things in your life, fully utilize one's potential, and select a more positive and adaptable coping style. Therefore, healthcare providers can use mass media, such as health education lectures and social networking sites, to disseminate knowledge about autism and correct parents' and the public's misconceptions about the ASD. Referring to the application model of mindfulness therapy in other groups [16,44], we try to apply intervention models such as minds-based stress reduction and cognitive behavior therapy in parents of autistic children to cultivate parents' mindfulness, adjust their cognition and thinking style, improve their emotional regulation ability, improve their coping efficacy, and choose a more positive coping style to alleviate the affiliate stigma.

## **Conclusion**

The current study indicates that the affiliate stigma of parents of autistic children was at an upper-middle level. Mindfulness has a negative direct impact on affiliate stigma, positive coping style has a negative direct impact, and negative coping style has a positive direct impact. Additionally, positive coping styles and negative coping styles are parallel mediators in the relationship between mindfulness and affiliate stigma in parents of autistic children. It emphasizes the significance of coping styles and mindfulness, and it offers insightful information for developing intervention plans aimed at reducing affiliate stigma among parents of autistic children. It is essential to pay attention to and evaluate the affiliate stigma of parents of autistic children for their mental health and the rehabilitation of children. It will be a long process to change public perception and eliminate the stigma caused by social levels. In the meantime, medical professionals can provide mindfulness training, such as mindfulness-based stress reduction and cognitive behavioral therapy, to improve parents' mindfulness levels and promote positive coping to reduce affiliate stigma.

## **Study limitation**

Although our study has new findings, there are also several limitations. First, we only included a sample from one hospital, thus limiting the generalizability of the results. Second, the variables chosen in this research were grounded in self-reports, which may result in reporting bias.

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## Conflict of interest

The authors have no conflicts of interest relevant to this article to disclose.

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## Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.anr.2024.03.001>.

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## Research Article

## Development and Psychometric Testing of the Fathers' Self-Efficacy Scale for Newborn Care

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## SUMMARY

**Purpose:** Fathers' involvement in newborn care positively affects both work sharing between parents, newborn quality of life, and the relationship between father and newborn. However, there is no valid and reliable measurement tool to evaluate fathers' self-efficacy levels for newborn care. This study aimed to develop the fathers' self-efficacy scale for newborn care (FSSNC) and to examine its psychometric properties.

**Methods:** This study is an instrument development and validation study. After a comprehensive literature review, expert opinion, and pilot application stages, an item pool was developed. For validity and reliability analyses, data were collected between March and December 2022 from 442 individuals, including fathers with newborn babies and expectant fathers whose partners are pregnant. Validity assessments included content, exploratory and confirmatory factor analyses, and convergent validity. The scale was also evaluated for its internal consistency, and two-half-test reliability. In this study, the STROBE checklist was used as a guideline.

**Results:** The final version of the scale consisted of three subdimensions (hygiene, safety, and nutrition). The total number of items is 17. Confirmatory factor analysis results confirm the results of exploratory factor analysis. There was a strong correlation between the scale score and the participants' self-assessment score.

**Conclusions:** The study demonstrates that the FSSNC was a valid, reliable, and user-friendly measurement tool used to evaluate fathers' self-efficacy regarding hygiene, safety, and nutrition in newborn care.

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## Introduction

The newborn period includes the first 28 days of life after birth and is one of the most critical life stages requiring careful and sensitive care. During this period, mothers and fathers stated that they experienced intense stress regarding newborn care and that they needed the support of their relatives or healthcare professionals to improve their parenting roles in this regard [1–3]. Especially, fathers need more support than mothers in baby care. Because, fathers' parenting self-efficacy is lower than mothers [2,4,5]. Therefore, fathers express that they need more support

from mothers in matters related to newborn care [6,7]. Studies have shown that fathers who receive support in newborn care increase their self-efficacy levels and participate more actively in care activities such as feeding and bathing their babies [8,9]. Therefore, nurses and midwives should understand the needs of fathers in newborn care and make it easier for them to adapt to their new roles [7,10]. In addition, fathers who are not experienced in baby care need social support from clinical professionals such as midwives and nurses, as well as from experienced people who have had children before, such as relatives and grandparents [7,11].

Recently, in parallel with the cultural, social, and economic changes in society, positive developments have been made in the roles and participation of fathers in newborn care [9,12,13]. Fathers' active involvement in newborn care increases their motivation for newborn care, positive father–infant interaction, and father–infant bonding [14,15]. In addition, the babies of fathers participating in care in the neonatal period have better social and cognitive development, lead a healthy and happy life, are more likely to play

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independently with their toys, and are stronger in the face of problems in the future [16]. Hence, fathers desire to participate in housework and baby care to the same extent as their wives [14,17]. Nonetheless, fathers report having low self-efficacy levels to care for a baby during the newborn period and inadequate access to information on infant care, indicating a need for support in newborn care [18,19].

Bandura's theory of self-efficacy guided the development of the Fathers' Self-Efficacy Scale for Newborn Care (FSSNC). According to Bandura (1977), self-efficacy refers to the belief that individuals hold about their capabilities in various situations [20]. Additionally, self-efficacy influences the maintenance of behavior in terms of how people think and motivate themselves. If people's self-efficacy is low, they will not find themselves sufficient in the situation they face and will not be able to do the job even if they are capable of doing it [21]. In this context, fathers' lack of self-efficacy and knowledge in newborn care negatively affect their participation. Therefore, the measurement tools for determining the knowledge and skills of fathers caring for newborns regarding the characteristics of the period are extremely important for determining the current situation. A limited number of scales in the literature can assess fathers' self-efficacy in newborn care. These scales are generally developed for situations such as fathers' young children (0–12 months) care and breastfeeding self-efficacy [9,22,23]. Although fathers are thought to be the biggest supporters of mothers who have babies during the newborn period, there is no scale developed specifically for fathers [22]. Scales developed for parents were mostly used to evaluate mothers' self-efficacy levels. When this scale was used for fathers, some items were removed and it decreased from 3 dimensions to 2 sub-dimensions. This shows us that mothers participate in more aspects of baby care than fathers [9,22]. For example, while mothers breastfeed the baby, fathers can only support mothers in breastfeeding [23]. For this reason, different scales used to evaluate the self-efficacy of mothers and fathers regarding baby care will yield more accurate results. However, no valid and reliable measurement tool focusing on fathers' newborn care has been found. This study was more specific than other scales in the literature and aimed only to examine fathers' self-efficacy in caring for newborn babies.

Since the newborn period requires special attention and care, fathers often feel inadequate in caring for their babies and need clinical supports [1,9,19]. Therefore, the proposed scale was designed to determine the self-efficacy levels of fathers regarding their issues in newborn care. Using this scale will help researchers, midwifery, and pediatric nursing determine the needs of fathers, plan educational activities and organizations related to newborn care, and increase fathers' participation in newborn baby care. This increase in participation might promote job sharing between parents, marital satisfaction, positive father–infant interaction, and father–infant attachment. Ultimately, such interventions might have a positive impact in terms of improving newborn quality of life.

Hence, this study aimed to develop a valid and reliable measurement tool with psychometric qualities for assessing the father's self-efficacy for newborn care.

## Methods

### Study design

This cross-sectional study, which aimed to investigate the psychometric properties of the FSSNC, was designed to be conducted in three stages in line with the suggestions by Boateng et al [24]. These stages were (1) item development, (2) scale development, and (3) scale evaluation (Figure 1).

### Participants and setting

The sample for the study consisted of fathers with newborn babies and fathers whose partners are pregnant. It was suggested that a study group of 200 people would be sufficient for factor analysis, and both exploratory and confirmatory factor analyses should be performed in different sample groups [24–26]. Therefore, the aim was to reach at least 200 study groups for both exploratory factor analysis and confirmatory factor analysis.

The study group consisted of the husbands of women who presented for antenatal or postnatal check-ups at obstetric outpatient clinics between March and December, 2022, in a province in southern Turkey. Women presenting for antenatal check-ups were in their pregnancies, and their husbands were expectant fathers. Women who presented for postnatal check-ups had newborn babies, and their husbands were fathers. Fathers participating in the study were asked to have the following characteristics: their spouses had a healthy pregnancy and birth process, their babies did not have any congenital anomalies, they had not previously received training on newborn care, and they were willing to participate in the research voluntarily.

Convenience sampling method was used in the research. Research data were collected by the researchers from the participants using face-to-face interviews. The researchers first explained the study's purpose and inclusion and exclusion criteria and asked whether the participant had received neonatal care training prior to sharing the voluntary consent form. In the first stage, the data were collected from 219 individuals who agreed to participate in the study for exploratory factor analysis to determine the scale's factor structure. In the second stage, the data were collected from 223 individuals who agreed to participate in the study for confirmatory factor analysis to validate this structure. The data were collected from 442 participants.

### Data collection tools

#### Sociodemographic questionnaire

This form consisted of eight items related to the father's age, educational status, income, occupation, social security, place of residence, paternity status (fathers with newborn babies or fathers whose partners are pregnant), and whether the pregnancy was planned or not. At the end of the data collection, participants were asked to evaluate their self-efficacy for newborn care with a single question: Considering the questions you answered earlier, how ready do you feel to care for a newborn baby? The participants were asked to rate this question on a scale of 1 to 10 (1 = I do not feel ready at all; 10 = I feel completely ready).

#### Fathers' self-efficacy scale for newborn care

#### Development of the scale

The FSSNC items were created based on the review of research articles from various databases, including PubMed, The Cochrane Library, Science Direct, Web of Science, Ebsco, and Scopus. As a result of this review, scale studies [9,22,27,28], qualitative, randomized, and descriptive studies on the subject were found [1,7,14,19,29–33].

After the 64-item pool stage, the draft scale was submitted to expert opinion in line with the Davis technique. Ten experts (three faculty members working in the field of pediatrics nursing for more than 20 years, two faculty members working in the field of neonatal nursing health and diseases for more than 25 years, three faculty members working in the field of obstetrics and gynecology in midwifery department for more than 15 years, and two specialist nurses working in the neonatal service) evaluated the draft scale

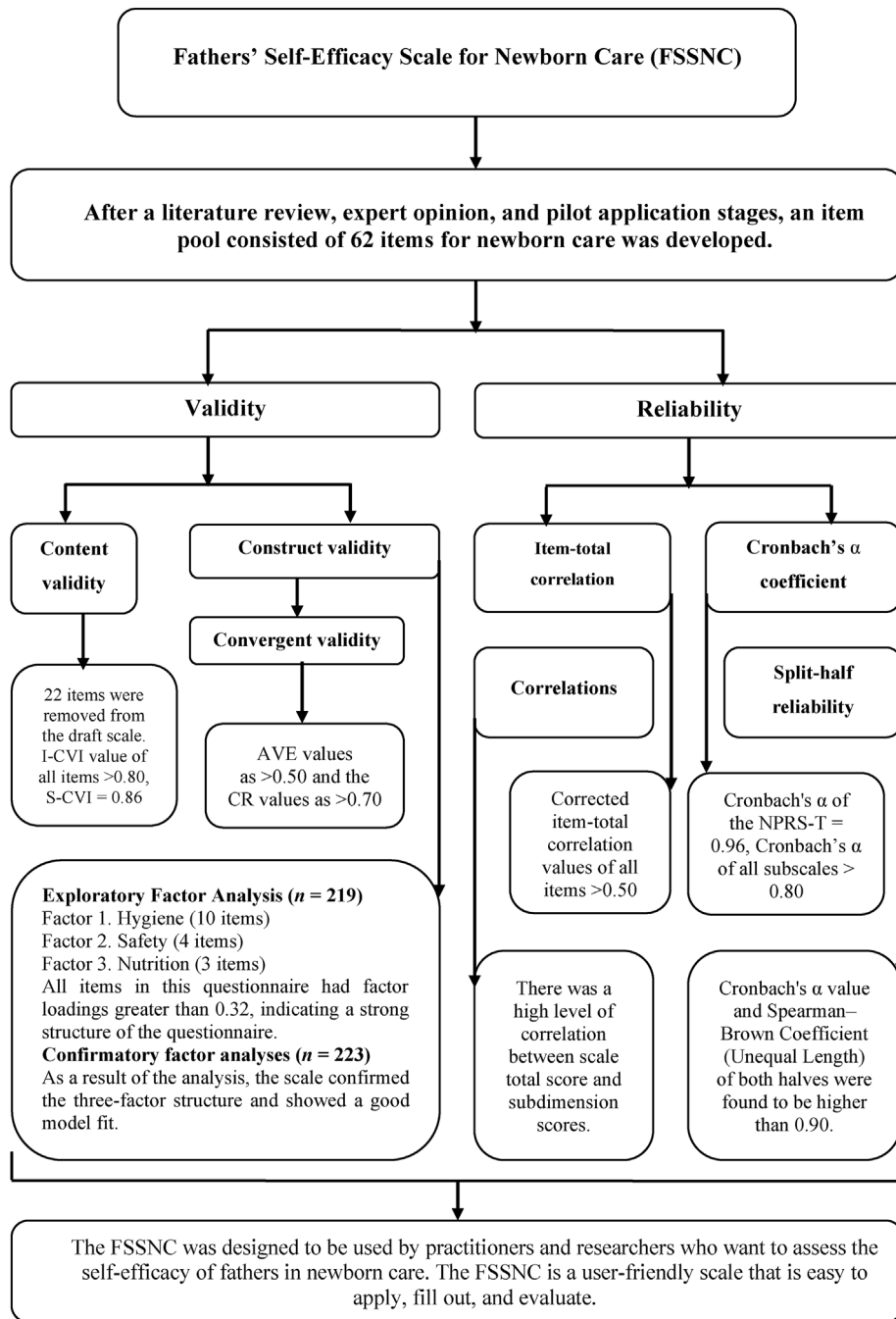


Figure 1. Scale Development Process of the Fathers' Self-Efficacy Scale for Newborn Care (FSSNC).

items in terms of comprehensibility and relevance (1 = not relevant; 2 = relevant to some extent; 3 = relevant; 4 = completely relevant) [34].

After obtaining expert opinions, a pilot study was conducted with 30 participants who met the criteria for participation in the study. The comprehensibility of the questions and the time taken by the participants to complete the draft scale were evaluated during the piloting process. Participants reported that the questions were understandable, and they completed the form in an average of 10 min. Participants who participated in the pilot study were excluded from the study sample. After the expert opinion and pilot application process, the draft scale consisting of 42 items and a 5-point Likert scale (1 = strongly disagree; 5 = strongly agree) was applied to the entire sample group.

#### Data analysis

The data were analyzed using SPSS 27 and AMOS 21 programs. The demographic characteristics of fathers were presented as frequency and percentage for categorical variables and as the mean and standard deviation for continuous variables. Content validity was used to assess whether the items in the scale adequately reflected the concepts explored and assessed with the content validity index (CVI). For the Item Content Validity Index (I-CVI), the reference minimum value considered acceptable was 0.80 [34]. The construct validity of the scale was examined using factor analysis. The exploratory factor analysis (EFA) and confirmatory factor analysis (CFA) were performed in two different sample groups. EFA was performed using principal axis factoring and direct oblimin rotation

factor analysis methods to create the potential factor structure of the scale. Prior to proceeding, the Kaiser–Meyer–Olkin (KMO) test and Bartlett's test of sphericity were conducted to assess the appropriateness of the data for factor analysis. If the KMO value is above 0.80, it indicates that the sample size is suitable for factor analysis. Additionally, a statistically significant result in Bartlett's test of sphericity ( $p < .05$ ) demonstrates that the dataset is appropriate for factor analysis [35]. The factor structure obtained with EFA was confirmed with CFA. While a cutoff value of 0.40 is recommended for factor loadings in EFA results, the minimum factor loading accepted is 0.32. Typically, factors with eigenvalues of 1.0 and above are considered significant and retained in the model. A component with an eigenvalue less than 1 can usually be discounted [35].

In CFA analysis, the goodness-of-fit index (GFI), adjustment goodness-of-fit index (AGFI), comparative fit index (CFI), root mean square error of approximation (RMSEA), normed fit index (NFI), and Tucker–Lewis index (TLI) were calculated. Guidelines for interpreting goodness-of-fit indices are a subject of considerable debate within the statistical community. Debates often center on questions such as which indices should be utilized and what cutoff criteria should be applied to differentiate between good and poor model fits. For instance, it is generally recommended that if the root mean square error of approximation (RMSEA) is greater than or equal to 0.1, the model should be rejected as it indicates a poor fit. Conversely, an RMSEA value less than 0.05 is often considered indicative of a good fit. Moreover, RMSEA values between 0.05 and 0.1 are typically seen as indicating an acceptable fit, suggesting that while the model may not perfectly represent the data, it is still reasonably accurate [35].

Convergent validity is a type of validity that indicates a significant correlation between measures of theoretically similar concepts. Commonly used indicators of convergent validity were average variance extracted (AVE) and construct reliability (CR). The convergent validity is good when the AVE value is greater than 0.50 and the CR value is greater than 0.70 [26].

The reliability of the scale was examined with Cronbach  $\alpha$  coefficient, two-half-test reliability, and item-total score correlation. The relationship between the scale and its subdimensions and self-assessment scores was examined by Pearson correlation analysis. The normal distribution of the total scale score was examined by calculating the kurtosis and skewness values. For all analyses, a  $p$  value  $< .05$  indicated statistical significance.

#### Ethical approval

The study design process started in October 2021, and the researchers collected data after receiving ethics committee approval (decision no: 100) on March 29, 2022. The research permission (no: 932) was granted by a hospital. All participants provided written informed consent. The study was completed on December 14, 2022.

## Results

The demographic characteristics of the participants are presented in Table 1. The mean age of the participants was  $31.23 \pm 5.02$  years (min = 20, max = 47). It was determined that 62.0% of the participants were university graduates, 90% had social security, 46.6% had income equal to expenses, and 79.9% lived in the city center. Further, 57.9% of the participants were fathers with newborn babies, and 42.1% were expectant fathers whose wives were pregnant. Also, 79.9% of the participants stated that their wives' pregnancies were planned. The mean self-assessment score of the participants was  $6.16 \pm 2.55$  (min = 1, max = 10).

In developing the item pool, the researchers first searched various academic databases to collect relevant publications and

**Table 1** Demographic Characteristics of the Participants ( $n = 442$ ).

Descriptive characteristics	Mean	SD (Min–Max)
<b>Age</b>	31.23	5.02 (20–47)
	<b>n</b>	<b>%</b>
<b>Education level</b>		
Primary school	88	19.9
High school	80	18.1
University	274	62.0
<b>Social security</b>		
Yes	398	90.0
No	44	10.0
<b>Income status</b>		
Income less than expenditure	140	31.7
Income equals expenditure	206	46.6
Income more than expenditure	96	21.7
<b>Your residential location</b>		
District	67	15.2
Village	22	5.0
City	353	79.9
<b>Paternity status</b>		
Fathers with newborn babies	186	42.1
Fathers whose partners are pregnant	256	57.9
<b>Pregnancy planning</b>		
It was planned	353	79.9
It was not planned	89	20.1

conducted a comprehensive literature review on the topic. This rigorous process involved identifying and reviewing relevant scales, descriptive studies, randomized controlled trials, and qualitative studies. Thanks to this review of the existing literature, the researchers created the item pool required for the scale topic. The item pool consisted of a total of 64 items.

## Item development and tool development stage

### Validity analysis

#### Content validity

Following expert reviews of the items, CVIs were calculated for 64 items. As a result of these evaluations, 22 items which were based on CVI below .80, as required by the Davis technique, were removed from the draft scale. The remaining 42 items of the draft scale had a CVI of .91. The item-based content validity indices ranged between .88 and 1.00. After expert opinions were incorporated into the pilot sample group, the 42-item draft scale was obtained and its comprehensibility was evaluated.

#### Exploratory factor analysis ( $n = 219$ )

The exploratory and confirmatory factor analyses were conducted on different sample groups. For construct validity, the EFA was first conducted using the data of 219 participants. Bartlett's test of sphericity was significant ( $\chi^2 = 6356.277$ ,  $df = 171$ ,  $p < .001$ ), indicating that factor analysis was appropriate for the data. The KMO statistic was .96 ( $> .80$ ), indicating that the data were suitable for factor analysis. The 25 items with factor loadings below .30 were removed. The final scale consisted of 17 items. According to the EFA results, three factors had initial eigenvalues greater than one. The first factor, the hygiene subscale, consisted of 10 items with factor loadings ranging from .515 to .947. The second factor, the safety subscale, consisted of four items with factor loadings ranging from .623 to .905. The third factor, the nutrition subscale, consisted of three items with factor loadings ranging from .329 to .949. The total scale explained 70.6% of the total variance. The results of the factor analysis are presented in Table 2.



**Table 2** Factor Loading of the Fathers' Self-Efficacy Scale for Newborn Care (FSSNC).

Item No		Factor		
		Hygiene	Safety	Nutrition
h1	I can help my partner give my baby a bath (adjusting the temperature of the bath water, preparing the bath tools, etc.).	<b>.755</b>	.186	-.030
h2	I can take care of my baby when cradle cap/seborrheic dermatitis (yellowish crusty flakes on the scalp) occurs.	<b>.947</b>	-.014	-.106
h3	I can care for my baby's eyes when pus, discharge, redness, etc. occurs.	<b>.895</b>	.026	.003
h4	I can care for my baby's mouth when canker, thrush, redness, etc. occurs.	<b>.849</b>	.000	.092
h5	I can care for my baby's ears when discharge, wax, etc. occurs.	<b>.826</b>	.021	.054
h6	I can care for my baby's nose with the tools used in nose cleaning (nasal aspirator, etc.) when discharge, congestion, etc. occurs.	<b>.811</b>	-.045	.054
h7	I can keep the navel area of my baby dry and clean and care for it in case of discharge, redness, etc. until the umbilical cord falls off.	<b>.876</b>	-.104	-.001
h8	I can cut my baby's nails appropriately (fingernails round, toenails flat).	<b>.686</b>	.043	.045
h9	I can do diaper care (cleaning, diaper rash control, diaper change, etc.) when my baby's diaper is dirty.	<b>.527</b>	.014	.167
h10	I can change my baby's clothes.	<b>.515</b>	.346	.031
s11	I can ensure my baby's environmental safety (a flat floor where they will not fall, a suitable position where they can breathe easily, etc.).	-.080	<b>.905</b>	.046
s12	I can hold my baby safely (by supporting their head, shoulders, and waist).	.208	<b>.808</b>	-.154
s13	I can carry my baby in the appropriate position with baby carriers (kangaroo bag, stroller, bag-type carrier, etc.).	-.095	<b>.875</b>	.087
s14	I can safely burp my baby in the appropriate position (on my lap, with their head resting on my shoulder, patting their back).	.210	<b>.623</b>	.098
n15	If their mother is unable to breastfeed, I can prepare the right amount of formula at the right temperature when my baby is hungry.	.166	.415	<b>.329</b>
n16	If their mother is unable to breastfeed, I can feed my baby correctly with the appropriate bottle or spoon when my baby is hungry.	.063	-.024	<b>.949</b>
n17	If their mother cannot breastfeed, I can understand when my baby is full when I feed them formula.	.039	.054	<b>.758</b>
Rotation Sums of Squared Loadings Total		8.936	6.308	5.428
Initial Eigenvalues (Total)		9.952	1.734	1.083

Extraction method: Principal axis factoring.

Rotation method: Oblimin with Kaiser normalization.

h = hygiene; s = security; n = nutrition.

### Confirmatory factor analyses ( $n = 223$ )

The CFA was conducted using the data of the remaining 223 participants to confirm the three-factor structure identified based on the results of the exploratory factor analysis. The correlations among error variances were allowed to improve model fit based on the modification indices generated using the AMOS program. The analysis confirmed the three-factor structure of the scale and showed a good model fit. According to CFA,  $\chi^2/df = 2.665$ , GFI = 0.865, AGFI = 0.815, CFI = 0.935, RMSEA = 0.087, NFI = 0.900, and TLI = 0.921. The path diagram showing the factor loadings drawn using the AMOS program is presented in [Figure 2](#). The factor loadings of the first subdimension were between .66 and .82, the factor loadings of the second subdimension ranged between .70 and .88, and the factor loadings of the third subdimension ranged between .83 and .91 ([Figure 2](#)).

### Convergent validity

The AVE estimates for the three subdimensions of the FSSNC were .55, .62, and .77, and the CR values were .92, .87, and .91. The convergence validity of the FSSNC was considered acceptable.

### Reliability analysis

Cronbach's  $\alpha$  coefficient for the whole scale was .964. The Cronbach's  $\alpha$  coefficients of the subdimensions were .946 for hygiene, .884 for safety, and .919 for nutrition. The corrected item-total correlations ranged from .637 to .846, indicating that the items were fairly homogeneous. [Table 3](#) presents the item mean

scores, item-total correlations, and Cronbach's  $\alpha$  coefficient with the item deleted for each item in the scale.

A statistically significant positive and extremely strong linear relationship was found between the total scale score and the hygiene subscale ( $r = .979, p < .001$ ). Further, a statistically significant positive and strong linear relationship was observed between the total scale score and the safety subscale ( $r = .878, p < .001$ ). Moreover, a statistically significant positive and extremely strong linear relationship was noted between the total scale score and the nutrition subscale ( $r = .902, p < .001$ ). Also, a statistically significant positive linear relationship was found between the fathers' self-assessment score and the total scale score at a strong level ( $r = .822, p < .001$ ), between the hygiene subscale at a strong level ( $r = .790, p < .001$ ), between the safety subscale at a strong level ( $r = .724, p < .001$ ), and between the nutrition subscale at a strong level ( $r = .783, p < .001$ ).

Within the scope of split-half reliability, the scale was divided into two halves according to the odd-even rule. The Cronbach's  $\alpha$  coefficient of the first half, which included odd-numbered items in each subscale, was calculated as .928, and the Cronbach's  $\alpha$  coefficient of the first half, which included even-numbered items, was calculated as .932. The correlation coefficient between the two halves was .938. Spearman-Brown coefficient (unequal length) value was .968, and the Guttman split-half coefficient value was .968.

### Discussion

In this study, a valid and reliable new scale that could be used to assess fathers' self-efficacy for newborn care was developed. The researchers followed the validity and reliability steps recommended by Boateng et al [24] during the scale development process.

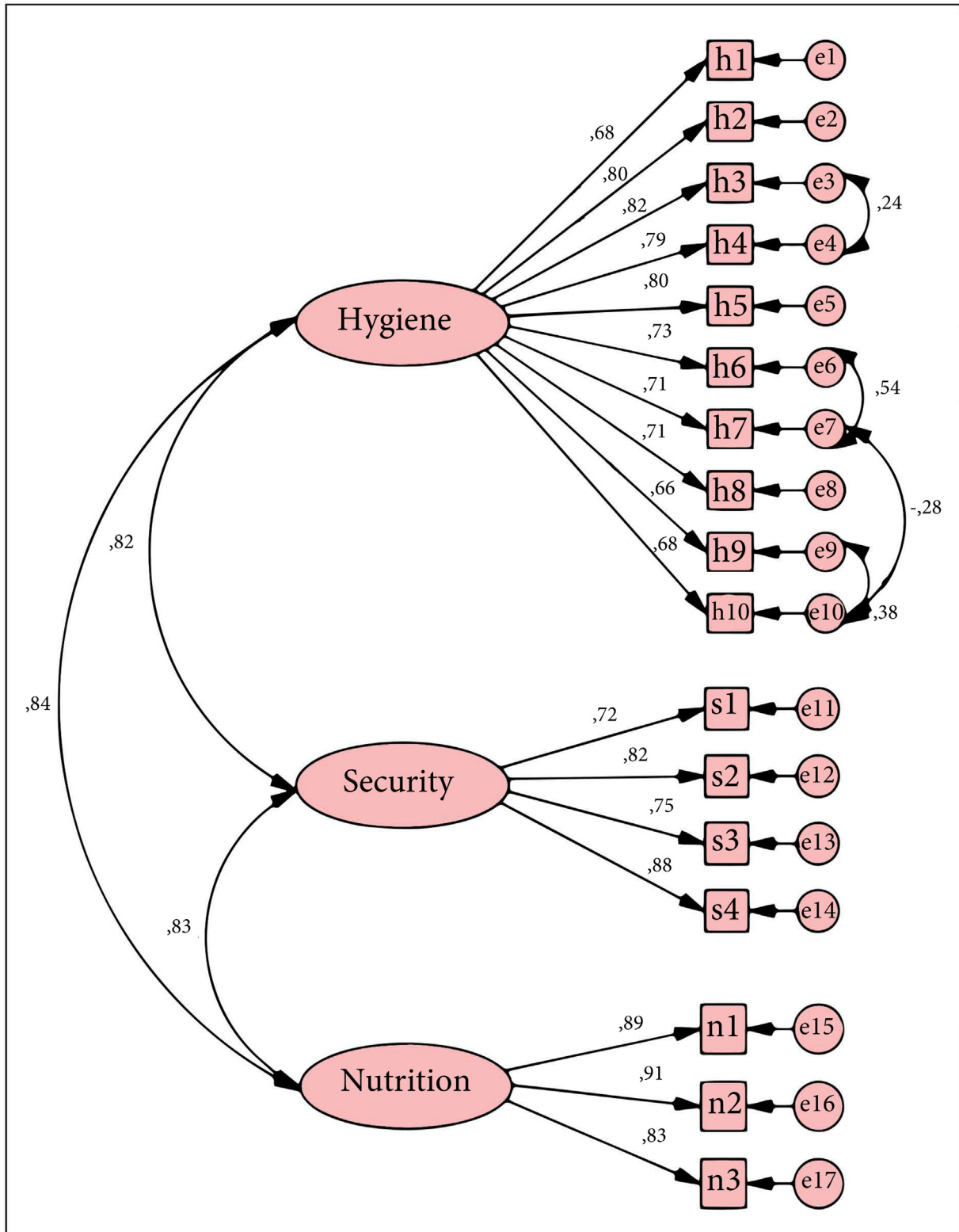


Figure 2. Confirmatory Factor Analysis of Fathers' Self-Efficacy Scale for Newborn Care (FSSNC).

*Validity of the scale*

*Content validity*

The content validity assesses the extent to which an instrument measures its intended constructs, including the sufficiency and

distribution of its items [36]. The content validity values were found to be high at both the scale and item levels. These results revealed that the scale had sufficient content validity [34]. In addition, in the pilot study, the participants did not report any serious problems regarding the comprehensibility of the scale items.

**Table 3** Fathers' Self-Efficacy Scale for Newborn Care (FSSNC) Item Mean Scores, Item Corrected Total Correlations, and Subscale Cronbach's  $\alpha$  Coefficient.

	Mean $\pm$ SD	Corrected item-total correlations	Cronbach's $\alpha$ Coefficient
<b>Hygiene</b>	37.04 $\pm$ 10.87		.946
h1	4.22 $\pm$ 1.04	.657	
h2	3.44 $\pm$ 1.40	.831	
h3	3.86 $\pm$ 1.13	.831	
h4	3.56 $\pm$ 1.39	.846	
h5	3.94 $\pm$ 1.05	.789	
h6	3.52 $\pm$ 1.47	.824	
h7	3.22 $\pm$ 1.59	.813	
h8	3.57 $\pm$ 1.40	.739	
h9	3.67 $\pm$ 1.34	.709	
h10	4.05 $\pm$ 1.28	.745	
<b>Security</b>	17.51 $\pm$ 3.37		.884
s1	4.67 $\pm$ 0.69	.637	
s2	4.50 $\pm$ 0.83	.756	
s3	4.18 $\pm$ 1.17	.735	
s4	4.17 $\pm$ 1.13	.823	
<b>Nutrition</b>	11.25 $\pm$ 3.74		.919
n1	3.92 $\pm$ 1.33	.835	
n2	3.81 $\pm$ 1.26	.806	
n3	3.52 $\pm$ 1.43	.795	
<b>Total scale</b>	65.81 $\pm$ 16.98		.964

### Construct validity

The construct validity assesses the extent to which the scale corresponds to the test results and explains whether the structure of the scale is consistent with its theoretical concept and structure [37]. Factor analysis is commonly used to assess construct validity, and this technique categorizes highly correlated observed variables into groups based on specific rules, with each group sharing a common factor representing the underlying structure of the scale. EFA is an extremely useful analytical method that can empirically determine how many constructs, latent variables, or factors underlie a set of items [25]. The construct validity of the questionnaire was evaluated by factor analysis and convergent validity. The loading value obtained in factor analysis is the critical value that determines whether an item belongs to a particular subfactor or not. Generally, items with factor loadings  $<.30$  should be removed from the questionnaire [38]. All items in this questionnaire had factor loadings greater than  $.30$ , indicating a strong structure of the questionnaire. The 25 items with factor loadings below  $.30$  were removed. The final scale consisted of 17 items. Finally, according to the final exploratory factor analysis results, the 17 items grouped under three factors explained 70.6% of the total variance. CFA confirmed the three-factor structure determined by EFA in different sample groups. In the CFA analysis, the factor loading values of all items were calculated to be above  $.50$ . Calculating the AVE values as  $>.50$  and the CR values as  $>.70$  indicates that convergent validity has been achieved [26,35]. No international standard exists on which fit indices should be reported after CFA analysis [39]. In this study, the values of  $\chi^2/df$ , GFI, AGFI, CFI, RMSEA, NFI, and TLI were calculated within acceptable limits [25,39,40].

### Reliability of the scale

The Cronbach's  $\alpha$  coefficient of the scale was  $.964$ , and the Cronbach's  $\alpha$  coefficients of all subdimensions were higher than  $.80$ . In addition, the corrected item-total correlation values of all the items were higher than  $.50$  [41,42]. These results confirmed that the internal consistency of the scale was high. Thus, it was interpreted that the items of the scale had a homogeneous structure within themselves. Within the scope of split-half reliability, Cronbach's  $\alpha$

coefficient and Spearman–Brown coefficient (unequal length) of both halves were calculated to be higher than  $.90$  [25,26]. The results obtained from all reliability analyses revealed that the scale was reliable.

Statistically significant correlations were expected between the total scores of the scale and subdimensions measuring the same construct. The scale's total score was highly correlated with the total scores of the subdimensions. At the end of the data collection form, participants were asked to evaluate their self-efficacy toward newborn care with a single question. Participants scored this question between 1 and 10 (1 = I do not feel ready at all; 10 = I feel completely ready). A strong correlation was found between the participants' self-efficacy assessment score for neonatal care and the total scale score. These results showed that the developed scale was compatible with itself. In addition, the participants' self-assessment scores and the scores they obtained from the scale showed a high level of parallelism.

The FSSNC was developed as a self-efficacy questionnaire that used a 5-point Likert scale across 17 items. The measure consisted of three factors: hygiene (1), safety (2), and nutrition (3). The first factor in the FSSNC dealt with the self-efficacy of fathers in taking care of their babies' eyes, ears, nose, mouth, face, belly, nails, and head, to what extent they could help their wives while bathing their babies, and to what extent they could change diapers and dirty clothes. In many studies conducted with fathers on newborn care, it was observed that fathers mostly lacked skills and self-confidence in bathing their babies. It was found that fathers generally could not wash their babies alone; they washed them with their spouses or helped their spouses while washing their babies [14,19]. In addition, many fathers expressed the need for mothers' support in various aspects of newborn care. Mothers generally handled tasks such as changing diapers and did not want to involve fathers in other caregiving practices [19]. The initial factor structure of the FSSNC investigated which hygienic practices fathers found inadequate to perform in baby care. Practical training sessions should be organized by midwives and nurses to address these issues in which fathers may lack confidence. Further, both parents should participate in these trainings together.

The second factor in the FSSNC was security. It included items that evaluated fathers' self-efficacy regarding providing a safe environment for their babies, carrying them in appropriate positions with carrier materials, holding them in their arms safely, and burping the baby. In a study, fathers were hesitant to safely hold, carry, and touch babies because babies were sensitive and fragile [30]. It stated that especially those who would become fathers for the first time needed more support and training on these issues [1,2], and that real babies should be used instead of artificial babies to learn these practices [19]. In addition, a comparative study conducted with young and adult first-time fathers found that adult fathers were better at care practices, such as holding the baby and burping the baby, compared with young fathers [31]. Young fathers who become fathers for the first time should be given more detailed information about ensuring the baby's safety.

The third factor in the FSSNC consisted of items addressing fathers' self-efficacy regarding preparing formula if breast milk was not available, understanding when the baby should be fed, and recognizing when the baby was full. It was found that breastfeeding and feeding the baby were among the topics that fathers found themselves inadequate in baby care and needed more information [9,14,22]. As breastfeeding the newborn baby is of great significance, fathers' breastfeeding self-efficacy should be developed and supported [17,23]. However, in some cases where the mother cannot breastfeed, fathers should prepare the formula if the breast milk is not readily available. They should discern whether their babies are hungry and full.



The scale developed for parents in the literature consists of 3 sub-dimensions and 15 items. Additionally, this scale is related to the care of babies between 0 and 12 months [22]. When this scale was adapted only to fathers with 0–4 year old children, a two-factor structure emerged. Additionally, two items from this scale were removed and the number of scale items became 13 [9].

The FSSNC we have only developed for fathers is more specific than the scales developed for parents and fathers, focuses only on neonatal care, and consists of three sub-dimensions: “hygiene”, “safety”, and “nutrition”. In addition, although there are a few items on the baby’s nutrition in these two developed scales, there are no items on hygienic care and safety. Identifying fathers’ shortcomings in this area and providing essential support are crucial to increase their participation in newborn care. The FSSNC is expected to play an essential role in this process.

### Limitations

The scale proposed in this study had several limitations. First, the development of the scale was based on a sample of a specific geographical region in Turkey. This has raised the questions of its validity and reliability in other regions or among fathers from different cultural or socioeconomic backgrounds. Second, the perception of self-efficacy is a subjective concept, and participants are likely to modify their responses based on social desirability or other individual factors. This may limit the scale’s ability to measure self-efficacy accurately. Additionally, although the scale addresses some self-efficacy elements in newborn care, it is possible that other important elements may be left out. Further studies are needed to determine whether the scope of the scale fully covers all facets of self-efficacy in newborn care.

### Conclusions

The authors of this study anticipated that the FSSNC might be useful for assessing fathers’ self-efficacy for newborn care. This scale was designed to be used by practitioners and researchers who wanted to evaluate the self-efficacy of expectant fathers whose spouses were pregnant and those with newborn babies. The FSSNC is an easily implemented and user-friendly scale. Furthermore, the scale can be used to evaluate the effectiveness of different educational programs and interventions to improve practice skills by comparing FSSNC scores before and after any intervention for newborn care. In addition, the FSSNC can be used to investigate the factors affecting a father’s self-efficacy toward newborn care. In conclusion, the FSSNC is a valid and reliable measurement tool that can be used to assess fathers’ self-efficacy for newborn care. At the end of the evaluation, nurses and midwives should determine the issues related to newborn care that fathers need in the clinic, support them, and facilitate their adaptation to their new roles.

### Ethic approval

The study design process started in October 2021, and the researchers collected data after receiving ethics committee approval (decision no: 100) on March 29, 2022. The research permission (no: 932) was granted by a hospital. All participants provided written informed consent. The study was completed on December 14, 2022.

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### Author contribution

**Sevilay Ergün Arslanlı:** Conceptualization; Data curation; Formal analysis; Investigation; Methodology; Project administration; Validation; Resources; Writing-original draft; Review & Editing. **Ayda Çelebioğlu:** Conceptualization; Data curation; Formal analysis; Investigation; Project administration; Supervision; Review & Editing. **İsa Çelik:** Conceptualization; Data curation; Formal analysis; Investigation; Methodology; Validation; Resources; Writing-original draft; Review & Editing. **Nezaket Bilge Uzun:** Conceptualization; Data curation; Formal analysis; Supervision; Review & Editing.

### Conflict of interest

The authors declare no conflicts of interest.

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### Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.anr.2024.04.001>.

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## Research Article

# A Nomogram for Predicting the Infectious Disease-specific Health Literacy of Older Adults in China

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## Keywords:

aged  
communicable diseases  
health literacy  
nomograms

## SUMMARY

**Purpose:** To identify the predictors of infectious disease-specific health literacy (IDSHL), and establish an easy-to-apply nomogram to predict the IDSHL of older adults.

**Methods:** This cross-sectional study included 380 older adults who completed the IDSHL, self-rated health, socio-demographic and other questionnaires. Logistic regression was used to identify the IDSHL predictors. Nomogram was used to construct a predictive model.

**Results:** Up to 70.1% of older adults had limited IDSHL. Age, education, place of residence, self-rated health, and Internet access were the important influencing factors of IDSHL. The established nomogram model showed high accuracy (receiver operating characteristic curve: 0.848).

**Conclusions:** The IDSHL of Chinese older adults was significantly deficient. The constructed nomogram is an intuitive tool for IDSHL prediction that can not only contribute toward rapid screening of high-risk older adults with limited IDSHL but also provide guidance for healthcare providers to develop prevention strategies for infectious diseases.

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## Introduction

With the globalization of economy, trade, and physical distribution, newly emerging and reemerging infectious diseases pose a continuous threat to human health [1]. It is estimated that infectious diseases kill nearly 15 million people every year and have rendered at least 1 billion people chronically infected [2,3]. Compromised health and disability caused by infectious diseases account for nearly 20.0% of all disability-adjusted life years (DALYs) worldwide [4]. Infectious disease has become a major public health challenge in today's world [5].

Older adults are undoubtedly among the most seriously affected groups by infectious diseases owing to the increase in age and decreased immunity. In the United States alone, about 70.0% of influenza-related deaths occur in people aged 75 and above [6]. In Israel, the proportion of older people hospitalized for infectious diseases increased from 16.9% to 19.3% in 10 years [7]. In China, the reported rate of tuberculosis in people over 60 years old is 2–3 times that of young people [8]. The World Health Organization (WHO) reported that older adults were more likely to develop serious illnesses when suffering from COVID-19 [9]. Understandably, infectious diseases are increasingly becoming medical challenges in today's aging society [10].

Health literacy is defined as an individual's ability to obtain, understand, and evaluate health information to make health-related decisions and improve health status [11]. Health literacy plays a vital role in the effectiveness of infectious disease control and the improvement of health status [12–14]. Limited health literacy is related not only to the inability to develop personal preventive health behaviors [15,16], but also to various adverse health outcomes, including the exacerbation of underlying chronic diseases among older adults, high morbidity and mortality, and

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increasing medical costs [17,18]. In the United States, inadequate health literacy has led to additional health care costs of \$215 billion [18].

Although the role of health literacy in infectious diseases has been proven [19], various studies have mainly focused on the effect of the general health literacy on patients with infectious diseases, and without specificity, it is not sufficient to evaluate the characteristics of infectious diseases-specific health literacy to guide further tailored interventions. Silva et al [20] used the Newest Vital Sign questionnaire to survey and found that better health literacy was associated with better attitudes toward preventive strategies against COVID-19 among college students. Anderson et al [21] used the Short-Test of Functional Health Literacy and discovered that higher health literacy was associated with higher compliance with medical treatment among HIV-infected patients. Sun et al [22] used the general health literacy scale to investigate and found that the level of health literacy was positively correlated with health behavior and health status among patients with infectious respiratory diseases.

It is widely known that infectious diseases can be spread by various pathways. As it is quite limiting to only evaluate the general health literacy among patients with infectious diseases, it is crucial to comprehensively evaluate the level of infectious disease-specific health literacy with different routes of transmission. Tian et al [23] developed a comprehensive scale for measuring the infectious disease-specific health literacy (IDSHL). Du et al [24] conducted a survey among rural migrant workers in three provinces of China and found that nearly half of the participants had limited IDSHL, and the education level of migrant workers and their access channel to health information were the influencing factors of IDSHL.

The IDSHL is a vital determinant of public health and healthy behaviors [25]; however, not everyone has the ability to access infection-related information, develop healthy behaviors, and make positive decisions, especially for older adults [13]. The IDSHL of older adults is often overlooked, and there are no specific studies predicting the IDSHL among Chinese older adults.

The nomogram visualized the regression equation and obtained the predicted probability of risk occurrence by calculating the sum of

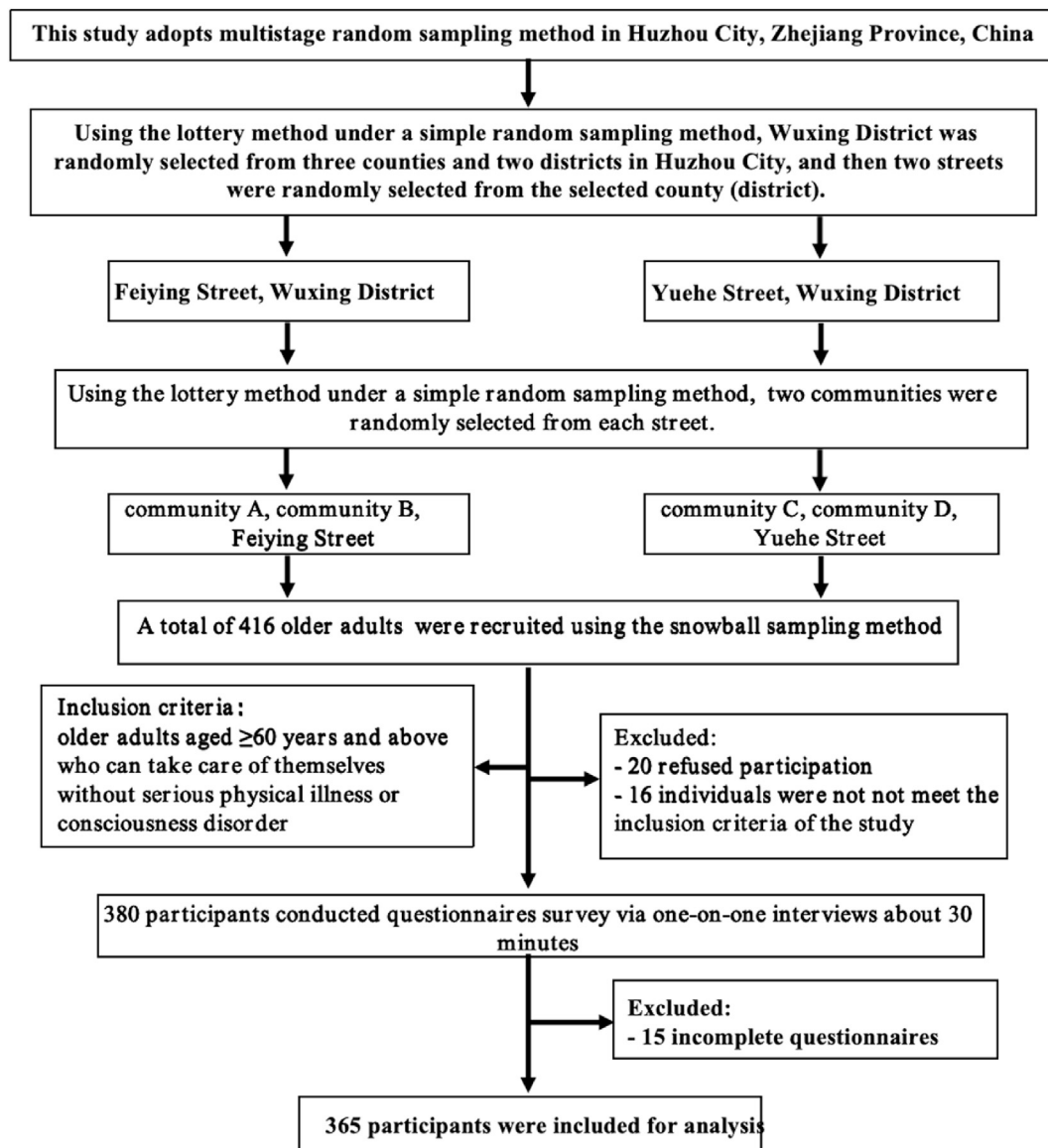


Figure 1. Flowchart of the Participant Selection.



the scores of each independent risk factor. Compared with the traditional regression equation, the nomogram can realize individualized prediction and make the prediction results more readable. At present, nomograms are widely used for risk prediction, such as sarcopenia, self-regulated learning levels, and e-health literacy [26–28].

This study aimed to investigate the IDSHL status of older adults, identify the predictors of IDSHL, and establish a nomogram of IDSHL among older adults in China. We hope that by using the easy-to-apply nomogram, it will eventually be helpful for policymakers and healthcare providers to conveniently and quickly screen older adults with insufficient IDSHL. This, in turn, will facilitate healthcare providers to develop a tailored IDSHL promotion strategy and improve the health outcomes of older adults.

**Methods**

*Study design and target population*

A cross-sectional study was conducted from May to October 2022 among older adults (age: ≥60 years) in Huzhou City in Zhejiang Province, China. A multistage random sampling method was used. Using the lottery method under a simple random sampling method, Wuxing District was randomly selected from three counties and two districts in Huzhou City; Two streets (Feiyong Street and Yuehe Street) were randomly selected from the Wuxing District; Randomly select two communities from each street; Then, older adults were randomly selected from each of the four selected communities by the snowball sampling method. Participants in this study were older adults aged ≥60 years and above who can comprehend explanations, those without cognitive disabilities. Figure 1 shows the flowchart of the participant selection.

Sample size evaluation was based on the following sample size calculation formula:  $n = \frac{z^2 \cdot p(1-p)}{d^2}$ , where Z is the standard 95.0% confidence level, and was 1.96 by checking the standard normal distribution quantile table, and the error value  $d = 0.05$ . According to the results of the health literacy survey in China in 2021, the level of IDSHL was 27.6%. Therefore,  $n = \frac{1.96^2 \cdot 27.6\%(1-27.6\%)}{0.05^2} = 307.06 =$

307. Taking into account the 10.0% non-response rate, at least 338 participants were needed. A total of 416 older adults were recruited using the snowball sampling method, and 380 participants who met the inclusion criteria filled out questionnaires via one-on-one interviews (Figure. 1).

*Data collection*

First of all, 30 older adults were conveniently sampled to test the reliability and validity of these questionnaires before the study began. With the introduction of community health workers, the uniformly trained researchers explained the purpose and significance of the study to the participants. These questionnaires were completed via one-on-one interviews for about 30 minutes. For those who had difficulty reading, the researcher helped complete these questionnaires in question-and-answer format.

*Ethical approval*

This study was approved by the Ethics Committee of the Medical College of Huzhou University (approval number: 2022-03-16). All participants signed the informed consent form.

*Measures*

IDSHL was measured by the Infectious Disease-Specific Health Literacy Scale, which was developed and validated by Xiao et al. in 2016 and comprises 22 items in 4 dimensions (basic knowledge and concepts of infectious diseases, prevention of infectious diseases, management and treatment of infectious diseases, identification of pathogens and sources of infection) [23]. The total score ranges from 0 to 38.62 points, and a total score less than 16.74 points indicates limited IDSHL. The IDSHL scale has previously been tested in a large-scale population in China, and takes about 20 minutes to complete [24]. In this study, Cronbach's  $\alpha$  coefficient was 0.80.

This study referred to previous literature and finally selected candidate variables after expert letter inquiry [23,25,29,30]. Six experts were invited, including two infectious disease specialists,

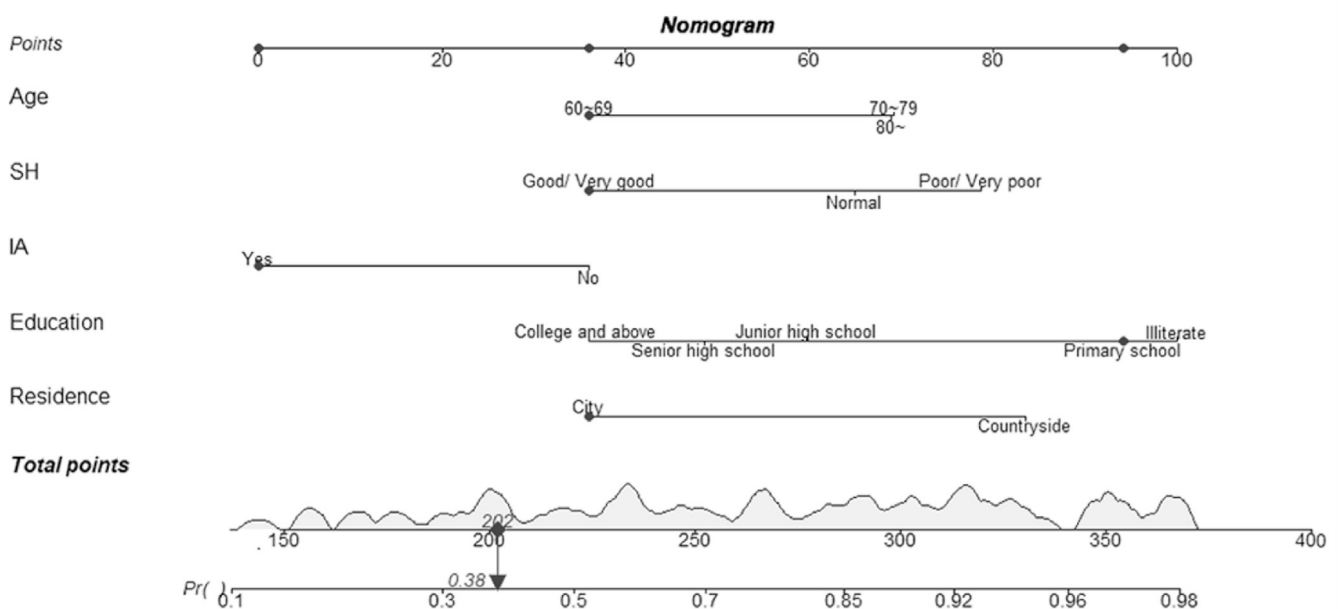


Figure 2. The Nomogram for Predicting Limited IDSHL. Note. IA = internet access; IDSHL = infectious disease-specific health literacy; Pr = probability; SH = self-rated health.

two health management professors, and two infectious disease nurses who have been engaged in the study or treatment of infectious diseases. Socio-demographic and other characteristics including gender, age, religious belief, place of residence, education, occupation, personal monthly income, Internet access, participants' chronic disease, and self-rated health were recorded. The presence of chronic diseases was assessed by asking participants to indicate if they had physician-diagnosed chronic diseases. Internet access was assessed by asking whether they had access to the Internet and whether they used the Internet to obtain medical or health information related to infectious diseases. Self-rated health included three categories, namely very poor/poor, normal, and good/very good, it was assessed by asking "What do you think of your current health status?"

### Statistical analysis and model development

Data analysis was conducted by SPSS 25.0. Continuous variables were presented as means  $\pm$  standard deviations ( $\bar{x} \pm s$ ), and classified variables were presented as frequency and percentage. The chi-square test was used to determine the related factors of IDSHL level, and the factors with  $p < .05$  were included in the

logistic regression model to determine the independent influencing factors of IDSHL. Multicollinearity analysis was further conducted by computing variance inflation factor (VIF). Using the R software, the nomogram visualized the logistic regression model. Each predictor variable could obtain a corresponding score on the top point line of the nomogram, and the sum of the scores of each predictor variable was the final total score. Each final total score corresponds to the predicted probability at the bottom risk line (Figure. 2).

Receiver operating characteristic curve (ROC) and calibration curves were used to evaluate the nomogram accuracy and identification capabilities, and Hosmer–Lemeshow test was used to evaluate the correction effect of the prediction model.

## Results

### Socio-demographic and other characteristics of older adults

Table 1 summarizes the socio-demographic and other characteristics of the participants. A total of 380 older adults who met the inclusion criteria filled out questionnaires, and 365 valid questionnaires were collected, with a response rate of 96.56%. The mean

**Table 1** Differences of IDSHL among Different Demographic Groups.

Characteristics	N (%)	IDSHL scores (mean $\pm$ SD)	Health literacy levels [N (%)]		$\chi^2$	p
			Adequate	Limited		
<b>Age (years)</b>						
60–69	155 (42.5)	15.75 $\pm$ 8.04	61 (39.4%)	94 (60.6%)	11.769	.003**
70–79	143 (39.2)	13.04 $\pm$ 6.91	34 (23.8%)	109 (76.2%)		
$\geq 80$	67 (18.4)	12.19 $\pm$ 5.41	14 (20.9%)	63 (79.1%)		
<b>Gender</b>						
Men	183 (50.1)	14.61 $\pm$ 7.13	60 (32.8%)	123 (67.2%)	1.498	.221
Women	182 (49.9)	13.46 $\pm$ 7.48	49 (26.9%)	133 (73.1%)		
<b>Ethnicity</b>						
Han	352 (96.4)	14.15 $\pm$ 7.38	108 (30.7%)	244 (69.0%)	2.161	.142
Others	13 (3.6)	10.89 $\pm$ 4.44	1 (7.7%)	12 (92.3%)		
<b>Religious belief</b>						
No	336 (92.1)	14.10 $\pm$ 7.43	101 (30.1%)	235 (69.6%)	0.078	.780
Yes	29 (7.9)	13.29 $\pm$ 5.83	8 (27.6%)	21 (72.4%)		
<b>Place of residence</b>						
Countryside	172 (47.1)	10.59 $\pm$ 4.81	20 (11.6%)	152 (88.4%)	51.642	<.001***
City	193 (52.9)	17.10 $\pm$ 7.80	89 (46.1%)	104 (53.9%)		
<b>Education</b>						
No formal education	81 (22.2)	8.81 $\pm$ 3.89	6 (7.4%)	75 (92.6%)	68.731	<.001***
Primary school	124 (34.0)	12.22 $\pm$ 5.55	21 (16.9%)	103 (83.1%)		
Junior high school	84 (23)	15.86 $\pm$ 6.28	37 (44.0%)	47 (56.0%)		
Senior high school	46 (12.6)	19.50 $\pm$ 7.71	27 (58.7%)	19 (41.3%)		
College and above	30 (8.2)	22.16 $\pm$ 8.84	18 (60.0%)	12 (40.0%)		
<b>Occupation</b>						
Farmers	110 (30.1)	10.28 $\pm$ 4.53	12 (10.9%)	98 (89.1%)	36.367	<.001***
Factory workers	156 (42.7)	14.85 $\pm$ 6.94	57 (36.5%)	99 (63.5%)		
Public institution	63 (17.3)	19.01 $\pm$ 8.80	32 (50.8%)	31 (49.2%)		
Others	36 (9.9)	13.26 $\pm$ 7.03	9 (22.2%)	28 (75.7%)		
<b>Personal monthly income (Yuan)</b>						
<2000	65 (17.8)	9.68 $\pm$ 4.39	5 (7.7%)	60 (92.3%)	42.930	<.001***
2000–4000	130 (35.6)	12.23 $\pm$ 5.83	29 (22.3%)	101 (77.7%)		
4000–6000	100 (27.4)	14.76 $\pm$ 6.73	36 (36.0%)	64 (64.0%)		
$\geq 6000$	70 (19.2)	20.40 $\pm$ 8.37	39 (55.7%)	31 (44.3%)		
<b>Internet access</b>						
No	214 (58.6)	11.17 $\pm$ 5.64	32 (15.0%)	182 (85.0%)	54.902	<.001***
Yes	151 (41.4)	18.09 $\pm$ 7.51	77 (51.0%)	74 (49.0%)		
<b>Chronic disease</b>						
No	109 (29.9)	15.18 $\pm$ 8.05	39 (35.8%)	70 (64.2%)	2.598	.107
Yes	258 (70.1)	13.55 $\pm$ 6.94	70 (27.3%)	186 (72.7%)		
<b>Self-rated health</b>						
Poor/Very poor	87 (23.8)	10.98 $\pm$ 4.95	13 (14.9%)	74 (85.1%)	36.946	<.001***
Normal	143 (39.2)	12.46 $\pm$ 6.29	31 (21.7%)	112 (78.3%)		
Good/Very good	135 (37.0)	17.68 $\pm$ 8.11	66 (48.9%)	69 (51.1%)		

Note. IDSHL = infectious disease-specific health literacy; N = number; SD = standard deviation;  $\chi^2$  = chi-square.

\*\* $p < .01$ ; \*\*\* $p < .001$ .

age of the participants was  $71.68 \pm 8.60$  years, ranging from 60 to 97 years. The gender distribution was similar (50.1% were men). Most participants had no formal education (22.2%) or primary education (34.0%). Furthermore, 41.4% of participants had Internet access to health information on infectious diseases. 258 (70.1%) participants had chronic disease. About one-third of participants rated their health as good/very good (37.0%). The score of IDSHL was  $14.03 \pm 7.31$ , and 70.1% participants were identified with limited IDSHL.

#### Predictive variables selection of the IDSHL among older adults

Univariate analysis showed that age, place of residence, education, occupation, personal monthly income, Internet access, and self-rated health were associated with limited IDSHL (Table 1). Seven variables obtained from the univariate analysis were fed into the binary logistic regression model. In the present study, the VIF values ranged between 1.10 and 1.82, which was below the cautionary threshold of 3 [31], and it was free from colinearity. The regression results found that older adults aged  $\geq 70$  years, living in countryside, no formal education, no Internet access, and self-rated health as poor/very poor were high-risk population with limited IDSHL (Table 2). Therefore, we finally identified five important predictors of IDSHL: age, place of residence, education, Internet access, and self-rated health.

#### Construction of the nomogram predicting IDSHL

Based on the results of the logistic regression model, an easy-to-apply nomogram for predicting the IDSHL was established, and the model included five prediction factors (Figure 2). For example, an older adult aged 60–69 years (point 36), self-rated health as good/very good (point 36), the Internet access (point 2), has primary

**Table 2** Binary Logistic Regression Analysis of Factors Influencing Limited IDSHL.

Variables	OR	95% CI of OR	p
<b>Age (Years)</b>			
60–69	Reference		
70–79	2.662	1.382 ~ 5.127	.003**
$\geq 80$	2.731	1.182 ~ 6.309	.019*
<b>Place of residence</b>			
Countryside	Reference		
City	0.290	0.137 ~ 0.613	.001**
<b>Education</b>			
No formal education	Reference		
Primary school	0.924	0.318 ~ 2.688	.885
Junior high school	0.406	0.135 ~ 1.225	.110
Senior high school	0.325	0.095 ~ 1.111	.073
College and above	0.248	0.062 ~ 0.985	.048*
<b>Occupation</b>			
Farmers	Reference		
Factory workers	0.832	0.343 ~ 2.016	.683
Public institution	0.753	0.258 ~ 2.194	.603
Others	1.504	0.428 ~ 5.278	.524
<b>Personal monthly income (Yuan)</b>			
<2000	Reference		
2000–4000	0.711	0.202 ~ 2.502	.595
4000–6000	0.874	0.234 ~ 3.260	.841
$\geq 6000$	0.547	0.136 ~ 2.195	.394
<b>Internet access</b>			
No	Reference		
Yes	0.413	0.228 ~ 0.747	.003**
<b>Self-rated health</b>			
Poor/Very poor	Reference		
Normal	0.733	0.310 ~ 1.729	.478
Good/Very good	0.339	0.154 ~ 0.747	.007**

Note. CI = confidence interval; IDSHL = infectious disease-specific health literacy. OR = odds ratio; \* $p < .05$ ; \*\* $p < .01$ .

school education (point 93), and lives in city (point 35). The total score is  $36 + 36 + 2 + 93 + 35 = 202$ , and the corresponding probability is 38.0%, indicating that is a low-risk older adult with limited IDSHL.

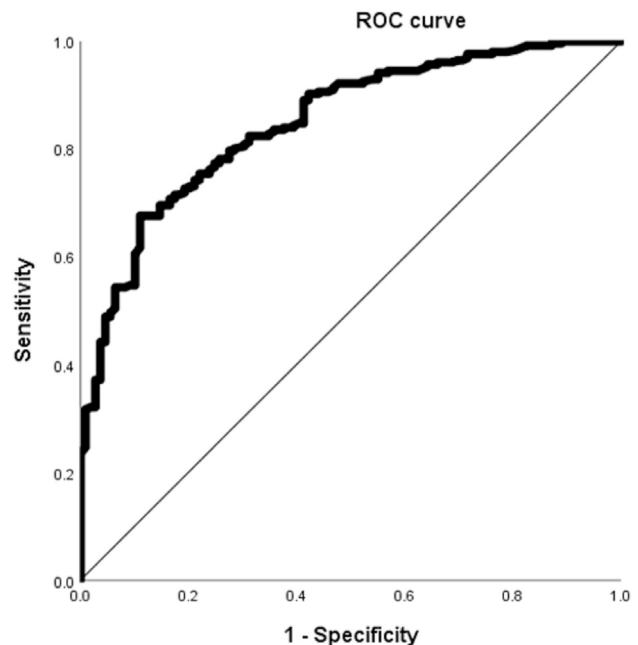
#### Validation of the nomogram for IDSHL

The ROC curve shows that the Area Under Curve of the model was 0.848 (95% CI = 0.808–0.889,  $p < .001$ ; Figure 3). The model cut-off value was 0.794, and when the probability of an individual was greater than 79.4%, it was determined to be a high-risk older adult with limited IDSHL. The sensitivity and specificity of the model were 0.676 and 0.890, respectively. The calibration curve of the nomogram showed good consistency between the predicted and observed probability values (Figure 4). The Hosmer–Lemeshow test showed that the correction effect of the prediction model was good ( $\chi^2 = 4.781$ ,  $p = .781$ ).

#### Discussion

Infectious diseases can lead to the aggravation of chronic diseases among older patients, as well as result in higher rates of hospitalization, disability, and mortality [5,7,17,18]. Early screening and detection of older adults with limited IDSHL is crucial. The IDSHL plays an important role in the epidemic prevention and control of infectious diseases [14]. Despite the IDSHL scale being a valid tool to identify individuals with limited IDSHL, it is difficult for older adults with impaired cognitive function, poor vision, and low education level to fill out it [32].

Since nomograms can visualize the prediction model as a simple and intuitive graph, making prediction more convenient, they have been widely used for the prediction of disease prognosis [33,34]. However, the related models for predicting health literacy are few, and only one study has established the nomograms for predicting electronic health literacy of primary and secondary school students [26]. To our knowledge, this is the first study to develop an easy-to-



**Figure 3.** ROC Curve for the Prediction Model of the IDSHL. Note. IDSHL = infectious disease-specific health literacy; ROC = receiver operating characteristics.



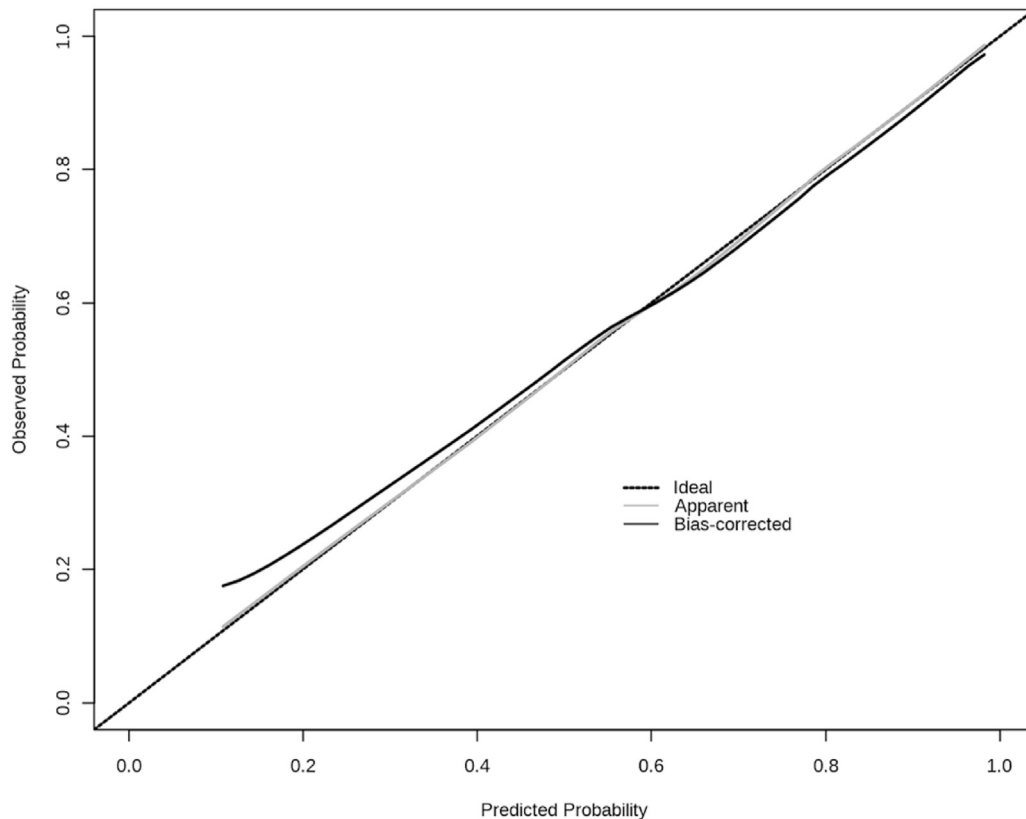


Figure 4. Calibration Curve of the Nomogram for IDSHL. Note. IDSHL = Infectious Disease-Specific Health Literacy.

apply nomogram model to predict and rapidly identify high-risk community-dwelling older adults with limited IDSHL.

This study indicated that limited IDSHL was prevalent among older adults, accounting for 70.1%, which was much higher than the survey results (26.6%) of general residents (aged 15–69 years) across three provinces of China [29]. Previous studies have emphasized that people with limited health literacy, especially less-educated older adults, find it difficult to understand medical materials and communicate with medical staff [35,36]. This phenomenon was commonly observed during the COVID-19 pandemic. It was observed that 46% of older German individuals expressed confusion about health information [37]. Furthermore, 29.1% of Turkey's older population did not understand the impact of infectious diseases on their health, and 15.5% of them changed their medication time or dose without consulting a doctor [37,38]. Therefore, early warning of IDSHL, timely intervention, and prevention are crucial to improve the health outcomes of older adults.

Education is considered to be the most critical factor in shaping individual health literacy [39]. People with higher education levels have higher acceptance of new information and show better compliance for preventive behaviors [29]. This study found that 56.2% of older adults had a primary school education or less, similar to a previous study in Hong Kong [40]. In addition, the IDSHL level of older adults living in cities was significantly higher than those living in countryside. The reason might be that rural residents lack good health services and access to health information, so they have limited IDSHL [41]. It is very important for healthcare providers to develop video-based health education materials or carry out health education through face-to-face health communication.

Internet access has been shown to be an important predictor of IDSHL among older adults. A previous study showed that people

who had no access to the Internet were nearly three times more likely to have limited health literacy than those with Internet access [42]. Older adults who frequently use the Internet will be affected imperceptibly, thus they have the chance to enhance their awareness and understanding of infectious diseases and undertake appropriate prevention steps [43]. It is noteworthy that older adults able to access the Internet and recognize false information are able to take timely preventive measures related to infectious diseases [44,45].

Various studies have confirmed that health literacy is a factor affecting self-rated health. Nie et al [46] pointed out that individuals with higher health literacy, such as infectious disease literacy, had better self-rated health. Lin et al [35] suggested that one possible mechanism linking better health literacy to better self-rated health was self-management. Interestingly, our study found that self-rated health is an influencing factor of IDSHL. The possible reason was that people with good self-rated health were more willing to actively obtain health information related to infectious diseases, and maintain their health. Further studies are needed to ascertain whether there is a mutual influence between IDSHL and self-rated health.

We constructed and validated a nomogram model for predicting the finite probability of IDSHL in older individuals. This nomogram shows that age, education, place of residence, Internet access, and self-rated health have good predictive power for limited IDSHL among older adults. The results of internal verification showed that the nomogram had high discrimination and accuracy. All five variables in the nomogram are easily obtained from personal information. The easy-to-apply nomogram can serve as a valid tool to screen high-risk older adults with limited IDSHL.

The risk stratification of IDSHL was quantified by calculating the total score using the five variables. When the probability is less than 79.4%, continuous monitoring is sufficient for older adults. However, for those with a probability greater than 79.4%, the older adult will be considered as high-risk population with limited IDSHL. For example, for an older adult who is between 70 and 79 years (point 70), self-rated health as normal (point 65), no access to the Internet (point 35), has completed primary school education (point 93), and lives in the city (point 33), the total score is  $70 + 65 + 35 + 93 + 33 = 296$ . The probability is 86% ( $>79.4\%$ ), indicating that the older adults will be a high-risk population with limited IDSHL. Further detailed evaluation of IDSHL and the tailored-IDSHL intervention will be needed.

In conclusion, the nomogram was an intuitive tool to assist positive clinical decision-making and facilitate implementation of hierarchical health management of IDSHL in community. The easy-to-apply nomogram constructed in this study can be used to rapidly screen high-risk older adults with limited IDSHL. When the probability is  $>79.4\%$ , detailed evaluation is further needed, and it will help the policymakers and healthcare providers to develop a tailored-IDSHL intervention as early as possible to improve health outcomes and quality of life for older adults with limited IDSHL.

### Limitations

This study has some limitations. First, all the participants were from Zhejiang Province, China, and the results of this study have not been extended to the older population groups in different countries, and the external validity can therefore not be reported. Second, because of the COVID-19 pandemic during the investigation period, the sample size is relatively small. Therefore, future studies should expand to different regions or countries and increase the sample size to verify the external validity of the nomogram. Third, we overlooked the impact of older adults living with family on IDSHL, and we will add this variable in the external validation study of large samples in future studies.

### Conclusions

The IDSHL of Chinese older adults was significantly deficient, and the five important predictors of IDSHL were age, place of residence, education, Internet access, and self-rated health. The easy-to-apply nomogram constructed in this study has practical significance and good discriminating potential. It can help healthcare providers to effectively and rapidly identify older adults with limited IDSHL. Ultimately, this study may provide a reference and suggestions for researchers and healthcare providers to develop a tailored IDSHL promotion in different countries.

### Ethics approval and consent to participate

The study was approved by the Ethics Committee of Medical College of Huzhou University (approval number: 2022-03-16). The study was conducted in accordance to the Declaration of Helsinki. All participants signed the informed consent before data collection. All instruments of the study were used with permission of its developers.

### Funding

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### Availability of data and material

Data used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

### Conflict of interest

No potential conflict of interest was reported by the author(s).

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## Research Article

Automated Personalized Self-care Program for Patients With Type 2 Diabetes Mellitus: A Pilot Trial<sup>☆</sup>Gaeun Park,<sup>1</sup> Haejung Lee,<sup>1,\*</sup> Yoonju Lee,<sup>1</sup> Myoung Soo Kim,<sup>2</sup> Sunyoung Jung,<sup>1</sup> Ah Reum Khang,<sup>3,4</sup> Dongwon Yi<sup>3,4</sup><sup>1</sup> Department of Nursing/Research Institute of Nursing Science, Pusan National University, South Korea<sup>2</sup> Department of Nursing, Pukyong National University, South Korea<sup>3</sup> Division of Endocrinology and Metabolism, Department of Internal Medicine, Pusan National University Yangsan Hospital/Department of Medicine, Pusan National University School of Medicine, South Korea<sup>4</sup> Research Institute for Convergence of Biomedical Science and Technology, Pusan National University Yangsan Hospital, South Korea

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## SUMMARY

**Purpose:** Providing continuous self-care support to the growing diabetes population is challenging. Strategies are needed to enhance engagement in self-care, utilizing innovative technologies for personalized feedback. This study aimed to assess the feasibility of the Automated Personalized Self-Care program among type 2 diabetes patients and evaluate its preliminary effectiveness.

**Methods:** A parallel randomized pilot trial with qualitative interviews occurred from May 3, 2022, to September 27, 2022. Participants aged 40–69 years with type 2 diabetes and HbA1c  $\geq 7.0\%$  were recruited. The three-month program involved automated personalized goal setting, education, monitoring, and feedback. Feasibility was measured by participants' engagement and intervention usability. Preliminary effectiveness was examined through self-care self-efficacy, self-care behaviors, and health outcomes. Qualitative interviews were conducted with the intervention group.

**Results:** A total of 404 patients were screened. Out of the 61 eligible patients, 32 were enrolled, resulting in a recruitment rate of 52.5%. Retention rates at three months were 84.2% and 84.6% in the intervention and control groups, respectively. Among the intervention group, 81.3% satisfied adherence criteria. Mobile application's usability scored 66.25, and participants' satisfaction was 8.06. Intention-to-treat analysis showed improvements in self-measured blood glucose testing, grain intake, and HbA1c in the intervention group. Qualitative content analysis identified nine themes.

**Conclusion:** Feasibility of the program was verified. A larger randomized controlled trial is needed to determine its effectiveness in self-care self-efficacy, self-care behaviors, and health outcomes among type 2 diabetes patients. This study offers insights for optimizing future trials assessing clinical effectiveness.

**Trial registration:** Clinical Research Information Service, KCT0008202 (registration date: 17 February 2023).

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## Introduction

The prevalence of diabetes has steadily increased, with rates rising from 3.6% in the 30s to 10.6%–31.8% for individuals aged 40 and above [1,2]. Maintaining hemoglobin A1c (HbA1c) levels  $\geq 7.0\%$  was associated with increased odds of the chronic diabetic complications, including cardiovascular disease, neuropathy, nephropathy, and peripheral vascular disease [3]. These complications significantly impacted the quality of life (QOL) of patients with type 2 diabetes mellitus (T2DM) [4]. To reduce HbA1c levels and



minimize complications, regular self-care is crucial [5]. In a previous randomized controlled trial (RCT) and meta-analysis of RCTs, interventions promoting self-care have improved diabetes self-efficacy [6], exercise, and foot care outcomes [7], and reduced HbA1c levels and depression [8]. As lifestyle changes require continuous reinforcement, intervention with ongoing support are needed for effective behavior changes and optimal health maintenance in patients with T2DM [6]. However, providing continuous self-care interventions to the growing diabetes population is challenging. Strategies are needed to support continuous self-care among patients with T2DM.

Advancements in wearables and mobile applications (apps) have facilitated widespread Information and Communication Technology (ICT)-based interventions to support continuous self-care in patients with T2DM [9–11]. In previous RCTs, ICT-based self-care interventions involved customized education, personalized messages, and solutions to barriers, effectively lowering HbA1c levels [7,12,13]. Components such as blood glucose (BG) and medication monitoring, automated feedback, and communication with healthcare professionals were advantageous [12]. Although the effectiveness of ICT-based self-care interventions depends on the engagement of the participants [14–16], there was a tendency for a decrease in device usage during the intervention period [17,18]. Using two or more apps added to the burden on participants, and monitoring only certain self-care areas or having fixed goals was insufficient to motivate participants to engage in the ICT-based self-care interventions [14,19]. Additionally, focusing only on total calorie consumption limited the ability to provide specific feedback for making meaningful behavioral changes [20]. Thus, tailored goals and feedback based on individual needs and self-care levels are essential.

To address these limitations of existing ICT-based self-care interventions, an Automated Personalized Self-Care (APSC) program was developed [21]. The APSC program integrated various self-care behaviors into one user-friendly app. The APSC program differs from previous approaches by not only managing total calorie intake but also by guiding dietary intake based on food groups such as grains, protein foods, vegetables, fruits, and dairy. This approach offers tailored feedback to facilitate specific and significant behavioral changes in participants. Furthermore, the program prioritizes managing behaviors according to the required order of improvement and provides goals tailored to each patient's level of self-care [21]. This promotes steady and progressive enhancements in self-care, aligning with the Centers for Disease Control and Prevention's recommendation [6].

Furthermore, considering that only 37.5% of patient-centered self-care interventions for T2DM utilized theoretical models in previous studies [7], the APSC program was developed based on Bandura's self-regulation theory. Bandura's self-regulation theory viewed humans as self-regulating beings, where behaviors are regulated through self-observation, self-judgment, and self-reaction [22]. By incorporating personalized goals and feedback, the program can empower patients with T2DM to actively monitor their self-care behaviors, evaluate their progress, and adjust their behaviors accordingly. Moreover, managing diabetes requires simultaneous changes in multiple behaviors such as exercise, diet, and medication therapy, emphasizing the critical role of self-regulation [23].

Conducting a pilot trial before implementing a program on a larger scale is crucial, as it serves to address uncertainties around the feasibility of intervention trial methods, or test preliminary effectiveness of the intervention [10,12,24,25]. We intended to resolve potential issues based on the results of this pilot study. The aim of this pilot study was to evaluate the feasibility and preliminary effectiveness of the APSC program using both quantitative and qualitative methods. We confirmed the feasibility of the APSC

program by exploring participant engagement rates and intervention usability, as well as assessed the preliminary effectiveness on self-care self-efficacy, self-care behaviors, and health outcomes. Additionally, we explored participants' experience during the intervention because this can influence the program's effectiveness and sustainability [26].

## Methods

### Study design

The study employed a parallel randomized pilot trial with an inductive content analysis [27] to identify the feasibility and preliminary effectiveness of the three-month APSC program among patients with T2DM in South Korea. The program period was based on prior RCTs [6,13], which demonstrated a significant improvement in diabetes self-efficacy, exercise, HbA1c levels, and depressive symptoms after a three-month ICT-based self-care intervention. Reporting guidelines were based on the CONSORT 2010 statement: extension to randomized pilot and feasibility trials [28]. This study was registered Clinical Research Information Service (KCT0008202).

### Participants

Participants were recruited from Pusan National University Yangsan Hospital's diabetes outpatient clinic. The inclusion criteria were T2DM diagnosis, aged 40–69, HbA1c  $\geq$  7.0% in last three months, Android smartphone ownership, and ability to walk without assistive devices. The criteria of age and HbA1c level were based on the higher risk of the onset of diabetes [1,2] and diabetic complications [3].

The exclusion criteria were having difficulty using smartphones, serious pain, cognitive problems, and participating in other self-care research. Additionally, we excluded clinically unstable patients who received acute treatment (e.g., chemotherapy or intensive care unit treatment) within the past year. The minimum number of participants required was 12 per group in a pilot study [29]. A total of 32 patients were recruited with a dropout rate of 25.0% [11]. Considering the higher dropout rate in the intervention group [11], patients were randomly assigned to the intervention or control group at a ratio of 3:2 using the random number generating function in Microsoft Excel 2016 (Microsoft Excel, Microsoft Corporation, Redmond, The United States of America).

### Study intervention

The study intervention was described in Table 1. The development and detailed description of the APSC program was published in Park et al [21].

### Goal setting

Goal setting corresponds to the forethought phase in self-regulation theory. Exercise goal was set based on the health-enhancing physical activity (HEPA) guideline from International Physical Activity Questionnaire (IPAQ) [30], the fitness program by Mayo Clinic [31], and cohort studies related to physical activity (PA) and mortality [32]. It started at 50 minutes per session, seven days a week, increasing 10.0% weekly until reaching 120 minutes per session, seven days a week, when the previous week's goal was achieved. Exercise was recommended after meals, and participants were advised to rest immediately and consume a prepared snack if symptoms of hypoglycemia occurred during exercise. Medication schedule was followed as prescribed.

**Table 1** Strategies of the Automated Personalized Self-care Program.

Component	Description	Strategies
Goal setting	<ol style="list-style-type: none"> <li>1) Exercise <ul style="list-style-type: none"> <li>• Start at 50 min/day, daily</li> <li>• Increasing by 10.0% weekly until reaching 120 min/day, daily</li> </ul> </li> <li>2) Diet <ul style="list-style-type: none"> <li>• Adjust 50.0–130.0% of initial goal based on weekly achievement rate for each food group</li> </ul> </li> <li>3) Medication: 100.0% compliance</li> <li>4) BG testing: More than once a day</li> <li>5) Smoking cessation</li> <li>6) Foot care: More than 5 days/week</li> </ol>	<ul style="list-style-type: none"> <li>• Encourage participants to make plans based on individual self-care levels and preferences</li> <li>• Offer help to establish achievable and sustainable goals</li> </ul>
Education	<ul style="list-style-type: none"> <li>• Importance and positive effects of self-care (one educational material per week)</li> </ul>	<ul style="list-style-type: none"> <li>• Educational materials using cartoons and videos on the app</li> <li>• Interactive activities with human facilitator to enhance engagement</li> </ul>
Monitoring	<ul style="list-style-type: none"> <li>• 5 days/week: Exercise, diet, BG, and medication intake</li> <li>• Once a week: Smoking habits and foot care</li> </ul>	<ul style="list-style-type: none"> <li>• Display goal achievement rate on the app</li> <li>• Activity tracking features on the app to monitor exercise duration and intensity</li> <li>• Food photo diary function to track dietary intake</li> </ul>
Feedback	<ol style="list-style-type: none"> <li>1) Automated message <ul style="list-style-type: none"> <li>• Goal achievement rate for previous day (daily)</li> </ul> </li> <li>2) Mileage incentives <ul style="list-style-type: none"> <li>• For achieving goals, viewing educational materials and feedback messages, or recording self-care</li> </ul> </li> <li>3) Positive feedback from facilitator via phone or text message (weekly)</li> <li>4) Diabetic complication risk <ul style="list-style-type: none"> <li>• Calculated based on participant's characteristics and self-care levels</li> </ul> </li> </ol>	<ul style="list-style-type: none"> <li>• Personalized feedback based on individual progress and goals</li> <li>• Incorporate gamification elements</li> </ul>

Note. BG = blood glucose.

Dietary goals were adjusted 50.0%–130.0% of the initial goal based on the weekly goal achievement rate for each food group. The medication goal was 100.0% compliance, BG testing at least once a day, and foot care at least five days a week. Smokers urged to quit. Weekly, intensive self-care area chosen based on goal achievement rate and participants' involvement, with facilitator aiding tailored plans.

### Education

Education corresponds to the forethought phase in self-regulation theory and focused on the importance of self-care behaviors and their positive effects [5]. Educational materials were created using cartoons and videos for participants to view on the mobile app. Participants were encouraged to watch at least one educational material per week, and the facilitator

ensured that they were able to explain what they had learned every week.

### Monitoring

Monitoring corresponds to the performance or volitional control phase in self-regulation theory. Monitoring was encouraged five days a week for exercise, diet, BG, and medication intake, as well as once a week for foot care and smoking habits. The mobile app graphically displayed the goal achievement rate.

### Feedback

Feedback corresponds to the self-reflection phase in self-regulation theory. At 8:00 a.m. daily, an automated message provided feedback on the highest and lowest goal achievement rate among self-care areas for the previous day. Mileage incentives were given for achieving goals, viewing educational materials and feedback messages, or recording self-care behaviors. Facilitator offered weekly positive feedback via phone or text message and encouraged consistent app use. Diabetic complication risk was calculated and shared via phone or text message.

### Outcome measures

#### Feasibility

Participants engagement rates were assessed through recruitment, retention, and treatment adherence rate [10,33]. Recruitment rate measured the proportion of enrolled participants among potential participants who passed the screening. Retention rate calculated the proportion of participants who completed the three-month follow-up among randomly assigned participants. Treatment adherence rate determined the proportion of intervention group participants monitoring exercise, diet, BG, and medication intake on the app four or more days a week.

Intervention usability was evaluated through mobile app usability and participants' satisfaction. Mobile app usability was measured using Korean-translated System Usability Scale (SUS) [34], consisting of ten items scored on a five-point Likert scale from 1 = "strongly disagree" to 5 = "strongly agree." Scores were calculated by subtracting 1 for items 1, 3, 5, 7, and 9, subtracting the scale position from 5 for items 2, 4, 6, 8, and 10, summing the contributions, and then multiplying the total score by 2.5. Total score ranged from 0–100, with higher scores indicating better usability. Scores of 90–100 were interpreted as "excellent," 80–89 as "good," 70–79 as "acceptable," 60–69 as "marginally acceptable," 50–59 as "low marginally acceptable," and below 50 as "unacceptable" [35]. Cronbach's  $\alpha$  was 0.91 in a previous study [35] and 0.62 in this study. Participants' overall satisfaction with the program was rated on a 10-point Likert scale from 1 = "not very satisfied" to 10 = "very satisfied."

#### Preliminary effectiveness

Self-care self-efficacy was assessed by a Korean-translated diabetes management self-efficacy scale (DMSES) [36]. A 20-item scale measures self-efficacy in nutrition, weight, medical treatment, exercise, and blood sugar. Participants rated items on a five-point Likert scale. Higher scores indicated better self-care self-efficacy. Cronbach's  $\alpha$  was .95 in a previous study [36], and .90 in this study.

Self-care behaviors were evaluated through diabetes self-care activity, PA, and dietary intake. Diabetes self-care activity was measured using the Korean version of revised summary of diabetes self-care activities (SDSCA) [37]. It consisted of 11 items, covering diet, exercise, BG monitoring, foot care, and smoking. Participants rated the frequency of these activities (0–7 points) and "Yes" (1 point) or "No" (0 point) for smoking in the past seven days. Total scores ranged 0–71, indicating better self-care with higher scores.

Test–retest reliability was  $r = .25-.78$  [37]. Cronbach's  $\alpha$  was .76 in this study.

PA was measured using the Korean version of IPAQ [38]. IPAQ measured duration and frequency of PA over the past seven days. It calculated the sum of the Metabolic equivalent of task (MET) scores of PA. The results were presented categorically (inactivity, minimally active, HEPA) and continuously. Test–retest reliability was  $\rho = .43-.65$ , and the validity compared with the accelerometer was  $r = .27$  [38].

Dietary intake was assessed by the principal investigator (GP) through participant reports of meals and snacks based on the standardized guidelines, using volume and weight measurements in milliliters or grams, or standardized tools such as bowls and plates [39]. The principal investigator received training in dietary intake assessment during prior research [21]. Throughout the training process, data collectors monitored each other to maintain consistency and identified and rectified any issues that arose during data collection. The Computer Aided Nutrition Analysis Program 4.0 was used for data analysis. Actual consumption ratios for each food group compared to recommended intake amounts [40] were calculated.

Health outcomes were assessed by BG, HbA1c, low-density lipoprotein cholesterol (LDL-C), depression, and QOL. BG, HbA1c, and LDL-C levels were from medical records. Pre-test medical records for 27 participants were obtained from the results on the day of data collection. As records for that day were not available for the remaining five participants, results within three months prior to the data collection date were collected. All post-test medical records were collected from the results on the day of data collection.

Depression was measured using the Korean version Center for Epidemiological Studies-Depression Scale (CES-D)-10 [41]. Total score ranged from 0–10, with higher scores indicating greater depression. The validity of the scale has been established in a previous study [41] and Cronbach's  $\alpha$  was .78 in this study.

QOL was measured using the Korean version SF-12v2 Health Survey [42] from QualityMetrics. The SF-12v2 included physical and mental component summary measures. Item scores ranged 2–5, and the total score ranged 0–100, higher scores indicating better QOL. The test–retest reliability was  $r = .76-.89$  [42].

#### Qualitative interview

The key questions of qualitative interview included, “How was your experience participating in the program for the past three months?” “What challenges did you encounter while participating in the program?” “What efforts did you make to stay engaged in the program?” “What changes have you noticed during your participation in the program?” and “What were your thoughts and feelings when you participated well/did not participate well in the program?”

#### Procedure

For recruitment, a notice requesting participation in the research was posted in the diabetes outpatient clinic. When patients visited the clinic, their eligibility was screened. Potential participants were informed about the purpose and design of the study, and those who agreed to participate in the research were enrolled and randomly assigned to the intervention or control group using a random number generating function in Excel 2016. Both intervention and control groups were recruited simultaneously. Blinding was not possible due to the nature of the intervention. To minimize potential contamination during simultaneous recruitment of both groups, data collection and education, such as how to use the mobile app, were conducted independently in separate rooms, and access to the mobile app required approval

from the researcher. As this study was outpatient-based, the possibility of interaction between participants was minimal.

Pre-test data collection occurred from May 3 to June 9, 2022, including self-care self-efficacy, self-care behaviors, and health outcomes. Height and weight were measured using an automatic height and weight machine, while BG, HbA1c, and LDL-C levels were measured through venous blood sampling after an eight-hour fasting period. The survey took 15–20 minutes to complete. Intervention group received the APSC program for three months, while the control group received the standard care. Post-test was conducted three months later, from July 25 to September 27, 2022. Intervention group participated in qualitative interviews with the researcher, lasting 10–25 minutes. After the post-test, we offered control group participants the opportunity to experience the program if they wished, thus ensuring ethical considerations. The program was available for them to use as desired, and feedback from the facilitator was provided for one month.

#### Data analysis

Quantitative data analysis used IBM SPSS 26.0, with significance levels set at  $p < .05$ . Intention-to-treat population was analyzed. Missing values from dropouts ( $n = 5$ ) were imputed using regression imputation method. Normality of dependent variables was tested using the Kolmogorov-Smirnov test. Baseline homogeneity was assessed using  $t$ -test, Mann–Whitney U test, chi-square analysis, or Fisher's exact test. Descriptive statistics were used to present the baseline characteristics. Preliminary effectiveness was analyzed using  $t$ -test or Mann–Whitney U test. Per-protocol analysis was conducted, excluding participants who dropped out ( $n = 5$ ) and those with low treatment adherence ( $n = 3$ ). The results of the analysis were included in [Supplementary material A](#).

Qualitative data analysis followed an inductive content analysis approach [27]. The 132 pages of transcripts were comprehensively read to understand the collected data and their context. Meaningful statements relevant to the participants' experiences in the program were extracted and coded. Similar codes were grouped into abstract and higher-level categories. Rigor in this analysis was achieved through credibility, fittingness, auditability, and confirmability [43]. Credibility was ensured by using open-ended questions, maintaining a non-judgmental attitude, and clarifying ambiguous information through additional questions. To ensure fittingness and auditability, data were collected until no new information emerged, and a detailed description of the research process was provided. To ensure confirmability, participants' responses were quoted in the results to allow readers to verify the researchers' interpretations and analysis.

#### Ethical consideration

This pilot study was approved by Pusan National University Yangsan Hospital Institutional Review Board (IRB) before the baseline data collection (No. 04-2021-051), which was separate from the approval obtained for the previous study [21]. Prior to randomization, all participants were provided with information about the study purpose and procedures, voluntary participation, and study confidentiality. Participants were informed that they could withdraw from the study at any time and would not be penalized for doing so. Subsequently, written informed consent was obtained from each participant.

Although clinical trials are required to be registered prior to the enrollment of the first participant, our trial was registered retrospectively due to an oversight on our part. However, upon realizing that the trial had not been registered, we promptly registered it and confirmed that registration is possible even after the study had

**Table 2** Participants' Baseline Characteristics (N = 32).

Characteristics		IG (n = 19)	CG (n = 13)	p
		n (%) or M ± SD		
Gender	Men	14 (73.7)	6 (46.2)	.159 <sup>a</sup>
	Women	5 (26.3)	7 (53.8)	
Age (years)	<60	8 (42.1)	7 (53.8)	.513
	≥60	11 (57.9)	6 (46.2)	
	M ± SD	58.16 ± 6.99	58.23 ± 8.91	.705 <sup>b</sup>
Level of education	≤High school	10 (52.6)	10 (76.9)	.267 <sup>a</sup>
	≥College	9 (47.4)	3 (23.1)	
Marital status	Married	18 (94.7)	12 (92.3)	>.999 <sup>a</sup>
	Single	1 (5.3)	1 (7.7)	
Employment status	Employed	12 (63.2)	11 (84.6)	.249 <sup>a</sup>
	Unemployed	7 (36.8)	2 (15.4)	
Monthly income (won)	<2 million	6 (31.6)	5 (38.5)	.721
Body mass index (kg/m <sup>2</sup> )	≥2 million	13 (68.4)	8 (61.5)	
	18.5–22.9	2 (10.5)	1 (7.7)	>.999 <sup>a</sup>
	23.0–24.9	4 (21.1)	3 (23.1)	
	≥25.0	13 (68.4)	9 (69.2)	
Time since DM Dx (years)	M ± SD	25.93 ± 2.84	26.03 ± 2.70	.924
	<10	8 (42.1)	5 (38.5)	.837
	≥10	11 (57.9)	8 (61.5)	
Diabetes Tx	M ± SD	12.68 ± 7.71	12.46 ± 6.74	.933
	OHA only	9 (47.4)	5 (38.5)	.688 <sup>a</sup>
	Insulin Tx only	3 (15.8)	1 (7.7)	
Other Chronic diseases	OHA and insulin Tx	7 (36.8)	7 (53.8)	
	No	11 (57.9)	6 (46.2)	.513
	Yes	8 (42.1)	7 (53.8)	
	Hypertension <sup>c</sup>	4 (21.1)	4 (30.8)	.684 <sup>a</sup>
DM complications	Heart disease <sup>c</sup>	2 (10.5)	2 (15.4)	>.999 <sup>a</sup>
	Others <sup>c,d</sup>	5 (26.3)	3 (23.1)	>.999 <sup>a</sup>
	No	15 (78.9)	8 (61.5)	.427 <sup>a</sup>
	Yes	4 (21.1)	5 (38.5)	

Note. CG = control group; DM = diabetes mellitus; IG = intervention group; M = mean; n = number; OHAs = oral hypoglycemic agents; SD = standard deviation.

<sup>a</sup> Fisher's exact test.

<sup>b</sup> Mann–Whitney U test.

<sup>c</sup> Multiple response.

<sup>d</sup> Arthritis, cancer, chronic kidney disease, and stroke.

commenced [44]. We conducted the trial in full compliance with the approved protocol after obtaining ethical approval from the IRB on January 21, 2022, and the trial registration was based on the same content as the trial plan submitted to the IRB.

## Results

### Characteristics of the sample

Table 2 showed the characteristics of the sample. More men and patients older than 60 years were in the intervention group than in the control group. Both groups had mostly below high school education, were married, employed, and had a monthly income of more than two million won. Most were obese (body mass index ≥ 25.0 kg/m<sup>2</sup>), had a DM duration of over 10 years, and were free of diabetes complications. There were no significant differences in baseline data between intervention and control groups, confirming homogeneity. Participants' self-care self-efficacy, self-care behaviors, and health outcomes were homogeneous at baseline in both groups (Supplementary material B).

### Feasibility

Table 3 summarized the feasibility outcomes of the program.

#### Participants engagement rates

From May 3 to June 9, 2022, 404 patients were screened, and 32 out of 61 eligible patients enrolled, resulting in a recruitment rate of 52.5% (Figure 1). Participants were randomly assigned to the

**Table 3** Feasibility Outcomes of the Program.

Categories	n (%) or M ± SD
<b>Participant engagement rates</b>	
Recruitment rate (N = 61)	32 (52.5)
Retention rate (N = 32)	27 (84.4)
Intervention group (N = 19)	16 (84.2)
Control group (N = 13)	11 (84.6)
Treatment adherence rate (N = 16)	
Number of monitoring per week	
Exercise	4.61 ± 1.39
Diet	5.77 ± 1.25
Blood glucose	4.90 ± 1.81
Medication	5.62 ± 1.19
Average	5.22 ± 1.16
Number of participants ≥ monitoring 4 days/week	
Exercise	11 (68.7)
Diet	15 (93.7)
Blood glucose	13 (81.3)
Medication	16 (100.0)
Average	13 (81.3)
<b>Intervention usability (N = 16)</b>	
Mobile app usability <sup>a</sup>	
Statement 1: use the system frequently	12 (75.0)
Statement 2: unnecessarily complex system	2 (12.5)
Statement 3: easy to use	12 (75.0)
Statement 4: need technical support	5 (31.3)
Statement 5: integrated various functions	11 (68.8)
Statement 6: too much inconsistency	0 (0.0)
Statement 7: learn to use this system quickly	10 (62.5)
Statement 8: cumbersome to use	2 (12.5)
Statement 9: confident using the system	8 (50.0)
Statement 10: need to learn a lot of thing	4 (25.0)
Total score	66.25 ± 11.03
Participants' satisfaction	8.06 ± 1.88

<sup>a</sup> Number of participants who agree or strongly agree with each statement.

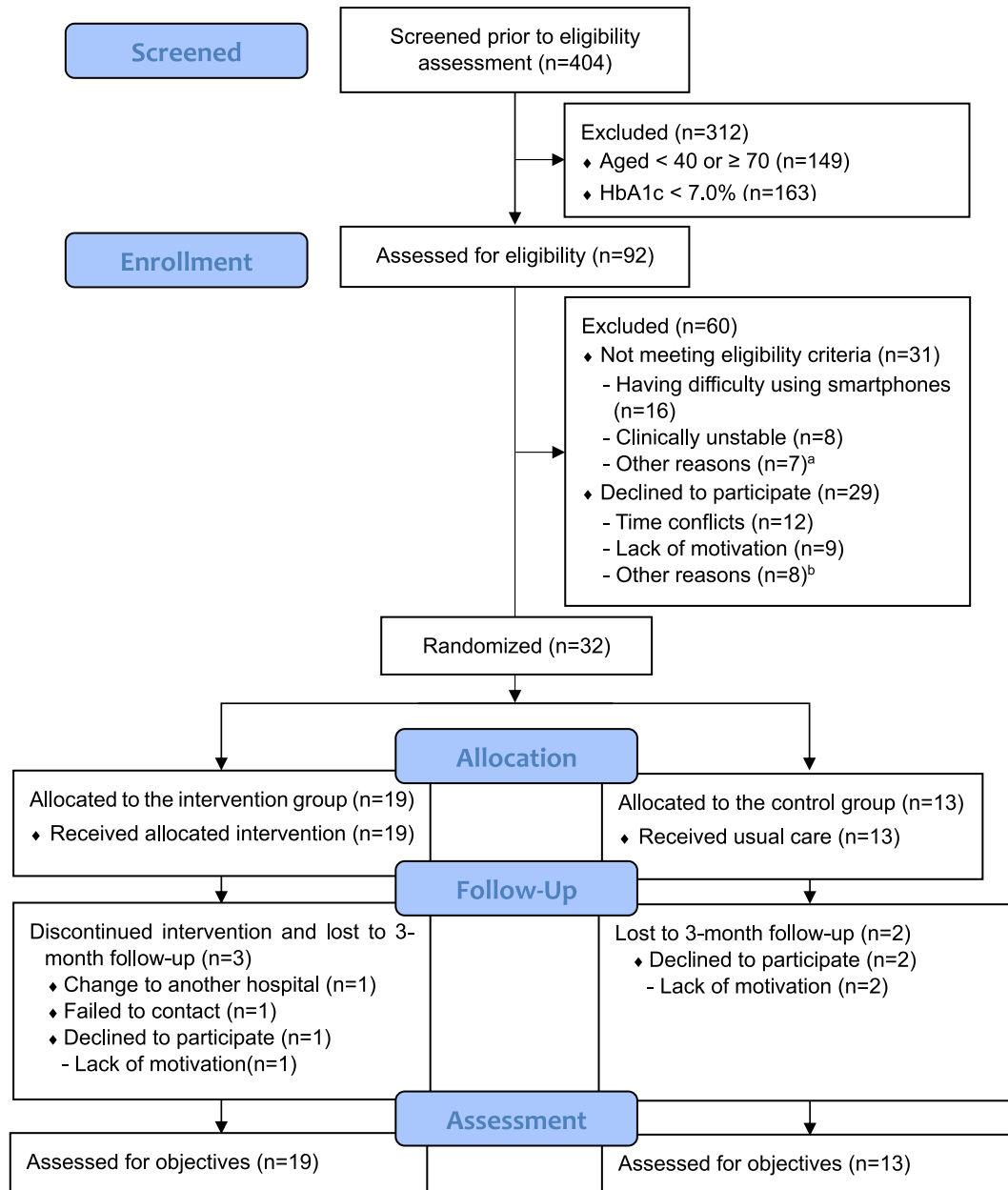


Figure 1. Flow Diagram of the Study.

Note. <sup>a</sup>Non-Android smartphone ( $n = 2$ ), participation in another self-management study ( $n = 2$ ), inability to walk ( $n = 2$ ), planning to change to another hospital ( $n = 1$ ); <sup>b</sup>Desire to manage alone ( $n = 4$ ), lack of confidence ( $n = 4$ ).

intervention ( $n = 19$ ) and control ( $n = 13$ ) groups. Over three months, three from the intervention group and two from the control group dropped out, yielding retention rates of 84.2% and 84.6%, respectively. The average number of exercises, diet, BG, and medication monitoring per week were  $4.61 \pm 1.39$ ,  $5.77 \pm 1.25$ ,  $4.90 \pm 1.81$ , and  $5.62 \pm 1.19$ , respectively. The average days of all self-care monitoring activities per week was  $5.22 \pm 1.16$ , and 13 participants (81.3%) performed activities more than four days/week.

#### Intervention usability

The mobile app's usability scored  $66.25 \pm 11.03$ , indicating a marginally acceptable level [45]. In the intervention group, 75.0% would like to use it frequently and found the app easy to use.

Additionally, 62.5%–68.8% agreed that the app's functions were well integrated and easy to learn. However, only 50.0% felt confident using the app. Two participants (12.5%) agreed that the app was unnecessarily complex and cumbersome to use, while 25.0%–31.3% agreed that technical support or extensive learning was required to continue using the app. Participants satisfaction was  $8.06 \pm 1.88$ .

#### Preliminary effectiveness

Table 4 summarized the preliminary effectiveness of the program on self-care self-efficacy, self-care behavior, and health outcomes.



**Table 4** Preliminary Effectiveness of the Program (N = 32).

Outcome variables	IG (n = 19)		CG (n = 13)		T <sub>2</sub> -T <sub>1</sub>	
	T <sub>1</sub>	T <sub>2</sub>	T <sub>1</sub>	T <sub>2</sub>	t or Z	p
<b>Self-care self-efficacy</b>	71.95 ± 11.49	72.84 ± 13.56	72.54 ± 11.84	71.85 ± 13.37	-0.85 <sup>a</sup>	.404
<b>Self-care behaviors</b>						
Diabetes self-care activities						
General diet	6.84 ± 4.46	8.47 ± 3.34	6.77 ± 4.11	8.54 ± 3.93	-0.11	.915
Specific diet	8.21 ± 3.28	8.16 ± 1.92	9.38 ± 2.75	9.62 ± 2.79	-0.22	.825
Exercise	6.95 ± 4.22	8.68 ± 2.89	7.46 ± 4.99	7.15 ± 3.72	1.39	.174
BG testing	7.79 ± 4.76	10.89 ± 4.24	6.92 ± 4.96	5.15 ± 4.76	-2.82 <sup>a</sup>	.005
Foot care	7.84 ± 4.09	8.37 ± 4.75	6.46 ± 5.87	6.31 ± 5.22	-0.67 <sup>a</sup>	.520
Smoking	0.68 ± 0.48	0.68 ± 0.48	0.85 ± 0.38	0.85 ± 0.38	<0.01 <sup>a</sup>	>.999
Total	38.32 ± 14.80	45.26 ± 10.77	37.85 ± 13.03	37.62 ± 12.22	1.53	.137
Physical activity (MET-min/week)						
Inactive	2 (10.5)	0 (0.0)	2 (15.4)	0 (0.0)	1.50 <sup>b</sup>	.221
Minimally active	11 (57.9)	9 (47.4)	8 (61.5)	9 (69.2)		
HEPA active	6 (31.6)	10 (52.6)	3 (23.1)	4 (30.8)		
M ± SD	2229.26 ± 1244.87	3384.74 ± 1491.93	2429.92 ± 1791.73	2964.38 ± 1164.43	1.18	.247
Dietary intake per day (% RFI)						
Grains	144.7 ± 55.4	112.3 ± 40.1	136.3 ± 46.3	157.3 ± 77.8	-2.38	.024
Protein foods	127.7 ± 65.9	107.2 ± 66.4	113.4 ± 58.3	133.4 ± 84.9	-1.20	.239
Vegetables	70.5 ± 48.6	63.8 ± 24.0	69.5 ± 29.9	61.3 ± 36.4	0.09	.932
Fruits	32.1 ± 32.7	35.2 ± 41.5	36.2 ± 53.5	52.6 ± 71.5	-0.54	.591
Dairy	8.5 ± 16.2	28.2 ± 20.0	6.2 ± 12.3	8.6 ± 13.9	-1.85 <sup>a</sup>	.071
<b>Health outcomes</b>						
Blood glucose (mg/dL)	167.00 ± 62.16	163.11 ± 56.08	188.92 ± 75.15	169.00 ± 64.22	0.57	.574
HbA1c (%)	8.3 ± 0.9	7.4 ± 0.8	8.2 ± 1.1	8.0 ± 1.2	-2.29	.029
LDL-C (mg/dL)	56.63 ± 27.23	50.58 ± 16.78	51.92 ± 23.07	60.31 ± 30.89	-1.48 <sup>a</sup>	.147
Depression	1.37 ± 1.80	0.53 ± 1.12	0.92 ± 1.94	1.77 ± 2.80	-1.85 <sup>a</sup>	.077
Quality of life						
PCS	45.56 ± 7.59	49.68 ± 6.37	48.99 ± 7.90	49.09 ± 10.36	1.15	.261
MCS	48.82 ± 12.88	52.82 ± 9.81	51.17 ± 8.02	51.27 ± 11.59	0.93	.358

Note. CG = control group; HbA1c = hemoglobin A1c; HEPA = health-enhancing physical activity; IG = intervention group; LDL-C = low-density lipoprotein cholesterol; M = mean; MCS = mental component summary; MET = metabolic equivalent; n = number; PCS = physical component summary; RFI = recommended food intake; SD = standard deviation; T<sub>1</sub> = baseline; T<sub>2</sub> = three-month follow-up; % RFI = actual intake/recommended foods intake in the MyPlate guideline.

<sup>a</sup> Mann-Whitney U test.

<sup>b</sup> Chi-square test at T<sub>2</sub>.

### Self-care self-efficacy

Self-care self-efficacy increased from 71.95 to 72.84 in the intervention group and decreased from 72.54 to 71.85 in the control group; however, there was no significant difference between the groups.

### Self-care behaviors

Among the diabetes self-care activities, BG testing increased from 7.79 to 10.89 in the intervention group and decreased from 6.92 to 5.15 in the control group, showing significant differences between groups. There were no significant differences between the groups in terms of diet, exercise, foot care, and smoking. The proportion of participants with HEPA increased from 31.6% to 52.6% in the intervention group and from 23.1% to 30.8% in the control group, but there was no significant difference between groups. The actual intake of grain ratio to the recommended amount decreased from 144.7% to 112.3% in the intervention group and increased from 136.3% to 157.3% in the control group, and there was a significant difference between the groups. There was no significant difference between the groups regarding intake of protein foods, vegetables, fruit, and dairy.

### Health outcomes

HbA1c decreased from 8.3% to 7.4% in the intervention group and from 8.2% to 8.0% in the control group, showing significant differences between the groups. There were no significant differences between the groups in BG, LDL-C, depression, and QOL.

### Qualitative outcomes

#### Experience of participating in the intervention

All 16 participants in the intervention group who participated in the three-month follow-up agreed to participate in the qualitative interview. Most of the participants were men (75.0%). The mean age of participants was 57.69 years, with a mean duration of diabetes diagnosis of 11.75 years. Additional information regarding participant characteristics can be found in [Supplementary material C](#). As a result of analyzing participants' qualitative interview data, 100 meaningful statements were extracted, and after classification according to common attributes, nine themes were derived.

#### Theme 1: Reflection on the past when diabetes self-care was neglected

Participants said that they reflected on their indolence in not independently taking care of their health in the past, which was contrary to their current self.

"I feel like I could have managed my condition better. I've been reflecting a lot. I realize I haven't been taking care of myself enough." (Participant 4)

"I used to ... eat whatever I wanted, hang out with friends and drink, and I think that's why my health got worse. It's like, as people often say ... I lived however I wanted, you know? I guess I was hoping someone else would take care of my body instead of taking responsibility for it myself." (Participant 11)

"It's something I do for my health, but have I neglected it too much in the past? When I record self-care on the mobile app ... it came to my mind that when I was busy, I would forget to take care of my health ... I should say that this was a bit of a reflection." (Participant 12)

#### Theme 2: A sense of duty for self-care and monitoring

Participants said that it took three days to one month for them to get used to self-care monitoring through mobile app. In the process, they felt a sense of duty for self-care and monitoring, and they tried to record in the mobile app immediately after engaging in self-care.

"I tried to record right after eating. Otherwise, I did not know what I ate or how much I ate, so I tried to open this (mobile app) right away, as soon as possible, like the habit of taking medicine." (Participant 4)

"Before that, as long as I didn't exercise, I could just skip it, but by recording this, I felt burdened and if I didn't do it, I felt a little depressed so I had to do it." (Participant 5)

#### Theme 3: Self-reflection through self-care monitoring

Participants recognized their shortcomings through self-care monitoring and aimed to achieve their goals using the automated and personalized goals on the mobile app as a guide.

"I was interested in self-care, but it seemed I was not managing it well in the past ... I ate only a little vegetables, milk, and fruits ... As I kept records, I learned what I lacked, what I ate less of, and whether I exercised less, and I made up for those things" (Participant 1)

#### Theme 4: Attempt to change behavior after self-reflection

Before participating in this program, participants did not eat enough vegetables and dairy products, did not measure their BG regularly, and set vague self-care goals. Through this program, participants pledged and attempted specific behavioral changes after objective self-reflection through the goal achievement rate.

"Previously, I just looked at my meal roughly, ... I didn't care too much about the amount of food. While participating in this program, I was very careful about the amount of food and ate, so my overeating also decreased ... From such a vague thought, I am now trying to regulate myself to a specific extent and keep at it." (Participant 5)

#### Theme 5: Feeling frustrated when self-management did not go well

Participants' self-care deteriorated when special events such as vacations, meetings, and funerals occurred. Once it deteriorated, they returned to their original lifestyle. They felt frustrated when they could not manage themselves as they hoped, and they felt burdened that they had to continue such management for the rest of their life.

"I thought I should be careful with food. I just thought ... nothing came of it. I thought a lot about eating carefully. I know I need to exercise more ... but I hate exercise, so I could not do it. I feel frustrated with myself." (Participant 2)

"A little ... despair? When I'm negligent, I feel like I neglect myself too much because everything is so busy." (Participant 9)

#### Theme 6: Motivation through feedback from the facilitator

Participants reported that self-care monitoring and automated and personalized messages via the mobile app helped improve their self-care. Participants also said they were motivated by the facilitator.

"The facilitator's regular phone calls were the best thing for me ... the fact that someone was checking up on me (made me

motivated) ... and automated and personalized feedback messages were sent every day. I guess those were what motivated me ...” (Participant 3)

#### *Theme 7: Having an opportunity to receive support from family*

Participants' families supported the individuals who started participating in the program and engaged in health behaviors together with them. Participants said that participating in the program provided an opportunity to receive support from their families.

“My husband encouraged me, said that I was doing well, and helped me to perform self-care. We also exercised together. As I was controlling my diet, my husband also reduced the amount of rice ...” (Participant 4)

“My wife told me I was great when I went out to exercise. Before participating in the program, I exercised just one day and then didn't continue ... I only did a little exercise ... (so I didn't receive that kind of praise.)” (Participant 11)

#### *Theme 8: Confidence in self-care and expecting positive outcomes*

Participants gradually achieved their goals and spoke of the results to those around them. They claimed to have gained confidence in self-care and attempted to set new goals independently, expecting positive outcomes following their performance.

“Wouldn't I be slimmer and healthier? I have a desire to grow muscles, so I'm thinking about going to the gym ... I think I can control the amount of food without using the mobile app now ... I think the basic framework of self-care has been set.” (Participant 4)

#### *Theme 9: Invigoration in daily life*

Participants confirmed their self-regulation by seeing their self-measured BG decreased through steady self-care and said that they felt light, stable, and energetic in their daily lives.

“My blood glucose level dropped a lot, and I became energized, which helped me a lot. In the past, it was a little difficult to get through the day. There was a lot of anxiety, but I have found stability these days. ... I feel a lot better now, so I have more energy at work and when I wake up in the morning, I wake up right away and there is no hesitation or irritation.” (Participant 11)

#### *Intervention usability*

Participants suggested that the types of food should be more diverse, and the intensity of exercise should be reflected in the goal achievement rate. When an error in the mobile app was discovered, trust in the program was lowered, making it difficult for participants to expect good results. Therefore, immediate error improvement was required.

## **Discussion**

This study evaluated the feasibility and preliminary effectiveness of the APSC program. The recruitment rate of this study was 52.5%, which was lower than the 71.4% achieved in a previous study on an eight-week self-regulation mobile app intervention for reducing sedentary time in T2DM patients [10]. Among the 61 eligible patients in our study, 29 declined to participate, with time conflicts and lack of motivation being common reasons for refusal. These results suggest that emphasizing the value and importance of research participation to patients is necessary for enhancing their

motivation [46]. Since this may not be adequately conveyed while patients are waiting for routine physician consultations, proactive methods such as utilizing social media, posters, and collaborating with physicians should be considered. Additionally, there is a need to further emphasize that the APSC program allows for remote participation and offers flexible scheduling option to address issues related to time conflicts. The retention rate of this study was 84.4%. A minimum of 80.0% of outcome data from participants was required to determine the feasibility of conducting larger-scale clinical trials [10,33], making our retention rate appropriate.

Treatment adherence was 81.3% in this study, aligning with acceptable rates of 80.0% or higher [24]. A mobile app-based self-care intervention study reported exercise and dietary monitoring rates of 5.3% and 24.9%, respectively, and medication monitoring rate of 84.0% [14]. Although direct comparison was challenging, our study showed exercise and dietary monitoring of 4.61 times/week (65.9%) and 5.77 times/week (82.4%), respectively, with medication monitoring at 5.62 times/week (80.3%). These rates were comparable or higher than Oh and colleagues' study [14]. Previous study reported discontinuation of monitoring due to perceived ineffectiveness, app usage difficulties, data entry burden, and lack of personal relevance [14]. However, our participants responded that they became familiar with the app within three days to a month and felt obligated to monitor and achieve app-guided goals, potentially contributing to higher treatment adherence.

The app's usability scored 66.25 out of 100, indicating marginal acceptability [35]. Although SUS was the most frequently used measurement in mobile app usability testing, apps evaluated using SUS were often related to mental disease or cancer [47]. The SUS score for an exercise coaching app for adults with prediabetes was 78.00 [48], and for a self-care app for Korean pregnant women was 67.82 in previous studies [49]. Participants in our study showed relatively high agreement rates for the statements “need technical support” (31.3%) and “need to learn a lot of things” (25.0%), while indicating a relatively low agreement rate for the statement “confident using the system” (50.0%), suggesting areas for improvement. Qualitative interviews confirmed inconvenience due to limited food options, complicating data entry.

In response to these comments, we received a tutorial from app developers on how to add food to the app for timely technical support. We included educational materials in the app to address repetitive questions from participants and added quiz sessions to enhance participants' confidence in using the app for learning and self-care. Additionally, we reinforced positive feedback during facilitator phone calls. These improvements should be evaluated to assess their impact on improving mobile app usability and intervention effectiveness in the following large-scale RCT.

In our study, the intervention group showed a significant rise in self-measured BG. Previous research found mobile app intervention with education, monitoring, feedback, and achievable goals effectively raised self-monitoring [9]. Self-monitoring BG was crucial for diabetes management, lowering HbA1c levels [14]. Improved self-monitoring of BG enabled accurate assessment and better patient-healthcare provider communication, ultimately improving patient outcomes [5]. Therefore, the increase in self-measured BG was highly significant.

The intervention group demonstrated significant improvement in grain intake and HbA1c reduction, aligning with prior research on whole grain impact on BG control [50]. MyPlate-based intervention also reduced BG and HbA1c levels [51]. MyPlate simplifies understanding of portion sizes and recommended food groups, making it easier for participants to adhere to dietary modifications [40] compared to complex nutritional information. Utilizing MyPlate in our study was effective in facilitating dietary modifications and achieving notable reductions in HbA1c levels.

In qualitative interviews, participants reported enhancing self-care behavior and health outcomes through self-monitoring and self-reflection. They gained confidence in self-care, expected positive outcomes, and experienced increased vitality. However, quantitative analysis did not show a statistically significant self-care self-efficacy change, implying a need for large-scale studies in the future. Despite frustration when self-care behavior did not improve as expected, participants adapted through self-reflection, motivated by facilitator feedback. Similar findings were reported in a previous research, emphasizing human support's role in self-care intervention [6]. Human involvement was vital in such interventions.

This study demonstrated that the APSC program did not lead to statistically significant changes in outcome variables other than BG testing, grain intake, and HbA1c levels. However, participants in the intervention group had a trend of improvement in diabetes self-care activities, PA, protein and dairy intake, LDL-C, and QOL. The nonsignificant results might be attributable to the present pilot study with a relatively small sample size. With respect to QOL, one possible reason may be that our choice of a general QOL measurement tool instead of a disease-specific diabetes QOL measure [52,53]. Nonetheless, the larger increase in QOL scores in the intervention group, which was not observed in the control group, attests to the potential of the APSC program. A larger sample size may be necessary to statistically detect significant differences in outcome variables.

The limitations of this study include the small sample size, as discussed above, which can limit the generalizability of the results. Blinding of participants and the facilitator was not possible due to the nature of the intervention. Furthermore, the reliability of the SUS to measure mobile app usability was lower than desired. The reliability analysis showed that excluding statements 2, 4, and 10 increased Cronbach's  $\alpha$  to .63, .64, and .63, respectively, remaining low. Caution is needed in interpreting the results of the mobile app usability in this study. However, since this study explored the mobile app usability through qualitative interviews, it was considered that this limitation was partially addressed.

Despite these limitations, our findings offer valuable insights, suggesting that the APSC program holds promise for future research with a larger sample size. Strategies using automated and personalized mobile app support, along with proactive facilitator assistance, ensured high retention and adherence rates. Qualitative data on participant experience have provided rich descriptions. In response to issues that may have limited recruitment rates, we requested physicians' cooperation in promoting the importance of research participation to patients, and in terms of mobile app usability, modification has been made for use in a future RCT. If the effectiveness of the APSC program is confirmed in the future RCT, the program may serve as an alternative to facilitate self-care and effective communication with healthcare providers amidst the pandemic. Besides, the integration of self-regulatory theory into the intervention may aid in its successful implementation and improve outcome variables.

## Conclusions

This study's importance lies in confirming the feasibility and preliminary effectiveness of the APSC program for T2DM patients. Recommendations include enhancing recruitment via social media and physician collaboration. Enhancing the app's usability with a prompt error resolution system was highlighted. With these improvements, the APSC program can be effectively implemented in larger RCT in the future.

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## Conflict of interest

The authors declare no conflicts of interest.

## Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.anr.2024.04.003>.

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## Research Article

## Frailty and Health-Related Quality of Life in Elderly Patients Undergoing Esophageal Cancer Surgery: A Longitudinal Study

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## SUMMARY

**Purpose:** This study aims to elucidate the longitudinal alterations in frailty and health-related quality of life experienced by elderly patients undergoing surgical treatment for esophageal cancer. Additionally, it seeks to ascertain the impact of preoperative frailty on postoperative health-related quality of life over time.

**Methods:** 131 patients were included in the prospective study. Patients' frailty and health-related quality-of-life were assessed utilizing the Tilburg and European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 at preoperative, 1 week, 1 month, and 3 months, postoperatively. Statistical analyses were performed using generalized estimating equations, repeated-measures analysis of variance, and linear mixed models (LMMs).

**Results:** Out of 131 patients, 28.2% had frailty before surgery, and the prevalence of frailty consistently higher after surgery compared with baseline (67.9%, 51.9%, and 39.7%). There was no significant change in frailty scores in preoperative frail patients within 3 months following surgery ( $p = .496$ ,  $p < .999$ ,  $p < .999$ ); whereas in preoperative non-frail patients, the frailty scores increased at 1 week ( $p < .001$ ) and then decreased at 1 month ( $p = .014$ ), followed by no change at 3 months. In addition, preoperative frail patients had significantly worse global quality-of-life ( $\beta = -4.24$  (-8.31; -.18),  $p = .041$ ), physical functioning ( $\beta = -9.87$  (-14.59; -5.16),  $p < .001$ ), role functioning ( $\beta = -10.04$  (-15.76; -4.33),  $p = .001$ ), and social functioning ( $\beta = -8.58$  (-15.49; -1.68),  $p = .015$ ), compared with non-frail patients.

**Conclusions:** A significant proportion of participants exhibited a high prevalence of preoperative frailty. These patients, who were preoperatively frail, exhibited a marked reduction in health-related quality-of-life, a more gradual recovery across various functional domains, and an increased symptom burden during the follow-up period. Therefore, it is crucial to meticulously identify and closely monitor patients with preoperative frailty for any changes in their postoperative physiology, role, and social functioning.

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## Introduction

Frailty, defined as impaired physiological reserves and multi-system dysfunction in the organism, leading to increased vulnerability and reduced stress resistance, is a crucial concept within

geriatric oncology [1]. Studies have demonstrated that older individuals exhibit a higher incidence of frailty due to factors such as decreased physical activity [2], co-morbidities, and polypharmacy compared with their younger counterparts [3,4]. Patients with esophageal cancer are particularly vulnerable to frailty, as both the disease itself and subsequent treatment impose additional stress on their physiologic reserves [5,6]. As the population ages, there is a gradual increase in the number of elderly patients with esophageal cancer, accounting for approximately 83.1% of all esophageal cancer cases over the age of 60 [7]. Consequently, the frailty of these elderly patients presents a significant concern.

Surgery serves as the primary treatment modality for esophageal cancer, with applications ranging from curative to palliative care, or in conjunction with radiotherapy or chemotherapy, contingent upon patient demographics and disease stage [8]. Study indicates that

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frailty manifests as a dynamic phenomenon [9]. Patients with preoperative dysphagia and inadequate intake due to esophageal cancer are susceptible to malnutrition and muscle weakness [10]. These conditions can be further exacerbated by postoperative physiological alterations that render patients vulnerable to reflux, loss of appetite, and gastrointestinal dysfunction—all of which are significant risk factors for frailty [11]. Consequently, a substantial prevalence of frailty is observed among patients undergoing surgery for esophageal cancer, potentially increasing the likelihood of complications and even mortality [12,13]. Hence, it is imperative to conduct longitudinal assessments of frailty in elderly patients preparing for surgery for esophageal cancer.

In the evolving landscape of clinical medicine, preoperative frailty is increasingly recognized as a risk factor and predictor of adverse clinical outcomes, including elevated mortality rates, higher readmission rates post-discharge, and extended hospital stays [14,15]. Furthermore, studies have demonstrated that preoperative frailty correlates with poorer postoperative health-related quality-of-life (HRQoL) in tumor cohorts [16,17]. Consequently, clinicians are recognizing preoperative frailty as a significant predictor of postoperative outcomes in cancer surgery.

However, current research focuses on the correlation between frailty and subsequent cancer recurrence, survival, and complications. While these studies provide an objective reflection of patients' health outcomes, it does not account for their subjective experience of survival [18]. As postoperative cancer survival rates rise, patient-reported outcomes are gaining prominence [19]. For instance, HRQoL may be deemed more significant than survival in older patients [20]. In recent years, the use of self-reported HRQoL as an outcome measure for cancer treatment has gained increasing recognition, particularly among older postoperative patients with esophageal cancer [21,22]. Evidence indicates that patients diagnosed with esophageal cancer experience a significant short-term postoperative symptom burden and substantial deterioration in HRQoL due to surgical trauma and the reconstruction of the digestive tract [23]. Prior study has demonstrated that patient HRQoL was markedly diminished by symptoms such as pain and fatigue one week post-surgery, with the levels failing to return to baseline by one month post-surgery [23]. At three months post-surgery, fatigue emerged as the most prevalent and severe symptom among patients, while reflux, anorexia, and sleep disorders all adversely impacted postoperative recovery [24]. Consequently, nurses should prioritize the management of HRQoL during the short-term postoperative period in these patients. Despite the existing literature, the impact of preoperative frailty on quality-of-life in elderly patients with esophageal cancer remains underexplored. Therefore, this study endeavored to investigate the influence of preoperative frailty on HRQoL in esophageal cancer patients over a three-month period, aiming to raise awareness among healthcare professionals about the significance of frailty and HRQoL in this specific patient group.

In conclusion, the current research endeavors to elucidate frailty in elderly patients with esophageal cancer undergoing surgical procedures. Furthermore, given that preoperative frailty may influence postoperative HRQoL, this study will delve deeper into the disparities in postoperative HRQoL between frail and non-frail cohorts. Ultimately, the investigation will probe into the impact of preoperative frailty on alterations in HRQoL during the brief follow-up phase subsequent to treatment.

## Methods

### Study design

This prospective observational study comprises four data points: preoperative ( $T_0$ ), 1 week after surgery ( $T_1$ ), 1 month after

surgery ( $T_2$ ), and 3 months after surgery ( $T_3$ ). The primary purpose of the study was to elucidate the longitudinal changes in frailty and HRQoL in elderly patients undergoing surgical treatment for esophageal cancer, and to determine the influence of preoperative frailty on postoperative HRQoL over time.

### Setting and sample

The sample size for this study was calculated as:  $N = (U_{\alpha/2}S/\delta)^2$  [25], in which  $S$  and  $\delta$  represent the standard deviation and allowable error, where the allowed error was controlled at 9% of the mean value. The sample size of 131 individuals was maximized at  $\alpha = .05$ ,  $\bar{x} = 3.01$ ,  $S = 1.58$ ,  $\delta = .27$ . We also considered a 10% dropout rate, so the actual sample size for the initial survey was at least 146. According to the inclusion criteria, 146 esophageal cancer patients aged 60 years or older intended to receive surgery were recruited from a tertiary-level hospital in Hefei city, Anhui province, during the study period from March 2023 to August 2023. The inclusion criteria were patients (1) pathologically diagnosed as esophageal cancer and hospitalized in preparation for surgical treatment; (2) 60 years or older; (3) aware of their condition and cancer diagnosis; and (4) those who possessed a certain level of comprehension as well as verbal ability and agreed to participate in this study. We excluded (1) those with previous or current mental illness and disorders of consciousness; (2) comorbidity with other malignancies or serious life-threatening illnesses; and (3) participation in other clinical trials.

### Measurements

#### Demographic and clinical characteristics

Participants were interviewed at  $T_0$  using a structured questionnaire to assess demographic and lifestyle characteristics. Laboratory data (e.g., albumin levels), disease-related information (e.g., chronic comorbidities), histopathology, cancer stage, and previous treatment were obtained from medical records. Staging was conducted in accordance with the eighth edition of the Union for International Cancer Control TNM classification system for malignant tumors [26].

#### Assessment of frailty

The study evaluated changes in patients' frailty using the Tilburg Frailty Scale [27], which consists of 15 items in three dimensions: physical (8 items), psychological (4 items), and social (3 items). Physical dimensions include: physical health, weight loss, difficulty walking, poor balance, poor vision, poor hearing, lack of hand strength, and fatigue; psychological dimensions include: memory loss, depressive symptoms, anxiety, and reduced coping skills; social dimensions include: living alone, lack of social relationships, and reduced social support. The scale was scored using a dichotomous scoring system, with the presence of each item counting as 1 point and the absence of each item counting as 0 points. The total score ranges from 0 to 15, while  $\geq 5$  was regarded as frailty, with higher scores correspond to a more pronounced degree of frailty [27]. The reliability with Cronbach  $\alpha$  coefficient of the original English scale was .73 [27] and was .70 in present study.

#### Evaluation of HRQoL

Patient self-reported HRQoL was investigated using European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC-QLQ-C30) [28], a key component of the system for measuring cancer patients' quality-of-life and applicable to all oncology patients, HRQoL was examined. The Cronbach  $\alpha$  coefficient for the original scale was .75 [28]. The QLQ-C30 has 30 entries that can be categorized into 15 domains,

including 5 functional domains: physical, role, cognitive, emotional, and social functioning, 3 symptomatic domains: fatigue, pain, nausea, and vomiting, 1 domain of global quality-of-life (QL), and 6 single domains: dyspnea, sleep disturbance, appetite loss, and constipation. In the QLQ-C30, patients' scores were converted to 0–100 according to the EORTC manuals. The study showed that the QLQ-C30 summary score, which excludes economic impact and QL, was more responsive to overall patient response than QL [29], so the summary score was used in this study for subsequent analysis. We evaluated large, medium, and small differences between groups in QLQ-C30 scores (preoperative frailty vs non-frailty) according to guidelines developed by Kim Cocks et al [30], larger differences indicate more clinical significance. The reliability of the QLQ-C30 questionnaire was evaluated prior to the commencement of formal data collection. The Cronbach  $\alpha$  coefficient for the C30 questionnaire in this study was determined to be .79.

#### Data collection

To determine longitudinal changes in frailty and HRQoL, as well as the influence of baseline frailty on postoperative HRQoL, assessments of frailty and HRQoL were completed at preoperative ( $T_0$ ), 1 week after surgery ( $T_1$ ), 1 month after surgery ( $T_2$ ), and 3 months after surgery ( $T_3$ ). Patients who underwent surgery were typically discharged one week after surgery; therefore, face-to-face interviews were executed with patients at  $T_0$  and  $T_1$ , and telephone follow-ups were conducted at  $T_2$  and  $T_3$ .

#### Ethical considerations

The study was approved by the Ethics Review Committee of the Anhui Medical University (Approval no. 84230023). Throughout the study period, the investigator elucidated the objectives and procedures to eligible patients. Those who consented to participate were subsequently enrolled in the study after signing an informed consent form.

#### Statistical analysis

All statistical analyses were conducted utilizing SPSS Statistics 25.0 software (IBM). Descriptive statistics are presented as mean and standard deviation (SD) for continuous variables, while frequency (percentage) is used for categorical variables. Data characteristics were employed to analyze demographic and disease information. The  $t$  tests were applied to normally distribute continuous data, Mann–Whitney  $U$  tests were utilized for non-normality, and Chi-square tests or Fisher exact tests were implemented for categorical data to discern differences between groups. The generalized estimating equation (GEE) was employed to examine the fluctuations in the incidence of frailty. Concurrently, a repeated-measures analysis of variance (ANOVA) was utilized to investigate longitudinal alterations in both frailty and HRQoL from the initial baseline to the postoperative period.

Linear mixed models (LMMs) were employed to examine the influence of preoperative frailty on health-related quality of life over a three-month postoperative period. LMMs are suitable for analyzing longitudinal data because it allows for the presence of missing data without discarding the entire case. QLQ-C30 scores for  $T_1$ ,  $T_2$ , and  $T_3$  were defined as the dependent variable in the analyses, and  $T_0$  scores were used as an adjustment variable. Given that the postoperative HRQoL can be influenced by a variety of factors such as patients' preoperative treatment, age, gender, tumor stage, comorbidities, and baseline QLQ-C30 score [31–34], all models were meticulously adjusted to account for these variables. Fixed effects for each model consisted of time, group, group  $\times$  time, and

adjustment variables. For random effects, between-subject differences included intercepts, covariate types were diagonal. Estimation was restricted maximum likelihood.

## Result

### Patient characteristics

Table 1 provided a comprehensive summary of the baseline characteristics of the patient cohort. Of the total number of patients who met the inclusion criteria, 146 were included in the study. However, three patients opted not to continue in the follow-up process, seven patients declined for physical reasons, and five patients succumbed to their illnesses. Ultimately, 131 patients participated throughout the entire process, yielding a response rate of 95.6%. The mean (SD) age of the participants was found to be 70.11 (5.94) years, with 77.1% ( $N = 101$ ) being male. Predominantly, patients were farmers (65.5%), residing in rural areas (75.6%), possessing an education level of primary school or less (69.5%), and their per capita monthly income was below 1000 (71.0%). Squamous esophageal cancer was the most prevalent diagnosis among these patients at 80.2%, followed by adenocarcinoma at 16%. Only a minimal proportion of patients were diagnosed with other types of esophageal cancer (3.8%). Furthermore, 96 patients (73.3%) were classified as clinical stage II–III, while only 25 patients (19.1%) underwent neoadjuvant therapy preoperatively. A comparative analysis of the sociodemographic and clinical characteristics between the preoperative frail and non-frail groups revealed that the baseline data of both groups were largely comparable, with the exception of living situation ( $p = .009$ ).

### The prevalence of frailty and longitudinal change

Table 2 presents the evolution of frailty prevalence from  $T_0$  to  $T_3$ . The preoperative frailty rate ( $T_0$ ) among esophageal cancer patients who underwent surgery was 28.2%, which escalated to 67.9% for  $T_1$ , subsequently declining to 51.9% and 39.7% for  $T_2$  and  $T_3$ , respectively. A GEE analysis revealed a significant increase in frailty incidence at  $T_1$  ( $B = 1.75$ ,  $p < .001$ ) compared with preoperative levels. This incidence remained consistently higher than baseline levels in both  $T_2$  ( $B = 1.06$ ,  $p < .001$ ) and  $T_3$  ( $B = .61$ ,  $p = .023$ ). Despite a decrease overall, there was a notable prevalence of postoperative frailty.

Table 3 summarized the longitudinal changes in frailty severity in the preoperative frail and non-frail groups. At baseline, 37 (28.2%) patients were categorized as frail and 94 (71.8%) patients were categorized as non-frail, with a significant difference in the degree of frailty between the two groups ( $p < .001$ ). The frail group consistently scored higher than the non-frail group at  $T_1$  ( $p = .046$ ),  $T_2$  ( $p = .037$ ), and  $T_3$  ( $p = .033$ ). In addition, the trajectories of frailty scores over time were significantly different between the two groups ( $p < .001$ ). In the non-frail cohort, the mean frailty score at  $T_1$  was significantly higher than preoperative levels ( $p < .001$ ). Mean scores then decreased at  $T_2$  ( $p = .041$ ) and did not change significantly at  $T_3$  ( $p = .149$ ), but were still significantly higher ( $p < .001$ ) than preoperative levels. In the frailty cohort, the mean frailty scores consistently high (mean score  $>5$ ) at baseline and all follow-up time points, with no significant changes in severity over time.

### Frailty and quality-of-life

In general, the preoperative frail cohort had significantly lower baseline scores than non-frail patients in most categories of the QLQ-C30, including global quality-of-life ( $p < .001$ ), summary score

**Table 1** Patient Characteristics of the Included Cohort (N = 131).

Patient characteristics	All patients N = 131 (%)	Non-Frail N = 94 (%)	Frail N = 37 (%)	p
<b>Baseline</b>				
<b>Age</b>				
Mean ± SD	70.11 ± 5.94	69.74 ± 5.70	71.05 ± 6.49	.313 <sup>a</sup>
Median (interquartile range)	71 (67–75)	70 (66.7–74)	72 (68–76)	
<b>Gender</b>				
Men	101 (77.1)	75 (79.8)	26 (70.3)	.243 <sup>b</sup>
Women	30 (22.9)	19 (20.2)	11 (29.7)	
BMI (mean ± SD)	22.16 ± 3.19	22.16 ± 3.05	22.20 ± 3.54	.927 <sup>c</sup>
Albumin (mean ± SD)	43.14 ± 4.35	43.52 ± 4.28	42.18 ± 4.44	.155 <sup>a</sup>
<b>Residence</b>				
City	12 (9.2)	8 (8.5)	4 (10.8)	.879 <sup>b</sup>
Town	20 (15.3)	15 (15.9)	5 (13.5)	
Rural	99 (75.6)	71 (75.5)	28 (75.7)	
<b>Living situation</b>				
Living alone	13 (9.9)	5 (5.3)	8 (21.6)	.009 <sup>d*</sup>
Living with others	118 (89.1)	89 (94.7)	29 (78.4)	
<b>Education level</b>				
Primary or less	91 (69.5)	66 (70.2)	25 (67.6)	.140 <sup>d</sup>
Secondary	38 (29)	28 (29.8)	10 (27.0)	
Tertiary	2 (1.5)	0	2 (5.4)	
<b>Marital</b>				
Unmarried	2 (1.5)	0	2 (5.4)	.091 <sup>d</sup>
Married	121 (92.4)	89 (94.7)	32 (86.5)	
Divorced or widowed	8 (6.1)	5 (5.3)	3 (8.1)	
<b>Employment</b>				
Jobless	11 (8.4)	4 (4.3)	7 (18.92)	.058 <sup>d</sup>
Farmer	86 (65.5)	65 (69.1)	21 (56.8)	
Worker	12 (9.2)	8 (8.5)	4 (10.8)	
Retirement	22 (16.9)	17 (18.1)	5 (13.5)	
<b>Income</b>				
<1000	93 (71)	67 (71.2)	26 (70.3)	.795 <sup>b</sup>
1000–3000	21 (16)	14 (14.9)	7 (18.9)	
>3000	17 (13)	13 (13.9)	4 (10.8)	
<b>Smoking habit</b>				
No (Never)	55 (42)	37 (39.4)	18 (48.6)	.332 <sup>b</sup>
Yes (Current & Former)	76 (58)	57 (60.6)	19 (51.4)	
<b>Alcohol use</b>				
No (Never)	52 (39.7)	34 (36.2)	18 (48.6)	.189 <sup>b</sup>
Yes (Current & Former)	79 (60.3)	60 (63.8)	19 (51.4)	
<b>Site of tumor</b>				
20–25 cm (Distance from incisors)	8 (6.1)	3 (3.2)	5 (13.5)	.069 <sup>d</sup>
25–30 cm (Distance from incisors)	69 (52.7)	52 (55.3)	17 (46.0)	
30–40 cm (Distance from incisors)	43 (32.8)	33 (35.1)	10 (27.0)	
Gastroesophageal junction	11 (8.4)	6 (6.4)	5 (13.5)	
<b>Histopathology</b>				
Squamous carcinoma	105 (80.2)	78 (83.0)	27 (73.0)	.247 <sup>d</sup>
Adenocarcinoma	21 (16)	12 (12.8)	9 (24.3)	
Other	5 (3.8)	4 (4.3)	1 (3.7)	
<b>Stage of tumor</b>				
1	20 (15.3)	14 (14.9)	6 (16.2)	.985 <sup>b</sup>
2	43 (32.8)	32 (34.0)	11 (29.7)	
3	53 (40.5)	39 (41.5)	14 (37.8)	
4	7 (5.3)	5 (5.3)	2 (5.4)	
<b>Metastasis</b>				
Yes	44 (33.6)	32 (34.0)	12 (32.4)	.861 <sup>b</sup>
No	87 (66.4)	62 (66.0)	25 (67.6)	
<b>Co-morbidity</b>				
Yes	77 (58.8)	52 (55.3)	25 (67.6)	.200 <sup>b</sup>
No	54 (41.2)	42 (44.7)	12 (32.4)	
<b>Preoperative treatment</b>				
Yes	25 (19.1)	17 (18.1)	8 (21.6)	.643 <sup>b</sup>
No	106 (80.9)	77 (81.9)	29 (78.4)	

Note. a, Mann–Whitney *U* test; b, Chi-square test; c, *t*-test; d, Fisher exact test; SD = standard deviation; \**p* < .05; Missing items: Stage of tumor = 4.

(*p* < .001), physical functioning (*p* < .001), role functioning (*p* < .001), emotional functioning (*p* = .002), and cognitive functioning (*p* < .001). Additionally, the preoperative frail group demonstrated a higher likelihood of experiencing postoperative fatigue (*p* = .016), pain (*p* = .004) and sleep disturbance (*p* = .006).

Figure 1 illustrated the longitudinal changes in QLQ-C30 scores across each dimension for preoperative frail and non-frail patients. When compared with the non-frail cohort, frail patients exhibited a

more protracted recovery period and demonstrated significantly poorer QL (T<sub>3</sub>: *p* = .017) as well as a summary score (T<sub>2</sub>: *p* = .012; T<sub>3</sub>: *p* = .002) postoperatively. In terms of physical functioning, frail patients had consistently displayed inferior scores at all post-operative intervals (*p* < .001, *p* < .001, *p* = .035). Cognitive assessments revealed lower scores in frail patients at T<sub>2</sub> (*p* = .001); moreover, at T<sub>3</sub>, frail patients manifested significantly diminished scores in both role functioning (*p* < .001) and social functioning



**Table 2** Changes in the Incidence of Frailty Over Time by Generalized Estimating Equations.

	N (%)	B	SE	95% CI		Wald $\chi^2$	p
				Lower	Upper		
Intercept		-6.49	1.73	-9.88	3.10	14.10	<.001
Preoperative (T <sub>0</sub> )	37 (28.2)	Reference					
1 week (T <sub>1</sub> )	89 (67.9)	1.75	.28	1.20	2.30	39.15	<.001
1-month (T <sub>2</sub> )	68 (51.9)	1.06	.27	.53	1.60	15.16	<.001
3 months (T <sub>3</sub> )	52 (39.7)	.61	.27	.08	1.13	5.13	.023

Note. CI = confidence interval; N = number of frailty; SE = standard error.

( $p < .001$ ) relative to non-frail patients. Additionally, preoperative frail patients were more prone to experiencing fatigue (T<sub>2</sub>:  $p = .008$ ), nausea and vomiting (T<sub>1</sub>:  $p = .019$ ), pain (T<sub>3</sub>:  $p = .007$ ) and sleep disturbances (T<sub>2</sub>:  $p = .028$ ), along with increased financial challenges (T<sub>2</sub>:  $p = .017$ ; T<sub>3</sub>:  $p < .001$ ). As per the QLQ-C30 guidelines [30], the disparity between the two patient groups' scores across various domains was categorized as “small to medium” and clinically significant.

Linear mixed model analysis revealed that except for comorbidities, preoperative treatment, age, gender, tumor stage, and baseline QLQ-C30 score were correlated with the different dimensions of postoperative HRQoL. Hence these variables were adjusted as confounding factors with the detailed data presented in the Supplementary file. Table 4 shows the effect of preoperative frailty on postoperative HRQoL changes after this procedure. In a linear mixed model adjusted for the covariates of interest, a significant association was observed between preoperative frailty and poorer QL during the three-month postoperative period ( $\beta = -4.24$  (-8.31; -1.18),  $p = .041$ ). Furthermore, preoperative frailty adversely affected functional recovery. Frail patients exhibited a more gradual recovery in physical function ( $\beta = -9.87$  (-14.59; -5.16),  $p < .001$ ), role function ( $\beta = -10.04$  (-15.76; -4.33),  $p = .001$ ), and social function ( $\beta = -8.58$  (-15.49; -1.68),  $p = .015$ ). In terms of symptom scales, sleep disturbance ( $\beta = -8.12$  (-15.92, -3.12),  $p = .042$ ) improved significantly over time in frail patients compared with non-frail patients, while their financial stress ( $\beta = 10.49$  (3.30, 17.68),  $p = .005$ ) remained significantly higher.

**Discussion**

To the best of our knowledge, this study represents the inaugural longitudinal investigation into frailty and HRQoL in elderly patients diagnosed with esophageal cancer. The principal finding was that the incidence of postoperative frailty is consistently

surpasses preoperative levels among older patients with esophageal cancer (28.2% vs 67.9% vs 51.9% vs 39.7%). Additionally, it was observed that patients who were frail before surgery maintained high levels of frailty after surgery, while non-frail patients experienced an increase followed by a decrease in frailty after surgery, with different trajectories of frailty in both groups. Moreover, preoperative frailty was associated with decreased QL, slower functional recovery, and greater symptom burden after esophageal cancer surgery, regardless of preoperative treatment, age, gender, stage, comorbidities, and baseline QLQ-C30 score.

The current study revealed a consistently higher prevalence of postoperative frailty compared with preoperative levels, a finding that contradicts with prior studies related to other types of patients. Earlier study reported a gradual decrease in frailty prevalence from pre-surgery to discharge as well as one month post-surgery in patients undergoing colorectal cancer surgery [35]. Furthermore, this study revealed a higher prevalence of frailty than previously reported. The previous study indicated that 16.2% of patients were frail prior to cardiac surgery, and 20.5% and 16.6% were frail one and three months after surgery [36], respectively. These disparities may be attributed to variations in the definition and measurement of frailty, as well as differences in population and disease types, which influence the incidence of frailty. Recent study suggests that frailty extends beyond physical aspects, manifesting in psychological and social subtypes [37]. The aforementioned studies employed the Frailty Phenotype Scale to evaluate physical frailty, potentially insufficient for a comprehensive assessment of frailty [35,36]. In contrast, the Tilburg Scale utilized in this study provides a holistic assessment of frailty in elderly esophageal cancer patients, considering the physiological-psychological-social medical model. This aligns with the principles of holistic nursing care and lays the groundwork for future preventive and interventional measures against frailty.

In comparison to the hospitalization phase (T<sub>1</sub>), preoperative non-frail patients demonstrated a reduction in frailty at T<sub>2</sub> and T<sub>3</sub> postoperatively. However, frail patients consistently exhibited elevated levels of postoperative frailty without substantial improvement. Preoperative frailty can have severe implications, including prolonged hospital stays [14,15], increased readmission rates [38], and postoperative complications [39,40]. These challenges can exert significant physical, psychological, and social effects on preoperatively frail patients, leading to slower recovery and heightened frailty. Therefore, it is crucial for healthcare professionals to prioritize the management of preoperative frailty and implement early interventions to mitigate its impact, ultimately enhancing the patient's prognosis.

This study found that preoperative treatment, age, gender, tumor stage, and baseline QLQ-C30 scores significantly influenced some domains of HRQoL after esophageal cancer surgery, which is consistent with previous studies. Preoperative adjuvant chemotherapy for advanced cancer, the severity of the disease and side effects of chemotherapy would severely affect their postoperative HRQoL [31,34]. In addition, age also affects postoperative HRQoL, with older patients tending to have a slower postoperative recovery and less likely to benefit from aggressive treatment [32]; whereas female patients tend to report severe symptoms, more postoperative symptoms than male patients [24]. Previous studies have shown that among patients with treated solid tumors, those with comorbidities at baseline have a higher risk of HRQoL decline than those without comorbidities [33]. The finding contrasts with the current study, potentially due to the homogeneity of the sample, where patients with severe comorbidities and extremely poor health status may choose nonsurgical treatment.

Despite aforementioned influencing factor, preoperative frailty can still have an impact on postoperative HRQoL recovery in elderly

**Table 3** Changes in Frailty Over Time in the Frail and Non-Frail Groups.

Time	Group		MD	SE	p	95% CI	
	Frail	Non-Frail				Lower	Upper
Preoperative (T <sub>0</sub> )	Frail	Non-Frail	3.37	.22	<.001	2.92	3.81
1 week (T <sub>1</sub> )	Frail	Non-Frail	.76	.38	.046	.01	1.51
1 month (T <sub>2</sub> )	Frail	Non-Frail	.89	.42	.037	.06	1.72
3 months (T <sub>3</sub> )	Frail	Non-Frail	1.00	.46	.033	.09	1.92
Group	Time	MD	SE	p	95% CI		
					Lower	Upper	
Frail	T <sub>0</sub> -T <sub>1</sub>	.58	.33	.496	-.31	1.48	
	T <sub>1</sub> -T <sub>2</sub>	-.52	.39	<.999	-1.57	.53	
	T <sub>3</sub> -T <sub>4</sub>	-.46	.42	<.999	-1.60	.67	
Non-frail	T <sub>0</sub> -T <sub>1</sub>	3.19	.20	<.001	2.65	3.72	
	T <sub>1</sub> -T <sub>2</sub>	-.64	.23	.041	-1.27	-.02	
	T <sub>3</sub> -T <sub>4</sub>	-.58	.25	.149	-1.26	.10	

Note. CI = confidence interval; MD = mean difference; SE = standard error.

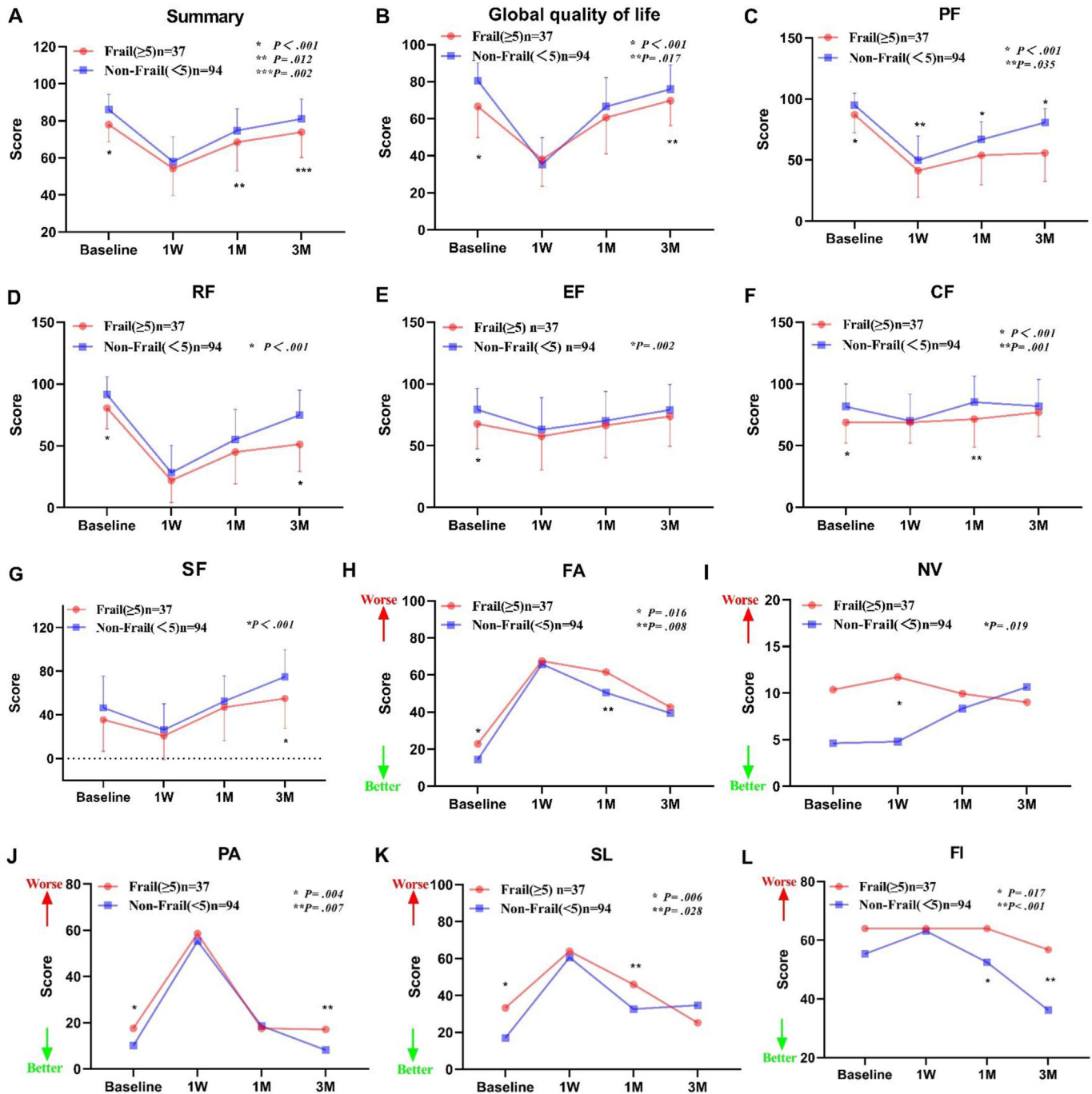


Figure 1. The Longitudinal Change of EORTC-QLQ-C30 Scores for Each Dimension in Preoperative Frail and Non-frail Patients. Note. CF = cognitive functioning; EF = emotional functioning; FA = fatigue; FI = financial impact; NV = nausea and vomiting; PA = pain; PF = physical functioning; RF = role functioning; SF = social functioning; SL = sleep disturbance.

patients with esophageal cancer. This study examined HRQoL in relation to preoperative frailty, revealing that patients exhibiting frailty demonstrated diminished functioning across multiple domains and experienced more pronounced symptoms at both baseline and short-term follow-up. The disparity in HRQoL scores between the two groups varied from 6 to 25, reaching clinically significant values as per the QLQ-C30 scoring guidelines. Prior study has indicated that preoperatively frail patients tend to report lower HRQoL scores at baseline, as well as during short-term and long-term follow-ups compared with their non-frail counterparts. Benedicte et al [16] recently investigated the longitudinal HRQoL of

non-frail and frail patients undergoing colorectal cancer surgery. The findings revealed that frail patients scored lower than non-frail patients across all scales following their elective surgery for colorectal cancer [16], a finding consistent with the results of the present study.

Compared with non-frail patients, preoperative frailty was associated with a slower rate of QL recovery within three months post-surgery. This was determined after adjusting for factors such as baseline QLQ-C30 score, age, gender, cancer stage, preoperative treatment, and comorbidities. The findings align with those of Julius et al who examined the correlation between baseline frailty

**Table 4** Linear Mixed Model Results for Frailty and EORTC-QLQ-C30.

EORTC-QLQ-C30 Scale	Parameters	Estimate( $\beta$ )	95% CI		p
Summary score <sup>a</sup>	Frail*Time	-1.98	-1.13	.26	.258
Global quality-of-life <sup>a</sup>	Frail*Time	-4.24	-8.31	-.18	.041*
<b>Functional scales<sup>a</sup></b>					
Physical functioning	Frail*Time	-9.87	-14.59	-5.16	<.001**
Role functioning	Frail*Time	-10.04	-15.76	-4.33	.001*
Emotional functioning	Frail*Time	.26	-6.10	6.61	.936
Cognitive functioning	Frail*Time	.48	-4.96	5.92	.860
Social functioning	Frail*Time	-8.58	-15.49	-1.68	.015*
<b>Symptom scales<sup>a</sup></b>					
Fatigue	Frail*Time	1.13	-4.69	6.96	.701
Nausea and vomiting	Frail*Time	-4.10	-8.68	.51	.080
Pain	Frail*Time	2.81	-3.49	9.11	.379
Dyspnea	Frail*Time	-1.40	-8.49	5.69	.697
Sleep disturbance	Frail*Time	-8.11	-15.92	-3.12	.042*
Appetite loss	Frail*Time	2.36	-8.08	12.79	.656
Constipation	Frail*Time	3.72	-2.13	9.57	.210
Diarrhea	Frail*Time	2.19	-3.26	7.64	.430
Financial difficulties	Frail*Time	10.49	3.30	17.68	.005*

Note. a: All models were adjusted for corresponding baseline EORTC-QLQ-C30 scale scores, age, gender, stage, treatment modality, and comorbidities; Frail\*Time refers to the interaction of frailty and time, indicating the amount of change in HRQoL over time for frail compared to non-frail patients; \* $p < .05$ ; \*\* $p < .001$ .

and QL alterations over two years postoperatively in head and neck cancer patients [41]. Their study indicated that preoperatively frail patients were at an elevated risk of further deterioration of their QL during postoperative follow-up, yielding clinically significant results [41]. In contrast, no influence of frailty on QL changes was observed in colorectal cases [16]. This study evaluated the association between preoperative frailty and change in HRQoL over a three-month span using geriatric assessment (GA). Despite the overall lower QL in the frailty group, there appeared to be no increased risk of reduced QL post-surgery. However, this study failed to consider the baseline disparities between frail and non-frail patients, which have been shown to be substantial at the initial stage [42]. In summary, frail patients demonstrate a diminished stress tolerance compared with their non-frail counterparts. They also encounter more challenges in recovering from trauma post-surgery [43], and are more susceptible to psychological issues [44], thereby resulting in a more gradual recovery from QL.

This study revealed that the trajectories of physical, role, and social functioning varied between preoperatively frail and non-frail groups in the three months post-surgery; frail patients exhibited a higher risk of diminished physical and social functioning post-surgery. This is similar to the findings of another study that utilized GA to assess frailty, revealing that older frail women diagnosed with breast cancer were at heightened risk for long-term deterioration in physical functioning and a decline in social roles [45]. Previous study has indicated that elderly esophageal cancer patients who undergo esophagectomy exhibit poorer physical and social functioning [24,46,47]. Patients undergoing esophagectomy may experience short-term weight loss [46], loss of appetite, and malnutrition [47], which can result in hand weakness, physical fatigue, and limitations in daily life activities [24]. Following surgery, patients are frequently discharged with tubes, leading to a stigmatization that impacts their psychological and social functioning [48,49]. In the QLQ-C30 questionnaire, role functioning pertains to whether the patient experiences limitations in daily activities and is unable to engage in leisure and recreational activities. Frailty often manifests as reduced muscle mass and slower movement, thereby limiting a patient's physical capabilities and leisure activities post-surgery [50,51]. This study discovered that preoperatively frail patients experienced a more severe degree of frailty throughout the follow-up period, potentially explaining their

increased physical limitations in daily activities and leisure activities post-surgery.

Cancer patients, particularly those with lower incomes, bear a significantly greater financial burden [52]. In the present study, no significant difference was observed in baseline income between the preoperative frail and non-frail groups. However, the frail group experienced a significantly higher financial burden three months post-surgery. This implies that additional factors may influence the financial burden of frail patients. Prior study indicates that preoperative frail patients are more likely to experience prolonged hospitalizations, non-family discharges, and subsequent readmissions after surgery [53]. Such outcomes can escalate healthcare expenditures and exacerbate financial challenges for patients. Additionally, this study revealed that patients in the preoperative non-frail group exhibited a slower recovery in sleep disturbance within three months post-surgery compared with their frail counterparts. This discrepancy might be attributed to the poorer preoperative baseline sleep quality of the frailty group, coupled with a higher medication usage rate, potentially resulting in less severe postoperative sleep disturbances.

The notable fact is that preoperative frailty has a predictive value on multiple dimensions of a patient's postoperative HRQoL, as well as an adverse effect on the patient's prognosis [12,54–56]. Therefore, it is significant to prioritize the assessment and mitigation of frailty in this population. Preoperative rehabilitation strategies might enhance their preoperative health and contribute to the improvement of prognosis and survival [57]. Future study should focus on prevention and intervention of preoperative frailty by conducting randomized controlled studies focusing on preoperative rehabilitation of frailty.

The objective of this study was to investigate the association between pretreatment frailty and postoperative HRQoL changes in patients with esophageal cancer. The strengths of this study encompass a prospective cohort design, an exhaustive evaluation of frailty based on the physiopsychosocial model utilizing the Tilburg Frailty Questionnaire, and a three-month follow-up period. Furthermore, LMMs were used for reliable statistical analyses after controlling for baseline differences and confounders. However, some limitations of this study include the non-exclusion of patients receiving preoperative neoadjuvant therapy, which may influence frailty and HRQoL. Further, due to the scarcity of research on frailty within this specific group of esophageal cancer, the comparison among various types of patients should be interpreted with caution given the heterogeneity of the sample. Additionally, this study was only conducted up to three months postoperatively, leaving open the question of how preoperative frailty impacts long-term postoperative frailty and HRQoL changes in elderly patients with esophageal cancer. Therefore, future study could delve into these patients' long-term outcomes following surgery. Lastly, the present excluded patients who either died or refused to continue during follow-up, potentially resulting in the exclusion of the frailest patients.

## Conclusion

As healthcare professionals, it is imperative that we prioritize the perioperative frailty and health-related quality-of-life of elderly patients diagnosed with esophageal cancer. The current study reveals a consistent increase in the rate of frailty in frail patients within three months post-surgery, relative to their preoperative state. Moreover, the severity of frailty did not show significant improvement following treatment for those who were already preoperatively frail. Patients exhibiting baseline frailty demonstrated a lower HRQoL than those without frailty during the short-term postoperative period, underscoring its clinical significance.



Additionally, preoperative frailty was found to be significantly correlated with slower QL and functional recovery following esophageal cancer treatment, potentially compromising patients' long-term prognosis and survival rates. Consequently, it is imperative to recommend that elderly patients diagnosed with esophageal cancer undergo a preoperative frailty screening. Furthermore, the development of targeted prehabilitation strategies should be pursued to either delay or potentially reverse the onset of frailty.

### Funding information

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### Conflicts of interest

The authors have no conflicts of interest to disclose.

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### Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.anr.2024.04.004>.

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## Research Article

# Pandemic Pressure: Changes in Hypertensive Management Adherence in Indonesia



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## SUMMARY

**Purpose:** This study aimed to determine factors associated with changes in adherence to hypertension management (medication adherence and blood pressure control) in respondents with hypertension before and during the COVID-19 pandemic in Bogor city, Indonesia.

**Methods:** An observational study was conducted using two sources of data (before and during COVID-19 pandemic). Data before the pandemic were derived from the 2019 Cohort Study of non-communicable disease risk factors. Data during the pandemic were derived from an online survey conducted in September and October 2020. Information from 880 participants were analyzed. The dependent variable was the change in adherence to hypertension management before and during the COVID-19 pandemic. Multivariate analysis was performed using logistic polynomial regression.

**Results:** Respondents who adhered to hypertension management decreased from 82.0% in 2019 to 47.8% in 2020. The likelihood of *non-adherence* (respondents who did not adhere to hypertension management both before and during the pandemic) increased in respondents below 55 years old, who did not own any healthcare insurance, who were not obese, and who had no other comorbidities. In the *partial adherence* group (respondents who did not adhere to hypertension management either before or during the pandemic), we found that most respondents adhered before the pandemic but no longer adhered during the COVID-19 pandemic. We found an increased partial adherence in young and highly educated respondents.

**Conclusions:** Efforts to improve adherence to hypertension management after the COVID-19 pandemic should target those who were young, highly educated, who did not have any healthcare insurance, and who did not perceive themselves as not having comorbidities.

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## Introduction

On January 30, 2020, the World Health Organization (WHO) declared coronavirus disease–19 (COVID-19) as an international public health emergency, and on March 11, 2020, its status was upgraded to a pandemic [1,2]. Since its declaration as a global pandemic, managing COVID-19 transmission has become a

significant challenge in many countries, particularly those with limited healthcare resources or systems [3–5].

One impact of the COVID-19 pandemic was the disruption of healthcare services [6]. According to a survey conducted by WHO in 155 countries, prevention and treatment programs for non-communicable diseases (NCDs) have been severely disrupted since the start of the COVID-19 pandemic. More than half (53%) of

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the surveyed countries experienced interrupted services for hypertension treatment [6].

A study in Klaten, Central Java, Indonesia, compared patient visits to hospitals during the initial phase of the pandemic with those in the previous year and reported a 46.3% reduction in the total number of visits [7]. The number of diagnoses for most diagnostic categories, including hypertension, also declined.

A basic health research has reported that hypertension in Indonesia has increased over the years—from 25.8% in 2013 to 34.1% in 2018 [8]. Only 8% of hypertension cases were diagnosed by healthcare workers. Slightly over half (54.4%) of the respondents with hypertension took regular medication [9]. From 2011 to 2021, a cohort study of NCDs risk factors (FRPTM) was conducted on permanent residents 25–65 years old (at baseline) in five sub-districts of Bogor Tengah District, West Java, Indonesia.

Using data from the FRPTM cohort study and a follow-up online survey, our analysis aimed to examine factors associated with changes in adherence to hypertension management (medication adherence and blood pressure control practices) before and during the COVID-19 pandemic. The results of this study may provide evidence of a change in treatment adherence for respondents with hypertension during the COVID-19 pandemic and may be used as a basis for further research to develop effective hypertension control and prevention strategies to reduce complications, particularly during a pandemic.

## Methods

### Data source

An observational study was conducted using two data sources (before and during the COVID-19 pandemic). Data before the pandemic were obtained from the cohort study of non-communicable diseases risk factors (FRPTM) for Permanent Residents in five sub-districts of the Bogor Tengah district, West Java, Indonesia. During the pandemic, a cross-sectional study was conducted between September 28 and October 9, 2020, using an online survey to acquire information from the same respondents in the FRPTM study. Both data sources examined the changes in hypertension management before and during the COVID-19 pandemic.

### Inclusion criteria

The following inclusion criteria were used: (1) respondents who were still followed up in the FRPTM cohort study, (2) respondents who had hypertension according to the initial collection of the data from FRPTM or identified during monitoring activities (2019), and (3) respondents who were willing to participate by filling out online questionnaires. Participants with incomplete data were excluded. Data collected in 2020 were gathered online, and no measurements were performed. Information from 880 participants was included in the analysis.

Based on the Joint National Committee 8 (JNC 8), respondents were classified as having hypertension when the systolic blood pressure was  $\geq 140$  mmHg or diastolic blood pressure  $\geq 90$  mmHg, while resting [10,11]. In the FRPTM cohort study, blood pressure was measured 2–3 times with a 5-minute break in each examination using an “AND” digital sphygmomanometer in the right arm and a sitting position used to diagnose hypertension. The Bogor City Health Office healthcare employees were trained to acquire blood pressure and anthropometric measurements [12].

### Dependent and independent variables

The dependent variable was adherence to hypertension management, which consisted of two components: (1) Controlling/monitoring blood pressure (conducting blood pressure checks at healthcare facilities), and (2) adherence to anti-hypertensive drug use. Measurements were taken on the right arm using a digital sphygmomanometer and conducted twice with a 5-minute interval between the readings. A third measurement was performed if the first two readings differed by 10 mmHg or more. The average blood pressure was calculated from the two readings that showed the smallest difference. Adherence to hypertension management was determined before (2019) and during the COVID-19 pandemic (2020).

Table 1 shows the adherence to hypertension management status in each period (Columns a and b). Respondents who controlled their blood pressure [control (+)] and took medication [medicine (+)] in the past week before data collection were considered as “adhered” to hypertension management (Column c). Respondents who failed to fulfill one of the hypertension management criteria [control (–) or medicine (–)] were considered as “not adhered” (Column c). In the final analysis, participants who adhered to both periods were categorized into the “**adherence**” group (Column d). Respondents who did not adhere in either 2019 or 2020 were categorized into the “**partial adherence**” group. Respondents who did not adhere in 2019 and 2020 were categorized into the “**non-adherence**” group (Table 1).

The independent variables were **sociodemographic** and **health factors**. Sociodemographic factors included age (<45 years, 45–54 years, and >54 years), gender (men and women), educational level (low: no school to elementary school graduates, middle: junior high to high school graduates, and high: university/college graduates), marital status (married, not married, including separated or divorced), occupation (working or not working), and health insurance (with or without any health insurance).

Health factors included obesity and comorbidities, such as diabetes mellitus (DM), coronary heart disease (CHD), stroke, and common mental disorders. Obesity was defined as a body mass index  $\geq 25$  kg/m<sup>2</sup> based on the criteria of the Asian population according to the guidelines for managing dyslipidemia [13]. Anthropometric measurements in the FRPTM cohort study, which were used to determine obesity, included height, measured with a fiberglass board, and weight, measured with a digital “AND” scale.

Examination of fasting blood sugar levels and two hours post-loading of 75 g glucose in 250 ml of drinking water in the FRPTM cohort study was used to diagnose DM, using the enzymatic clinical chemistry method performed by a certified healthcare laboratory [12]. DM was defined as a participant diagnosed with DM, or with fasting blood glucose levels  $\geq 126$  mg/dL, or with blood glucose levels two hours post-loading 75 g of glucose in 250 ml of drinking water  $\geq 200$  mg/dl, based on the criteria of the Association of Indonesian Endocrinologists in 2021 [14].

An electrocardiogram (ECG) examination in the FRPTM was used to diagnose CHD using an ECG device equipped with the Minnesota code. ECG results were read by a cardiologist and validated by two consultants. CHD is based on the results of ECG at rest or activity/stress showing ischemic heart abnormality/infarction [12].

Neurological examination in the FRPTM performed by a team of neurologists was also used for stroke diagnosis. Stroke was defined as a history of stroke, based on interviews and residual symptoms in the form of neurological deficits [12]. Mental-emotional disorders in the form of a person's mental condition that affected mood, cognition, and behavior were measured using 20 questions in a

**Table 1** Changes in Adherence to Hypertension Management Before (2019) and During the COVID-19 Pandemic (2020).

Adherence to hypertension management in 2019	Adherence to hypertension management in 2020	Changes in adherence to hypertension management between 2019 and 2020	Category
(a)	(b)	(c)	(d)
Control (+), medicine (+)	Control (+), medicine (+)	Adhered–Adhered	Adherence
Control (+), medicine (+)	Control (+), medicine (–)	Adhered–Not adhered	Partial adherence
Control (+), medicine (+)	Control (–), medicine (+)	Adhered–Not Adhered	Partial adherence
Control (+), medicine (+)	Control (–), medicine (–)	Adhered–Not Adhered	Partial adherence
Control (+), medicine (–)	Control (+), medicine (+)	Not Adhered–Adhered	Partial adherence
Control (+), medicine (–)	Control (+), medicine (–)	Not Adhered–Not Adhered	Non-adherence
Control (+), medicine (–)	Control (–), medicine (+)	Not Adhered–Not Adhered	Non-adherence
Control (+), medicine (–)	Control (–), medicine (–)	Not Adhered–Not Adhered	Non-adherence
Control (–), medicine (+)	Control (+), medicine (+)	Not Adhered–Adhered	Partial adherence
Control (–), medicine (+)	Control (+), medicine (–)	Not Adhered–Not Adhered	Non-adherence
Control (–), medicine (+)	Control (–), medicine (+)	Not Adhered–Not Adhered	Non-adherence
Control (–), medicine (+)	Control (–), medicine (–)	Not Adhered–Not Adhered	Non-adherence
Control (–), medicine (–)	Control (+), medicine (+)	Not Adhered–Adhered	Partial adherence
Control (–), medicine (–)	Control (+), medicine (–)	Not Adhered–Not Adhered	Non-adherence
Control (–), medicine (–)	Control (–), medicine (+)	Not Adhered–Not Adhered	Non-adherence
Control (–), medicine (–)	Control (–), medicine (–)	Not Adhered–Not Adhered	Non-adherence

- Column (a) and (b): **Control**: Control of blood pressure; **Medicine**: taking anti-hypertensive medication.
- Column (c): **Adhered**: controlled blood pressure and took anti-hypertensive medication; **Not Adhered**: either not controlling blood pressure or not taking anti-hypertensive medication.
- Column (d): **Adherence**: controlled blood pressure and took anti-hypertensive medication in both 2019 and 2020; **Partial adherence**: only adhered with controlling blood pressure and taking anti-hypertensive medication in one of the time periods (2019 or 2020); **Non-adherence**: adhered with controlling blood pressure and taking anti-hypertensive medication in both time periods (2019 and 2020).

self-reported questionnaire describing the conditions in the past two weeks before the interview [15].

#### Data analysis

Data were analyzed using a multinomial logistic test to identify the crude odds ratios (ORs) of potential predictors of changes in adherence to hypertension management. Multivariate analysis with multinomial logistic regression was used to determine factors that may be associated with changes in adherence to hypertension management. The final model presented the adjusted odds ratio (OR) of the variables that were significantly associated with the study outcome.

#### Ethics approval and consent to participate

A cohort study of NCDs risk factors was reviewed and approved by the Health Research Ethics Commission of the National Institute of Health Research and Development, Ministry of Health Republic of Indonesia (approval No. LB.02.01/2/KE.102/2019). The Health Research Ethics Commission of the National Institute of Health Research and Development, Ministry of Health Republic of Indonesia reviewed and approved the complementary cross-sectional study (approval no. LB.02.01/2/KE.511/2020). All consent requirements of the participants were met and approved before data collection.

#### Results

We analyzed information collected from 880 respondents with hypertension living in Bogor city in 2019 and 2020. Table 2 shows the characteristics of respondents included in our analysis. Our analysis revealed that 31.8% of the participants did not adhere to hypertension management before and during the COVID-19 pandemic (*non-adherence*), while 28.4% adhered before or during the pandemic (*partial adherence*). However, our analysis found that 39.8% of respondents adhered to hypertension management before and during the pandemic (*adherence*). In the *partial adherence* group, 88.7% of the respondents adhered before the pandemic but no longer adhered during the pandemic.

The changes in the components of hypertension management before and during the COVID-19 pandemic are shown in Figures S1a–b and S2a–b. The percentage of respondents with hypertension who monitored their blood pressure decreased from 82.0% in 2019 to only 47.8% in 2020 (Fig. S1a). Approximately 34.2% of the respondents who monitored their blood pressure in 2019 no longer did so in 2020, and only 47.8% consistently monitored their blood pressure in 2019 and 2020 (Fig. S1b). Fig. S2a shows that adherence to oral anti-hypertensive drugs decreased from 76.5% in 2019 to 59.3% in 2020. Approximately 22.7% of respondents who complied with taking anti-hypertensive drugs in 2019 no longer did so during the COVID-19 pandemic (Fig. S2b). The results of the crude analysis of factors associated with changes in adherence to hypertension management before and during the COVID-19 pandemic in respondents with hypertension are shown in Table 3.

**Table 2** Characteristics of Patients With Hypertension, Bogor City in 2020 (n = 880).

Variable		n	%
Location	Babakan	74	8.4
	Babakan Pasar	202	23.0
	Ciwaringin	187	21.3
	Kebon Kalapa	324	36.8
	Panaragan	93	10.6
Age group	<45 yr	116	13.2
	45–54 yr	280	31.8
	≥55 yr	484	55.0
Gender	Men	172	19.5
	Women	708	80.5
Working status	Working	141	16.0
	Not working	739	84.0
Education level	High (Finished diploma)	45	5.1
	Medium (Finished high school)	469	53.3
	Low (Finished elementary school)	366	41.6
Marital status	Married	666	75.7
	Not married	214	24.3
Ownership of health insurance	No	60	6.8
	Yes	820	93.2
Obesity	No	272	30.9
	Yes	608	69.1
Other comorbidities	No	402	45.7
	Yes	478	54.3

**Table 3** Factors Associated With Adherence to Hypertension Management Before (2019) and During the COVID-19 Pandemic (2020).

Variable	Adherence status						n	p		
	Non-adherence			Partial adherence					Adherence	
	%	p	OR (CI)	%	p	OR (CI)			%	OR (CI)
<b>Age group (years)</b>										
<45	45.7	<.001	3.05 (1.85, 3.05)	29.3	.006	2.13 (1.24, 3.66)	25.0	Ref	116	<.001
45–54	32.9	.010	1.59 (1.12, 2.28)	32.9	.003	1.74 (1.21, 2.49)	34.3	Ref	280	
≥55	27.9		Ref	25.6		Ref	46.5	Ref	484	
<b>Gender</b>										.125
Men	36.6	.445	1.16 (0.79, 1.71)	22.7	.169	0.74 (0.48, 1.14)	40.7	Ref	172	
Women	30.6		Ref	29.8		Ref	39.5	Ref	708	
<b>Working status</b>										.081
Working	39.7	.090	1.43 (0.95, 2.17)	23.4	.566	0.87 (0.55, 1.39)	36.9	Ref	141	
Not working	30.3		Ref	29.4		Ref	40.3	Ref	739	
<b>Education level</b>										.130
Low	30.3	.891	1.06 (0.47, 2.39)	30.6	.191	0.61 (0.30, 1.27)	39.1	Ref	366	
Middle	33.7	.779	1.12 (0.50, 2.51)	25.4	.050	0.49 (0.24, 1.00)	40.9	Ref	469	
High	24.4		Ref	42.2		Ref	33.3	Ref	45	
<b>Marital status</b>										.022
Married	34.2	.015	1.61 (1.10, 2.36)	27.3	.926	0.98 (0.68, 1.42)	38.4	Ref	666	
Not married	24.3		Ref	31.8		Ref	43.9	Ref	214	
<b>Ownership of health insurance</b>										.001
None	53.3	.001	2.88 (1.53, 5.44)	21.7	.601	1.22 (0.57, 2.62)	25.0	Ref	60	
Yes	30.2		Ref	28.9		Ref	40.9	Ref	820	
<b>Common mental disorder</b>										.109
No	32.5	.046	2.22 (1.02, 4.85)	28.5	.298	1.46 (0.72, 2.98)	39.0	Ref	835	
Yes	20.0		Ref	26.7		Ref	53.3	Ref	45	
<b>Obesity</b>										.227
No	35.7	.087	1.34 (0.96, 1.89)	27.9	.574	1.11 (0.78, 1.58)	36.4	Ref	272	
Yes	30.1		Ref	28.6		Ref	41.3	Ref	608	
<b>Other comorbidities</b>										.001
No	37.6	<.001	1.80 (1.31, 2.47)	28.1	.158	1.27 (0.91, 1.77)	34.3	Ref	402	
Yes	27.0		Ref	28.7		Ref	44.4	Ref	478	

CI = confidence interval; OR = odds ratio; Ref = reference group.

Table 4 presents the results of the multivariate analyses conducted in this study. We found increased odds of non-adherence in young respondents. The odds of non-adherence in participants <45 years old was 2.79 times that of respondents ≥55 years old (OR = 2.79, 95% confidence interval (CI): 1.64–4.74,  $p < .001$ ). Similarly, the odds of non-adherence in respondents 45–54 years old was 1.56 times the odds of respondents aged ≥55 years old (OR = 1.56, 95% CI: 1.07–2.29,  $p = .022$ ). Our study also found that the odds of non-adherence in respondents without health insurance were 2.69 times than that in respondents with health insurance (OR = 2.69, 95% CI: 1.41–5.15,  $p = .003$ ). Furthermore, individuals who were not obese were 1.42 times more likely not to adhere than those with obesity (OR = 1.42, 95% CI: 1.00–2.02,  $p = .047$ ). The odds of non-adherence in respondents with no comorbidity was 1.49 times than that in respondents with comorbidities (OR = 1.49, 95% CI: 1.0–2.09,  $p = .019$ ).

As in the non-adherence group, we also found that the odds of partial adherence in respondents <45 years old was 2.35 times the odds of respondents ≥55 years old (OR = 2.35, 95% CI: 1.33–4.15,  $p < .003$ ), while the odds of partial adherence in respondents aged 45–54 years old was 1.97 times the odds of respondents aged ≥55 years old (OR = 1.97, 95% CI: 1.34–2.89,  $p < .001$ ). Highly educated respondents also showed a reduced likelihood of adherence to hypertension management. The odds of partial adherence in respondents with middle-level education were 0.43 times than that of respondents with high-level education (OR = 0.43, 95% CI: 0.21–0.88,  $p = .022$ ).

## Discussion

### Main findings

Our findings showed a sharp reduction in adherence to hypertension management in respondents who participated in the

FRPTM study before and during the COVID-19 pandemic. The likelihood of *non-adherence* (respondents who did not adhere to hypertension management both before and during the pandemic) increased in respondents below 55 years old, who did not own any healthcare insurance, who were not obese, and who had no other comorbidities. In the *partial adherence* group (respondents who did not adhere to hypertension management either before or during the pandemic), most respondents adhered before but no longer did so during the pandemic. Only a small percentage of respondents did not adhere before but adhered during the pandemic. The odds of partial adherence increased in respondents who were young and highly educated. Program managers may use our findings to design effective strategies to improve adherence to hypertension management and other NCDs prevention programs, particularly during public health emergencies that disrupt routine healthcare services.

### Decline of medication adherence during the COVID-19 pandemic

We found a sharp decline in adherence to hypertension management during the pandemic. A study from the United States of America reported similar finding that an estimated 40.9% of adults avoided medical care due to concerns about COVID-19, including those avoiding emergency and routine care [16]. A study from Saudi Arabia also reported that 29.2% of 1066 patients with chronic diseases did not comply with treatment during the pandemic, and 68.3% hesitated to visit a healthcare center because of the fear of contracting viral infections [17]. Consistent with these results, a study in Aceh, Indonesia found that the number of patients visiting the hospital's hypertension care services decreased by 22.7% [18].

The COVID-19 pandemic created major challenges in providing high-quality, affordable, and universally accessible healthcare, particularly in low- and middle-income countries [19]. The COVID-19 pandemic caused service disruptions, including reduced patient



**Table 4** Factors Associated With Changes in Medication Adherence Before and During the COVID-19 Pandemic.

Variable	Adherence status							p
	Non-adherence			Partial adherence			Adherence	
	p	OR	95% CI	p	OR	95% CI	OR	
<b>Age group (years)</b>								
<45	<.001	2.79	1.64, 4.74	.003	2.35	1.33, 4.15	Ref	<.001
45 – 54	.022	1.56	1.07, 2.29	.001	1.97	1.34, 2.89	Ref	
≥55		Ref			Ref		Ref	
<b>Education level</b>								
Low	.703	1.18	0.51, 2.70	.273	0.66	0.32, 1.38	Ref	.034
Middle	.987	0.99	0.44, 2.26	.022	0.43	0.21, 0.88	Ref	
High		Ref			Ref		Ref	
<b>Ownership of health insurance</b>								
No	.003	2.69	1.41, 5.15	.644	1.20	0.56, 2.59	Ref	.004
Yes		Ref			Ref		Ref	
<b>Obesity</b>								
No	.047	1.42	1.00, 2.02	.360	1.18	0.82, 1.70	Ref	.140
Yes		Ref			Ref		Ref	
<b>Other comorbidities</b>								
No	.019	1.49	1.07, 2.09	.618	1.09	0.77, 1.54	Ref	.054
Yes		Ref			Ref		Ref	

CI = confidence interval; OR = odds ratio; Ref = reference group.

visits at scheduled examinations or controls, closing screening activities at the population level, and transferring human resources to manage COVID-19 [6,20]. The impact of social distancing policies and lockdowns to prevent transmission of COVID-19 also prevented patients with chronic diseases from accessing necessary medication or healthcare services for routine care.

We found that some respondents in this analysis partially adhered to hypertensive management strategies. Before the COVID-19 pandemic, they adhered to hypertensive management; however, during the COVID-19 pandemic, their adherence levels declined. This indicates a valuable opportunity for enhancing their adherence to hypertension management strategies. Proactive interventions to address the changes in healthcare delivery during crises, such as the COVID-19 pandemic, are required by prioritizing patient education, leveraging telemedicine solutions, and fostering a supportive healthcare environment.

#### Factors associated with adherence to hypertension management

Our study showed that respondents with hypertension in the younger age group were more likely to be less adherent or non-adherent than those in the older age group. Age is often positively correlated with experience, knowledge, understanding, and views regarding a disease or event, which may shape perceptions and behaviors. Additionally, time constraints for younger age groups in the labor force may result in low adherence [21]. A previous study showed that younger patients tend to be non-adherent to treatment owing to asymptomatic illness [22], which may be the reason for the low adherence in non-obese respondents or those without comorbidities.

Interestingly, our study found that highly educated individuals did not consistently comply with hypertension management. Highly educated people tend to have better access to health-related literature and, consequently, could question and ignore conventional health practices, including hypertension management [23]. Studies demonstrated that education level did not directly influence adherence. Instead, health literacy was found to be directly linked to adherence [24,25]. High education levels do not equate to high health literacy as health-related knowledge is not solely acquired through formal education. Instead, it can also be gained through various information, education, and communication activities, including mass media exposure and counseling sessions

[25]. Given that knowledge about health constitutes a primary aspect of health literacy, enhancing awareness and understanding among the highly educated population to foster positive health practices remains essential. A study conducted in Iran demonstrated that health education significantly enhanced adherence to anti-hypertensive medication [26].

Moreover, our findings indicate that participants lacking healthcare insurance were less likely to adhere to hypertension management than those with coverage. This underscores the importance of having healthcare insurance, consistent with previous research findings [27,28]. Moreover, ensuring access to healthcare insurance is beneficial in reducing health disparities. A previous study showed that improving hypertension management in underprivileged groups significantly reduced health inequalities and mortality [29].

#### Potential interventions to improve adherence to hypertension management

Our analysis revealed the need for programmatic actions to improve adherence to hypertension management after the COVID-19 pandemic. The Ministry of Health of the Republic of Indonesia issued guidelines for preventing and controlling NCDs during the COVID-19 pandemic with the aim of effective, sustainable, and safe implementation [30]. These guidelines emphasize the implementation of screening and information technology for treatment. Healthy residents and NCDs survivors could be screened to control for existing risk factors for various NCDs, including hypertension. Screening can be conducted in different settings, including healthcare facilities, workplaces, campuses, or the community through *Posbindu* (integrated development post) for NCDs, considering the local government's pandemic-handling policies. However, several barriers to *Posbindu* implementation reported include a need for more operational funds and the limited capacity of cadres. Increasing the number of cadres and their competence in counseling and education, assisted by the development of supportive public policies and relevant regulations, is important for improving the availability and quality of *Posbindu* for NCDs [31–33]. Nurses are vital in overcoming these barriers as they possess the clinical expertise to perform health examinations and identify hypertension risk factors during screenings. Furthermore, nurses play a crucial role in educating individuals about the importance of

blood pressure monitoring, lifestyle modifications, and adherence to treatment plans.

The Indonesian government recommends the use of technology and information for treatment. As telemedicine and e-health are commonly used nowadays, access to patients for necessary treatments during the pandemic has changed. These potential changes may improve the management of patients with NCDs after the pandemic [34]. In Indonesia, the government's efforts include developing telemedicine and drug delivery services by healthcare employees from local healthcare centers to patients' homes. Nurses could be encouraged and trained to use telemedicine and e-health services for the treatment of NCDs, particularly hypertension. They could assist in remotely monitoring patients' blood pressure, provide management guidance as well as deliver patient education on hypertension management strategies. Additionally, nurses could help to ensure continuity of care by facilitating virtual consultations between patients and healthcare providers, promoting medication adherence, and addressing any concerns or questions patients may have about their condition. By leveraging these services, nurses will empower patients to participate in their healthcare while expanding access to essential treatments. This will contribute greatly to the prevention and management of hypertension within the communities.

#### Strengths and limitations

Only a few studies from Indonesia have used cohort data to examine potential changes in respondent's adherence to disease management before and during the COVID-19 pandemic. This study used a large sample size to examine predictors of changes in adherence to hypertension management. However, this study had several limitations. In 2020, the survey was conducted online; therefore, researchers could not easily identify whether participants fully understood the questions or provided explanations. In addition, the survey only involved respondents who were familiar with the use of electronic devices. There may also be an issue with recall bias because respondents provided all the information retrospectively. Because the data analyzed in this study were derived from a cohort study, the findings do not represent populations from a specific location in Indonesia.

#### Conclusions

Our study found a decline in adherence to hypertension management during the COVID-19 pandemic. The reduced likelihood of adherence was found in hypertensive respondents who were young, highly educated, had no healthcare insurance, were not obese, and had no other comorbidities. Health promotion intervention is required to improve adherence, particularly by targeting the population with an increased likelihood of not complying with hypertension management. The development and promotion of telemedicine and e-health facilities to support respondents' active communication with healthcare professionals are required, particularly during a pandemic. Efforts to ensure the availability and accessibility of *Posbindu* for NCDs services through intersectoral collaboration will improve the community-to-service points and help control the risk factors associated with NCDs independently and sustainably.

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#### Availability of data and materials

The datasets are not publicly available but are available from the corresponding author upon reasonable request.

#### Conflict of interest

The authors have no conflicts of interest associated with the material presented in this paper.

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#### Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.anr.2024.04.005>.

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## Research Article

# Association Between Family Functioning and Health-related Quality of Life in Stroke Survivor–Informal Family Caregiver Dyads



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## SUMMARY

**Purpose:** Stroke survivors and their informal family caregivers may share the impact of the disease, which may affect family functioning and quality of life (QoL) for both. This study compared the perceptions of stroke survivors and informal family caregivers regarding family functioning and QoL and examined the QoL of those reporting effective versus ineffective family functioning.

**Methods:** A cross-sectional study design and convenience sampling were used. Stroke survivor–informal family caregiver dyads were recruited from a medical university hospital. We assessed participants' demographic and clinical variables, including disease severity, family functioning, and QoL. Independent *t*-test, paired *t*-test, Wilcoxon signed-rank test, and Mann–Whitney *U* test were used to analyze the data. **Results:** Seventy-one stroke survivor–informal family caregiver dyads participated in the current study. Most stroke survivors and informal family caregivers reported effective family functioning, with no significant differences. However, significant differences existed in the seven domains (physical functioning, role-physical, bodily pain, general health, vitality, social functioning, and role-emotional) of QoL, except emotional health. Stroke survivors reporting ineffective family functioning had a significantly lower mental component summary score, unlike informal family caregivers.

**Conclusions:** Our findings suggest that family functioning is crucial to ensure stroke survivors' QoL, particularly regarding their mental health. Health professionals should prioritize mental health assessments and provide appropriate care interventions for stroke survivors in the first 1–6 months after stroke onset.

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## Introduction

Stroke survivors often experience diverse forms of disability during their recovery period and rely on family members or other caregivers for assistance with their daily activities. A recent scoping review revealed that informal caregivers who report higher care

burdens also have a lower quality of life (QoL) [1]. Further, Opara and Jaracz [2] reported that stroke has a significant impact on the QoL of patients and their caregivers who provide long-term day-to-day care. In a past study, 17.0–50.0% of the caregivers were observed to have anxiety and depression [2]. Among informal caregivers, about 80.5% experienced significant burden, while 78.0% of the stroke survivors had a low QoL score [3]. Therefore, stroke survivors and their informal family caregivers may share the impact of the disease, which in turn may affect the QoL of both the parties [3].

Informal family caregivers are generally defined as those who provide care, often unpaid, to relatives with a chronic illness, disability, or other long-term healthcare needs [4]. These caregivers often act as the primary support for dependent or vulnerable individuals facing healthcare decisions [5,6]. Therefore, informal family caregivers face myriad complex problems, and their QoL is

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likely to be intertwined with that of the care recipient. Okoye et al [3] suggested that the caregiver and stroke survivor QoL were significantly correlated; specifically, if the stroke survivors' QoL was poor, their caregivers also had lower QoL. A stroke survivor–caregiver dyad study also showed significant correlations between the QoL of care recipients and that of their caregivers [7]. In a scoping review by Moura et al [1], informal caregivers of stroke survivors with higher levels of QoL also presented higher perceived QoL. Bergström et al [8] further showed a significant inverse relationship between caregiver burden and the life satisfaction of the stroke survivor–caregiver dyad. These findings highlight the importance of assessing perceived QoL in stroke survivor–informal family caregiver dyads.

Additionally, Mei et al [9] found that better family functioning is associated with better mental health. In fact, family functioning may be an important protective factor against the strain caused by the dealings with the disease of a family member [10]. Similarly, researchers have suggested an association between QoL and family functioning in patients with other diseases such as pediatric cancer [11], Parkinson's disease [12], cervical cancer [13], brain injury [14], and type 2 diabetes [15].

Visitor restrictions during the coronavirus disease 2019 (COVID-19) pandemic have had a negative impact on the health and well-being of both patients and their family members. Family relationships and communication have also been affected [16]. Thus, although the current literature provides relevant evidence on the relationship of family functioning with mental health and QoL, this research adds to the existing knowledge by examining this relationship in the context of stroke survivor–informal family caregiver dyads during the COVID-19 pandemic. In particular, this study examined how stroke survivors and their informal family caregivers perceive family functioning and QoL and the QoL of those reporting effective versus ineffective family functioning. The results of this study can potentially guide the development of programs for stroke survivor–informal family caregiver dyads. In this study, informal family caregivers were defined as individuals who provide unpaid caregiving to patients and are important decision-makers in the family [4–6]. Meanwhile, family functioning was defined as the ability of family members to solve problems, mutually exchange information, role accountability, affective responsiveness and involvement, and behavior control [17].

## Methods

### Design

A cross-sectional study design was used to examine the perceived family functioning and QoL of stroke survivors and their informal family caregivers during the subacute recovery period (i.e., 1–6 months after stroke).

### Participants

A convenience sample of stroke survivors and their informal family caregivers was recruited from a rehabilitation ward of a medical university hospital in Taiwan. Stroke survivors' eligibility criteria were as follows: (a) language expression ability; (b) over 20 years of age; (c) a duration of 1–6 months from stroke onset; and (d) willingness to participate. The eligibility criteria of informal family caregivers were as follows: (a) unpaid caregiving; (b) the main financial, psychological, and emotional support persons of the stroke survivor; (c) important decision-makers in the family; (d) living with or close to the stroke survivors; and (e) at least 20 years of age. G\*Power (version 3.1) was used to determine the sample size. As a general rule of thumb, if two related groups are to be

compared using an independent *t*-test with a medium effect size of 0.5 and an expected power of 0.8, then each group requires a sample size of 64 participants. However, a smaller effect size of 0.2 will require a larger sample size of 99 participants per group. In our study, the 71 stroke survivor–informal family caregiver dyads recruited fell in the middle of the range.

### Measures

We employed the Chinese versions of all scales, except the McMaster Family Assessment Device–General Functioning Subscale (FAD–GF). We therefore requested two specialists who were fluent in both Chinese and English to translate the FAD–GF into Chinese via back-translation. Further, three nursing experts were invited to help us determine whether the content of each scale was appropriate for our participants. The content validity index was greater than .80.

### Social demographics

A six-item demographic questionnaire was used, which included items on age, sex, stroke type, education level, health insurance status, and the duration in months from stroke onset. Two items about whether a formal (paid) caregiver was employed and whether there were family members to help with care were also used. The relationship between stroke survivors and informal family caregivers (e.g., child or spouse) was also assessed.

### National Institutes of Health Stroke Scale

The National Institutes of Health Stroke Scale (NIHSS) was used to evaluate neurological deficits in stroke survivors. This 11-item scale includes the following domains: level of consciousness, eye movements, the integrity of visual fields, facial movements, arm and leg muscle strength, sensation, coordination, language, speech, and neglect [18]. Each item was scored on a 3- or 4-point ordinal scale. The total score ranged from 0–42, with higher scores indicating more severe neurological deficits. The scores were further divided into mild (1–4 points), moderate (5–14 points), and severe ( $\geq 15$  points) [19].

### General functioning subscale of the McMaster family assessment device

The FAD–GF [17] was used to evaluate the participants' perception of overall health and family functioning. It comprises 12 items, with six items each for healthy (e.g., "In times of crisis we can turn to each other for support") and unhealthy family functioning (e.g., "We cannot talk to each other about the sadness we feel"). Items are rated on a 4-point scale from 1–4 (1 = strongly agree; 4 = strongly disagree), and negatively-worded items are reverse scored. Total scores were divided by the number of items on the scale, yielding a total score ranging from 1, reflecting the best functioning, to 4, reflecting poor functioning [17,20].

This scale has been assessed for criterion validity and showed a positive correlation with primary caregiver's psychological well-being, thus demonstrating the scale's appropriate validity [17]. Past researchers have used a cut-off score of 2 or higher for designating problematic or ineffective family functioning [21]. The Cronbach's  $\alpha$  coefficients in this study were .93 and .92 for the stroke survivor and informal family caregiver groups, respectively.

### Short-Form 12-item version 2 Health Survey

The Short-Form 12-item version 2 (SF-12v2) Health Survey was used to evaluate participants' QoL over the previous four weeks [22]. The tool is divided into two components, namely the physical component summary (PCS) and the mental component summary (MCS), and eight health domains, as follows: physical functioning

(PF), role-physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role-emotional (RE), and emotional health (MH) [23]. The scores for the eight domains were computed by summing up the items with multiple responses. Initially, the total raw scores of the health domain scales were transformed to 0–100 scores, which were then transformed to T Scores ( $M = 50$ , standard deviation ( $SD$ ) = 10). Higher scores indicated greater health-related QoL [23]. The criterion validity of this scale was examined through the correlations of SF-12v2 variables with those of other health-related QoL measures, and the validity was confirmed [23].

The PCS and MCS were also calculated after weighing the eight subscales using the PRO CoRE 2.0 Smart Measurement® System [24]. In this study, Cronbach's  $\alpha$  coefficients for QoL, PCS, and MCS were .82, .72, and .75 for the survivors and .89, .82, and .90 for the informal family caregivers, respectively.

#### Data collection procedure

The researcher explained the purpose of the study to the hospitalized stroke patients and their informal family caregivers who met the inclusion criteria. All questionnaires were administered after obtaining mutual consent. The data were collected by five investigators, all of whom were senior registered nurses who had worked in the rehabilitation ward for more than five years, in the first week after patient admission (between August 2021 and October 2022). For data collection, the investigators made an appointment with the patient and the informal family caregiver to respond to the questionnaire. If the participant was unable to respond to the questionnaire, the investigator conducted a face-to-face interview to assist in the questionnaire responses; upon completing the questionnaire with the assistance of the investigator, the participant was asked to check and confirm whether the responded questionnaire reflected their own original intention. A gift of NT\$300 was presented to the stroke survivors and their informal family caregivers for their participation.

#### Ethical considerations

The institutional review board of Chung Shan Medical University approved this study's design and procedure (approval no. CS1-21079). Through the hospital's administrative procedures, stroke survivors and their informal family caregivers were invited to participate in this study. Those who agreed to participate in the study were asked to sign informed consent after the investigator explained the study's purpose and procedures. Participant anonymity and confidentiality were guaranteed during the study, and all questionnaires were numerically coded to ensure privacy.

#### Statistical analysis

SPSS version 22 (IBM) was used for data management and analysis. We used the Kolmogorov–Smirnov test to check for data normality. Paired  $t$ -test for normally-distributed data or Wilcoxon signed-rank test for non-normally-distributed data were used to compare pair sample (stroke survivor–informal family caregiver dyads) measurements and examine differences in mean perceived family functioning and QoL scores. Independent  $t$ -tests for normally-distributed data and Mann–Whitney  $U$  tests for non-normally-distributed data were conducted to examine differences in perceived QoL variables between those who reported effective and those who reported ineffective family functioning among both

the stroke survivor and informal family caregiver groups. Additionally, Cohen's  $d$  effect sizes were calculated using Psychometrica's effect size online calculator [25]; effect sizes were reported as small if in the range of 0.2–0.4, intermediate if in the range of 0.5–0.7, and large if  $>.8$  [26].

## Results

#### Participant characteristics

As shown in Table 1, data from 71 stroke survivor–informal family caregiver dyads were included in the analysis. Most stroke survivors (74.7%) were approximately in the 3–6-month poststroke stage, had suffered a moderate ( $M = 6.58$ ,  $SD = 3.35$ ; NIHSS range, 0–14 points) ischemic stroke (47, 66.2%), and had a mean age of 62.10 (age range, 20–90 years). Moreover, most stroke survivors were men (41, 62.0%), had a high school diploma or were less educated (50, 70.4%), had no health insurance (50, 70.4%), and employed formal (paid) caregivers to assist with care (50, 70.4%).

Informal family caregivers were, on average, approximately 10 years younger than stroke survivors (age range 25–72 years;  $M = 49.89$ ), primarily women (46, 64.8%), some were the patients' spouses (26, 36.6%;  $M = 58.38$ ,  $SD = 1.70$ ), and some were their children (32, 45.1%;  $M = 43.13$ ,  $SD = 1.60$ ). Most informal family caregivers were more educated than the stroke survivors (Table 1).

#### Family functioning and QoL in stroke survivor–informal family caregiver dyads

Table 2 presents the mean scores of family functioning and the eight QoL domains in the two groups. In all variables, the stroke survivor group had lower scores. The mean FAD-GF scores of the stroke survivors and informal family caregivers were 1.78 ( $SD = 0.51$ ) and 1.74 ( $SD = 0.47$ ), respectively. This reflected a higher-level perception of family functioning (i.e., a score below 2). We observed no significant differences between the two groups ( $Z = -0.371$ ,  $p = .711$ ,  $d = 0.06$ ).

Stroke survivors' PCS scores were lower than those of informal family caregivers ( $Z = -7.102$ ,  $p < .001$ ,  $d = 1.48$ ). We also observed significant differences ( $p < .001$ ) between stroke survivors and informal family caregivers regarding scores for the four domains of the PCS, as follows: PF ( $Z = -7.066$ ), RP ( $Z = -6.249$ ), BP ( $Z = -4.928$ ), and GH ( $Z = -5.653$ ), and the Cohen's  $d$  values of these domains ranged from 0.91–1.47, showing a large effect size.

Stroke survivors' MCS scores were lower than those of informal family caregivers, albeit the difference was non-significant ( $t = -0.960$ ,  $p = .340$ ,  $d = 0.15$ ). We observed that the scores of stroke survivors for the three domains of the MCS were significantly lower than those of the informal family caregivers, as follows: VT ( $Z = -3.117$ ,  $p = .002$ ), SF ( $Z = -4.995$ ,  $p < .001$ ), and RE ( $Z = -5.375$ ,  $p < .001$ ), and the Cohen's  $d$  values of these domains ranged from 0.54–1.01, showing medium to large effect sizes. The exception was the MH domain, which showed a non-significant difference ( $Z = -1.367$ ,  $p = .172$ ,  $d = 0.23$ ).

#### Comparison of the QoL of patients and informal family caregivers by perceived family functioning effectiveness

We grouped participants by family functioning effectiveness (effective versus ineffective family functioning) to compare their QoL and ascertain whether there were significant differences in QoL by personal characteristics (e.g., age, gender, and education) based

**Table 1** Demographic and Clinical Characteristics of Participants (N = 142).

Variables	Stroke survivors (n = 71)		Informal family caregivers (n = 71)	
	Mean or n	SD or %	Mean or n	SD or %
Age (years)	62.10	13.54	49.89	11.55
Gender				
Men	44	62.0	25	35.2
Women	27	38.0	46	64.8
Time since stroke (months)				
<3	18	25.4	—	—
3–6	53	74.7	—	—
Type of stroke				
Hemorrhagic	24	33.8		
Ischemic	47	66.2		
Stroke survivors' NIHSS score	6.58	3.35		
1–4 points	19	26.8		
5–14 points	52	73.2		
Level of education				
High school or lower	50	70.4	31	43.7
College/university or higher	21	29.6	40	56.3
Health insurance				
Insured	21	29.6	—	—
Uninsured	50	70.4	—	—
Employed formal (paid) caregivers to assist with care				
Yes			50	70.4
No			21	29.6
Other family members to assist with care				
No			21	29.6
Yes			50	70.4
Relationship between caregiver and stroke survivor (mean and SD of age)				
Parent			2 (62.50)	2.8 (1.5)
Spouse			26 (58.38)	36.6 (1.70)
Child			32 (43.13)	45.1 (1.60)
Sibling			9 (49.44)	12.7 (3.51)
Other			2 (37.00)	2.8 (4.00)

Note. NIHSS = National Institutes of Health Stroke Scale; SD = standard deviation.

**Table 2** Differences in the Mean Scores of Perceived Family Functioning and Quality of Life Between Stroke Survivors and Informal Family Caregivers (N = 142).

Variables	Stroke survivors (n = 71)		Informal family caregivers (n = 71)		Z or t	p	Effect size (d)
	Mean	SD	Mean	SD			
Family functioning <sup>a</sup>	1.74	0.47	1.78	0.51	−0.371	.711	0.06
PCS <sup>a</sup>	32.70	6.80	50.28	8.03	−7.102	< .001	1.48
PF <sup>a</sup>	30.12	7.94	50.74	8.58	−7.066	< .001	1.47
RP <sup>a</sup>	33.74	8.48	46.85	8.43	−6.249	< .001	1.23
BP <sup>a</sup>	40.07	10.50	49.80	9.77	−4.928	< .001	0.91
GH <sup>a</sup>	33.56	10.05	46.38	11.66	−5.653	< .001	1.08
MCS <sup>b</sup>	44.86	8.45	46.26	9.64	−0.960	.340	0.15
VT <sup>a</sup>	48.10	9.57	53.78	9.38	−3.117	.002**	0.54
SF <sup>a</sup>	37.36	8.59	45.88	7.88	−4.995	< .001	0.92
RE <sup>a</sup>	34.03	10.37	43.91	9.06	−5.375	< .001	1.01
MH <sup>a</sup>	45.55	9.13	47.73	9.35	−1.367	.172	0.23

Note. BP = bodily pain; GH = general health; MH = emotional health; MCS = mental component summary; PCS = physical component summary; PF = physical functioning; RP = role-physical; RE = role-emotional; SF = social functioning; VT = vitality.

<sup>a</sup> Wilcoxon signed-rank test.

<sup>b</sup> Paired Sample t-test; \*\*p < .01.

on the subgroups of family functioning; however, there were no significant differences ( $p > .05$ ). Thus, a Mann–Whitney  $U$  test or an independent sample  $t$ -test was used to assess all possible correlations simultaneously, rather than just a specific correlation (Table 3). Approximately half of the stroke survivors (37, 52.1%) and informal family caregivers (35, 49.3%) reported effective family functioning (score below 2). The results showed that stroke survivors who reported ineffective family functioning had significantly lower scores for the GH ( $Z = -2.710$ ,  $p = .007$ ), MCS ( $t = 2.260$ ,  $p = .027$ ), VT ( $Z = -2.416$ ,  $p = .016$ ), and MH ( $Z = -2.344$ ,  $p = .019$ ) domains. The Cohen's  $d$  values for these domains ranged from

0.54–0.68, showing medium effect sizes. Moreover, no significant differences in QoL were found among informal family caregivers by perceived family functioning effectiveness.

## Discussion

This study's first objective was to compare the perceptions of stroke survivors and informal family caregivers about family functioning and QoL. Our findings showed that both stroke survivors and informal family caregivers reported a high level of family functioning. Although informal family caregivers scored slightly

**Table 3** Quality of Life of Patients and Informal Family Caregivers Reporting Effective Versus Ineffective Family Functioning (N = 142).

Variables/Domains	Stroke survivors (n = 71)				Effect size (d)		Informal family caregivers (n = 71)				Effect size (d)			
	Effective (n = 37, 52.1%)		Ineffective (n = 34, 47.9%)		z or t	p	Effective (n = 35, 49.3)		Ineffective (n = 36, 50.7%)		z or t	p		
	Mean	SD	Mean	SD			Mean	SD	Mean	SD				
PCS <sup>a</sup>	33.70	7.07	31.61	6.41	-1.283	.199	0.31	50.34	8.22	50.23	7.96	-0.058	.954	0.01
PF <sup>a</sup>	30.90	8.31	29.28	7.56	-1.017	.309	0.24	50.99	7.89	50.50	9.31	-0.066	.947	0.02
RP <sup>a</sup>	34.47	8.61	32.94	8.38	-0.717	.473	0.17	46.94	9.26	46.77	7.67	-0.452	.651	0.11
BP <sup>a</sup>	41.40	10.60	38.63	10.36	-1.083	.279	0.26	48.10	11.98	51.45	6.76	-1.063	.288	0.25
GH <sup>a</sup>	36.63	10.84	30.21	7.99	-2.710	.007**	0.68	47.75	11.51	45.05	11.81	-0.969	.332	0.23
MCS <sup>b</sup>	46.97	7.77	42.56	8.67	2.260	.027*	0.54	46.85	8.54	45.68	10.70	0.509	.612	0.12
VT <sup>a</sup>	50.66	9.13	45.31	9.38	-2.416	.016*	0.60	55.25	9.25	52.35	9.40	-1.392	.164	0.34
SF <sup>a</sup>	37.67	9.73	37.02	7.28	-0.410	.682	0.10	45.47	8.23	46.28	7.61	-0.484	.629	0.12
RE <sup>a</sup>	35.49	10.61	32.43	10.01	-1.133	.257	0.27	44.25	8.34	43.58	9.82	-0.083	.934	0.02
MH <sup>a</sup>	48.09	8.75	42.78	8.85	-2.344	.019*	0.58	48.15	8.33	47.32	10.35	-0.361	.718	0.09

Note. BP = bodily pain; GH = general health; MCS = mental component summary; MH = emotional health; PCS = physical component summary; PF = physical functioning; RE = role-emotional; RP = role-physical; SF = social functioning; VT = vitality.

<sup>a</sup> Mann-Whitney U test.

<sup>b</sup> Independent Sample t-test; \*p < .05, \*\*p < .01.

higher than stroke survivors on family functioning, the difference was insignificant. Our findings differ from those of a previous study by Li et al [27] that found caregivers to have poorer general family functioning than stroke patients. One of the reasons behind the difference could be that their patients were in the acute stage of stroke and hence required greater caregiver assistance which in turn increased the caregiver burden. Another reason could be the age of the study participants; participants in Li et al's study [27] were older than our study participants, both patients and caregivers. However, future studies could further examine whether family functioning in this dyad is maintained or undergoes change after long-term rehabilitation.

A significant difference was observed between the QoL scores of stroke survivors and informal family caregivers. This finding concurs with those of the study by Okoye et al [3], which reported poorer QoL in stroke survivors (vs. informal caregivers). Our evidence also corroborates the findings of two other studies, as follows: stroke significantly influences the patients' and family caregivers' QoL [2], and the QoL of care recipients positively correlated significantly with that of their caregivers [1,7]. In contrast, our findings are inconsistent with those of a previous study that reported no significant differences in QoL between stroke survivors and caregivers [28]. This inconsistency may be related to the use of different QoL scales. It is also possible that differences in care burden influence QoL in dyads [1,8]. Specifically, stroke survivors in our sample showed moderate stroke severity (NIHSS score, 6.58), which typically indicates a noticeable but not severe impairment. Nevertheless, patients at this acuity level require rehabilitation and ongoing care management. However, the study conducted by Medea et al [28] does not report on disease severity. Therefore, we recommend for future studies examining QoL in the stroke survivor-informal family caregiver dyad to include disease severity and caregiver burden in their assessments and analyses. Regarding clinical implications, this finding emphasizes that health professionals must pay attention to the QoL of stroke patients at all times, be able to conduct a timely assessment of the eight domains of their QoL, and provide targeted care for the domains that are importantly affected in the patient.

Our results also inform that the scores for the PCS and three domains of the MCS (VT, SF, and RE) of stroke survivors were significantly lower than those of their informal family caregivers. The findings for the three MCS domains showcase that hospitalized patients in the time span of 1–6 months after stroke onset experienced lower vitality, social functioning, and limitations on daily activities because of emotional problems. Thus, we suggest for rehabilitation nurses to give due consideration to hospitalized stroke patients'

perceptions of own vitality, social functioning, and emotion. Our results also showed that the difference in the scores for the MH domain in the dyad was non-significant, indicating that both stroke survivors and their informal family caregivers experience the influence of the disease on their mental health. Clinical nurses are therefore recommended to provide timely mental health care interventions for patients' family caregivers during clinical care.

Our findings add to the scientific evidence on the relationship between family functioning and QoL. The results showed that stroke survivors who reported effective family functioning had higher QoL scores than those who reported ineffective family functioning. In particular, there were significant differences in the scores for the GH, VT, MH, and MCS. Our results however are inconsistent with those of Walker et al [29], who reported that family functioning was not associated with QoL. These inconsistent results may be because their sample was younger (median = 52.50 years) than ours (M = 62.10 years). It is worth noting that in our study, stroke survivors' perceived family functioning effectiveness had no significant relationship with the PCS of QoL, especially PF, RP, and BP even though these are all post-stroke disability states. Therefore, the role of family functioning effectiveness in improving a patient's physical functions appears to be limited, which further highlights the importance of professionals in assisting the patient's rehabilitation. However, our study provides empirical evidence confirming the association between perceived effective family functioning and QoL for stroke survivors, especially in the mental component of QoL. Thus, this study shows the potential importance of effective family functioning for stroke survivors' mental health. These pieces of evidence underpin that clinical care should place great focus on the QoL of those with weak perceived family functioning, and if necessary, implement care interventions to improve family functioning, such as holding family care meetings.

Moreover, previous studies on family caregivers of patients with different illnesses (e.g., Parkinson's disease, brain injury, and cervical cancer) have shown a significant correlation between family functioning and QoL [12–14]. In our study, no significant differences were found between informal family caregivers reporting effective family functioning and those reporting ineffective family functioning across all QoL domains. This inconsistency may be related to differences in the illnesses of care recipients across studies, or even the timing of our survey, which was conducted during the COVID-19 pandemic; this specific period entails that informal family caregivers in our sample may have faced different, and potentially unique, burdens because of the situation evoked by this global health crisis. In addition, our results demonstrated that



70.4% of the families employed foreign or formal (paid) caregivers to aid in patient care. This likely reduced the burden on family caregivers and may have influenced the relationship between family functioning and QoL. This reality of employment of formal caregivers is also likely related to the recent changes in Taiwan's age and family demographics; specifically, Taiwanese families have generally changed their structures from large families to small families. Therefore, families must now rely on external resources to meet the care needs of sick family members.

### Limitations

This study had some limitations. First, this study's sample size was small, and the re-categorization based on family functioning produced a yet smaller sample size for subgroups, which may limit the conclusions that can be drawn from the data. Although we have made every effort to present effect sizes that are better tailored to the results of this investigation, we propose that sample sizes be expanded in the future to enable a more thorough examination of categorization discrepancies. Second, this was a cross-sectional study; therefore, whether the association of family functioning and QoL changes over time or not remains unclear. We suggest that future research should adopt a longitudinal study design that would allow for the discovery of correlations and trajectories of change in the QoL and family functioning of stroke patients and their caregivers. Finally, the study period coincided with the COVID-19 pandemic, thus, the findings for family functioning during the studied period may differ from those of previous studies.

### Conclusion

To the best of our knowledge, this is the first study to explore the association between family functioning and health-related QoL in stroke survivor–informal family caregiver dyads during the COVID-19 pandemic. Both stroke survivors and informal family caregivers had low family functioning scores, indicating effective family functioning. Stroke survivors' QoL scores were lower than those of their informal family caregivers. Moreover, stroke survivors reporting ineffective family functioning (vs. effective family functioning) had significantly lower MCS scores, albeit this was not the case for informal family caregivers. Our study clearly shows that family functioning is crucial in ensuring stroke survivors' QoL, especially in the mental component. Health professionals should prioritize mental health assessments and provide appropriate care interventions to address poor family functioning among stroke survivors during the first 1–6 months after stroke onset.

### Ethical considerations

The Institutional Review Board of Chung Shan Medical University Hospital approved this study's design and procedure (CSMUH No: CS1-21079). The data were collected between August 2021 and October 2022. Through the hospital's administrative procedures, stroke survivors and their informal caregivers were invited to participate in this study. They signed a consent form after the investigator had explained the study's purpose and procedures. Participant anonymity and confidentiality were guaranteed during the study, and all questionnaires were numerically coded to ensure privacy.

### Author contributions

Hsiang-Chu Pai, Chia-Chi Li, and Su-Ju Tsai were responsible for the study conception and design. Chia-Chi Li, Jo-Ching Tai, Shu-Mei

Tsai, Tzu Jun Wu, and Shu-Chuan Kao performed the data collection. Hsiang-Chu Pai involved in data analysis, drafting of the manuscript, and made critical revisions to the paper for important intellectual content.

### Conflict of interest

Authors declare that they are no conflict of interests.

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## Research Article

# Factors Contributing to Increased Workplace Violence Against Nurses During COVID-19 in the Healthcare Settings of a Lower Middle-income Country: A Qualitative Study



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## SUMMARY

**Purpose:** The aim of this study was to provide the perceptions of nurses, nursing supervisors, and nursing administrators about factors contributing to increased workplace violence (WPV) against nurses within the healthcare settings in Pakistan during the first wave of the COVID-19 pandemic.

**Methods:** This study used a Descriptive Qualitative design, with a purposive sampling technique. From September to December 2021, in-depth interviews of 45 to 60 minutes, using a semistructured interview guide, we collected data from a private and a public healthcare setting in Pakistan. Given the travel restrictions during the COVID-19 pandemic, these interviews were conducted online, using Zoom audio features. Bedside nurses, nursing supervisors, and nursing administrators with at least six months of work experience participated in this study.

**Results:** The qualitative data analysis steps suggested by Braun and Clarke (2013) were used for thematic analysis. The overarching theme emerging from the data was “Factors perceived by nurses that contributed to increased WPV in their work settings during the first wave of COVID-19, in a lower middle-income country” The subthemes from the participants’ narrations were (a) highly stressed patients, attendants, and healthcare workers; (b) the financial burden on patients and their families; (c) lack of resources and shortage of staff; (d) restricted visiting policy and a weak security system; (e) lack of awareness about the seriousness of COVID-19; (f) misconceptions about COVID-19 vaccines and nurses’ role in disseminating awareness.

**Conclusions:** The current pandemic increased the intensity of WPV against nurses in healthcare settings in Pakistan. Despite any supposed reasons for WPV, exposure to violence should never be an acceptable part of nursing. The healthcare system in Pakistan needs to pay equal attention to funding, resource provision, and ensuring a safe working environment for healthcare workers.

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## Introduction

The American Nurses Association suggests that “Workplace violence is any act or threat of physical violence, harassment, intimidation or other threatening, disruptive behavior from

patients, patient's family members, external individuals, and hospital personnel. It includes physical, sexual, and psychological assaults” [1, p. 1]. Evidence indicates that COVID-19 is the most devastating pandemic in a century. As of December 19, 2023, the World Health Organization (WHO) has confirmed 772,838,745 cases of COVID-19 and 6,988,679 deaths around the globe [2]. Across the world, healthcare systems have been terribly affected during consecutive waves of COVID-19 [3]. However, the impact was not uniformly distributed—low-middle-income countries with limited health resources, economic crises, and political instability experienced acute challenges [4]. For example, Pakistan, a low-middle-income, developing country, with a population of 240 million, faced numerous problems due to a lack of public awareness

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about the severity of this disease, scarcity of required health resources, and the inability of the healthcare system to manage the severity of the crisis [5,6]. However, before we dive into the specifics of the crisis in Pakistan, let us first consider a global trend facing healthcare workers. As a consequence of COVID-19, healthcare workers have endured an increase in health and safety concerns, including a spike in workplace violence (WPV) [7]. A global survey conducted by the International Council of Nurses, the International Committee of the Red Cross, the International Hospital Federation, and the World Medical Association stated that when the COVID-19 pandemic began, only 10% of the respondents stated that WPV had increased due to COVID-19. However, over time, attacks on healthcare workers continued. At the height of the pandemic, 60% of respondents believed that cases of WPV had increased during the pandemic [8]. Significantly, the prevalence reported in this global survey is merely a snapshot of the WPV that so many healthcare workers faced during the pandemic.

During the COVID-19 pandemic, many quantitative, qualitative, and mixed-methods studies conducted to assess the prevalence of WPV have estimated that the severity of this issue is extreme and that healthcare workers have been suffering many forms of violence. A systematic review of 14 studies, assessing 3452 doctors, 5738 nurses, and 2744 allied health workers, estimated the pooled prevalence of WPV to be 42.0% [9]. Similarly, another systematic review, comprised of 17 studies, assessing 17,207 healthcare workers, reported a 47.0% pooled prevalence of WPV during the COVID-19 pandemic [10]. A study conducted in Israel mentioned a 71.0% prevalence of WPV among healthcare workers [11]. Another cross-sectional study conducted in Egypt estimated a 63.2% prevalence of WPV among healthcare professionals [12]. A cross-sectional study conducted in Sudan reported that 78.3% of healthcare workers experienced WPV and that an estimated 66.0% of participants had encountered more than three incidents of WPV from August to December 2021 [13]. Another study, conducted through an online survey from February to May 2020, reported that 67.8% of nurses faced verbal abuse and that 44.4% of nurses experienced physical abuse [14]. Taken together, these studies show a disturbing increase in WPV, globally.

To manage WPV during the pandemic, the WHO and International Labour Organization (ILO) published new guidelines to address the COVID-19-related health and safety issues of healthcare workers, in which they recommend that healthcare systems initiate health and safety programs to provide a safe working environment [15]. However, while almost every country planned and implemented strategies to protect healthcare workers from violence, guidelines, policies, and standard workplace prevention strategies were ineffective in decreasing the magnitude of WPV during the COVID-19 pandemic. [16,17]. In Pakistan, a study conducted with 356 healthcare workers across 24 COVID-19 healthcare facilities reported that 42.0% of participants had experienced WPV in just a two-month period [18]. Other descriptive studies also reported that the frequency and number of WPV incidents increased in Pakistan during the pandemic. Further, these studies note that under-reporting of violence is a significant issue in Pakistan, leading to the inevitable conclusion that many incidents of WPV go uncounted [19,20].

Pakistan's healthcare sector is comprised of public and private healthcare settings. The public healthcare system faces numerous challenges due to financial constraints, lack of resources, and staffing shortages [21]. A survey conducted in 106 hospitals in Pakistan suggested that 71.7% of public hospitals struggle to build and maintain structured health systems, adequate staffing, and appropriate infrastructure. When the pandemic began, most public hospitals lacked the ability to care for COVID-19 patients. Only 19.8% of hospitals had negative pressure rooms; 55.6% of hospitals

did not have adequate quarantine facilities; 31.1% of hospitals did not follow any staffing model; and only 45.2% of hospitals had sufficient staff to provide adequate care to COVID-19 patients [22]. Naturally, given this dearth of resources, the public healthcare settings faced extreme difficulties as the pandemic intensified. Meanwhile, the private healthcare settings in Pakistan also faced numerous challenges due to limited resources and a high influx of patients. Some fared better than others—there are differences in the standard of care in different private healthcare settings in Pakistan. Many private healthcare settings are very costly, yet they remain unregistered with the health ministry [23]. To complicate matters, a private hospital was not necessarily the first choice of many individuals during the COVID-19 pandemic; however, due to the unavailability of beds elsewhere, people were forced to go private [6]. Hence, the incidents of workplace violence increased in both settings. A survey conducted by the International Committee of the Red Cross reported around 600 cases of WPV against healthcare workers in the initial six months of the COVID-19 pandemic in both public and private healthcare settings in Pakistan [24]. That said, another study indicates that healthcare workers in public healthcare settings experienced higher levels of WPV [19].

However, the question remains: what precisely led to this change? What lies behind the increased rates of WPV that occurred in the private and public healthcare settings in Pakistan? By collecting and evaluating data from both healthcare settings, this study aims to explore the perceptions of nurses, nursing supervisors, and nursing administrators regarding the factors contributing to a high number of incidents of WPV against nurses in Pakistani hospitals during the first wave of the COVID-19 pandemic.

## Methods

### Study design

This study is part of a larger project assessing the facilitators of and barriers to creating a workplace violence reporting system in Pakistan. A Qualitative Descriptive design has been used in this study. In the current era, qualitative design is recognized by researchers, policymakers, and funders as the most appropriate method for assessing the perceptions, concepts, and experiences of research participants in a compelling way [25].

### Setting and sample

Using a purposive sampling technique, nurses with at least six months of work experience were selected for in-depth interviews (IDIs). Given the travel restrictions during COVID-19, these interviews were conducted online, using Zoom audio features. The data were collected from nurses, nursing supervisors, and nursing administrators of two large tertiary private and public healthcare settings in Pakistan.

### Data collection/procedure

Altogether, 17 IDIs were conducted from two locations, one public and one private, with relatively equal numbers coming from both. The principal investigator (PI) received the list of participants from the human resource department of the private healthcare setting and the hospital administrator of the public healthcare setting. The placement for each interview was decided by considering the comfort of the study participants. Mostly, participants preferred to participate from their homes. Due to travel restrictions during COVID-19, the data were collected in a private meeting space, via Zoom. Zoom uses end-to-end encryption to protect users' privacy and security. The infrastructure for online data collection

has been developed to accommodate both healthcare settings. To achieve this, one research assistant (RA) was assigned to each study setting. They provided logistics support during the data collection process. The assigned RA met with the study participants to provide them with the consent form. Then, the RA provided a Zoom link so the participant could join the interview. All IDIs were conducted by the PI with only those participants who returned the signed informed consent to the assigned RA.

Table 1 provides the details of the study settings and participants, whereas Table 2 provides the demographic and professional profile of the research participants. All IDIs were conducted by the PI between September 2021 and December 2021. The duration of each interview was around 45 to 60 minutes.

The following inclusion and exclusion criteria were utilized:

*Inclusion criteria*

- 1- Bedside nurses with at least six months of work experience (these nurses are divided into two categories [a] junior nurses—6 months to 2 years of work experience and [b] senior nurses—more than two years of work experience).
- 2- Nurses working in any supervisory positions (head nurses, clinical nurse instructors, managers, nursing supervisor, and nursing superintendent)

*Exclusion criteria*

- 1- Nurses with less than six months of work experience
- 2- Nurses who failed to give written consent.

*Data analysis*

All IDIs were recorded, transcribed, and translated into English from Urdu. For the thematic analysis, the qualitative data analysis process suggested by Braun and Clarke [26] was utilized, including (a) reading and re-reading the IDIs, for familiarization with the depth and breadth of the data; (b) data coding—generating initial codes; (c) developing the theme and subthemes based on descriptions; (d) reviewing the theme and subthemes; (e) defining and naming the theme and subthemes; and (f) writing the report. The PI used Microsoft Word to create the codebook and NVivo 12 software to organize the data and to create the coding framework to ensure accuracy in the coding process. In addition, the PI and one more researcher (CM) independently coded two transcriptions to enhance coding consistency.

*Ethical consideration*

This study was approved by the institutional review board of the Research Ethics Board, University of Toronto (Approval no. 41544). Further, permission to conduct the study was obtained from the

**Table 1** Study Settings and Participants.

Study settings			
Private hospital in Pakistan		Public hospital in Pakistan	
IDIs participants			
Male nurses	03	Male nurses	02
Female nurses	02	Female nurses	03
Nursing supervisors	02	Nursing supervisors	03
Nursing administrator	01	Nursing administrator	01
<b>IDIs</b>	<b>08</b>	<b>IDIs</b>	<b>09</b>

IDIs = in-depth interviews.

**Table 2** Demographic and Professional Characteristics of Nurses.

Variables	Private healthcare setting N = 8 n (%)	Public healthcare setting N = 9 n (%)
<b>Gender</b>		
Man	05 (62.5%)	02 (22.2%)
Woman	03 (37.5%)	07 (77.8%)
<b>Age</b>		
25–29 years	02 (25.0%)	00 (0%)
30–34 years	00 (0%)	00 (0%)
35–39 years	02 (25.0%)	06 (66.7%)
40–44 years	02 (25.0%)	00 (0%)
45–49 years	02 (25.0%)	01 (11.1%)
50–54 years	00 (0%)	02 (22.2%)
<b>Education</b>		
BScN	00 (0%)	01 (10.0%)
Post RN BScN	05 (62.5%)	08 (90.0%)
Diploma in Nursing	03 (37.5%)	00 (0%)
<b>Work experience</b>	07 months–14 years	02 years–30 years
<b>Work setting</b>		
Inpatient unit	05 (62.5%)	05 (55.5%)
Outpatient unit	02 (25.0%)	02 (22.2%)
Both	01 (12.5%)	02 (22.2%)

BScN = Bachelor of Science in Nursing, RN = Registered Nurse.

administrators of both healthcare settings. Moreover, because this issue is sensitive, to help participants process any emotional stress that might have arisen, a referral system with a clinical psychologist from the Aga Khan University was implemented (although the referral system was not used by any participant). To compensate the participants for their time, an honorarium of Pakistani rupee 500 was provided after completion. As the interviews were conducted online, participants were also provided with internet cards to compensate them for their internet data expenses. The confidentiality and privacy of the study settings and study participants were maintained throughout the study period. Pseudonyms and unique identifiers were assigned to each transcript. Participants were not asked about their personal experiences of WPV during the COVID-19 pandemic but rather were asked about their perceptions of WPV within their healthcare setting.

**Trustworthiness**

The trustworthiness of this study was confirmed by considering the four factors (credibility, transferability, confirmability, and dependability) suggested by Lincoln and Guba [27]. To ensure **credibility**, the PI has been working on WPV in Pakistan since 2010 and is well-equipped with subject expertise and cultural context. The initial coding of all transcripts was done by the PI. Further, this study was supervised by CM, a well-known research scientist with expertise in gender equity and health. They ensured the verification of the initial coding scheme by independently coding one transcript from the private and one from the public healthcare settings. There were no significant differences found in the coding done separately by the authors. For minor differences, consensus was ensured by both researchers. The other coauthors (EH, AJV, PS) are also experienced researchers with expertise in violence, qualitative design, and the thematic analysis process. The PI sought ongoing consultation from the research team whenever needed. Approval from the research team was acquired before moving to the next step of the thematic analysis process. Member checking was not performed, because WPV is a sensitive issue for the individual participants and the organization as well. Approaching the study participants and presenting the data to them for feedback may cause stress to participants due to recalling the traumatic events again. Moreover, the high influx of COVID-19 patients during the study period led to high



workloads among nurses, which constrained the time permitted by the administrators in each healthcare setting for nurses to participate in the study during their work schedules. Sending transcripts to participants for reviewing may cause further time constraints for them. **Transferability** was ensured by collecting the data from a diverse group of people (nurses, nursing supervisors, and nursing administrators) who worked during the first and second waves of the COVID-19 pandemic. Moreover, collecting data from both a private and a public setting enhanced the transferability of study findings to other healthcare settings in Pakistan. To ensure **confirmability**, the PI practiced reflexivity and ensured that responses from the participants were not influenced by the researcher. Therefore, the data shows the real perspectives of the study participants. Furthermore, the PI also ensured that every interview was collected at a place chosen by the study participant. Only the audio features of the Zoom platform were used, so that the comfort level of the participants was maintained. Finally, for **dependability**, the research team ensured the rigor of this study by assessing the components and progress on an ongoing basis. This study can be replicated in other healthcare settings of Pakistan and developing countries with a similar context. The two-step coding process was utilized in this study, in which the initial coding was done manually by the PI (RS), using Microsoft Word, and then NVivo version 12 was utilized for data organization and the identification of themes and subthemes. All coauthors approved the thematic framework created by RS. Finally, the Consolidated Criteria for Reporting Qualitative Research has been utilized for reporting the study findings [28].

**Results**

The primary question that was asked during the IDIs to nurses, nursing supervisors, and nursing administrators in private and public healthcare settings was In your experience, are incidents of workplace violence increasing due to COVID-19 in your healthcare setting? [probes: workload, burnout, unavailability of equipment, lack of support, high stress level]. Most of the respondents had the perception that WPV had increased over the eight to ten months of the pandemic, and the study participants shared some of the underlying factors for increased WPV within their respective healthcare settings. Table 3 identifies the theme and subthemes that emerged from the narration of study participants in each setting.

**Theme:** Factors perceived by nurses that contributed to increased workplace violence in their work settings during the first wave of the COVID-19 pandemic in a lower middle-income country.

This section highlights participants' perceptions about the severity of and some significant factors contributing to the increased WPV against nurses during the COVID-19 pandemic. During the IDIs, respondents connected the high magnitude of workplace violence to COVID-19. Common issues identified by

participants in both public and private healthcare settings included the following: (a) highly stressed patients, family members, and healthcare workers during the first wave of the COVID-19 pandemic, (b) lack of resources, (c) staff shortages, and (d) lack of awareness about the seriousness of COVID-19. However, differences were also observed between public and private settings. Study participants employed in private healthcare settings identified the restricted visiting policy for attendants, and the inflated financial burden on patients and their family members as leading to increased violence against nurses. In contrast, study participants from the public healthcare setting identified the weak security system in their hospital as a central feature of increased incidents of violence. Furthermore, a lack of awareness about the COVID-19 vaccine among the general population and the role of nurses in disseminating awareness were identified by the participants from the public healthcare setting as crucial contributing factors for increased incidents of WPV.

**Subtheme 1: Highly stressed patients, family members, and healthcare workers during the first wave of COVID-19**

During the first wave of the COVID-19 pandemic, the environment within and outside healthcare settings was highly stressful due to a lack of information about the disease, the stigma associated with the disease, overcrowding, and the fear of being infected. During the IDIs, the study participants described how the high-stress level of patients, their family members, and healthcare workers was one of the major reasons for increased WPV within the healthcare setting. As one bedside nurse from the private healthcare setting commented:

*“Yes, due to COVID, stress level of nurses is increased. Moreover, patients and their relatives are also very stressful.” SMP-1*

Another respondent, a nursing administrator of the private healthcare setting, went into more detail:

*“There are some common issues during COVID, such as visiting hours are decreased, patients' stays at the hospital are increased in length, and patients' hospital bills have increased. These issues have created a high stress level for patients and their families, and for staff also.” NAFP-1*

Similarly, participants in the public healthcare setting also mentioned a panicky environment within the healthcare setting. They reported that everyone was trying to understand the circumstances and identify ways to cope with the situation, but the environment was very tense. As a senior nurse explained:

*“This is the most difficult task for us, sharing the news with patient's family when a COVID patient expires. They create violence*

**Table 3** Theme and Subthemes.

Theme: Factors perceived by nurses that contributed to increased workplace violence in their work settings during the first wave of COVID-19 in a lower-middle-income country	
Private healthcare setting in Pakistan	Public healthcare setting in Pakistan
<b>Subthemes</b>	<b>Subthemes</b>
<b>Subtheme 1:</b> Highly stressed patients, attendants, and healthcare workers	<b>Subtheme 1:</b> Highly stressed patients, attendants, and healthcare workers
<b>Subtheme 2:</b> Lack of resources and shortage of staff during COVID-19	<b>Subtheme 2:</b> Lack of resources and shortage of staff during COVID-19
<b>Subtheme 3:</b> Lack of awareness about the seriousness of COVID-19	<b>Subtheme 3:</b> Lack of awareness about the seriousness of COVID-19
<b>Subtheme 4:</b> Financial burden on patients and their family members	–
<b>Subtheme 5:</b> Restricted visiting policy	<b>Subtheme 5:</b> Weak security system
–	<b>Subtheme 6:</b> Misconceptions about the COVID-19 vaccine and nurses' role in disseminating awareness

even though they are already aware of their patient's critical health status, even our staff became the victim of physical violence by the attendant in a COVID ward when a patient expired." SMG-1

A nursing supervisor also reflected on anxiety engendered by social media and the spread of misinformation:

*"There is a lot of panic here because people see on social media that patients eventually die due to COVID-19. Patients' family members fight with nurses due to this panic and stress."* NSFG-3

A bedside nurse also shared that it was very difficult for nursing staff to perform duties during COVID-19—he said:

*"Staff working in hospitals during COVID-19 are mentally stressed due to many reasons. They have many issues at home as well. It is difficult for them to face issues in the hospital".* SMG-1

### **Subtheme 2: Lack of resources and shortage of staff during COVID-19**

The ongoing lack of resources and staff in healthcare settings set the stage for WPV, and these conditions were exacerbated during the pandemic. An overwhelming number of study participants in private and public healthcare settings mentioned that the lack of resources in their healthcare setting causes many issues for front-line nurses. It not only led to patient and attendant acts of aggression but also to violence from other hospital staff as well. It was extremely difficult for nurses to provide quality care to COVID-19 patients due to the scarcity of resources. As a senior nurse in the private healthcare setting said:

*"Patient numbers also increased during COVID. Sometimes patients come to the hospital with minor issues due to fear of COVID. We don't have enough resources to manage so many patients in the hospital. Patients and their family members become aggressive when they don't get timely care."* Asif- SMP-1

Study participants also shared their opinions about a lack of human resources and PPE kits. A junior nurse said:

*"Violence is increased because the staff is short. Some staff also hesitate to accept duties in the COVID-19 wards because they say that they don't have experience working with COVID-19 patients. When management pushes them to work with COVID-19 patients, then workplace violence increases."* JMP-1

The same study participants elaborated further, saying:

*"Actually, we are short of Personal Protective Equipment (PPE). If any doctor, I mean a senior doctor, comes to visit a patient or any infection-control nurse comes to visit the ward, then they become aggressive with us for not wearing masks and not using PPE kits."* JMP-1

Study participants also highlighted another concern. As a senior nurse stated:

*"I want to say that the hospital should have a proper communication room in which they communicate COVID-19 protocols to attendants before admitting their patient. Patient's family members should be guided properly, so they know that, if they meet their*

*patient, then they may also get the infection and they can spread the infection to others."* SMP-2

Without this venue to communicate with patients and attendants, it can be difficult for the public to understand and respect hospital protocols and Standards of Practice (SoPs).

This paucity of resources directly impacted nurses and rates of WPV, particularly in the public healthcare settings, where resources were already scarce prior to the pandemic. As one nursing supervisor said:

*"See, COVID-19 created many issues everywhere. We also faced many issues. Lack of medical surgical supplies, lack of medicines. Everyone was so stressed. In such situations, aggression and violence are very common."* NSFG-2

A senior nurse also expressed the situation similarly. He said:

*"During COVID, we had a huge shortage of PPE, which we needed for our safety. When I was on duty in the COVID ward, often there was a shortage of gloves and sanitizers in the ward. It is very difficult to provide care to patients in such situations. The frustrated patients and their relatives don't understand these issues, so they abuse us."* SMG-1

A nursing supervisor shared that:

*"Many workplace violence incidents happened in our hospital. During COVID-19, the patient ratio was very high, and we had a shortage of staff. We were unable to provide quality care to patients due to this problem. Staff should not be blamed if a patient in their ward expired."* NSFG-2

A junior nurse also described a similar situation:

*"Another big issue is a shortage of staff in our hospital. Due to COVID-19, the hiring in our hospital is closed. This is also the main reason for violence in our hospital."* JMG-1

### **Subtheme 3: Lack of awareness about the seriousness of COVID-19**

A lack of understanding of patients and their family members about the cause, spread, and impact of COVID-19 was a common issue in many countries, including Pakistan. A nursing supervisor in the private healthcare setting highlighted this, noting that a limited understanding of COVID-19 and vaccines became the major reason for increased violence within healthcare settings. Patients and their family members become agitated upon learning that a patient tested positive for COVID-19 or because mitigation efforts limited their access to their loved ones. He shared:

*"If I talk about my hospital, visitors coming to the hospital don't have a clear understanding of COVID. They think there is no disease like COVID. Even if we admit a suspected COVID patient, submit their COVID test for analysis, and keep the patient in the isolation ward, the patient's attendants start shouting at us."* NSMP-1

He further emphasized the importance of counseling and proper communication with COVID-19 patients and their family members who come to the hospital:

*“Doctors and paramedic staff counsel patients’ family members that they have to cooperate with staff as all patients in the COVID-19 ward are critical and visitors are not allowed into the COVID-19 ward. We need to clarify with them that only staff working inside the ward are allowed to enter, and only when wearing personal protective equipment (PPE). Even staff need to go directly home from the ward when they are off shift.” NSMP-1*

A junior nurse in the private healthcare setting also described such difficult situations and said:

*“Most people are not even vaccinated; therefore, they are counseled that, since they are not vaccinated, their risk of getting infected is high. The condition of their patient is explained carefully to them. Still, they don’t understand and start arguing with nurses.” JMP-1*

A junior nurse working in the public healthcare setting shared his frustration with similar challenges:

*“The most difficult part is to make people understand the severity of COVID-19. Here, people don’t follow SoPs—Standards of Practice—when a patient’s condition becomes severe, and they are on a ventilator or BIPAP, then relatives create violence in the hospital.” Hanif- SMG-1*

A junior nurse in the public healthcare setting explained:

*“Incidents are mainly due to COVID-19 protocols. When we follow COVID-19 protocols and ask attendants to wear masks and maintain social distancing, then they get aggressive with us.” JMG-1*

#### **Subtheme 4: Financial burden on patients and their family members**

Financial stress due to the toll of the disease and medical costs also significantly increased during the COVID-19 pandemic. A senior nurse in the private healthcare setting expressed her feelings in the following excerpt and identified the increased financial burden on patients and their families as one of the key contributing factors that caused their frustration and violence against nurses. She said:

*“Patients’ stay at the hospital is increased due to COVID. There is a huge financial burden on patients if we keep them in an isolation room or order a COVID kit [test] for them. This is obviously very expensive for them. When these expenses are added to their hospital bills, then attendants create a lot of violence in the ward. Nurses need to deal with situations where the financial burden on patients increased due to COVID-19.” SFP-1*

A nursing administrator of the private healthcare setting also shared that:

*“When patients and their family have financial issues, then also they create fuss in the hospital. They have this issue that their patient is not getting better, but the hospital is charging a high amount to them.” NAFF-1*

#### **Subtheme 5: Restricted visiting policy and a weak security system**

To protect patients and their caregivers from the spread of COVID-19, many healthcare settings restricted visiting times. Reflected in almost all study participants’ excerpts was the

observation that limited visiting hours during COVID-19 contributed significantly toward violence against nurses. A nursing supervisor in the private healthcare setting stated that:

*“Usually, we allow a patient’s family to meet their patients during visiting hours. Even if the patient is in the ICU, family members can see their patients. However, if a patient is in a COVID-19 ward, then family members are not allowed to meet their patient at all. Some family members force nurses to allow them to meet their relatives. If nurses do not allow them to, then they become aggressive and abuse nurses.” NSMP-2*

A senior nurse in the private healthcare setting asserted:

*“The visiting hours are reduced, and only one family member is allowed with a patient. Therefore, family members mostly create violence for not letting them visit their patients in the COVID-19 ward. This is the major cause of violence between family members, nurses, and security guards.” SFP-1*

A senior nurse also highlighted the same issue and reflected that:

*“This is the main reason for violence: when family members are not allowed to visit their patients in the COVID ward. Some hospitals have guidelines, and they have even placed banners saying that people cannot enter the COVID-19 zone. Mostly, family members become angry when they are not allowed to see their patients.” SMP-2*

A nursing supervisor in the public healthcare setting asserted that an inadequate number of security guards and locked doors to control entry of patients’ family members also impact safety:

*“During COVID-19, we had many incidents of workplace violence. The main reasons are the same which I have just shared with you. We don’t have proper security systems in the hospital to control visitors.” NSFG-2*

Similarly, a nursing administrator in the public health care setting stated:

*“Security guards never reach to the ward when any incident happened. During COVID-19 when the incident was happened, this was security guards’ responsibility to take the attendants out from the ward.” NAFG-1*

#### **Subtheme 6: Misconceptions about the COVID-19 vaccine and nurses’ role in disseminating awareness**

Participants also shared that patients and their family members have incorrect notions about COVID-19 vaccines. Due to widespread misinformation, people coming to the hospital argued with physicians and nurses. A senior nurse in the public healthcare setting, who experienced such situations, stated that:

*“Violence is increased due to COVID. Many people were doubtful about the efficacy of vaccines because rumors were spread that if women have this vaccine, they will not get pregnant, and men will become impotent. Rumors were also spread that people are being forcefully taken to hospitals to get this vaccine, in order to kill them, and hospital staff is getting money for injecting and killing people with the vaccine.” SMG-1*

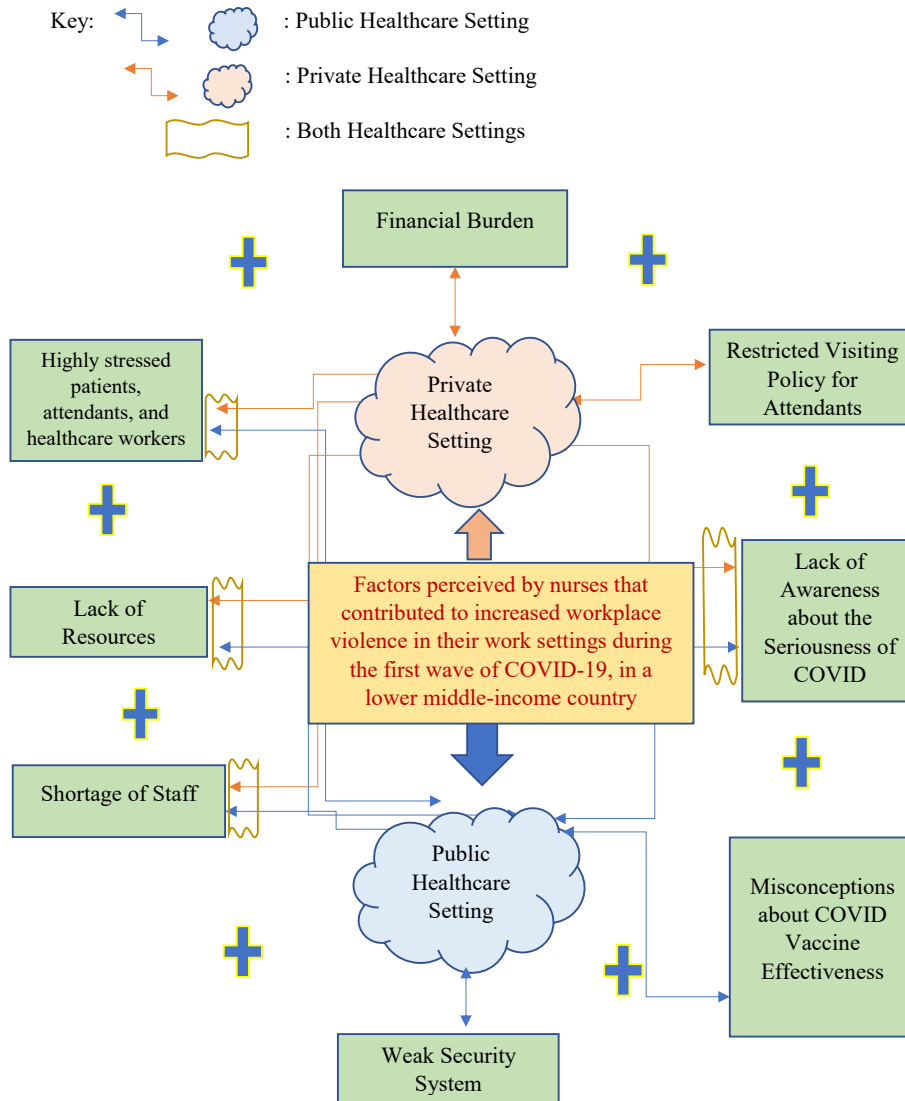


Figure 1. Factors Perceived by Nurses that Contributed to Increased Workplace Violence in Their Work Settings during the First Wave of COVID-19, in a Lower-Middle-Income Country.

This quote speaks to the difficulty faced by nurses in changing people's mindsets about the misinformation they accept as truth regarding the COVID-19 vaccine. Because nurses are extremely busy providing care to COVID-19 patients, they don't have time to engage themselves in argumentative situations.

These subthemes, as highlighted by the study participants, which have caused a surge in WPV, will be discussed in the context of some evidence-based literature to suggest some ways forward for the healthcare system.

**Discussion**

In this study, frontline nurses, nursing supervisors, and nursing administrators shared their perceptions of the challenges in their respective healthcare settings in Pakistan that resulted from the COVID-19 pandemic and led to increased rates of WPV. Figure 1 depicts the factors contributing to the high prevalence of WPV in both private and public healthcare settings in Pakistan. The

following section will discuss the factors which led study participants to recognize an increase in WPV across healthcare settings in Pakistan during the COVID-19 pandemic.

*Highly stressed patients, family members, and healthcare workers*

Understanding the causal relationship between stress in the hospital and violence is essential as the literature suggests that anxiety, risk, stress, and uncertainty lead to unhealthy behaviors and inevitable reactions [29,30]. During the COVID-19 pandemic, an increased level of uncertainty was pervasive, and its impact was observable in hospitals [31]. More significantly, a lack of control over constantly changing information on the causes and main routes of transmission, and the unknown course of illness following transmission, undoubtedly increased the vulnerability of patients and their family members [32].

Studies conducted in other countries have also reported that the onset of COVID-19 created a high degree of stress and anxiety among patients, their family members, and healthcare workers. A

study conducted in a healthcare setting in Egypt mentioned that in a six-month period during COVID-19, the prevalence of psychological violence was 42.6% and that of physical violence was 9.6%. Mostly, nurses experienced violence from patients' relatives. Despite contextual differences, the potential triggers of increased WPV described are similar to the factors identified in the current study, such as a lack of knowledge about COVID-19, inadequate resources, and a panicky environment in the hospital [33]. Another cross-sectional study conducted in Jordan reported that 65.5% of healthcare workers experienced exposure to WPV over a two-month period during the COVID-19 pandemic and that patients' relatives were found to be the perpetrators in most incidents. This study observed that the most common triggers of WPV against healthcare workers were the high stress levels of patients and their relatives, long waits for care, and high expectations of healthcare workers. This study also mentioned that due to the intense workload and stress level of healthcare providers, the quality of care was compromised [34].

Furthermore, the findings from the current study suggest that the disproportionate focus by the media on the most serious effects of COVID-19 created highly charged, emotional situations. Pakistan was not the only country where people were skeptical and experienced anxiety due to exaggerated information provided by the media about the severity of COVID-19. Other studies have reported similar findings. For example, a study conducted in India reported that the mass media focused more on deaths and the negative consequences of disease, rather than how to control the spread of the virus [35]. Similarly, a study conducted in the USA identified news reports about the high rates of COVID-19 infections, social isolation, ambiguities around vaccines, and fear of infection as causing further stress among people [36].

#### *Lack of resources*

Participants in the current study stated that family members displace aggression onto frontline nurses when the quality of care was compromised, as was often the case due to a lack of resources. Another study conducted in Pakistan identified two kinds of factors impeding nurses and doctors from providing effective care to COVID-19 patients. These included institutional factors such as limited resources and inadequate staffing and personal factors such as healthcare workers being afraid of catching the infection and feeling powerless in the situation [37], yet even when faced with these obstacles, Pakistan tried to take some short-term measures to limit the transmission of COVID-19, such as a smart lockdown. Nonetheless, the care requirements of COVID-19 patients admitted to the hospitals devastated the healthcare system of Pakistan [38]. The increased incidents of WPV against nurses due to a lack of resources are not limited to low-income countries. The pandemic also overwhelmed the healthcare systems of wealthy countries [39]. For instance, a study conducted in a public hospital in Israel found that 45.0% of participants reported a lack of resources to provide care to patients as one of the major reasons for violence against healthcare workers [11].

#### *Shortage of staff*

Along with a paucity of resources, staff shortages were also reported as one of the major factors for increased WPV against nurses in the current study. Another study found that many frontline nurses contracted COVID-19; therefore, absenteeism in nursing staff increased, and there was no mechanism in the hospital to replace nurses who were on sick leave [40]. Another cross-sectional study conducted with 288 nurses in a healthcare setting in Pakistan

reported that 48.6% of nurses experienced severe emotional fatigue and psychological distress during the COVID-19 pandemic. Many nurses made the decision to quit the profession for this reason [41]. As a result, the nurses who stayed in the healthcare system were subjected to further exhaustion and burnout [42]. Worse still, because there were fewer nurses and more patients, when patients' needs are not met, or they do not receive timely care, patients and their family members can become aggressive and violent [19]. This is a vicious cycle: when nurses experience violence in the healthcare sector, it further impacts their psychological health and workability, which makes them more vulnerable to WPV [43].

#### *Lack of awareness about the seriousness of COVID-19*

A lack of awareness about COVID-19 in Pakistan contributed to WPV against nurses, according to the participants of this study. Similarly, another study conducted in Pakistan reported a lack of awareness about COVID-19 precautionary measures and a sometimes casual attitude toward the severity of the pandemic among the general public [44]. A further study identified that many people in Pakistan were not aware about COVID-19 [45]. These findings are not limited to low-middle-income countries such as Pakistan, where many people do not have access to authentic information about COVID-19 from public health or other global organizations. A study conducted in Saudi Arabia, with 591 individuals of the general public, identified that more than 60.0% of study participants were violating the preventive measures for COVID-19 [46]. Similarly, a study conducted in Israel pointed out that a limited understanding of the pandemic affects people's behaviors and leads to violence in healthcare settings [11]. One more study, conducted in Jordan, mentioned that a lack of public awareness during the pandemic was one of the main reasons for the high prevalence of WPV among healthcare workers [47]. On the other hand, a few studies also mentioned that nurses were not prepared to provide satisfactory information about COVID-19 to patients and that many nurses became the victims of WPV due to a lack of training, communication skills, and inadequate information about COVID-19 [10,48,49].

#### *Restricted visiting policy and a weak security system*

The current study found that the restricted visiting policy for patients' family members in the private healthcare setting was one of the major factors for violence against frontline nurses. Similar findings, reported in a review conducted with local newspapers in Pakistan, found that patients and their relatives perpetrated violence against nurses when they were forced to adhere to COVID-19 visiting policies [19]. Globally, to avoid the spread of the virus, a restricted visitor policy in the healthcare sector was recommended by the WHO [50]. However, different consequences of enforcing this policy have been reported in a number of studies. A study conducted in a healthcare setting in China reported that a restricted-access policy for visitors, such as on-door security guards and electric doors, reduced incidents of WPV in the wards [51]. However, another study identified that restricted-visiting and physical-distancing protocols in the hospital caused severe anxiety and uncertainty in patients and their family members [52]. An integrative review of 17 studies concluded that visiting restrictions impacted care provision and negatively affected the mental health of patients [53]. Therefore, the WHO also recommended limiting visiting hours during the COVID-19 pandemic, instead of implementing a no-visitation policy [50]. However, assuring compliance with a restricted visiting policy is a challenge for healthcare settings in Pakistan. When patients' family members are not allowed to



meet with them, they can become violent. No doubt, this was partly caused by a lack of trust in healthcare professionals and health services, which was identified as a major reason why family members tried to stay with patients [18,19,54].

#### *Financial burden on patients and their family members*

When families in financial crisis received hospital bills with added expenditures for COVID-19 testing, isolation rooms, medications, ventilators, and other medical-surgical supplies, they were more likely to exhibit violence in the hospital. The selected private healthcare setting in this study is located in a low socioeconomic region of the city, where many people struggle financially. To make matters worse, during COVID, there was income loss due to the forced lockdowns, job loss, and expenditures on COVID-19 treatment [55].

Unlike developed countries, in Pakistan, the health insurance system and publicly funded programs are not well established. Consequently, the general population often has to pay their hospital bills out-of-pocket [56]. A recent World Bank report revealed that in Pakistan, out-of-pocket costs account for 55.44% of health spending [57]. Thus, since spending on treatment and paying hospital bills is extremely difficult for poor families, they end up in a financial crisis, which can lead to anger [58].

#### *Misconceptions about COVID-19 vaccines and nurses' role in disseminating awareness*

This study also explored the possibility that violence in healthcare settings increased due to misconceptions about COVID-19 vaccines in the general population. A population-based study conducted in Pakistan, utilizing the 3Cs model (complacency, confidence, and convenience), identified that 42.0% of the population was not vaccinated for COVID-19 because they mistrusted vaccines [59]. Misconceptions about vaccines are a chronic issue in Pakistan. For instance, many people are still skeptical about the polio vaccine, even as the country is working to eradicate polio [60]. Though vaccine hesitancy is a global issue, the threshold of vaccine hesitancy is lower in developed countries than in Pakistan. A population-based study conducted in a Canadian province found that only 11.0% of the population were refusing the vaccine [61]. Similarly, a global study on vaccine hesitancy, with participants from 23 countries, mentioned that 24.8% of the population reported nonacceptance of the COVID-19 vaccine. This was due to misconceptions about vaccine development, vaccine efficacy, and sickness caused by the vaccine [62]. In Pakistan, meanwhile, many cultural, social, and spiritual factors cause vaccine hesitancy.

#### **Recommendations**

The pandemic amplified numerous challenges to healthcare settings in Pakistan and caused healthcare workers to experience increased levels of WPV. Some of the broader issues mentioned by the study participants, such as a lack of resources, a two-tier healthcare system, and skepticism around COVID-19 vaccines, should be addressed at the health system level. The general population must be mindful that, regardless of circumstance, they cannot exhibit violence against nurses. In addition, the healthcare system should budget funds for such nurse-retention strategies as advanced training, monetary compensation, paid sick leave, and mental health counseling. These types of incentives will motivate nurses to remain in the profession. Moreover, the healthcare system should create a structured mechanism through which funds,

medical surgical supplies, and other resources reach public hospitals. A comprehensive program, with wealthy countries and global organizations contributing, can be further reinforced to build financial support for COVID-19-related resource management. The government must ensure that the funds are utilized to increase the service quality of public hospitals, so people don't need to go to expensive private hospitals that they cannot afford.

Furthermore, on-the-job training mechanisms, regarding the precautionary measures that healthcare professionals need to take, must be organized so that nurses can provide authentic information to patients and family members. There should be a counseling room in each healthcare facility; and, on patients' admission, a trained nurse or a doctor should counsel patients and their family members about the COVID-19 prevention policy and the importance of adherence to precautionary measures. Furthermore, awareness campaigns by healthcare workers and medical/nursing students need to be initiated in the remote areas of Pakistan, where people do not have access to reliable information from global organizations. To manage COVID-19 vaccine hesitancy, social media is a good platform for providing accurate information about vaccine development, efficacy, and adverse effects. In addition, community-level strategies, such as the engagement of religious and social leaders, as well as schemes to build partnerships between people who trust vaccines and individuals with vaccine hesitancy, can be further strengthened to build confidence and trust in vaccine safety and efficacy; thereby building acceptance. Pakistan's Electronic Media Regulatory Authority must take strict actions against people who disseminate fake news about COVID-19 and COVID-19 vaccination. In the context of Pakistan, further studies need to be conducted to assess the perceptions and experiences of patients and family members regarding their negative attitudes toward healthcare workers that arose during the COVID-19 pandemic.

#### **Strengths and limitations**

This is one of the first qualitative studies to explore the perceptions of nurses, nursing supervisors, and nursing administrators from public and private healthcare settings in Pakistan. The findings detail the major factors contributing to WPV against nurses during the COVID-19 pandemic and can inform the healthcare system, government agencies, and nongovernmental organizations, so that they develop effective strategies for overcoming violence against healthcare workers. The findings of this study can be transferable to other healthcare settings in Pakistan as the study provides perspectives from both public and private setups.

This study has certain limitations. The findings are limited to exploring the reasons for increased WPV against nurses during the COVID-19 pandemic in the context of Pakistan. Furthermore, to limit the scope of the study, only nurses' perceptions are contained in the study. However, the literature suggests a high magnitude of WPV against all healthcare workers, including nursing assistants, nursing technicians, student nurses, physicians, lab assistants, pharmacists, and community health workers. Moreover, in compliance with COVID-19 travel restrictions, the online IDIs were conducted using Zoom. Throughout this study, close attention to ethical, technical, and social components has been paid, so that the study's rigor can be maintained. However, with online IDIs that lacked visual information, it was difficult to interpret the emotions and sentiments within the participants' responses. Lastly, this study was conducted at the start of the second wave of COVID-19 in Pakistan. Therefore, the responses from participants are limited to the first wave of the COVID-19 pandemic.

## Conclusion

The pandemic increased the intensity of WPV against nurses in private and public healthcare settings in Pakistan. Regardless of the circumstances for patients and their family members, exhibiting violence against nurses is unacceptable. Government-led awareness programs that decrease apprehension among the general population about the pandemic are important. Overall, this pandemic leverages a lesson for healthcare systems in all countries, if they are going to deal effectively with crises, manage resources efficiently, retain a trained workforce, and save lives. From now on, global health organizations and national health sectors should be more vigilant in dealing with global health emergencies. Pakistan needs to pay equal attention to funding, resource provision, and strategies to deal with pandemics and related consequences.

## Institution and ethics approval and informed consent

The Research Ethics Board, University of Toronto (REB- Uoft) approved this study (protocol # 41544). Furthermore, permission to conduct the study was obtained from the hospital administrators of both (one private and one public) healthcare settings in Pakistan. The IDI was conducted with only those participants who returned a signed informed consent form.

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## Authors' contributions

RS and CM conceptualized the manuscript; RS did the initial data analysis and interpretation of findings. CM, AJV, PS, and EMH contributed to the revisions of the thematic framework and findings. RS created the first draft, and all authors contributed to critical revisions of the manuscript. All authors approved the final submission of the manuscript to the journal.

## Data statement

The research data are confidential.

## Disclaimer

None.

## Conflict of interest

The authors declare no conflicts of interest.

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## Research Article

## Factors Related to Post-traumatic Stress Disorder Symptoms Among Intensive Care Unit Nurses

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## SUMMARY

**Purpose:** The aim of this study was to identify the factors affecting the post-traumatic stress disorder (PTSD) symptoms of intensive care unit (ICU) nurses. The variables include event experiences, cognitive flexibility, and co-worker support.

**Methods:** A survey was conducted among 153 ICU nurses working in a general hospital or an advanced general hospital. The questionnaire was completed between October and December 2018, and 153 copies were used for the final analysis. Data were analyzed using multiple linear regression to determine the factors associated with PTSD symptoms among ICU nurses.

**Results:** The level of PTSD symptoms of ICU nurses was  $1.20 \pm 0.82$  out of 4. Full PTSD, signified by a total score of 25 or more, was reported by 45.1% of the study's 153 participants. The significant influencing factors of PTSD symptoms among ICU nurses were the "experience of traumatic events," "trusted alliance," which is a subarea of "coworker support," and both "control" and "alternative," which are subareas of "cognitive flexibility." The explanatory power (49.8%) was statistically significant.

**Conclusions:** These results suggest that a program to enhance the cognitive flexibility and coworker support of ICU nurses needs to be developed to reduce the PTSD symptoms of ICU nurses.

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## Introduction

Intensive care unit (ICU) nurses need greater professional knowledge and proficiency as well as quick and precise clinical judgment in an emergency to care for critically ill patients whose lives are threatened by real or potential health problems [1]. Notably, ICU nurses are repeatedly exposed to traumatic events—they perform cardiopulmonary resuscitation frequently, witness the death of patients under their care, and experience legal and ethical dilemmas, such as end-of-life care in an aging society, violence from patients with low levels of consciousness, and verbal abuse from guardians and fellow healthcare workers [2]. These negative incidents cause job stress among ICU nurses, leading to an increase in mental issues, such as anxiety, depression, and burnout syndrome [3]. Accordingly, work-related stress has recently been

recognized as a traumatic event, and interest has been growing in its influence on physical and mental health.

Post-traumatic stress disorder (PTSD) symptoms refer to the three specific symptoms of intrusion, avoidance, and hyperarousal experienced by a person who has experienced a traumatic event, and they can also be caused by less severe but repeated traumatic events [4]. PTSD symptoms are not limited to those who are directly affected by a traumatic event; medical practitioners, such as healthcare providers who work with trauma patients, are also at risk for PTSD. In addition, repeated traumatic-event experiences have been reported to be a strong trigger for PTSD symptoms [5]. According to domestic and overseas studies on the PTSD symptoms experienced by ICU nurses, over 20.0% of U.S. ICU nurses [2] and 39.9% of domestic ICU nurses have experienced PTSD symptoms [6].

PTSD symptoms are triggered by a number of personal and environmental factors in addition to the traumatic event [7]. In situations where stress is chronic, personal predisposition or vulnerability, rather than the intensity of the trauma, has a greater impact on the development of PTSD symptoms [8]. Therefore, not everyone who experiences a traumatic event will develop PTSD symptoms, and the severity of PTSD symptoms may vary depending on the individual's subjective response [9].

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Among the many factors that influence PTSD symptoms in nurses, national and international researchers have identified environmental factors such as traumatic-event experience [6,10], social support [6], and supervisory support [11], and personal factors such as a distressed personality (Type D) characterized by negative emotions and social inhibition [6,12] and resilience [13].

Cognitive flexibility, which is a personal predisposition that may protect from PTSD symptoms, is the ability to perceive complex problematic situations as controllable and produce multiple alternative explanations for them [14]. Nurses with high cognitive flexibility are able to cope with cumulative and indirect exposure to traumatic events by utilizing emotional intelligence to make decisions, reframing situations, and considering alternatives through critical thinking and an optimistic approach [13]. In contrast, ICU nurses lacking cognitive flexibility suffer from PTSD symptoms and are reminded of their personal traumatic experiences during work, which could result in the inability to care for certain patients and a lack of flexibility in thinking [15,16].

Another environmental factor that influences PTSD symptoms is social support: nurses with positive social networking are more likely to have strong collaborations with physicians and fellow nurses when they require help, whereas nurses diagnosed with PTSD have difficulties communicating with their colleagues and tend to perceive their work environment negatively, such as by viewing a lack of support [13]. The lack of social support has been reported as the strongest risk factor for PTSD symptoms [17].

The literature suggests that cognitive flexibility is a trainable personal coping ability [18] that can help ICU nurses with high job stress to control their thinking and find multiple alternatives in difficult situations. Social support, especially support from co-workers or supervisors, plays a mediating role in reducing stress and depression in nurses [11]. In these regards, an examination of the factors influencing PTSD symptoms in ICU nurses, focusing on the experience of traumatic events, cognitive flexibility, and coworker support, is required. Therefore, this study aims to identify the factors affecting the PTSD symptoms of ICU nurses, with variables including traumatic-event experience, cognitive flexibility, and coworker support.

## Methods

### Research design

This descriptive survey study aims to investigate the relationship between traumatic-event experience, cognitive flexibility, and coworker support and PTSD symptoms among ICU nurses and identify influential factors related to the development of PTSD symptoms.

### Samples

The study included 166 ICU nurses working at advanced general hospitals and general hospitals in the Seoul metropolitan area, who agreed to participate in the study. The following specific inclusion criteria were used: 1) not having a mental illness or are not undergoing related treatment; 2) having worked in an ICU for at least 3 months and having participated in direct care; and 3) understanding of the purpose and methods of the study and consent to participate in it.

The number of participants was calculated using the G-power 3.1 program. Seventeen predictor variables (PTSD symptoms, traumatic-event experience, two subdomains of cognitive flexibility, five subdomains of coworker support, and eight personal environmental characteristics) were selected. The sample size was calculated by applying the program to show the explanatory power

of the study through multiple regression analysis. A significance level of 0.05, a statistical power of 0.90, and an effect size of 0.2 were set based on a previous study by Cho [6], which had a similar design to this study and the required minimum number of participants was 138.

The questionnaires were distributed to 166 participants, considering a 20.0% dropout rate. Neonatal and pediatric ICU nurses were excluded owing to differences in their traumatic-event experience from that of adult ICU nurses. The questionnaire return rate was 100.0%, with all 166 copies returned. After excluding 13 questionnaires with incomplete responses, a total of 153 questionnaires were used in the final analysis.

### Measurements

#### PTSD symptoms of ICU nurses

The Impact of Event Scale-Revised Korean Version (IES-R-K) was used to measure PTSD symptoms of ICU nurses. The IES-R-K was developed by Weiss and Marmar [19], and it was adapted into Korean by Eun et al. [20] to evaluate its psychometric properties. This questionnaire is a highly sensitive self-report measure for diagnosing PTSD symptoms [21]. It consists of 22 questions, specifically, 6 questions on hyperarousal, 8 questions on avoidance, and 8 questions on intrusion, extracted from 3 subfactors of the IES-R-K. Each item is evaluated through self-reporting on the frequency of symptoms over the past month, with a total score ranging from 0 to 88 points. This measure is composed of a 5-point Likert scale from 'never happened (0)' to 'very often (4).'

A higher total score indicates more severe PTSD symptoms. To estimate the risk of PTSD symptoms, the IES-R-K categorized a score of 17 or less as normal, 18–24 as partial PTSD, and 25 or more as full PTSD [20]. The Cronbach's  $\alpha$  (reliability) was .98 in a study by Weiss and Marmar [19], .83 in a study by Eun et al. [20], and .96 in this study.

#### ICU nurses' traumatic-event experience

This study used the instrument developed by Cho [6] to assess ICU nurses' traumatic-event experience. It is a 5-point Likert-scale tool in which ICU nurses respond regarding the frequency of their experience, from never (1) to very often (5), with 11 types of traumatic events they may have experienced on duty in the past month, including end-of-life and post-end-of-life care, unexpected death of a patient, and verbal or physical violence by a caregiver. A higher score indicates that ICU nurses report experiencing traumatic event more frequently. Additionally, respondents were asked to select the most distressing of the 11 traumatic events. In Cho's [6] study, the scale had a Cronbach's  $\alpha$  of .80, and in this study, it was .79.

#### The cognitive flexibility inventory

We used the cognitive flexibility inventory created by Dennis and Vander Wal [14] and adapted and validated by Heo [22] to measure the cognitive flexibility of ICU nurses. The cognitive flexibility inventory is a 20-item, self-report test with two subareas: 7 "control" questions and 13 "alternative" questions. The "control" subfactor of cognitive flexibility comprises questions that measure "the tendency to perceive difficult situations as controllable." "Alternative" comprises questions that measure the ability to offer multiple alternative explanations for an event and devise multiple solutions. It is scored on a 7-point Likert scale, from strongly disagree (1) to strongly agree (7), and the total score is summed, with higher scores indicating higher levels of cognitive flexibility. Some items on the control subscale are reverse-scored.

In Dennis and Vander Wal's [14] study, the Cronbach's  $\alpha$  at the time of development was .90 for the overall test, .86 for the control

subscale, and .91 for the alternative subscale. In Heo's [22] study, it was .86 for the overall test, .84 for the control subscale, and .91 for the alternative subscale. In this study, the Cronbach's  $\alpha$  was .94 for the overall test, .88 for the control subscale, and .67 for the alternative subscale.

#### *The Social Provisions Scale*

We used the Social Provisions Scale developed by Cutrona and Russell [23] and modified by Yang [24] to measure coworker support among ICU nurses. While Cutrona and Russell's [23] instrument includes friends, family, coworkers, and the community, Yang's [24] instrument is limited to coworkers, i.e., supervisors, coworkers, and juniors at work.

The original instrument by Cutrona and Russell [23] comprises six subscales: attachment, social integration, opportunity for nurturance, reassurance of worth, reliable alliance, and guidance, whereas Yang's [24] instrument comprises five subscales, as it excludes the reassurance of worth subscale, and totals 20 items. It is a 5-point Likert scale, from strongly disagree (1) to strongly agree (5), with higher scores indicating stronger peer support. At the time of development, Cronbach's  $\alpha$  = .93 in Cutrona and Russell's [23] study and .95 in Yang's [24] study. Cronbach's  $\alpha$  measured .94 in this study. Cronbach's  $\alpha$  for the subscales was .79 for trusted alliance, .77 for attachment, .77 for guidance, .80 for opportunity for nurturance, and .78 for social integration.

#### *Personal and environmental characteristics of ICU nurses*

Based on a review of the literature [10,11,16], we included sex, age, marital status, religion, and highest level of education as personal characteristics as they have been reported to be associated with PTSD symptoms. We included hospital size, ICU type, position, clinical practice experience, ICU experience, work type, and average weekly work hours as environmental characteristics.

#### *Data collection*

The data were collected from 166 ICU nurses from five hospitals, comprising three advanced general hospitals over 1000 beds, as well as two general hospitals with less than 500 beds, located in Seoul, Gyeonggi, and Busan. The data collection period spanned from October 29 to December 2, 2018. The questionnaire for data collection included information on the study's purpose, participant anonymity, data confidentiality, and withdrawal from the study, and written consent was obtained to ensure voluntary participation.

For data collection, the nursing department was contacted, and the purpose and method of this study were described through the head of the nursing department and the head nurse of the ICU, and their cooperation was requested for data collection. The ICU nurses were then visited, and the purpose and method of this study were explained. The questionnaire was distributed to the ICU nurses who understood the study's purpose and voluntarily gave written informed consent, and the completed consent form and questionnaire were separated and enclosed in an opaque envelope to protect the anonymity of the study subjects.

The completed questionnaires were retrieved by the researcher in person, by mail, or through the nursing department one week later. The results were coded to ensure that no personal identifiable information was included in the publication and presentation of the results, and they were stored in a locked cabinet only accessible to the researcher to prevent leakage of precoded personal information. The collected questionnaires and consent forms were transferred to the archivist of the institutional review board of the affiliated institution after study completion to be kept for 3 years. Out of the total of 166 questionnaires distributed to the ICU nurses,

153 were used in the final analysis, and 13 questionnaires, which lacked at least one answer, were excluded.

#### *Data analysis*

The collected data were analyzed using SPSS/WIN 25.0. The personal and environmental characteristics of ICU nurses were analyzed using descriptive statistics, specifically, frequencies, percentages, means, and standard deviations. To determine the extent of PTSD symptoms according to the individual and environmental characteristics of ICU nurses, independent two-sample *t*-tests and one-way analysis of variance were conducted. Pearson's correlation coefficient was used to examine the correlation of PTSD symptoms with the main variables of this study: traumatic-event experience, cognitive flexibility, and coworker support. Multiple linear regression was used to identify the influencing variables of PTSD symptoms among ICU nurses.

#### *Ethical considerations*

Approval for conducting this study was obtained from the Institutional Review Board of Kyung Hee University Hospital (KHUH 2018-07-014-008).

## **Results**

#### *Personal and environmental characteristics of ICU nurses*

The demographic and work characteristics of the ICU nurses, the target of this study, are summarized in Table 1. The majority of nurses were female  $n = 144$  (94.1%), the mean age was 29.92 years, were single (79.1%), and followed no religion (55.6%). In terms of education level, 75.8% of respondents had a bachelor's degree.

The most common hospital bed size reported by the ICU nurses was 500–1000 beds (78.4%). By ICU type, internal medicine ICUs were the most prevalent (46.4%), followed by surgical ICUs (32.0%), and general ICUs (21.6%). In terms of position title, the majority were staff nurses (93.5%), followed by nurses with other position (6.6%).

Clinical working experience averaged  $6.73 \pm 7.16$ , with the most common being 1–3 years (25.5%) and more than 10 years (23.5%). ICU experience averaged  $4.36 \pm 4.20$ , with the most common experience being 1–3 years (28.8%) and less than 1 year (24.2%). The average number of hours worked per week was 40 hours or less (51.0%) for most of the respondents, followed by 41–50 hours (39.2%) and 51 hours or more (9.8%).

#### *PTSD symptoms, traumatic-event experience, cognitive flexibility, and coworker Support among ICU nurses*

Table 2 presents statistics regarding the PTSD symptoms, traumatic-event experience, cognitive flexibility, and coworker support of ICU nurses in this study. The mean of ICU nurses' PTSD symptoms is 1.20 ( $\pm 0.82$ ) out of 4, and the mean of their total score is 26.49 ( $\pm 18.04$ ) out of 88. Full PTSD, signified by a total score of 25 or more, was reported by 45.1% of the study's 153 participants. ICU nurses' degree of traumatic-event experience in the past month was 2.83 ( $\pm 0.60$ ) out of 5, and the mean total score was 31.09 ( $\pm 6.57$ ) out of 55.

The study participants had a mean cognitive flexibility score of 4.62 ( $\pm 0.65$ ) out of 7. When broken down by subarea, it was 4.31 ( $\pm 0.99$ ) for control and 4.82 ( $\pm 0.69$ ) for alternative. The mean of coworker support for ICU nurses in this study was 3.95 ( $\pm 0.57$ ) out of 5. By subdomain, trusted alliance was the highest at 4.13 ( $\pm 0.63$ ), followed by guidance at 4.03 ( $\pm 0.72$ ), attachment at 3.97 ( $\pm 0.70$ ), opportunities for nurturance at 3.82 ( $\pm 0.57$ ), and social integration at 3.75 ( $\pm 0.67$ ).

**Table 1** Demographic Variables and Job Characteristics of ICU Nurses (N = 153).

Variables	Categories	N (%)	M ± SD	Range
Gender	Male	9 (5.9)		
	Female	144 (94.1)		
Age (yr)	≤25	52 (34.0)	29.92 ± 7.21	23–55
	26–30	50 (32.7)		
	≥31	51 (33.3)		
Spouse	No	121 (79.1)		
	Yes	32 (20.9)		
Religion	Christian	30 (19.6)		
	Catholic	23 (15.0)		
	Buddhism	11 (7.2)		
	No religion etc.	85 (55.6) 4 (2.6)		
Education level	Associate degree	19 (12.4)		
	Bachelor degree	116 (75.8)		
	≥Master degree	18 (11.8)		
Hospital bed size	<500	14 (9.2)		
	500–1000	120 (78.4)		
	>1000	19 (12.4)		
Type of ICU	General	33 (21.6)		
	Surgical	49 (32.0)		
	Medicine	71 (46.4)		
Position title	Staff nurse	143 (93.5)		
	≥Other position	10 (6.6)		
Working experience (yr)	<1	28 (18.3)	6.73 ± 7.16	0.25–32
	1–3	39 (25.5)		
	3–5	22 (14.4)		
	5–7	11 (7.2)		
	7–10	17 (11.1)		
	>10	36 (23.5)		
ICU experience (yr)	<1	37 (24.2)	4.36 ± 4.20	0.25–18
	1–3	44 (28.8)		
	3–5	25 (16.3)		
	5–7	13 (8.5)		
	7–10	18 (11.8)		
	>10	16 (10.5)		
Average weekly working hours (hour)	≤40	78 (51.0)	44.22 ± 7.02	30–84
	41–50	60 (39.2)		
	≥51	15 (9.8)		

ICU = intensive care unit; M = mean; SD = standard deviation.

**Table 2** Descriptive Statistics of Measured Variables (N = 153).

Variables	M ± SD	Min	Max	Skewness	Kurtosis
PTSD symptoms	1.20 ± 0.82	0	3.73	0.60	−0.23
Traumatic-event experience	2.83 ± 0.60	1.64	4.36	0.05	−0.51
Cognitive flexibility	4.62 ± 0.65	2.85	6.35	0.26	0.31
CF_control	4.31 ± 0.99	1.75	6.38	0.08	−0.29
CF_alternative	4.82 ± 0.69	1.33	6.33	−0.81	3.49
Coworker support	3.95 ± 0.57	1.95	5.00	−0.77	1.06
CS_reliable alliance	4.13 ± 0.63	1.00	5.00	−1.46	4.44
CS_attachment	3.97 ± 0.70	1.25	5.00	−0.87	1.50
CS_guidance	4.03 ± 0.72	1.50	5.00	−0.93	0.83
CS_opportunities for nurturance	3.82 ± 0.57	2.00	5.00	−0.20	−0.01
CS_social integration	3.75 ± 0.67	1.50	5.00	−0.62	0.53

Abbreviations: CS = coworker support; CF = cognitive flexibility; M = mean; PTSD = post-traumatic stress disorder; SD = standard deviation.

### Differences in PTSD symptoms by personal and environmental characteristics of ICU nurses

The differences in PTSD symptoms among the ICU nurses in this study according to personal and environmental characteristics are presented in Table 3. There were no statistically significant differences in PTSD symptoms by individual and environmental characteristics.

### Correlation between major variables

The correlations between traumatic-event experience, cognitive flexibility, coworker support, and PTSD symptoms among the ICU nurses in this study are summarized in Table 4. PTSD symptoms were significantly positively correlated with the degree of traumatic-event experience ( $r = 0.42, p < .001$ ) and negatively correlated with control ( $r = -0.40, p < .001$ ) among the cognitive

**Table 3** Differences in Post-traumatic Stress Disorder Symptoms by Demographic Variable (N = 153).

Variables	Categories	M ± SD	t/F(p)
Gender	Male	25.67 ± 13.16	-0.14 (.888)
	Female	26.54 ± 18.34	
Marital status	Single	27.27 ± 18.50	1.09 (.298)
	Married	23.53 ± 16.11	
Religion	Christian	25.00 ± 17.39	0.12 (.975)
	Catholic	27.17 ± 19.60	
	Buddhist	28.27 ± 15.71	
	No religion	26.44 ± 18.68	
	Others	30.00 ± 10.33	
Education level	Associate degree	25.26 ± 17.73	0.28 (.760)
	Bachelor degree	26.25 ± 18.41	
	≥Master degree	29.33 ± 16.55	
Hospital bed size	<500	19.36 ± 18.18	0.84 (.473)
	500–1000	27.42 ± 18.09	
	>1000	25.89 ± 17.32	
Type of ICU	General	23.00 ± 16.43	1.35 (.255)
	Surgical	25.54 ± 22.48	
	Medicine	30.01 ± 18.46	
Position title	Staff nurse	26.81 ± 18.09	0.40 (.669)
	≥Other position	21.90 ± 17.60	
Average weekly working hours	≤40	24.67 ± 17.91	0.94 (.441)
	41–50	28.77 ± 18.91	
	≥51	26.87 ± 14.91	

Abbreviation: ICU = intensive care unit.

**Table 4** Correlation Between Key Variables (N = 153).

Classification	1	2	3	4	5	6	7	8	9	10	11	12
1. PTSD symptoms	1											
2. Traumatic-event experience	0.43**	1										
3. Cognitive flexibility_control	-0.40**	0.01	1									
4. Cognitive flexibility_alternative	0.13	-0.01	0.27**	1								
5. Coworker support_reliable alliance	-0.34**	-0.12	0.19*	0.04	1							
6. Coworker support_attachment	-0.23**	-0.05	0.17*	-0.03	0.77**	1						
7. Coworker support_guidance	-0.19*	-0.03	0.17*	-0.01	0.81**	0.85**	1					
8. Coworker support_opportunities for nurturance	-0.07	0.01	0.30**	0.26**	0.56**	0.64**	0.61**	1				
9. Coworker support_social integration	-0.11	-0.02	0.16*	-0.04	0.65**	0.79**	0.74**	0.63**	1			
10. Age	-0.02	0.15	0.41**	0.36**	0.09	0.11	0.20*	0.20*	0.08	1		
11. Working experience	0.02	0.12	0.42**	0.35**	-0.01	0.02	0.12	0.15	0.00	0.88**	1	
12. ICU experience	-0.04	0.15	0.41**	0.31**	-0.00	0.07	0.10	0.18*	0.04	0.69**	0.78**	1

\*p < .05 \*\*p < .01.

Abbreviations: ICU = intensive care unit; PTSD = post-traumatic stress disorder

**Table 5** Factors Affecting Post-traumatic Stress Disorder Symptoms Among ICU Nurses (N = 153).

Independent variables	B	β	SE	t	p
Traumatic-event experience	1.05	0.38	0.17	6.39	<.001
Cognitive flexibility_control	-1.05	-0.46	0.15	-7.25	<.001
Cognitive flexibility_alternative	0.54	0.25	0.14	3.81	<.001
Coworker support_reliable alliance	-2.99	-0.40	0.81	-3.71	<.001
Coworker support_attachment	-1.04	-0.16	0.85	-1.23	.222
Coworker support_guidance <sup>33</sup>	1.01	0.16	0.82	1.23	.222
Coworker support_opportunities for nurturance	0.96	0.12	0.70	1.38	.171
Coworker support_social integration	1.15	0.17	0.69	1.66	.100

Adj. R<sup>2</sup> = 0.50, F = 17.84, p < .001.

Abbreviation: ICU = intensive care unit.

flexibility subscales and trusted alliance ( $r = -0.34, p < .001$ ) among the coworker-support subscales.

#### *PTSD symptom–related factors among ICU nurses*

The analysis results of the effects of traumatic-event experience, cognitive flexibility, and coworker support on PTSD symptoms among ICU nurses are presented in Table 5. We conducted multiple regression analysis among the independent variables to check whether the assumptions of the regression analysis were fulfilled. The tolerance values ranged from 0.199 to 0.965 (above 0.1) and the variance inflation factor values ranged from 1.036 to 5.033 (below 10), indicating no issue of multicollinearity among the independent variables of the regression model in this study. Moreover, we checked the independence of the residuals, and a Durbin–Watson value of 2.02 was obtained. As this value is close to 2, they are not autocorrelated.

Influencing factors of PTSD symptoms in ICU nurses were found to be traumatic-event experience ( $\beta = 0.38, p < .001$ ), control ( $\beta = -0.46, p < .001$ ) and alternative ( $\beta = 0.25, p < .001$ ) among the cognitive flexibility subareas, and reliable alliance ( $\beta = -0.40, p < .001$ ) among the coworker-support subareas. The model was found to have an explanatory power of 49.8%, and it was statistically significant ( $F = 17.84, p < .001$ ).

## Discussion

This study aimed to determine the effects of traumatic-event experience, cognitive flexibility, and coworker support on PTSD symptoms among ICU nurses. The main findings of the study are discussed in the following. We analyzed the expected influencing factors of PTSD symptoms in ICU nurses with traumatic-event experience, cognitive flexibility, and coworker support as independent variables. We found that PTSD symptoms are influenced by traumatic-event experience; the subareas of cognitive flexibility; specifically, alternative and control; and trusted alliance, a subarea of coworker support.

In this study, the severity of PTSD symptoms among ICU nurses was found to have a mean score of 26.50 out of a total score of 88. This score is higher than the cut-off point of 25, indicating the presence of full PTSD symptoms [20]. Based on the cut-off criteria for PTSD symptom severity, 45.1% of ICU nurses in this study were classified into the full PTSD symptom group. This percentage is lower than the high-risk group ratio of 61.2% reported for ICU nurses using the same tool [25] but higher than the 23.0% reported by a previous study [2]. Additionally, it appears that ICU nurses experience a higher level of PTSD symptoms than emergency-room nurses (20.4%) [10] and general-ward nurses (29.7%) [26]. Considering the prevalence of PTSD in the general population, which ranges from 1% to 14% in the United States [4] and is reported as 4.7% in Korea [20], it is evident that ICU nurses are at a significantly higher risk of developing PTSD than the general population.

As far as the factor affecting PTSD symptoms in ICU nurses, the traumatic-event experience was found as the most influencing factor. ICU nurses often experience the death of patients they have cared for while attempting to protect critically ill patients, are indiscriminately exposed to verbal abuse, physical threats, and violent experiences from patients who behave abnormally and have communication difficulties, and are psychologically traumatized and experience many negative emotional effects after such traumatic experiences. These experiences result in emotional reactions, such as anger, shock, and depression; physical reactions, such as pain and body tension; and social reactions, such as fear of strangers and difficulty working. The most serious problem is that owing to the high pressure of the work environment, continuing to work with

violence often goes unnoticed and emotional wounds go unaddressed [27,28]. Verbal and physical violence have been shown to increase the risk of PTSD by 15.9 times and 5.3 times, respectively [26]. It would be safe to say that traumatic-event experience is highly associated with the development of PTSD symptoms.

The second influencing factor of PTSD symptoms in ICU nurses was the two subareas of cognitive flexibility; alternative had a significant negative effect on PTSD symptoms in ICU nurses, whereas control had a significant positive effect on PTSD symptoms. This indicates that the higher the PTSD symptoms of ICU nurses, the higher the use of alternatives and the lower the use of controls.

Most people who have experienced a traumatic event will ruminate about the event frequently to understand and work through it [21,29]. This finding is in line with previous studies that have demonstrated the moderating effects of alternative among the subfactors of cognitive flexibility during post-traumatic growth [30,31]. On the other hand, while the mechanisms by which higher PTSD symptoms are associated with reduced use of the control coping approach are not yet understood; it can be interpreted as the inability to perceive difficult and complex situations in the ICU as controllable, difficulty making decisions, and the feeling of being overwhelmed and out of control owing to extreme stress.

The third influencing factor of PTSD symptoms in ICU nurses was trusted alliance among the subareas of coworker support. ICUs are places in which cooperation and a team approach with fellow nurses is necessary in emergency situations, and social support through exploratory coping occurs by talking to someone who can do something about the problem or seeking advice from a respected senior or colleague in a difficult situation [32]. Previous studies have reported that sharing feelings and support with close colleagues when exposed to violence from patients and caregivers and receiving social support from coworkers and supervisors play a mediating role in reducing stress and depression in nurses, thus showing that support from coworkers is very important in a highly stressful ICU environment [27,33]. A study conducted among firefighters, professionals at high risk for PTSD symptoms, reported that coworkers can be an important source of support to share feelings of guilt or helplessness experienced in the field [30]. Another study conducted among regular office workers found that trust in coworkers leads to proactive problem solving rather than avoidance in difficult situations [17]. Building on these findings, it is strongly recommended that programs, such as group counseling to increase coworker support, be actively pursued as a way to reduce PTSD symptoms among ICU nurses.

To sum up, the influencing factors of PTSD symptoms in ICU nurses included traumatic-event experience; alternative and control (subareas of cognitive flexibility); and trusted alliance (subarea of coworker support). Despite continued research on the high stress and burnout experienced by ICU nurses and other high-risk-for-PTSD-symptoms groups and related factors, intervention is lacking. Burnouts and repeated stress develop into PTSD symptoms, leading to frequent turnovers and resignations, which negatively impact the hospital's financial situation.

The UK government funds a practitioner health program for doctors [34], and in Korea, some hospitals have been running employee counseling centers to help employees effectively manage stress and improve work efficiency. However, little attention has been paid to employee mental health in most hospitals, making it difficult to provide appropriate interventions. PTSD can be prevented, and its symptoms can be alleviated by establishing an individualized professional counseling system as an organizational effort to promote the mental health of employees, applying mindfulness-based cognitive therapy, which has been shown to be effective in reducing PTSD symptoms [35], and developing programs to foster camaraderie among coworkers.



This study has a few limitations. Firstly, it was limited to ICU nurses in some regions and was not randomized, which restricts the generalizability of the results to all ICU nurses. Additionally, it should be mentioned that the IES-R-K, used in this study to identify PTSD symptoms, is only a screening tool for PTSD symptoms and is not intended to diagnose PTSD. Despite these limitations, this study is significant in that it aimed to identify the factors influencing PTSD symptoms among ICU nurses. It applied traumatic-event experience, cognitive flexibility, and coworker support as variables, providing a foundation for the development of intervention programs to prevent and alleviate PTSD symptoms among ICU nurses. In light of these limitations, the suggestions for future research based on our findings are as follows. Firstly, this study was based on a convenience sample of ICU nurses working in advanced general hospitals and general hospitals in some regions, which limits the generalizability of the findings to all ICU nurses. Therefore, a repeated study with an expanded geographic area and sample size is warranted. Secondly, we recommend that future research include a wider range of variables that influence PTSD symptoms among ICU nurses, in addition to the variables selected in this study.

Understanding the factors contributing to PTSD in ICU nurses is crucial for targeted interventions and improving healthcare professionals' well-being. Insights from specific traumatic events, such as patient deaths and verbal abuse, help identify high-risk scenarios, emphasizing the importance of cognitive flexibility and adaptive coping strategies to mitigate PTSD symptoms.

## Conclusion

In this study, we found that traumatic-event experience; control and alternative, subareas of cognitive flexibility; and trusted alliance, a subarea of coworker support, were significant influencing factors of PTSD symptoms among ICU nurses. ICU nurses develop PTSD symptoms through repeated experience of traumatic events, and the lack of proper stress management leads to high resignation rates. However, most Korean healthcare organizations largely disregard the mental health of their employees. It is necessary for healthcare organizations and countries to establish systems to prevent PTSD and alleviate its symptoms based on previous research, rather than leaving the management of post-traumatic stress among ICU nurses to individuals.

## Relevance to clinical practice

Recognizing the factors contributing to PTSD in ICU nurses is pivotal for crafting precise interventions and enhancing the overall welfare of healthcare professionals. The specific traumatic events experienced by ICU nurses, including patient deaths, verbal abuse, and violence, offer invaluable insights to clinical practitioners, aiding in the identification of high-risk scenarios leading to potential PTSD among colleagues. The study underscores the significance of cognitive flexibility, particularly in alternative and control coping mechanisms. Clinical practitioners can integrate this understanding into therapeutic approaches, customizing cognitive strategies to fortify adaptive coping mechanisms and diminish the likelihood of PTSD symptoms.

The study's emphasis on the positive impact of trusted alliances and coworker support underscores the necessity of cultivating a supportive work environment. Clinical leaders can implement strategies to enhance teamwork, encourage communication, and establish support systems among ICU nurses, ultimately mitigating the effects of traumatic experiences. This study holds promise in informing targeted interventions, refining screening processes, and fostering a more supportive and resilient work atmosphere for ICU nurses. By applying these findings in daily practice, clinical professionals can actively contribute to the wellbeing of their

colleagues and ultimately enhance the standard of patient care in critical care setting.

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## Conflict of interest

There are no potential conflicts, real and perceived, for all named authors.

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## Research Article

## Development and Validation of the Resilience Scale for Kidney Transplantation (RS-KTPL)

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## SUMMARY

**Purpose:** This study developed a resilience scale for kidney transplantation (RS-KTPL) and assessed its reliability and validity.

**Methods:** During the tool development phase, the concept of resilience in 10 patients who had undergone a kidney transplant was analyzed by integrating results from the theoretical and field research stages. Initial tool items were then derived. These items underwent content validity verification, item review, and a preliminary survey. The validation phase involved two main surveys, conducted using the preliminary 59 items derived from the development phase for data gathering. The first survey had 266 participants, and the second had 205 participants. Using the collected data, the structural validity, convergent validity, discriminant validity, criterion validity, and reliability of the tool items were verified, ultimately establishing the final items.

**Results:** The RS-KTPL comprises six factors with 27 items confirmed through exploratory factor analysis (EFA) and confirmatory factor analysis (CFA) on a 4-point Likert scale: positive thought transition through recovery belief, supportive relationships with others, self-awareness of negative psychological reactions, physical health control, homeostasis control, and supportive relationships with medical staff. The cumulative explanation of the tool was 50.71%. The model fit of the RS-KTPL was represented as follows: GFI 0.88, CFI 0.93, TLI 0.91, RMSEA 0.04, and SRMRI 0.06. Convergent, discriminant, and criterion validity were also secured. The reliability of the tool, measured by Cronbach  $\alpha$  was 0.87.

**Conclusions:** The RS-KTPL can be used to identify the level of resilience in patients who have undergone a kidney transplant, enabling them to recognize their strengths and areas of improvement for enhanced resilience. This tool can be applied in clinical nursing practices to comprehensively assess the resilience of patients with a kidney transplant, providing direction for nursing intervention plans to enhance patient resilience.

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## Introduction

Kidney transplantation offers several positive aspects for patients with end-stage renal failure, enabling them to enjoy a normal daily life not bound by dialysis or the symptoms of uremia, leading to improved kidney function, extended life expectancy, enhanced quality of life, and reduced medical costs [1,2]. However, patients who undergo kidney transplantation may experience negative effects

such as fever, pain, infection, and rejection reactions post-surgery [3,4]. Particularly, those facing kidney transplant rejection may encounter life crises and psychological distress as they undergo treatments such as plasma exchange, immunoglobulin therapy, high-dose steroid pulse therapy, and pharmacotherapy or resume dialysis [4,5]. Additionally, these patients endure severe stress due to hospitalizations for re-evaluation of the transplanted kidney and the possibility of kidney removal if renal functions do not recover after transplantation [6]. The treatment process for kidney transplant patients is complex, and post-transplant, they may encounter various issues such as physical and psychological stress, changes in social support, and financial problems [7]. Moreover, these patients may encounter other challenges, including potential complications and challenges related to medication regimens, requiring long-term

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medical care [4,5,7]. Therefore, emphasizing the importance of resilience becomes imperative as it empowers patients to navigate through adversities and thrive despite the hurdles they may encounter, thereby enhancing their ability to overcome negative experiences and return to normal daily life [8].

*Resilience* is generally defined as a dynamic process of responding to hardships or adversities [9]. This involves effectively dealing with intense stress experienced in difficult or crisis situations, positively transforming negative emotions, and overcoming crises [9,10]. Resilience encompasses psychosocial, physical, role, relational, and philosophical traits [11]. A core element of resilience is the ability to accept, overcome, and develop in the face of crises. Therefore, it is pertinent to enhance resilience in patients after kidney transplantation to address unexpected physical and mental challenges. To date, there has been a lack of research focused on overcoming and recovering from unexpected difficult situations, such as complications or rejection reactions after kidney transplantation. Moreover, there is a scarcity of instruments for assessing resilience in these patients. The specific factors and attributes necessary for measuring resilience are not clearly understood, highlighting the need to develop a resilience scale that can assess the various meanings and attributes of resilience in kidney transplant patients.

Some of the widely used resilience scales include the Conner–Davidson Resilience Scale (CD-RISC) [12] and the Resilience Scale (RS) [10]. These tools are primarily composed of indicators that assess resilience with a focus on the psychosocial aspects. Specifically, the CD-RISC evaluates resilience traits associated with anxiety, depression, and stress, encompassing robustness, control, dedication, adaptability, and goal orientation. This resilience measurement tool was initially developed for various populations, including individuals experiencing mental distress in the community, outpatient psychiatric patients, and those diagnosed with anxiety disorders or post-traumatic stress disorder. Unlike the CD-RISC, the RS assesses resilience and positive traits that enhance adaptation, focusing on older women's ability to overcome adversity. It also considers attributes such as equanimity and perseverance to aid stress coping. However, while these tools may be useful for assessing psychological resilience, they have limitations in evaluating resilience in individuals with physical pathologies, such as kidney transplant patients. Given that physical characteristics play an important role in kidney transplant patients, existing tools that mainly focus on psychosocial aspects fail to adequately reflect these physical characteristics. Therefore, comprehensively assessing resilience in kidney transplant patients requires a tool that considers various aspects, including personal dispositional traits, pathological characteristics, socioeconomic interactions, relationships with healthcare staff, and individual recovery beliefs. Consequently, the instrument should be chosen carefully to study resilience in kidney transplant patients, and tools that have been validated through theoretical analysis must be employed [13].

Currently, resilience scales that consider pathological characteristics have been developed for populations such as those with cardiovascular diseases [13], children with chronic diseases (e.g., asthma, diabetes mellitus, and nephrotic syndrome) [14], and patients undergoing hemodialysis [15]. These efforts aim to consider and reflect the disease characteristics, sociocultural backgrounds, stress situations, and relational support systems of individuals assessed with the respective resilience scale [13–15]. While it is possible to assess resilience in kidney transplant patients using the resilience scales designed for hemodialysis patients, such scales primarily consist of items focused on the meaning of life or relationship-centered aspects after dialysis [15], which limits their applicability in analyzing the resilience of kidney transplant patients. Thus, there is a need to develop tools that consider the unique characteristics of kidney transplant patients, encompassing

physical and mental characteristics experienced by patients after kidney transplantation surgery, adverse drug reactions with immunosuppressants, adverse postoperative events or complications, methods of overcoming difficulties in daily life or individual coping abilities, and self-awareness. Moreover, it is important to develop an instrument that considers comprehensive attributes such as personal strengths, positive recovery beliefs, family and social environment, and economic support to facilitate the recovery of kidney transplant patients.

Accordingly, this study aims to explore the meaning and significance of resilience in kidney transplant patients and develop a scale that can measure the characteristics of resilience from various perspectives. The scale is expected to allow a comprehensive analysis of personal, cultural, socioenvironmental, and even economic dimensions of resilience. Furthermore, we aim to facilitate research on resilience in kidney transplant patients by administering the scale to such patients and providing the evidence required for theoretical development and clinical nursing interventions.

## Conceptual framework

### *Resilience nursing model*

This study is grounded in Polk's Resilience Nursing Model, a middle-range nursing theory that includes dispositional, relational, situational, and philosophical patterns [11]. These patterns encompass various aspects, such as psychosocial attributes, intelligence, health, emotional and physical properties, family dynamics, social interactions, stress assessment skills, coping mechanisms, and the search for positive meaning through self-reflection.

Polk's model conceptualizes humans as dynamic energy fields that interact with the environment; it further delineates these interactions into patterns. Furthermore, it considers individuals as holistic entities, suggesting that human–environment interaction patterns contribute to health. Events or adversities that individuals experience are seen as part of the overall life process, with patterns enhancing individual energy believed to strengthen life processes and create new energy fields. The model embodies the nursing paradigm of simultaneity and consistency, viewing humans as engaging dynamically with the environment, where human–environment energy fields flow freely together.

In this context, the four patterns within Polk's model synergize with the human–environment energy field, contributing to integration. Therefore, this study perceives challenges faced by kidney transplant patients post-transplantation through the lens of the individual–environmental energy field within Polk's model. These challenges are considered essential domains inherent to kidney transplant patients, and strengthening them is believed to enhance resilience. Thus, the study conceptualizes the four patterns presented in Polk's model as dimensions relevant to kidney transplant patients, hypothesizing that the enhancement of these patterns will improve resilience and better equips patients to cope with post-transplant adversities or events.

### *Conceptual framework of this study*

This study established its conceptual framework by analyzing qualitative research data collected through a literature review and field research phases. Its specific conceptual framework is as follows:

Firstly, in the dispositional dimension, kidney transplant patients exhibit attributes such as physical health regulation, coping strategies, and positive cognitive shifts, emphasizing individual effort for recovery. This highlights the need for self-management to



prevent post-transplantation complications, with a desire for self-fulfillment and overcoming negative psychological reactions such as anxiety or depression. The dispositional dimension also encompasses an individual's intelligence, health, and temperament, focusing on physical health, crisis coping, and cognitive processes for positive thinking.

Secondly, in the relational dimension, kidney transplant patients receive support from family, healthcare professionals, and society. This includes social and economic assistance, such as seeking employment for economic independence while considering their health status or accessing information about supportive government agencies and social institutions. Therefore, this dimension highlights the role and relationships that contribute to resilience, including familial, social, and economic support.

Thirdly, regarding the situational dimension, kidney transplant patients confront the stress of transplantation, assessing their abilities and adapting their self-perception accordingly. They navigate post-transplant stressors by reflecting on themselves deeply. Thus, this dimension involves self-awareness amid stress and the process of self-reflection.

Lastly, in the philosophical dimension, kidney transplant patients maintain positive recovery beliefs, trusting in their ability to overcome challenges and improve their health over time. This includes having faith in better outcomes and embracing spiritual beliefs, reflecting their convictions, beliefs, and values.

## Methods

### Study design

This study is a methodological study aiming to develop and validate the Resilience Scale for Kidney Transplantation (RS-KTPL).

### Setting and sample

Inclusion criteria encompassed patients aged 18 and over [16,17] who had undergone kidney transplantation at least a year ago were recruited [18,19]. Patients who fulfilled any of the specified criteria were subsequently excluded from this study. A total of 505 patients were enrolled, with 34 patients involved in the scale development process (qualitative study  $n = 10$ , pilot survey  $n = 24$ ) and 471 patients involved in the scale validation stage (first survey  $n = 266$ , second survey  $n = 205$ ). Participants were recruited through posted announcements on social media and a bulletin board at a tertiary hospital in Korea, and data were collected from February 2022 to March 2023.

### Scale development process

To develop the RS-KTPL, we referenced the scale development guideline by DeVellis [20], and the scale development and validation stages consisted of the steps outlined below.

### Scale development stage

**Step 1. Defining the construct:** As a foundational step, we undertook a theoretical study and field (qualitative) study to define the construct of resilience in kidney transplant patients. The theoretical research included an analysis of 18 documents using databases such as Research Information Sharing Service, Korean Studies Information Service System, PubMed, and Cumulative Index to Nursing and Allied Health Literature. The field research phase involved confirming the attributes of resilience concepts derived from theoretical studies and discovering new concepts through individual interviews. In this phase, participants who

could provide rich data on the experience of kidney transplantation were selected [21]. Due to the qualitative nature of the research methodology, interviewing all kidney transplant patients was not feasible; hence, a sample of 6–8 participants with similar characteristics was chosen [22,23]. Ultimately, individual interviews were conducted with 10 kidney transplant patients who could realistically share their post-transplant experiences. The results from both studies were integrated to define resilience in kidney transplant patients and derive potential items for the RS-KTPL. The study commenced in January 2022. Step 1 lasted for a total of 1 year and 6 months or more. During this period, the literature review spanned approximately 12 months. The qualitative interview data collection commenced in February 2022, with the analysis requiring at least 3 months or more.

**Step 2. Creating an item pool:** An item pool for the RS-KTPL was created by comprehensively analyzing the theoretical study and field (qualitative) study results. A period of approximately 6 months was required to construct the final set of preliminary items derived from the final analysis.

**Step 3. Selecting the measurement scale:** To minimize central tendency bias [20], we used a four-point Likert scale. The RS-KTPL was rated on a scale consisting of 1 = “strongly disagree,” 2 = “disagree,” 3 = “agree,” and 4 = “strongly agree.”

**Step 4. Evaluating the content validity:** For content validity verification, forming an expert group consisting of a minimum of three and a maximum of ten members is desirable [24]. Accordingly, the expert groups for content validity verification in this study were as follows: for content validity, expert groups of eight and five members were formed for the first and second verifications, respectively. The first group comprised two nephrology professors, one resident, two nursing school professors, one nurse experienced in kidney transplantation, and two nurses with over five years of nephrology ward experience. The second group comprised one nephrology professor, two nursing school professors, and two experienced nurses from the nephrology ward. The scale-level content index/average (S-CVI/Ave) and the item-level content index (I-CVI) were calculated and analyzed, ensuring that the I-CVI is  $\geq .80$  and S-CVI/Ave is  $\geq .90$  [25]. The content validity analysis commenced in September 2022 and took approximately 2 months to complete.

**Step 5. Reviewing the items and conducting a pilot survey:** The items were evaluated by a Korean linguist for uniformity, appropriateness, and accuracy, based on which the items were deleted or revised. A pilot study was conducted in October 2022 to assess item comprehensibility, readability, and response time, and the completion of the pilot study and item review took approximately 2 months.

### Scale validation stage

**Step 6. First round of validation:** To conduct exploratory factor analysis (EFA), a sample size of at least five times the number of items was considered [26], with an additional 10% dropout rate. This resulted in an estimated sample size of 280 individuals. The results of the first main survey revealed a total of 270 survey participants, all of whom responded to the online questionnaire. After screening the collected data, EFA was performed using the data obtained from 266 kidney transplant patients collected in the first main survey. The data collection occurred from December 2022 to January 2023 using online survey systems on Internet portals, such as Naver and Daum Cafe, as well as social network systems (SNSs). Recruitment notices were also posted on bulletin boards at Hospital X's nephrology outpatient clinics

and wards. The first main survey results revealed a total of 270 participants, all of whom responded to the online questionnaire.

#### Construct validity testing through EFA

We first assessed the suitability of the data for factor analysis using the Kaiser–Meyer–Olkin (KMO) measure and Bartlett's test of sphericity [27,28]. Principal component analysis was performed to merge highly correlated variables, while varimax rotation was used to ensure that the factors remained independent. To check the construct validity of each item, we evaluated their communality and deleted any item with a communality below .30 [29,30]. We also removed items with a factor loading of less than .30 [29,31]. If an item had a factor loading of  $\geq 0.30$  across two or more factors, or if the difference in loadings was less than 0.10, we considered this as cross-loading and removed the item [32,33]. Finally, the number of factors was determined considering an eigenvalue  $\geq 1.0$  [27], Scree plot, cumulative explained variance, and elbow point.

**Step 7. Second round of validation:** The study aimed to conduct confirmatory factor analysis (CFA) with a minimum sample size of 200 individuals [30]. Considering a 10% dropout rate, the estimated sample size was 220 participants. In the second main survey, 215 participants responded, with 141 completing online questionnaires and 74 opting for paper-based ones. Following data screening, 205 data points from the second survey were selected for analysis. The data collection took place from February to March, 2023, following the same methodology as that of the first main survey. Convergent validity, discriminant validity, criterion validity, and reliability were tested.

#### Construct validity testing through CFA

The model fit of the developed scale was assessed using CFA with the maximum likelihood method, applying a standardized coefficient criterion of  $\geq .50$ . The model fit was determined using the  $\chi^2$  test, Chi-square minimum/degree of freedom [CMIN/DF ( $\chi^2/\text{df}$ )], goodness of fit index (GFI), comparative fit index (CFI), Tucker–Lewis index (TLI), root mean square error of approximation (RMSEA), and standardized root mean-square residual (SRMR). The specific fit criteria were as follows.

First, CMIN/DF evaluates model fit using the  $\chi^2$  statistic, degrees of freedom, and the ratio of  $\chi^2$  value to degrees of freedom. For this study, a value of 3.0 or lower was considered indicative of a good fit [34,35]. GFI, which indicates how well the collected sample data and the model align, is considered perfect when close to 1. In this study, we set the criterion to  $\geq .90$  [34–36]. To address the limitations of the  $\chi^2$  test, RMSEA was used, with a value of  $\leq .05$  considered indicative of a very good fit [34–36]. The association between variables was measured using CFI and TLI, with a value of  $\geq .90$  interpreted as a good fit [30–37]. Furthermore, SRMR was used to evaluate the residuals representing the difference between the sample's covariance matrix and the covariance matrix of the theoretical model. A value of  $\leq .08$  was considered indicative of a good model fit [38]. Additionally, modification indices were applied to enhance model fit, involving adding parameters to establish new correlations between the model's variables while maintaining the theoretical background and interpretability of the model [35]. Generally,  $\chi^2$  can significantly decrease when the modification index is 3.84 (of 5.0) or higher [34]. In particular, model fit was calculated considering the modification index when the modification index for the error terms of items within the same factor was 4.0 or higher.

#### Evaluation of convergent and discriminant validity

In this study, we used convergent validity to verify how consistently the derived factors represented the resilience of kidney transplant patients, using averaged variance extracted (AVE) and construct reliability (CR) with a cutoff of  $\geq .50$  and  $\geq .70$ , respectively [35]. Additionally, we evaluated discriminant validity to ascertain whether the factors independently explained different concepts, considering whether the AVE value was higher than the square of the correlation coefficients between factors. Additionally, two factors cannot be concluded to measure different concepts when their correlation is too strong ( $\geq .90$ ), and such cases were examined to ensure that factors were independently measuring intended concepts [35,37,39,40].

#### Evaluation of criterion validity

In this study, we analyzed the correlations between the developed scale and existing instruments to establish criterion validity [41]. The Conner–Davidson Resilience Scale (CD-RISC) was selected as the criterion to verify concurrent validity. The CD-RISC consists of 25 items and uses a five-point scale. At the time of development, the reliability of the tool (Cronbach's  $\alpha$ ) was .89. Criterion validity is considered established when the correlation coefficient between the total scores of two instruments is between .40 and .80. In general, a correlation coefficient  $\geq .60$  is deemed to indicate high validity [41]. In this study, we used the criterion of  $\geq .60$  to determine criterion validity.

#### Evaluation of reliability

To determine the consistency of the items of the RS-KTPL in measuring the resilience of kidney transplant patients, internal consistency reliability and split-half reliability were analyzed. We used Cronbach's  $\alpha$  to measure reliability with a cutoff of  $\geq .60$  [20].

**Steps 8. Finalizing the scale:** The items of the scale were finalized based on the validity and reliability results. The analysis of the data collected from STEPS 6 to 7 and finalizing the tool took approximately 7 months, from December 2022 to June 2023.

#### Data analysis

The collected data were analyzed using the SPSS 25.0 and AMOS 22.0 software. Participants' general characteristics were analyzed using descriptive statistics, and items were analyzed using mean, standard deviation, skewness, and kurtosis. The Pearson correlations between the item-factor score and item-total score were analyzed, and reliability after the removal of unfit items was analyzed. The suitability of the data for factor analysis was assessed using the KMO statistic and Bartlett's test of sphericity. EFA and CFA were conducted to evaluate the construct validity of the scale. Criterion validity was assessed using Pearson correlation coefficients, and the reliability of the scale was analyzed using Cronbach  $\alpha$  and the Spearman–Brown coefficient.

#### Ethical consideration

This study approved by the Seoul National University College of Medicine/Seoul National University Hospital (Approval Number: H-2201-062-1290), ensured participants' understanding of the study's purpose and procedures, confirmed their voluntary participation, and guaranteed anonymity. Participants were

informed of their right to withdraw consent at any time without negative consequences and reassured that there would be no disadvantages if they chose to withdraw from the study.

## Results

### Item generation

In the scale development stage, 18 existing studies were reviewed for theoretical research, and interviews were conducted with 10 kidney transplant patients as part of a qualitative field study. The findings were integratively analyzed. As a result, the resilience of kidney transplant patients was conceptualized into four dimensions (i.e., dispositional, relational, situational, and philosophical) and eight properties (i.e., physical health regulation, negative psychological response, coping strategies for recovery, positive thought transition, family support, socioeconomic support, self-awareness in a stress situation, and positive recovery beliefs), with a total of 59 items. These 59 items were selected as preliminary items for the scale.

### Content validity

The 59 preliminary items were evaluated for content validity in two rounds. In the first round, the S-CVI/AVE was .94, resulting in the deletion of seven items. Among these, five items were excluded

for not meeting the I-CVI criterion of .8. The remaining two items were removed due to redundancy, as their content overlapped with that of other items. In the second round, the S-CVI/AVE was .97, and one item was deleted for not meeting the I-CVI criterion of .8. After two rounds of content validity evaluation, 51 items were derived.

### Pilot test

A pilot test was administered to kidney transplant patients using the 51 items derived from the content validity evaluation, with 24 participants involved in the pilot test. In the pilot test, the mean score was  $3.83 \pm 0.92$  for “It was easy to understand the items,”  $4.21 \pm 0.72$  for “It was easy to read the items,” and  $3.71 \pm 0.81$  for “There were no ambiguous items.” The average time to complete the survey was  $7.55 \pm 6.60$  minutes.

### First and second survey sample characteristics

In this study, we conducted two rounds of main surveys to use separate data for the EFA and CFA in the evaluation of construct validity. A total of 266 patients were included in the first main survey (EFA), and 205 were included in the second main survey (CFA) (Table 1).

In the first survey, 51.9% of participants were female and 48.1% were male. The mean age was  $47.7 \pm 11.46$  years, with those aged 40–49 years accounting for 31.2% of the sample. Living donor

**Table 1** General Characteristics of First and Second Surveys.

Characteristic	First (N = 266)			Second (N = 205)	
	Category	n (%)	M ± SD	n (%)	M ± SD
Gender	Men	128 (48.1)		94 (45.9)	
	Women	138 (51.9)		111 (54.1)	
Age	20–29	14 (5.3)	47.7 ± 11.46	13 (6.3)	47.46 ± 11.13
	30–39	54 (20.3)		41 (20.0)	
	40–49	83 (31.2)		59 (28.8)	
	50–59	79 (29.7)		67 (32.7)	
	60–69	28 (10.5)		22 (10.7)	
	≥70	8 (3.0)		3 (1.5)	
Marital status	Single	67 (25.2)		54 (26.3)	
	Married	179 (67.3)		132 (64.4)	
	Other (e.g., separated, widowed, divorced)	20 (7.5)		19 (9.3)	
Education level	None	2 (.8)		3 (1.5)	
	Elementary school	11 (4.1)		7 (3.4)	
	Middle school	15 (5.6)		15 (7.3)	
	High school	40 (15.0)		29 (14.1)	
	College	177 (66.5)		137 (66.8)	
	Graduate school or higher	21 (7.9)		14 (6.8)	
Employment status	Yes	146 (54.9)		112 (54.6)	
	No	120 (45.1)		93 (45.4)	
Type of KTPL	Deceased donor	82 (30.8)		61 (29.8)	
	Living donor	184 (69.2)		144 (70.2)	
Time elapsed since KTPL (yr)			4.53 ± 5.09		3.73 ± 3.20
ReKTPL	Yes	13 (4.9)		9 (4.4)	
	1st	12 (4.5)		9 (4.4)	
	2nd	1 (.4)		0 (0)	
	No	253 (95.1)		196 (95.6)	
Type of dialysis before KTPL	PD	18 (6.8)		15 (7.3)	
	HD	116 (43.6)		89 (43.4)	
	Both PD and HD	16 (6.0)		15 (7.3)	
	Dialysis not performed	116 (43.6)		86 (42.0)	
Duration of PD before KTPL (yr)			2.98 ± 2.55		2.84 ± 1.99
Duration of HD before KTPL (yr)			3.12 ± 4.13		2.90 ± 2.88
Duration of PD and HD Before KTPL (yr)			7.60 ± 9.51		4.80 ± 6.50
Side effects and symptoms after KTPL	Yes	152 (57.1)		124 (60.5)	
	No	114 (42.9)		81 (39.5)	
Type of side effects and symptoms after KTPL	Physical	77 (50.7)		37 (29.8)	
	Mental	50 (32.9)		55 (44.5)	
	Both physical and mental	25 (16.4)		32 (25.8)	

Note. HD = hemodialysis; KTPL = kidney transplantation; PD = peritoneal dialysis.

transplant (69.2%) was the most common form of kidney transplant, and the mean time elapsed since transplantation was  $4.53 \pm 5.09$  years. A total of 43.6% of the participants had been on dialysis prior to kidney transplantation; of them, 6.8% were on peritoneal dialysis, while 6.0% were on hemodialysis and peritoneal dialysis. A total of 43.6% had not been on dialysis at all. In total, 152 patients experienced adverse effects and abnormal symptoms after kidney transplantation; 50.7% experienced physical symptoms, 32.9% experienced mental symptoms, while 16.4% experienced both physical and mental symptoms.

In the second survey, 54.1% of participants were female, and 45.9% were male. The mean age was  $47.46 \pm 11.13$  years, with 32.7% of participants in the 50–59 years age range. Living donor transplant was the most common (70.2%) form of kidney transplant, and the mean time elapsed since kidney transplantation was  $3.73 \pm 3.20$  years. A total of 43.4% of the participants had been on dialysis prior to kidney transplantation; of them, 7.3% were on peritoneal dialysis, while 7.3% were on hemodialysis and peritoneal dialysis. A total of 42.0% had not been on dialysis at all. In total, 124 patients experienced adverse effects and abnormal symptoms after kidney transplantation; 44.4% experienced mental symptoms, 29.8% experienced physical symptoms, while 25.8% experienced both physical and mental symptoms.

#### Item analysis

In total, 51 preliminary items were analyzed via EFA using the data collected in the first survey. The item scores ranged from 1.91 to 3.50, indicating that the scores were not skewed. Skewness ranged from  $-.96$  to  $.53$  and kurtosis from  $-1.08$  to  $1.75$ , confirming a normal distribution. Furthermore, four out of 51 initial items were deleted after item analysis. The reliability (Cronbach'  $\alpha$ ) of the remaining 51 items was  $.91$ , and this value remained consistent at  $.91$  after the removal of the four items.

The second survey, involving CFA, used 34 items derived from the EFA. An item analysis was performed prior to CFA to verify normal distribution. The item scores ranged from 1.97 to 3.54, indicating no skewness. Skewness ranged from  $-.80$  to  $.47$  and kurtosis from  $-.76$  to  $.82$ , confirming a normal distribution. Two out of the initial 34 items were deleted after the item analysis. The reliability (Cronbach'  $\alpha$ ) of the 34 items was  $.88$ , and this value remained consistent at  $.88$  after removing the two items.

#### Construct validity

##### EFA

Before conducting the EFA, the data were assessed for suitability for factor analysis. The KMO was  $.87$ , and the correlation matrix of the items in Bartlett's test of sphericity was significant at  $\chi^2 = 4521.48$ ,  $df = 1081$ ,  $p < .001$ , confirming the suitability of the data for factor analysis. Additionally, 11 factors had an eigenvalue of 1.0 or higher. However, the elbow points—points on the Scree plot at which the slope becomes more gradual—indicated that six factors were ideal. Since the change in eigenvalues for Factors 7 and 8 was within  $.10$ , we set the number of factors to six for the factor analysis.

After conducting four rounds of EFA, 34 items were derived, and none of the items had a communality  $< .30$ . Although four items (#13, 30, 32, and 35) were cross-loaded onto two factors, the factor loading difference was  $.10$ – $.20$ . Hence, we did not delete these items. Item number 33 cross-loaded onto two or more factors and had similar factor loadings, but it was retained because it presented the same rotated component matrix as in the second and third rounds of factor analysis. As a result, the scale was finalized with six factors and 34 items. The cumulative explained variance was

50.71%. Factor 1 comprised 13 items (eigenvalue 8.09, explaining 23.80% of the variance, factor loadings ranging from  $.44$  to  $.73$ ), and Factor 2 had six items (eigenvalue 2.62, explaining 7.69% of the variance, factor loadings from  $.49$  to  $.74$ ). Factor 3 included four items (eigenvalue 2.01, explaining 5.92% of the variance, factor loadings from  $.66$  to  $.76$ ), and Factor 4 also had four items (eigenvalue 1.69, explaining 4.96% of the variance, factor loadings from  $.51$  to  $.7$ ). Factor 5 comprised four items (eigenvalue 1.56, explaining 4.59% of the variance, factor loadings from  $.44$  to  $.74$ ), and Factor 6 comprised three items (eigenvalue 1.27, explaining 3.74% of the variance, factor loadings from  $.60$  to  $.69$ ) (Table 2).

The six factors and items derived from the EFA were reviewed to rename the factors as follows: Factor 1 “positive change of thoughts based on recovery beliefs,” Factor 2 “supportive relationship with others,” Factor 3 “self-awareness in negative psychological responses,” Factor 4 “physical health regulation,” Factor 5 “Homeostasis regulation,” and Factor 6 “supportive relationship with healthcare staff.”

##### CFA

We evaluated the suitability of the data collected through the second survey for the factor analysis. The KMO was 0.82, and Bartlett's test of sphericity indicated an  $\chi^2$  of 2198.91,  $df = 496$ ,  $p < .001$ , rejecting the null hypothesis and confirming the suitability of the data. A CFA was conducted on the 34 items derived from the EFA, and the RS-KTPL was finalized to 27 items after three rounds of CFA (Table 3) (Figure 1).

The model fit was as follows:  $\chi^2 = 409.35$ ,  $df = 298$ , CMIN/DF = 1.37, GFI = 0.88, CFI = 0.93, TLI = 0.91, RMSEA = 0.04, and SRMR = 0.06. To improve the fit of the modified study model based on the second CFA, a final CFA was performed with reference to the modification index [25,26]. In the final CFA, the model fit improved compared to that of the first EFA model and the second CFA model. Although the GFI in the final CFA fell slightly short of  $.90$ , at  $.88$ , it was close enough; thus, the established model was accepted. Furthermore, CFI ( $.93$ ) and TLI ( $.91$ ) were above the cutoff of  $.90$ , and RMSEA ( $.04$ ) and SRMR ( $.06$ ) were below the cutoffs of  $.05$  and  $.08$ , respectively, demonstrating a good fit. Although the standardized coefficient was below  $.50$  for items 10 and 37, these items were still retained owing to their importance in measuring their respective factors (Table 4). The study model established after three rounds of CFA did not meet all of the model fit criteria. However, it did have a good fit overall.

#### Convergent validity and discriminant validity

In this study, we performed an EFA and a CFA. Regarding the convergent validity of the six derived factors, the AVE values of Factors 1–6 were  $.57$ ,  $.60$ ,  $.59$ ,  $.69$ ,  $.57$ , and  $.66$ , respectively, and the CR values were  $.94$ ,  $.86$ ,  $.81$ ,  $.84$ ,  $.81$ , and  $.85$ , respectively. The AVE and CR for each factor were above the cutoff, thus establishing convergent validity (Table 4). Regarding discriminant validity, the correlation coefficients for the factors ranged from  $-0.17$  to  $.69$ , indicating an absence of skewness, and the AVE was greater than the square of the correlation coefficients. Thus, discriminant validity was established (Table 4).

#### Criterion validity

Criterion validity was established, as evidenced by a significant correlation between the RS-KTPL and CD-RISC total scores (correlation coefficient  $r = .69$ ,  $p < .01$ ). The RS-KTPL total score was also significantly correlated with all factors of the CD-RISC, namely hardiness ( $r = .67$ ,  $p < .01$ ), coping ( $r = .57$ ,  $p < .01$ ), adaptability/flexibility ( $r = .57$ ,  $p < .01$ ), meaningfulness/purpose ( $r = .49$ ,



**Table 2** Exploratory Factor Analysis for RS-KTPL.

Item	Community	Factor					
		1	2	3	4	5	6
27 I believe that I can achieve my dreams if I overcome the challenges.	.54	.73	.05	.01	.01	.06	.06
26 I believe that I can give someone hope.	.56	.71	.11	.09	-.07	.11	.17
50 I am confident that I can overcome any difficulty I encounter.	.50	.65	.00	.17	.21	-.51	.06
25 I consider failure as a challenge.	.43	.64	.07	.11	.06	-.06	.09
49 I am confident of an optimistic future.	.49	.63	.22	.01	.09	.01	.20
46 I pay attention to my inner self for introspection.	.41	.61	.17	.05	.05	.00	.01
44 I have a positive self-awareness through problem-solving.	.50	.61	.12	-.14	.11	.11	.26
24 I am confident in overcoming difficult situations.	.47	.61	.21	.05	.03	.23	-.03
35 I gain a sense of accomplishment through daily life.	.51	.61	.32	-.00	.03	.17	.01
47 I am confident that I can overcome the challenges (side-effects, complications) associated with kidney transplantation.	.42	.56	-.05	.21	.11	.09	.19
36 I can find appropriate information for health recovery.	.42	.48	.24	-.23	.10	.24	.10
23 I accept the current situation positively.	.41	.46	.25	.13	-.09	.32	-.02
45 I recognize that my perspective on health recovery has changed.	.37	.44	.21	-.11	.18	.11	.28
29 I can rely on my family's emotional support.	.61	-.07	.74	.08	.15	-.04	.19
31 I feel that I have grown as a valuable human being through my family's support.	.57	.28	.66	.06	.17	.10	.13
30 I try to fulfill my roles as a member of my family.	.54	.33	.62	-.03	-.08	.11	.14
28 My family's financial support is helpful.	.38	.08	.59	.04	.17	.06	-.03
32 I gain psychological stability through my relationships with others.	.39	.34	.50	-.05	.15	-.04	.03
33 I form a bond through relationships with others.	.47	.44	.49	-.02	.10	.11	.13
*10 I feel psychologically pressured to recover.	.63	.04	.02	.76	-.19	.12	.01
*7 I feel anxious about resuming dialysis.	.61	.09	.01	.75	.16	-.10	.01
*8 I have a fear of kidney transplantation failure.	.56	.06	.08	.71	.01	-.07	.21
*9 I blame myself if I develop health problems by not taking the immunosuppressants.	.50	.09	-.02	.66	-.05	-.09	-.19
1 I am consistently adhering to the diet regimen.	.66	-.01	.20	.04	.78	.03	.00
2 I control the volume of water that I drink in a day.	.61	.08	.15	-.03	.75	.14	.05
3 I maintain a consistent body weight.	.55	.21	.22	-.06	.66	.14	-.03
13 I exercise regularly.	.57	.41	-.13	-.02	.51	-.11	.33
5 I adjust the dose of drugs, such as immunosuppressants, based on my doctor's prescription.	.60	-.00	-.06	-.13	.04	.74	.20
14 I adhere to the immunosuppressant dosage schedule.	.58	.09	.00	.10	.08	.73	.17
15 I adhere to daily life tips for infection prevention.	.31	.26	.10	-.18	.25	.50	-.25
4 I periodically check for changes in voiding patterns.	.48	.13	.24	-.09	.47	.44	.17
38 I am continuously evaluated for symptom management through consultations with healthcare staff.	.61	.26	.07	-.08	.05	.23	.69
39 I trust in the healthcare staff and health technology.	.52	.17	.15	.11	.10	.20	.64
37 Empathy and consolation from the healthcare staff give me strength.	.47	.24	.22	.01	-.50	.05	.60
Eigenvalue		8.09	2.62	2.01	1.69	1.56	1.27
Percent explained variance (%)		23.80	7.69	5.92	4.96	4.59	3.74
Cumulative explained variance (%)		50.71					

Note. Items marked with "\*" are reverse-coded.

**Table 3** Model Fit Index According to Confirmatory Factor Analysis for RS-KTPL.

Criterion	$\chi^2 (p)$	df	CMIN/DF	GFI	CFI	TLI	RMSEA	SRMR
			<3.00	≥.90	≥.90	≥.90	≤.05	≤.08
1 <sup>st</sup> Study model	762.56 ( $p < .001$ )	449	1.70	.82	.83	.81	.06	.07
2 <sup>nd</sup> Modified model	502.17 ( $p < .001$ )	309	1.63	.85	.87	.86	.05	.07
3 <sup>rd</sup> Modification index applied	409.35 ( $p < .001$ )	298	1.37	.88	.93	.91	.04	.06

Note. CFI = comparative fit index; CMIN/DF = chi-square minimum/degree of freedom; GFI = goodness of fit index; RMSEA = root mean square error of approximation; SRMR = standardized root mean-square residual; TLI = Tucker–Lewis index.

$p < .01$ ), optimism ( $r = .50, p < .01$ ), regulation of emotion and cognition ( $r = .47, p < .01$ ), and self-efficacy ( $r = .56, p < .01$ ). However, the “homeostasis regulation” of RS-KTPL was not significantly correlated with the total CD-RISC score ( $r = .12$ ) and as the scores for each of the factors, with the exception of coping ( $r = .16, p < .05$ ), namely hardiness ( $r = .10$ ), adaptability/flexibility ( $r = .124$ ), meaningfulness/purpose ( $r = .07$ ), optimism ( $r = .03$ ), regulation of emotion and cognition ( $r = .80$ ), and self-efficacy ( $r = .11$ ).

**Reliability**

The Cronbach's  $\alpha$  of the RS-KTPL was .87, indicating good reliability. The half-split reliability of the tool was .81. By factors, Cronbach's  $\alpha$  ranged from .57 to .86 (Table 4).

**Discussion**

The RS-KTPL is a self-report questionnaire consisting of 6 factors and 27 items, each rated on a four-point Likert scale. To develop the scale, a literature review of previous studies and theoretical research analysis were conducted. Additionally, the items of the RS-KTPL were derived through a qualitative field study analysis, investigating the clinical symptoms and experiences of kidney transplant patients and the properties of resilience. Notably, the incorporation of Polk's resilience model, a middle-range nursing theory, structured the framework of the RS-KTPL, focusing on the specific situation of kidney transplantation. This application of the abstract concept of resilience in kidney transplant patients positions the RS-KTPL as a clinical indicator in nursing practice. Therefore, the RS-KTPL, developed based on previous research and



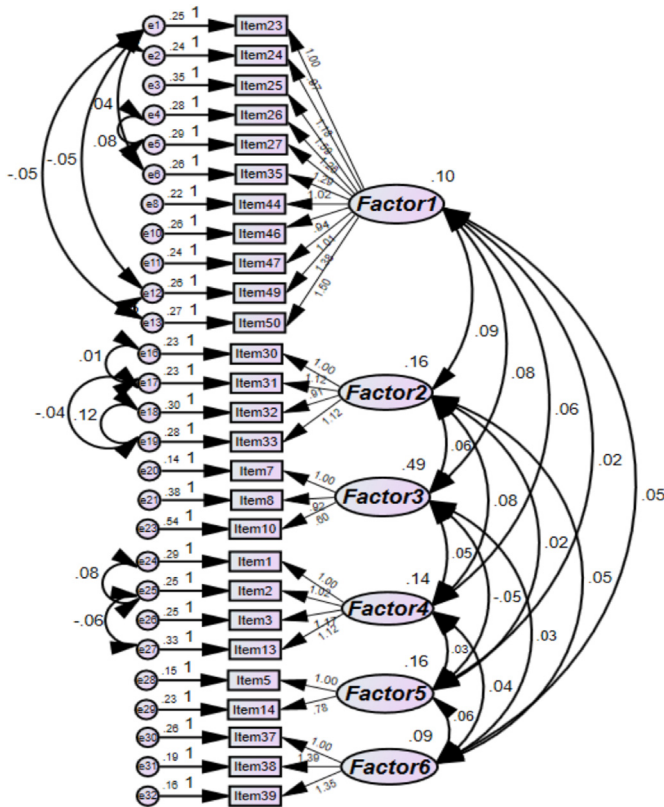


Figure 1. Confirmatory Factor Analysis for RS-KTPL. Note. Factor 1: Positive change of thoughts based on recovery beliefs; Factor 2: Supportive relationship with others; Factor 3: Self-awareness in negative psychological responses; Factor 4: Physical health regulation; Factor 5: Homeostasis regulation; Factor 6: Supportive relationship with healthcare staff.

theoretical evidence, can be considered a scale feasible for use in nursing settings, offering established objectivity and a rational basis for measuring resilience in kidney transplant patients.

For the development of the RS-KTPL, the first step was to conceptualize the construct of resilience in kidney transplant patients through theoretical research. The initial challenge emerged due to the scarcity of studies conceptualizing resilience among transplant patients, including those undergoing liver, heart, and lung transplants. Furthermore, generalizing items for the RS-KTPL solely based on theoretical research proved to be challenging. Therefore, individual interviews were conducted with kidney transplant patients as part of a field study to analyze the concept of resilience. This approach aimed to uncover and analyze empirical facts about resilience, validate theoretical research findings, and establish a scientific basis for applying these insights to the RS-KTPL items.

During the development stage, the resilience of kidney transplant patients was initially conceptualized as four dimensions (dispositional, relational, situational, and philosophical) and eight properties (physical health regulation, negative psychological response, coping strategies for recovery, positive thought transition, family support, socioeconomic support, self-awareness in a stress situation, and positive recovery beliefs). However, during the validation stages, these four dimensions and eight properties were abstracted to six factors. Although 51 items were initially derived during the development stage, the scale was finalized to 27 items after the validation stage, providing a more parsimonious and clear structure and allowing for a quick resilience assessment. Additionally, various indicators related to kidney transplantation, such as information

acquisition and sharing among transplant recipients, symptom management, compliance with treatment plans through consultations with medical staff [8,16–19,42], the establishment of inter-hospital cooperation [42], efforts to attain economic self-sufficiency, and economic support provided by government agencies or social institutions, were identified through theoretical and field research analyses during the development phases of the RS-KTPL [18]. However, some of these indicators were partially excluded during the evaluation phase. These indicators, which previously represented social and economic support, could be viewed as factors influencing resilience rather than attributes of resilience itself. Therefore, further discussion and re-evaluation through subsequent research on whether social and economic aspects impact resilience are necessary.

A unique aspect of this study is that Factor 3 of the final scale consists entirely of negatively worded items. Relying solely on positively worded items may reinforce cognitive biases; including negatively worded items can reduce response errors and enhance attention to the items [43]. Moreover, the inclusion of negatively worded items may mitigate the tendency to respond positively to similar items, regardless of the content of the question [43,44]. Thus, with both positively and negatively worded items, the RS-KTPL can be deemed an instrument fit to assist in reasonable decision-making with fewer errors from uncritical responses. However, combining positive and negative items might threaten internal validity during factor analysis after reverse coding of the negative items [44]. Therefore, careful attention should be given to the reverse coding of negative items when using the RS-KTPL, and the internal validity of the RS-KTPL items may need to be re-analyzed in the future. Additionally, the cumulative explained variance of the RS-KTPL in the EFA was somewhat low, at 50.71%. However, Henson and Roberts [45] pointed out that the cumulative percent explained variance can vary significantly across studies, highlighting the importance of considering the nature and meaning of the study data. Applying a uniform standard for cumulative explained variance is deemed unreasonable. Therefore, considering the significance of the content of each item, the RS-KTPL appears feasible for assessing resilience in kidney transplant patients.

This study identified several limitations. Specifically, the research conducted online and offline surveys in social network systems and limited medical institutions. Therefore, the representativeness of the subjects as kidney transplant patients is limited. Additionally, while all 270 (100%) respondents in the first main survey participated in online surveys, 141 (65.6%) participated in online and 74 (34.4%) in paper surveys in the second main survey. Considering the different means of participation, confirming whether participants responded through social network systems or via medical institution announcements was difficult, limiting the analysis of survey participation types. Finally, since the developed tool includes both positive and negative items, reverse coding must be performed with caution. There may also be a risk of inadequate reflection of responses for negative items, requiring careful interpretation of the results.

In summary, the RS-KTPL is a scale designed to assess self-awareness in negative psychological responses after kidney transplantation, patients' recovery beliefs, positive thinking, physical health regulation, the maintenance of homeostasis regarding drugs such as immunosuppressants, and relationships with family and others. Its scientific evidence has been established through a systematic process. Compared to instruments such as CD-RISC and RS that mainly assess psychosocial aspects, the RS-KTPL enables an analysis of the patient's recovery beliefs, personal strengths, and negative psychological states, and it facilitates the development of coping strategies for physical and mental health recovery by positively transforming thoughts. Moreover, it allows for evaluating the

**Table 4** Results of Construct Validity Verification Estimates, Convergent Validity, Discriminant Validity, and Reliability for RS-KTPL.

Factor	Items	Estimate			CR	AVE	Factor $r^2$						Cronbach $\alpha$	
		Unstandardized coefficient	Standardized coefficient	Standard error			1	2	3	4	5	6		
1	23	I accept the current situation positively.	1	.53									0.86	
	24	I am confident in overcoming difficult situations.	.97	.54	.15									
	25	I consider failure as a challenge.	1.17	.54	.21									
	26	I believe that I can give someone hope.	1.59	.39	.24									
	27	I believe that I can achieve my dreams if I overcome the challenges.	1.26	.60	.21									
	35	I gain a sense of accomplishment through daily life.	1.29	.62	.19									
	44	I have a positive self-awareness through problem-solving.	1.02	.57	.17									
	46	I pay attention to my inner self for introspection	.94	.50	.17									
	47	I am confident that I can overcome the challenges (side-effects, complications) associated with kidney transplantation.	1.01	.54	.17									
	49	I am confident of an optimistic future.	1.38	.65	.23									
50	I am confident that I can overcome any difficulty I encounter.	1.50	.68	.25										
2	30	I try to fulfill my roles as a member of my family.	1	.64		.86	.60	.69*** (.47)	1				0.75	
	31	I feel that I have grown as a valuable human being through my family's support.	1.12	.68	.17									
	32	I gain psychological stability through my relationships with others.	.91	.55	.17									
	33	I form a bond through relationships with others.	1.12	.64	.19									
3	*7	I feel anxious about resuming dialysis.	1	.88		.81	.59	.34*** (.12)	.24 (.06)	1			0.74	
	*8	I have a fear of kidney transplantation failure.	.93	.72	.12									
	*10	I feel psychologically pressured to recover.	.60	.49	.10									
4	1	I am consistently adhering to the diet regimen.	1	.57		.84	.57	.18*** (.03)	.52*** (.02)	0.20 (0.04)	1		0.71	
	2	I control the volume of water that I drink in a day.	1.02	.61	.15									
	3	I maintain a consistent body weight.	1.17	.66	.21									
	13	I exercise regularly.	1.12	.59	.21									
5	5	I adjust the dose of my drugs, such as immunosuppressants, based on my doctor's prescription.	1	.72		.81	.69	.53 (.28)	.15 (.02)	-0.17 (0.03)	0.19 (0.04)	1	0.57	
	14	I adhere to the immunosuppressant dosage schedule.	.78	.55	.21									
6	37	Empathy and consolation from the healthcare staff give me strength.	1	.50		.85	.66	.53*** (.28)	.44*** (.20)	0.17 (0.03)	0.37 (0.14)	0.48*** (0.23)	1	0.65
	38	I am continuously evaluated for symptom management through consultations with healthcare staff.	1.39	.68	.25									

Note:\*\*\* $P < .001$ , AVE = averaged variance extracted; CR = construct reliability. Items marked with "\*" are reverse-coded.

pathological characteristics of kidney transplant patients, such as the use of immunosuppressants, as well as supportive relationships with family, others, and healthcare staff, aiming for continuous health recovery. Given the lack of scales specifically measuring resilience for kidney transplant patients, the RS-KTPL demonstrates versatility in its application in the research of kidney transplant patients. Furthermore, it serves as foundational data for developing resilience scales for patients who have undergone other transplants.

## Conclusions

The RS-KTPL is a tool developed to measure the resilience of kidney transplant patients based on properties of resilience derived from a literature review and qualitative data analysis. It can serve as foundational data for analyzing the impact of resilience in kidney transplant patients and for interventional studies aimed at enhancing resilience. The RS-KTPL enables a meaningful assessment of resilience across various kidney transplant patient groups and can identify the impact of resilience on relationships with others. Additionally, self-assessment using this scale allows for evaluating one's level of resilience, facilitating the development of measures to improve resilience and set priorities. The RS-KTPL is expected to be utilized for identifying patients' needs and expectations, enhancing strengths, and increasing resilience through nursing education, provision of information, and systematic health management.

## Ethical approval

This study has been approved by the Institutional Review Board (IRB) of Seoul National University College of Medicine/Seoul National University Hospital (Approval Number: H-2201-062-1290). After IRB approval, permission was obtained from the specialists at Seoul National University Hospital, as well as the nursing staff and social support network system self-help group, for participant recruitment.

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## Data availability

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

## Conflict of interest

The authors declare no potential conflicts of interest.

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## Research Article

# Risk Prediction Model for Radiation-induced Dermatitis in Patients with Cervical Carcinoma Undergoing Chemoradiotherapy



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## ABSTRACT

**Purpose:** Radiation-induced dermatitis (RD) is a common side-effect of therapeutic ionizing radiation that can severely affect patient quality of life. This study aimed to develop a risk prediction model for the occurrence of RD in patients with cervical carcinoma undergoing chemoradiotherapy using electronic medical records (EMRs).

**Methods:** Using EMRs, the clinical data of patients who underwent simultaneous radiotherapy and chemotherapy at a tertiary cancer hospital between 2017 and 2022 were retrospectively collected, and the patients were divided into two groups: a training group and a validation group. A predictive model was constructed to predict the development of RD in patients who underwent concurrent radiotherapy and chemotherapy for cervical cancer. Finally, the model's efficacy was validated using a receiver operating characteristic curve.

**Results:** The incidence of radiation dermatitis was 89.5% (560/626) in the entire cohort, 88.6% (388/438) in the training group, and 91.5% (172/188) in the experimental group. The nomogram was established based on the following factors: age, the days between the beginning and conclusion of radiotherapy, the serum albumin after chemoradiotherapy, the use of single or multiple drugs for concurrent chemotherapy, and the total dose of afterloading radiotherapy. Internal and external verification indicated that the model had good discriminatory ability. Overall, the model achieved an area under the receiver operating characteristic curve of .66.

**Conclusions:** The risk of RD in patients with cervical carcinoma undergoing chemoradiotherapy is high. A risk prediction model can be developed for RD in cervical carcinoma patients undergoing chemoradiotherapy, based on over 5 years of EMR data from a tertiary cancer hospital.

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## Introduction

It is estimated that there are more than 604 thousand new cases of cervical carcinoma worldwide in 2020 [1] and more than 150 thousand deaths in 2022 in China [2]. Cervical carcinoma has the second-highest rate of morbidity and mortality after breast cancer in women worldwide [2]. The primary treatment options for cervical cancer are surgery, radiotherapy, and chemotherapy, which remain widely used. Single-treatment methods have limitations, and comprehensive treatment has become a hot topic in cervical cancer research and treatment trends.

Acute radiation-induced skin reactions are common side-effects of therapeutic ionizing radiation and are characterized by structural tissue damage, inflammation, and free-radical release [3]. Radiation-induced dermatitis (RD) is a reaction occurring as a result of exposure to biologically effective levels of ionizing radiation and is also referred to as radiation-induced skin toxicity (Common Terminology Criteria for Adverse Events [CTCAE] v4.03). After radiation therapy, damage to the skin is known as RD [4], and the outcome is a loss of skin barrier function caused by a reduction in stratum corneum hydration, an increase in transepidermal water loss, and an alteration in the skin pH [5]. In the early stages of radiation exposure, the skin may appear discolored, inflamed, and erythematous. In the chronic phase, radiation-induced fibrosis is a common pathology across various tissue types. Visible acute skin changes are determined by the dose, fractionation, irradiation volume, and radiosensitivity of the patient. These changes often lead to different types of discomfort such as itching, pain, and a diminished esthetic appearance, all of which affect patient quality of life and may delay cancer treatment [6,7]. According to reports, 4% to 52% of patients with cervical cancer who receive radiotherapy experience RD within 90 days [8–10]. Patients with cervical cancer are exposed to a large area of high-intensity radiation, especially in the perineal and perineal areas. The perineal skin is rich in peripheral nerves [11]; therefore, radiation can cause patients severe pain, and decreased activity and may be complicated by RD [8]. From the existing research on RD, which is caused by cervical cancer, it is less likely to attract more attention than head and neck and breast cancer radiotherapy [12–15], which means further attention is needed for RD among cervical cancer patients.

The development of RD in patients with cervical carcinoma undergoing chemoradiotherapy is linked to various demographic and medical factors [8]. However, the lack of systematic assessment tools that can accurately predict the risk of developing RD in patients with cervical carcinoma undergoing chemoradiotherapy remains a challenge. A reliable model could be created to predict RD using computer science and technology. The existing predictive models for RD are primarily for patients with head and neck cancers [12,13] or breast cancer [14,15]. In addition to single-factor analysis and logical regression, which are used to screen predictors of influencing factors and then construct prediction models, existing studies have taken full advantage of machine learning to predict the occurrence and severity of RD through supervised machine learning [16,17]. A Chinese study was conducted on 116 patients who received radiotherapy for cervical cancer, and logistic regression analysis was used to identify the influencing factors of RD [8]. A body mass index (BMI) of  $>28 \text{ kg/m}^2$ , the International Federation of Gynecology and Obstetrics (FIGO) stage IIa, conventional radiotherapy, and a history of diabetes were the factors identified to influence RD. The aforementioned research results provide useful references for selecting variables in this study.

Electronic medical records (EMRs) are commonly used for clinical decision support and surveillance of critical conditions [18]. In previous studies, researchers have successfully applied EMRs to construct a fall-risk prediction model [19] or combined it with chest

radiographs to predict lung cancer risk [20]. EMRs could also be used to improve the identification of patients with cervical carcinoma who are undergoing chemoradiotherapy and are at risk for developing RD. Sample selection based on EMRs can obtain data quickly and allows one to observe more metrics, on more individuals, at more timepoints, and a fraction of the cost of prospective cohort studies [21]. This study aimed to determine the prevalence of RD in patients with cervical cancer receiving chemoradiotherapy through the use of existing EMR data and develop and assess the performance of a risk prediction model to facilitate preventive measures.

## Methods

### *Setting and study population*

This retrospective study utilized the EMR data of Beijing Cancer Hospital over 5 years (2017.1–2022.8) to examine RD and predictors of RD among patients with cervical carcinoma undergoing chemoradiotherapy. Beijing Cancer Hospital is a tertiary and academic medical center. Patient data were retrospectively extracted, encrypted, and deidentified to protect the privacy of the patients. This study focused on diagnosis and prognosis and was approved by the institutional review board of the Beijing Cancer Hospital (Approved no.2022YJZ49). This study followed the Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis and Standards for the Reporting of Diagnostic Accuracy Studies reporting guidelines.

### *Patient eligibility and primary outcomes*

The inclusion criteria were as follows: (1) cervical cancer confirmed by tumor histology; (2) treatment with concurrent chemoradiotherapy; and (3) complete clinical data. The exclusion criteria were as follows: (1) previous history of trauma or radiotherapy; (2) metastatic cancer of the uterus; (3) primary malignant tumors in other sites, severe liver and kidney dysfunction, or nutritional and metabolic diseases; and (4) concurrent lactation.

According to the Prediction Model Risk Of Bias Assessment Tool [22,23], which was developed by a team led by Professor Moons at Utrecht University, when constructing a model in which the ratio of the number of study subjects with an outcome/candidate predictors is  $<10$ ; in addition to the quantitative assessment using various internal validation techniques, the parameters should be subsequently adjusted using shrinkage regression coefficients. If this is not done, the risk of bias will increase. Therefore, the sample size will be calculated based on the study's criterion of candidate predictors multiplied by 10. Assuming a candidate predictor of 10, the required sample size for the occurrence of the outcome is 100; assuming a 30% incidence of radiation dermatitis, the required sample size for inclusion in the modeling is 334 patients. The group ratio between the training and validation groups was 7:3, and the total sample size was 478.

Acute RISRs are primarily evaluated subjectively using visual classification systems such as the CTCAE and the Radiation Therapy Oncology Group/European Organization for Research and Treatment of Cancer [24,25]. The primary outcome of RD was the uniform standard according to the CTCAE, including grades 1–5, from faint erythema or dry desquamation to death. In this study, the RD was modeled in Y/N Categories.

### *Development and validation cohorts*

The original data in this study were derived from two databases. The first is the outpatient radiotherapy-patient database

established by the radiotherapy department outpatient clinic in mid-October 2017; this represented dataset 1 of cervical cancer patients who had undergone radiotherapy in the outpatient clinic since its establishment until August 2022 ( $n = 1498$ ). The second is the electronic database of cervical cancer patients in the radiotherapy ward from January 2017 to August 2022 extracted by the hospital information department using the keywords cervical cancer and chemotherapy (1029 total cases, with 4 data duplicates and 1025 final cases). We then performed data matching between dataset 1 and dataset 2 to generate three new types of datasets: dataset a ( $n = 852$ ) of cervical cancer patients who underwent radiotherapy and chemotherapy simultaneously with successful matching; dataset b ( $n = 133$ ) of patients who failed matching and underwent chemotherapy but did not have available outpatient radiotherapy records; and the dataset c ( $n = 40$ ) dated from January 2017 to October 2017 that could not be undergoing computerized data matching and required manual checking at a later stage. We merged dataset a with dataset c to form the data pool to be checked.

The researcher provided an interpretation of the related data to the three investigators and elucidated the methods for data extraction. Following this, the three investigators independently extracted 10 case data, including verifying essential patient information, data-simplifying predictors, and data extraction for outcome variables. The investigators then verified the data together to communicate about any inconsistencies and then reached a consensus. This process was performed to ensure the quality of manual checking between investigators and to avoid data bias due to manual checking. The investigators checked the pooled data item by item. The data that met the inclusion and exclusion criteria were screened, and a prediction model dataset was established. The data-screening process is presented in [Figure 1](#).

The final dataset included 626 patients and excluded 253 patients. The entire group was assigned randomly (using Stata random generation) to either the training or validation cohort (group ratio 7:3).

#### *Predictors of RD in the EMR*

We collected patient demographic information including age, marital status, BMI, history of smoking, alcohol consumption, diabetes, hypertension, and Eastern Cooperative Oncology Group performance status. The clinical information included tumor diameter ( $\leq 4$  cm or  $> 4$  cm), clinicopathological stage, lymph node metastasis status, serum albumin (ALB) concentration after chemoradiotherapy, absolute lymphocyte count after chemoradiotherapy, after surgery, neoadjuvant chemotherapy, targeted therapy, concurrent chemotherapy (single-drug or multidrug combination), concurrent chemotherapy cycles, total dose of radiotherapy, total dose of afterloading radiotherapy, and the days between beginning and conclusion of radiotherapy.

#### *Statistical analysis*

The data were divided into a training set ( $N = 438$ ) and a testing set ( $N = 188$ ).

All the statistical procedures were conducted using SPSS 26.0 and R software. The demographic and clinical variables and the RD are presented as the mean, standard deviation, median, frequency, and percentage. Fisher's exact test and  $\chi^2$  tests were used to compare the variables. The selection of predictive variables and the construction and validation of models were based on existing complete data. Variables that demonstrated differences between the two groups or were clinically meaningful were included in the Least Absolute Shrinkage and Selection Operator (LASSO) [26] to

pare down the large list of potential predictor variables. LASSO tends to produce zero coefficients, improving prediction accuracy by allowing bias to reduce variance [27]. The system determines the  $\lambda$  value by cross validation, and the principle of determining the value is to minimize the mean square error of the Lasso model [28]. As  $\lambda$  decreases, the model can select an increased number of predictor variables, and there may be a greater number of coefficients (or weights) that have non-zero value. The  $\lambda$  value is determined through cross validation during the statistical process to achieve the best effect of variable selection;  $\lambda = 0.01$  was used in this study. The variables selected from the LASSO procedure were included in a logistic regression model. The resulting model produced bias-corrected point estimates for the final output. To evaluate the reliability of the predictive model, its discrimination and calibration were analyzed. The area under the receiver operating characteristic curve (AUC) was used to assess the discriminatory ability of the predictive model. A Hosmer–Lemeshow goodness-of-fit test was conducted to test the calibration of the model. The final model trained on the training dataset was applied to the testing dataset. The AUC, sensitivity, and specificity were then estimated. A significance level of  $\alpha = 0.05$  was used.

## **Results**

### *Demographic and clinical characteristics*

During an over 5-year period, 626 patients received chemoradiotherapy and met the exclusion and inclusion criteria. The patient characteristics for both the training and testing sets are provided in [Table 1](#). The training set and testing set did not significantly differ in the terms of demographic or clinical characteristics.

Among the 626 patients, 548 patients (87.5%) developed grade 1 RD, 11 patients (1.8%) developed grade 2 RD, and only 1 patient (0.2%) developed grade 3 RD. The total incidence of radiodermatitis was 89.5% (560/626), with incidences of 88.6% (388/438) in the training group and 91.5% (172/188) in the testing group. The rates of RD in the two groups were not significantly different ( $\chi^2 = 3.65$ ,  $p = .302$ ).

### *Predictive model selection and predictor screening*

Using the occurrence of radiation dermatitis as the dependent variable, univariate analyses of the training group revealed that single or multiple drugs for concurrent chemotherapy and the total dose of afterloading radiotherapy influenced the development of RD ( $p < .05$ ). (See [Table 2](#)).

Age, boost dose for the lymph nodes, total dose of afterloading radiotherapy, single or multiple drugs for concurrent chemotherapy, days between the beginning and conclusion of radiotherapy, and serum ALB concentration after chemoradiotherapy were identified as the key predictors through LASSO regression. The variables with total importance scores near 60.0% (more than 5.0%) according to the random forest model were the serum ALB concentration after chemoradiotherapy, the total dose of afterloading radiotherapy, the days between the beginning and conclusion of radiotherapy, age, the absolute lymphocyte count after chemoradiotherapy, and BMI. After conducting the above analysis, we included a total of 8 variables in the binary regression analysis, including age, BMI, boost dose for the lymph nodes, the total dose of afterloading radiotherapy, the days between the beginning and conclusion of radiotherapy, the serum ALB after chemoradiotherapy, the use of single or multiple drugs for concurrent chemotherapy, and the absolute lymphocyte count after chemoradiotherapy. After excluding the BMI, the absolute lymphocyte count after chemoradiotherapy, and the boost dose for the lymph

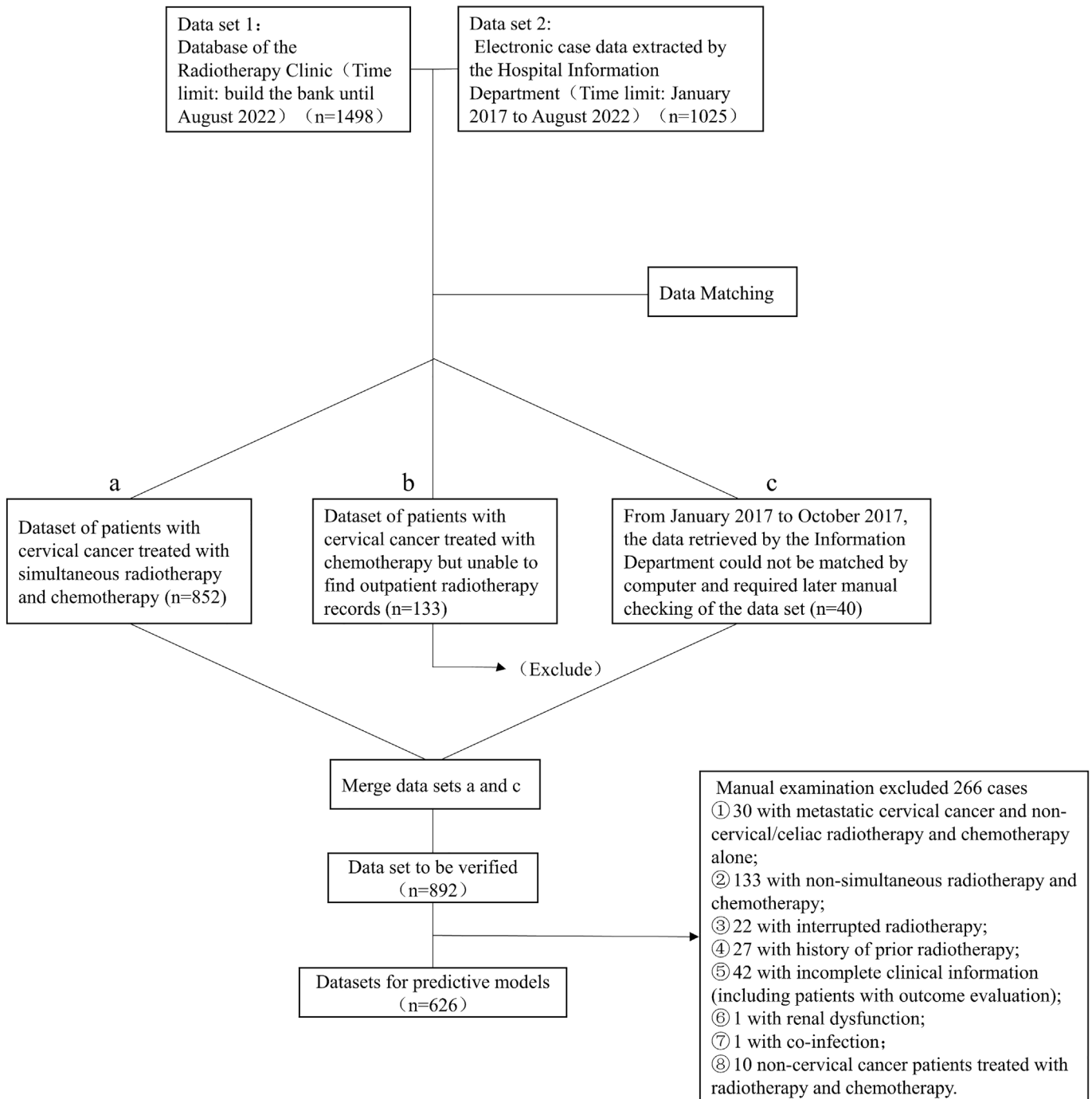


Figure 1. Data Screening Process.

nodes, the binary regression model was found to be effective ( $p < .05$ ).

Construction and validation of the visual predictive model

A visual nomogram prediction model based on a logistic model was developed to predict RD risk in patients with cervical carcinoma undergoing chemoradiotherapy (Figure 2). Age, the days between the beginning and conclusion of radiotherapy, the serum ALB concentration after chemoradiotherapy, the use of single or

multiple drugs for concurrent chemotherapy, and the total dose of afterloading radiotherapy were the five identified predictive factors. After the individual's predictive variable values are confirmed, they can be substituted into the visual model to calculate the total score and determine the outcome risk.

The nomogram calibration curves exhibit good concordance, indicating that the model can be used to predict RD risk in patients with cervical carcinoma undergoing chemoradiotherapy (Figure 3(A)). The Hosmer and Lemeshow test results for the total group were  $\chi^2 = 6.41, p = .601$ ; those for the training group were

**Table 1** Demographic and Clinical Characteristics of the Training and Testing Sets.

Characteristics	Total (n = 626)	Training set (n = 438)	Testing set (n = 188)	p
Age	53.44 ± 9.85	53.42 ± 9.87	53.50 ± 9.81	.924
Marital status				.662
Single or divorced	52 (8.3)	35 (8.0)	17 (9.0)	
Married	574 (91.7)	403 (92.0)	171 (91.0)	
BMI	24.36 ± 3.46	24.33 ± 3.54	24.44 ± 3.30	.709
Smoking history				.641
No	592 (94.6)	413 (94.6)	179 (95.2)	
Yes	34 (5.4)	25 (5.7)	9 (4.8)	
Alcohol consumption history				.219
No	596 (95.2)	414 (94.5)	182 (96.8)	
Yes	30 (4.8)	24 (5.5)	6 (3.2)	
History of diabetes				.718
No	586 (93.6)	409 (93.4)	177 (94.1)	
Yes	40 (6.4)	29 (6.6)	11 (5.9)	
History of hypertension				.278
No	503 (80.4)	347 (79.2)	156 (83.0)	
Yes	123 (19.6)	91 (20.8)	32 (17.0)	
ECOG performance status				.931
0	214 (34.3)	150 (34.4)	64 (34.0)	
1/2	410 (65.7)	286 (65.6)	124 (66.0)	
Tumor diameter				.443
≤4 cm	325 (51.9)	223 (50.9)	102 (54.3)	
>4 cm	301 (48.1)	215 (49.1)	86 (45.7)	
Clinicopathological stage				.319
I	182 (29.4)	125 (28.9)	57 (30.8)	
II	226 (36.6)	151 (34.9)	75 (40.5)	
III	174 (28.2)	130 (29.9)	44 (23.8)	
IV	36 (5.8)	27 (6.2)	9 (4.9)	
Lymph node metastasis status				.077
No	174 (27.8)	131 (29.9)	43 (23.0)	
Yes	451 (72.7)	307 (70.1)	144 (77.0)	
Serum ALB concentration after chemoradiotherapy	42.96 ± 3.85	43.06 ± 3.82	42.71 ± 3.90	.299
Absolute lymphocyte count after chemoradiotherapy	36.00 [25.00,50.25]	36.00 [25.00,50.00]	37.50 [23.25,53.00]	.635
After surgery				.641
No	516 (82.4)	359 (82.0)	157 (83.5)	
Yes	110 (17.6)	79 (18.0)	31 (16.5)	
Neoadjuvant chemotherapy				.157
No	487 (77.8)	334 (76.3)	153 (81.4)	
Yes	139 (22.2)	104 (23.7)	35 (18.6)	
Targeted therapy				.774
No	573 (91.5)	400 (91.3)	173 (92.0)	
Yes	53 (8.5)	38 (8.7)	15 (8.0)	
Bevacizumab	9 (1.5)	6 (1.4)	3 (1.6)	
Endostar	19 (3.0)	11 (2.5)	8 (4.3)	
Nitoxizumab	25 (4.0)	21 (4.8)	4 (2.1)	
Concurrent chemotherapy				.630
Single-drug	431 (68.8)	299 (68.3)	132 (70.2)	
Cisplatin	412 (65.8)	287 (55.6)	125 (66.5)	
Nedaplatin/carboplatin/lobaplatin	19 (3.0)	12 (2.7)	7 (3.7)	
Multi-drug combination	195 (31.2)	139 (31.7)	56 (29.8)	
TP	167 (26.7)	120 (27.4)	47 (25.0)	
TN/TC/TL/EP	28 (4.5)	19 (4.3)	9 (4.8)	
Concurrent chemotherapy cycles				.439
1	60 (9.6)	43 (9.8)	17 (9.0)	
2	152 (24.3)	109 (24.9)	43 (22.9)	
3	148 (23.6)	103 (23.5)	45 (23.9)	
4	114 (18.2)	71 (16.2)	43 (22.9)	
5	97 (15.5)	70 (16.2)	27 (14.4)	
6	55 (8.8)	42 (9.6)	13 (6.9)	
Boost dose for lymph node	60.00 [60.00,60.00]	60.00 [60.00,60.00]	60.00 [60.00,60.00]	.339
Exposure dose for lesions and lymphatic drainage	45.00 [45.00,45.00]	45.00 [45.00,45.00]	45.00 [45.00,45.00]	.199
The total dose of afterloading radiotherapy	2100.00 [1622.50,2800.00]	2100.00 [1595.00,2800.00]	2100 [1670.00,2800.00]	.614
The number of days between the beginning and after radiotherapy	42.76 ± 9.41	42.82 ± 9.06	42.62 ± 10.19	.801

Note: ALB = albumin; BMI = body mass index; ECOG = Eastern Cooperative Oncology Group; TP = paclitaxel + cisplatin; TN/TC/TL/EP = paclitaxel + nedaplatin/paclitaxel + carboplatin/paclitaxel + lobaplatin/etoposide + cisplatin.

$\chi^2 = 8.58, p = .379$ ; and those for the testing group were  $\chi^2 = 10.03, p = .263$ . There was no significant difference between the current model and the ideal perfect model. Additionally, the C-index was acceptable in all groups, including the total group, training group, and testing group, with scores of 0.66 (95% confidence interval [CI]: 0.59–0.73), 0.63 (95% CI: 0.54–0.72), and 0.74 (95% CI: 0.63–0.85), respectively. The overall sample achieved an AUC value of 0.66,

whereas the training and testing groups achieved values of 0.63 and 0.74, respectively (Figure 3(B)).

## Discussion

In this study, LASSO and random forest were used to obtain the most dominant factors influencing RD. The predictive



**Table 2** Differences in Demographic and Clinical Characteristics between Patients with and without Radiation-Induced Dermatitis in the Training Group.

Characteristics	With RD (n = 388)	Without RD (n = 50)	t/F/ $\chi^2$	p
Age	53.29 ± 10.03	54.42 ± 8.55	.76	.446
Marital status			.70	.404
Single or divorce	29 (7.5)	6 (12.0)		
Married	359 (92.5)	44 (88.0)		
BMI	24.34 ± 3.57	24.22 ± 3.32	-0.23	.820
Smoking history			.77	.381
No	364 (93.8)	49 (98.0)		
Yes	24 (6.2)	1 (2.0)		
Alcohol consumption history			.03	.874
No	366 (94.3)	48 (96.0)		
Yes	22 (5.7)	2 (4.0)		
History of diabetes			.24	.624
No	361 (93.0)	48 (96.0)		
Yes	27 (7.0)	2 (4.0)		
History of hypertension			1.58	.210
No	304 (78.4)	43 (86.0)		
Yes	84 (21.6)	7 (1.0)		
ECOG performance status			1.44	.229
0	129 (33.4)	21 (42.0)		
1/2	257 (66.6)	29 (58.0)		
Tumor diameter			.22	.643
≤4 cm	196 (50.5)	27 (54.0)		
>4 cm	192 (49.5)	23 (46.0)		
Clinicopathological stage			1.64	.650
I	114 (29.6)	11 (22.9)		
II	132 (34.3)	19 (39.6)		
III	114 (29.6)	16 (33.3)		
IV	25 (6.5)	2 (4.2)		
Lymph node metastasis status			.94	.332
No	119 (30.7)	12 (24.0)		
Yes	269 (69.3)	38 (76.0)		
Serum ALB concentration after chemoradiotherapy	43.05 ± 3.76	43.15 ± 4.30	.181	.857
The absolute lymphocyte count after chemoradiotherapy	35.00 [25.00,43.00]	41.00 [30.00,50.25]	-1.691	.091
After surgery			.15	.701
No	319 (82.2)	40 (80.0)		
Yes	69 (17.8)	10 (20.0)		
Neoadjuvant chemotherapy			2.13	.145
No	300 (77.3)	34 (68.0)		
Yes	88 (22.7)	16 (32.0)		
Targeted therapy			1.33	.248
No	357 (92.0)	43 (86.0)		
Yes	31 (8.0)	7 (14.0)		
Bevacizumab	4 (1.0)	2 (4.0)		
Endostar	10 (2.6)	1 (2.0)		
Nitoxizumab	17 (4.4)	4 (8.0)		
Concurrent chemotherapy			3.92	.048*
Single-drug	271 (69.8)	28 (56.0)		
Cisplatin	259 (66.8)	28 (56.0)		
Nedaplatin/carboplatin/lobaplatin	12 (3.0)	0 (0)		
Multidrug combination	117 (30.2)	22 (44.0)		
TP	103 (26.6)	17 (34.0)		
TN/TC/TL/EP	14 (3.6)	5 (10.0)		
Concurrent chemotherapy cycles			2.77	.736
1	36 (9.3)	7 (14.0)		
2	95 (24.5)	14 (28.0)		
3	92 (23.7)	11 (22.0)		
4	65 (16.8)	6 (12.0)		
5	64 (16.5)	6 (12.0)		
6	36 (9.3)	6 (12.0)		
Boost dose for lymph node	60.00 [60.00,60.00]	60.00 [60.00,60.00]	-0.03	.978
Exposure dose for lesions and lymphatic drainage	45.00 [45.00,45.00]	45.00 [45.00,45.00]	-1.57	.117
The total dose of afterloading radiotherapy	2100.00 [1870.00,2800.00]	2080.00 [1362.50,2715.00]	-2.07	.038*
The number of days between the beginning and conclusion of radiotherapy	43.07 ± 8.91	40.88 ± 10.04	-1.62	.107

Note: ALB = albumin; BMI = body mass index; ECOG = Eastern Cooperative Oncology Group; RD = radiation-induced dermatitis; TP = paclitaxel + cisplatin; TN/TC/TL/EP = paclitaxel + nedaplatin/paclitaxel + carboplatin/paclitaxel + lobaplatin/etoposide + cisplatin; \*p < 0.05.

factors included age, the days between the beginning and conclusion of radiotherapy, the serum ALB concentration after chemoradiotherapy, the use of single or multiple drugs for concurrent chemotherapy, and the total dose of afterloading radiotherapy. A predictive model was developed to identify the risk of RD in

patients with cervical cancer receiving chemoradiotherapy. To compare the RD risk in cervical cancer patients to RD in patients with head and neck and breast cancer and to explore the factors influencing RD in cervical cancer patients, the predictive model was assessed in greater detail in the testing group, and RD was found to

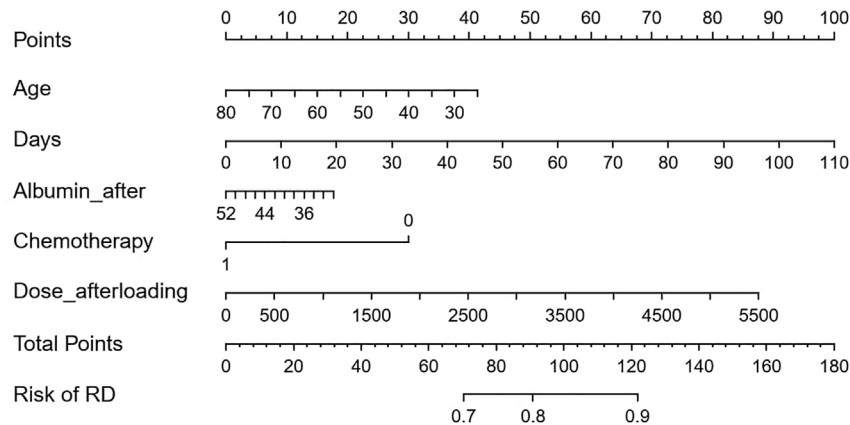


Figure 2. Nomogram Prediction Model for RD Risk in Patients with Cervical Carcinoma Undergoing Chemoradiotherapy. Note: Days means the number of days between the beginning and conclusion of radiotherapy. Albumin\_after means serum albumin (ALB) concentration after chemoradiotherapy. Chemotherapy means the single or multiple drugs for concurrent chemotherapy (1: multiple drugs, 0: single drug). Dose\_afterloading means the total dose of afterloading radiotherapy. Abbreviation: RD = radiation-induced dermatitis.

have an accepted predictive ability and performance in clinical decision-making. This study validated the practicality of using EMRs to assess a large sample of cervical cancer patients, quantified the impact of variables on RD, and presented a model visualized through a nomogram.

As RD affects patient quality of life, it is important to conduct individualized risk assessments of patients to identify those patients most at risk of developing RD. A scoring system divided 101 patients with head and neck cancer into three subgroups based on their  $V_{60Gy}$ , concurrent chemotherapy status, age, and BMI, with 0–1, 2–3, and 4–6 points and revealed a significant difference in the incidence of Grade 3 dermatitis among the three subgroups after recursive partitioning analysis [13]. A predictive model for grade 4+ RD in 455 breast cancer patients undergoing radiotherapy, in which the prediction variables included BMI, diabetes status, smoking history, higher ferritin levels, higher high-sensitivity C-reactive protein (hs-CRP) levels, and higher CD3 + T lymphocytes before radiotherapy, was developed through multivariate logistic regression analysis [15]. A nomogram was also constructed, and the AUC was .80 (95% CI: 0.75–0.86) [15]. Overall, the variables in the RD prediction models in different types of cancer were similar to the results of our study, confirming that RD has predictive value for including other treatment-related factors, such as chemotherapy and patient characteristics, such as age and BMI, in addition to radiation therapy itself. The performance of the prediction models makes them more discriminative than any single factor in predicting RD.

RD is a dose-dependent toxic effect. Accurately measuring the radiation absorption dose at the skin-entrance site is difficult. Therefore, the exact radiation exposure dose can only be estimated indirectly by using radiation emission rate and exposure time [29]. The results of our study confirmed that the total dose of afterloading radiotherapy was the factor that led to RD. It should be considered that multiple cumulative exposures were also an important aspect of time accumulation for dose accumulation. This also explains the increasing number of days between the beginning and conclusion of radiotherapy in the model group and greater points obtained, which further increases the risk of RD.

Our results demonstrated that the serum ALB concentration after chemoradiotherapy was a predictive factor. This factor was not included in a previous study on the analysis of influencing factors [8]. Yang et al investigated the link between prediagnostic serum ALB levels and cancer risk. Their findings suggested that there is an inverse and linear association between prediagnostic serum ALB

levels and cancer risk in the Chinese population [30]. ALB trajectories after peritoneal dialysis are better predictors of mortality risk than initial serum ALB levels. This suggests that the serum ALB concentration may be valuable for predicting and stratifying cancer risk. All of the aforementioned studies provide a reference for this study to include this index. The results also suggest that the serum ALB concentration after chemoradiotherapy is valuable for predicting RD risk.

In our study, age and the use of single or multiple drugs for concurrent chemotherapy were found to be significant predictors of RD and were also shown to be predictors of acute RD in patients who were diagnosed with head and neck cancer and treated with intensity-modulated radiotherapy [13]. Older patients may exhibit delayed wound repair [13]. However, in our study, there were few points associated with older age, so the risk of RD was low. This may be because younger patients are more sensitive to the occurrence of perineal-site RD and are thus more likely to report the occurrence of RD earlier. Platinum-based single-agent concurrent chemotherapy during radiotherapy is a common regimen for patients with intermediate to advanced cervical cancer [31]. In recent years, it has been shown that cisplatin-based doublets, especially cisplatin and paclitaxel, are more effective than cisplatin alone in terms of response rate and progression-free survival for patients with advanced cervical cancer [32]. A study [33] of patients with stage II to IV cervical cancer confirmed that the combination of paclitaxel and platinum was safer than single-agent cisplatin-concurrent radiotherapy, with a lower incidence of leukopenia, thrombocytopenia, nausea and vomiting, and diarrhea among the known indicators. In our study, most of the single drug used for concurrent chemotherapy was cisplatin, and most of the multidrug combinations used for concurrent chemotherapy were cisplatin plus paclitaxel. Moreover, combination chemotherapy has little risk for RD. It should be noted that this study focused only on the number of concurrent anticancer agents and did not compare the types and dosages of different anticancer agents, which limits the interpretation of anticancer agents in the model.

Consequently, this model can predict the risk of RD in patients with cervical carcinoma who are undergoing chemoradiotherapy at an early stage. The findings will assist in individualizing the evaluation, education, and treatment of patients undergoing chemoradiotherapy. It can be embedded into medical or nursing information systems to create a method of risk assessment for skin reactions and further develop RD warning tools for use in radiation therapy nursing. This can allow for early clinical intervention in

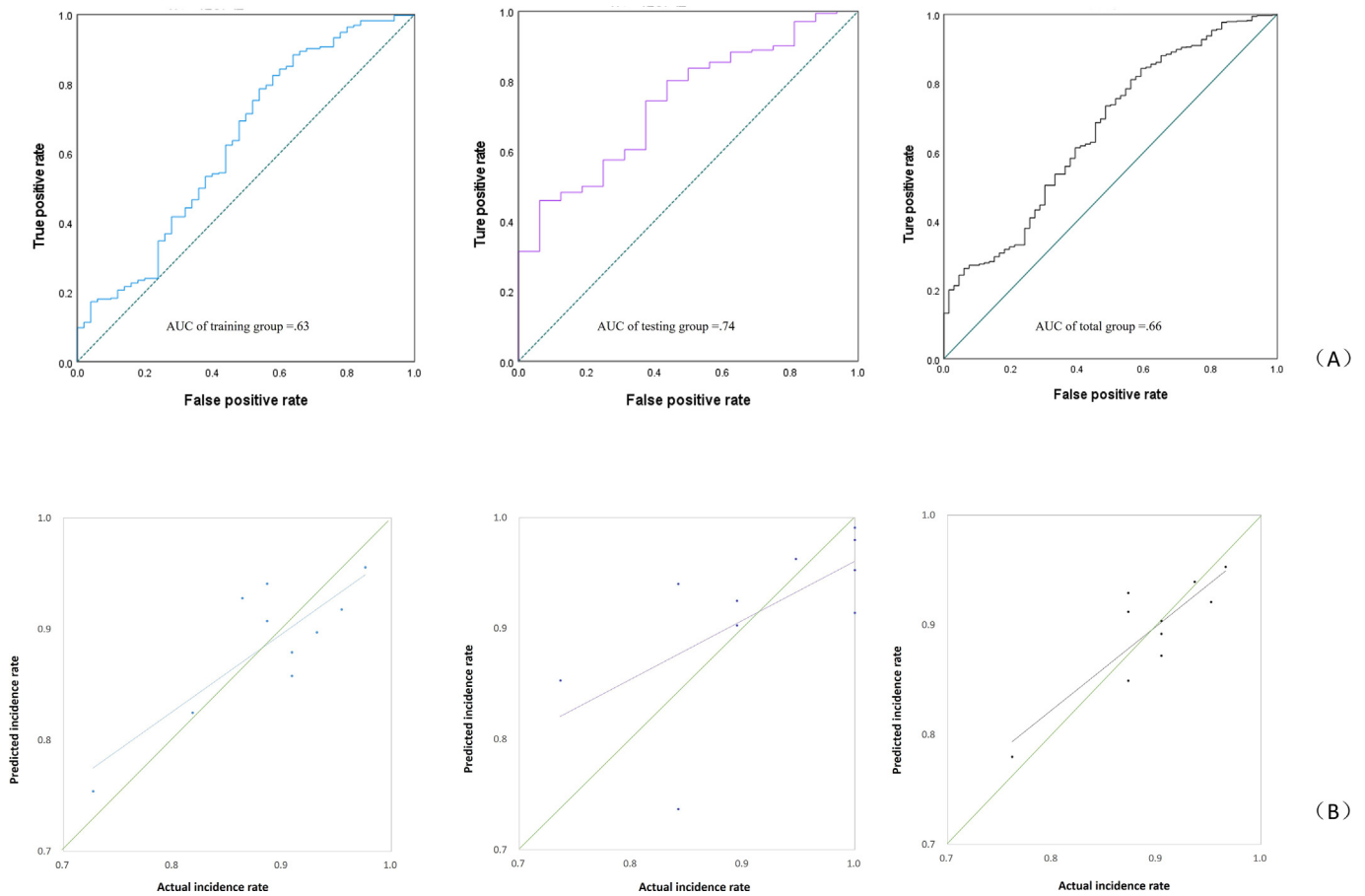


Figure 3. (A) ROC Curve. The AUC values for the training group (blue), the testing group (green), and the total group (black) were 0.63, 0.74, and 0.66, respectively. (B) Calibration curve of a model for predicting RD in patients with cervical carcinoma undergoing chemoradiotherapy. The closer combination of the dotted and solid lines indicates better predictive power. The training group (blue), the testing group (purple), and the total group (black). Abbreviations: AUC = area under the receiver operating characteristic curve; RD = radiation-induced dermatitis; ROC = area under the receiver operating characteristic curve.

patients with cervical cancer undergoing chemoradiotherapy to reduce the severity of skin reactions, especially for individuals at high risk of RD, improving long-term quality of life. From the perspective of prediction model development, the study will provide a basis for researchers to compare risk prediction models [34].

This article demonstrates the potential of using EMR data to construct predictive models for improving care in cervical carcinoma patients at risk of RD who are undergoing chemoradiotherapy. However, there is room for improvement. First, the research was conducted at a single institution, and further evaluation of the generalizability of the model through additional multicentre studies is necessary. Second, patients are the first to identify symptoms, but they are less likely to report at an early stage before the doctor discovers RD. Due to the reliance on self-reports, there may be discrepancies between patients' self-reports and the model's results. Therefore, a prospective study could help construct a more effective model. Third, in this study, through cooperation with the information department, the patients for the model and the needed predictive variables were obtained, but the patients' relevant test results that were not in our hospital could not be obtained directly and required resources such as natural language processing that extend beyond our current work; therefore, our team spent considerable time collating the data through the EMR further by manual checking to find the corresponding variable information. Finally, although EMR data were used to obtain the model's results, external data such as additional test

results were not directly included. Utilization of such external data may be necessary for future research endeavors. Therefore, the model provides the foundation for future research, and further studies are necessary to improve its sensitivity and specificity.

## Conclusion

In conclusion, we developed and validated a risk prediction model for RD in patients with cervical carcinoma undergoing chemoradiotherapy, based on data from more than 5 years of EMR data from a tertiary cancer hospital. The developed model utilized predictors that are commonly available or easily obtainable in general clinical or primary care settings. The model demonstrated acceptable performance in terms of both discrimination and calibration. It can be used as a foundation for future research aimed at creating a practical tool for identifying individuals at high risk for RD.

## Abbreviations

ALB: Albumin; CTCAE: Common Terminology Criteria for Adverse Events; ECOG: Eastern Cooperative Oncology Group; EMRs: Electronic medical records; FIGO: International Federation of Gynecology and Obstetrics; hs-CRP: high-sensitivity C-reactive protein; LASSO: Least Absolute Shrinkage and Selection Operator; PROBAST: Prediction Model Risk Of Bias Assessment Tool; RD:

Radiation-induced dermatitis, Radiodermatitis; ROC: Receiver operating characteristic; RT: Radiation therapy; RTOG/EORTC: Radiation Therapy Oncology Group/European Organization for Research and Treatment of Cancer; STARD: Standards for the Reporting of Diagnostic Accuracy Studies; TEWL: Trans-epidermal water loss; TRIPOD: Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis

### Ethics approval and consent to participate

The work described has been conducted following accepted national and international standards. This study was approved by the Institutional Review Board of the Beijing Cancer Hospital (Approved no.2022YJZ49).

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None.

### Authors' contributions

Hong YANG (First Author): Analyzed and interpreted patient data related to hematological diseases and transplants, developed the conceptual framework, contributed to the design and implementation of the methodology, conducted software analysis, curated data, performed formal analysis, created visualizations, and drafted the original manuscript.

Yaru ZHANG and Fanxiu HENG (First Author): Contributed to conceptualization, curated data, managed project resources, and provided supervision.

Wen LI, Yumei FENG, Jie TAO: Assisted in data curation.

Lijun WANG: Conducted data curation.

Zhili ZHANG: Participated in data curation and created visualizations.

Xiaofan LI, Yuhan LU (Corresponding Author): Conceptualized the study, developed the methodology, provided supervision throughout the project, contributed to the review and editing of the manuscript. All authors read and approved the final manuscript.

### Consent for publication

Not applicable.

### Availability of data and materials

Research data are stored in an institutional repository and will be shared upon request to the corresponding author.

### Conflict of interest

The authors declare that they have no conflict of Interest.

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## Review Article

# Factors Associated With Health-promoting Behaviors Among Nurses in South Korea: Systematic Review and Meta-analysis Based on Pender's Health Promotion Model



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## SUMMARY

**Purpose:** Although the importance of health promotion for nurses is increasing, there is a lack of meta-analyses targeting nurses in the world. This study aimed to identify the effect sizes between the health-promoting behaviors and related variables of nurses working in Korea. **Methods:** Systematic review and meta-analysis were conducted according to the PRISMA and MOOSE guidelines. The literature included in this meta-analysis was published between 1994 and 2022 in core databases such as KMBASE, KISS, KoreaMed, ScienceON, DBpia, NAL, RISS, CINAHL, CENTRAL, WoS, PubMed, and hand searched. In this study, the PICO-SD framework was applied with Participants being nurses actively working in various healthcare settings across Korea, and for a more comprehensive search, intervention and comparisons were not set. The outcomes measured were nurses' health-promoting behaviors, assessed using structured tools. The study design included observational studies. The Comprehensive Meta-Analysis and the R software program were used for meta-analysis. **Results:** In total, 50 articles were selected for the systematic review and meta-analysis. The total effect size of the 50 articles was moderate (correlation effect size [ESr] = 0.30). The individual variables presented in the 50 articles were classified into nine sub-categories according to Pender's Health Promotion Model (HPM). Among them, situational influences demonstrated the largest effect size (ESr = 0.44, number of studies [k] = 2), followed by perceived self-efficacy (ESr = 0.39, k = 10) and activity-related affect (ESr = 0.32, k = 12). **Conclusions:** To achieve the optimal health status of nurses through health promotion intervention programs, these effective variables – situational influences, perceived self-efficacy, and activity-related affect – should be considered when developing the intervention program for nurses. **Registration:** CRD42022299907.

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## Introduction

Nurses have been practicing as advocates of health in various settings, including hospitals, schools, and communities, to bring about better outcomes for nursing clients [1]. The focus of nursing

has been on individuals, families, and communities [2], but nurses who provide this care are also other clients of nursing care. Thus, it is also essential to maintain and promote nurses' health as clients, as well as caregivers.

However, previous studies reported that nurses experienced higher levels of anxiety and depression than doctors during the COVID-19 pandemic [3]. Among the 13 studies analyzed through a systematic review, six studies that investigated the prevalence of anxiety among nurses and doctors during the COVID-19 pandemic found that the anxiety prevalence rate was 25.8% for nurses and 21.7% for doctors [3]. Additionally, five studies on the prevalence of depression reported that nurses had a higher depression prevalence rate of 30.3%, compared to 25.3% for doctors [3]. Nurses who provide direct nursing care had a particularly high prevalence of stress, anxiety, and sleep disorders [4]. A study of nurses in Korea

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found that 42.6% experienced moderate or higher levels of depression, and only 28.2% responded that their health was good [5]. Consequently, efforts were suggested to improve the health status of nurses.

Health-promoting behaviors refer to a healthy lifestyle in which individuals or groups actively respond to their environment and maintain optimal well-being not only to prevent diseases but also for better health and the promotion of self-realization and personal satisfaction [6]. When health-promoting behaviors are integrated with a healthy lifestyle in all aspects of life, quality of life is improved throughout life [6].

Nurses are professionals who spend the longest time with patients in healthcare settings and provide nursing care, so the nursing practice settings where they work should advocate for and support nurses' health. However, nursing work environments that include heavy work, night shifts, and irregular work act as obstacles to the ability of nurses to practice health-promoting behaviors [7–9]. In addition, nurses were reported to lack physical activity or motivation to take care of their health [7,9–11]. Although nurses have sufficient knowledge about health and health promotion, they have difficulties applying it. Low sleep quality and irregular eating habits were shown to contribute to the increasing turnover rates of nurses [12], suggesting that nurses' insufficiently healthy lifestyles negatively impact the individual as well as the organization.

In contrast, nurses' health-promoting behaviors not only improve the health and satisfaction of individual nurses but also positively affect the productivity of nursing organizations. Previous research related to the health-promoting behaviors of nurses has reported that higher levels in sub-domain of health-promoting behaviors, such as health responsibility, spiritual growth, lead to improved quality of nursing performance [10] and increased job satisfaction [13]. In addition, since the level of health-promoting behaviors of nurses is related to the health outcomes of patients [13], their role in health promotion and disease prevention becomes even more crucial. As educators and role models, nurses' health-promoting behaviors are essential for the well-being of both patients and nurses in healthcare settings [1]. These findings suggest that nurses' health-promoting behaviors have important implications in nursing practice. Therefore, there is a need to broaden the focus of health-promoting behavior research from the general public and patients [13–15] to include nurses who provide care.

Nurses' health-promoting behaviors have been reported to differ according to sociocultural characteristics, such as the values and diet of the country in which people live [6]. Therefore, there will be regional and cultural differences in the factors that affect nurses' health-promoting behaviors. Systematic literature review and review studies, not meta-analysis, of the health-promoting behaviors among nurses have already been conducted in other countries. These include comprehensive reviews of barriers to health-promoting behaviors among nurses [7], detailed reviews of how nurses' own health behaviors can significantly affect patient care and outcomes [16], and the effectiveness of lifestyle health promotion interventions tailored specifically for nurses [17].

Studies related to health-promoting behaviors in Korea have focused on the relationships between nurses' health-promoting behaviors and nurses' individual and job-related variables, such as nursing performance [10,18], self-efficacy [19], and social support [18]. Only one meta-analysis study on the explanatory factors of health-promoting behaviors has been published in Korea [20], but it included Korean college students, general adults, and patients, excluding nurses. This paper, published two decades ago, faces challenges in relevance to contemporary nursing practices within the current healthcare environment. It does not account for significant factors such as the surge in demand for nursing services prompted by recent alterations in healthcare policy, the

intensification of workloads due to staffing shortages, and the insular nature of hospital organizational cultures [21]. Therefore, a meta-analysis that includes the most recent research on nurses' health-promoting behaviors is needed to provide a comprehensive and non-fragmented synthesis that is not limited by time period.

Meanwhile, recent efforts in conducting meta-analyses involve categorizing variables based on a theoretical model, followed by the analysis. This approach aims to refine and enhance the explanatory power of the respective theory [22,23]. The most used model in nursing research related to health promotion is the Health Promotion Model (HPM) developed by Pender. Pender's Health Promotion Model [6] enables a multidimensional elucidation of the influencing factors and interactions in health-promoting behaviors, comprising three domains: individual characteristics and experiences, behavior specific cognitive and affective factors, and behavioral outcomes. Individual characteristics and experiences consist of previous related behavior and personal factor, while behavior specific cognitive and affective factors include perceived benefits of action, perceived barriers of action, perceived self-efficacy, activity related affect, interpersonal influences, and situational influences. Behavior outcomes involve the development of a commitment to a plan of action the performance of health behaviors, influenced by immediate competing demands and preferences, with the initiation of health behavior being affected accordingly. The goal of this model is the promotion of health behaviors [6].

The model has been recognized as suitable for eliciting health promotion from nursing recipients based on previous studies of patients with chronic diseases [14,20,22], middle and high school students and college students [15,20,22], pregnant women and women of childbearing age, and general adults and workers [20,22,23]. Thus, studies conducted by applying Pender's Health Promotion Model have been recognized to improve the health of people at various levels and environments and their quality of life [22–24].

It is believed that conducting a meta-analysis based on nursing theory can enable more reliable interpretations through empirical validation of the theory. However, it has been difficult to find studies that systematically review and comprehensively conduct a meta-analysis on the status of health-promoting behaviors among nurses working in Korea based on a theoretical model.

Now, as the importance of nurses' health-promoting behaviors is increasing [3,4], it is necessary to synthesize related studies on nurses working in different health care settings in Korea to obtain integrated results. Therefore, this study aimed to systematically review the characteristics of relevant studies and related variables, and conduct a meta-analysis of the variables affecting Korean nurses' health-promoting behaviors, which have been fragmentarily studied so far [10,12,18,19], based on Pender's Health Promotion Model.

### *Purpose*

The specific objectives of this study were as follows: First, to find published papers that meet the criteria by searching and confirming the general characteristics. Second, to assess the quality of the study results. Third, to determine the overall effect size of the variables related to health-promoting behaviors. Fourth, to categorize the variables associated with health-promoting behaviors, and then determine the effect sizes for subcategories and individual variables.

### **Methods**

This was a systematic literature review and meta-analysis study conducted to comprehensively analyze the effect sizes of variables

related to Korean nurses' health-promoting behaviors. The study was conducted based on guidelines for systematic literature and meta-analysis by Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) [25], Meta-Analysis of Observational Studies in Epidemiology (MOOSE) [26], and the National Evidence-based Healthcare Collaborating Agency (NECA) [27]. The protocol of this study was registered with PROSPERO, an international prospective registry of systematic reviews (CRD42022299907).

#### *Inclusion and exclusion criteria*

The key questions for the literature search were, "What are the variables related to the health-promoting behaviors of nurses working in Korea?", "Are there differences in the effects of health-promoting behaviors depending on related variables?", and "Which variable has the strongest effect size on health-promoting behaviors?"

Health-promoting behaviors are those that maintain optimal health by positively changing daily lifestyle to improve individual's health [6]. In this study, nurses' self-reported health-promoting behaviors were evaluated using tools such as the Health-promoting Lifestyle Profile (HPLP), the Health-promoting Lifestyle Profile II (HPLP II), and the health-promoting lifestyle tool. Participants, interventions, comparisons, outcomes, and study design (PICO-SD) were established for the key questions of this study as follows. The study participants (P) were nurses, and for a more comprehensive search, intervention (I) and comparisons (C) were not set. The outcomes (O) were nurses' health-promoting behaviors, and the study design (SD) included observational studies, such as cohort studies or cross-sectional studies [26]. The specific inclusion criteria were (1) studies targeting nurses working in Korea, (2) studies presenting statistics, such as the number of samples (n) and t (critical ratio [CR]), or the correlation coefficient (r) or coefficient (B) and standard error [SE] for meta-analysis, and (3) studies published in an academic journal. The exclusion criteria were (1) studies that did not report statistics not only on nurses but also on participants other than nurses, (2) studies in which statistics on relationships between health-promoting behaviors and related variables were not reported, (3) studies that presented only the outcome variables of health-promoting behaviors, (4) studies for which the original text was unavailable, and (5) studies published in a language other than Korean or English.

#### *Literature search*

A data search was conducted from September 28 to October 5, 2021, and the period was not set limitation for a comprehensive literature searching. An additional data search of publications in other countries targeting Korean nurses was conducted from November 4 to November 9, 2022. Two researchers and a professional librarian independently conducted a database search and reviewed the retrieved data. Data searches were conducted in the Korean Medical database (KMbase), Korean Studies Information Service System (KISS), KoreaMed, and ScienceON, which were CORE databases recommended by the National Evidence-based Healthcare Collaborating Agency [27], as well as in the DataBase Periodical Information Academic (DBpia), National Assembly Library (NAL), and Research Information Sharing Service (RISS). In addition, the Korea Citation Index [KCI], the Cumulative Index to Nursing and Allied Health Literature (CINAHL), CENTRAL, Web of Science, and PubMed were manually searched.

Search terms were [nurse] AND [health promotion behavior] in the Korean database, and [nurs\*] AND [Korea\*] AND [health promotion behavio\*] in foreign databases ([Supplementary Appendix](#)

1). The collected literature was organized using EndNote X9 and Excel 2016.

#### *Study selection and data extraction*

The selection and screening of literature were carried out in two steps. In the first step, a search of the Korean database was conducted. A total of 5,413 publications were extracted through the data search, and after excluding 809 duplicate publications, the titles and abstracts of 4,604 articles were reviewed. Among them, 4,430 articles that did not meet the selection criteria were excluded. Then, the full texts of the remaining 174 articles were reviewed. Forty-eight papers were finally selected after excluding a total of 126 papers, including 18 studies that were not conducted on nurses; 56 studies that reported health conditions, health problems, health levels, etc., not health-promoting behaviors as results; 12 studies that did not include statistics for meta-analysis; nine studies that reported only the outcome variables of health-promoting behaviors, and 31 studies that were dissertations or theses.

In the second step, 315 articles were retrieved by manually searching the Korean nursing journals listed in the Korea Citation Index [KCI], CINAHL, CENTRAL, Web of Science, and PubMed. After checking the titles and abstracts of the extracted literature, 280 articles that did not meet the selection criteria were excluded. Then, by reviewing the full text of the 35 remaining articles, 33 duplicates with the step 1 search results were excluded, and finally, two articles were selected and included in hand searching. Through the data selection and screening processes of the first and second steps, 50 final articles were selected for systematic review and meta-analysis ([Figure 1, Supplementary Appendix 2](#)). The research team independently reviewed the literature according to the selection and exclusion criteria. In cases of disagreements, the full texts were reviewed through meetings until a consensus was reached, and then the literature was selected.

#### *Risk of bias assessment*

The Quality Assessment and Validity Tool for Correlation Studies [28] was used to evaluate the quality of the 50 chosen articles. This tool consists of 13 questions, including two items on study design, four on sampling, five on measurements, and two on statistical analysis. Among the evaluation questions, the question of "Was the result objectively measured?" was evaluated with 1 point in the case of a self-report and 2 points if it was measured by observation. The other questions were evaluated as 0 points for No and 1 point for Yes, for a total score of 14 points. The researchers independently conducted a quality evaluation and checked for agreement. A consensus was made through meetings in the case of disagreement.

#### *Data synthesis and analysis*

The Comprehensive Meta-analysis (CMA) 2.0 program was used to analyze the total effect size and publication bias of the finally selected 50 studies. The effect sizes of each sub-domain and variables and sensitivity were tested using the using the 'meta' package of R 3.6.2 software.

After checking the characteristics of the studies selected for this analysis, data, such as author, publication year, research participants, research setting, number of participants, health-promoting behavior measurement tools and reliability, health-promoting behavior-related variables, and statistics were coded. After the first coding by a member (first author) of this research team, another researcher (corresponding author) checked and corrected the accuracy of the coding. The general characteristics of the studies

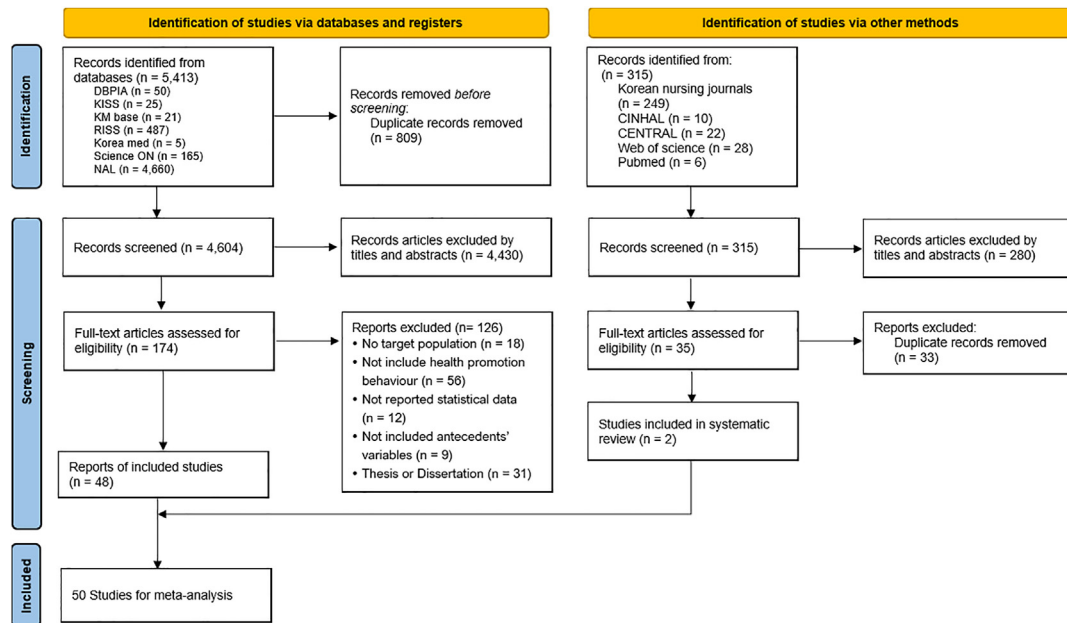


Figure 1. Selection Process of Studies Included in the Meta-analysis.

were analyzed by frequencies and percentages. The forest plot, Q test, and  $I^2$  tests were used for heterogeneity tests, which are visual tests. Values of up to 25% indicated small heterogeneity, 50% indicated medium, and over 75% was designated as large based on the  $I^2$  test results [29]. The correlation coefficients were coded for the effect sizes of the health-promoting behavior-related variables in this study. When the studies did not present the correlation coefficients, 'number of samples (n)' and 't (CR)' or 'regression coefficient (B)' and standard error (SE) were converted into correlation coefficients and then analyzed [30]. The correlation effect size (ESr) was interpreted as weak if it was between 0 and 0.1, modest if it was between 0.1 and 0.3, moderate if it was between 0.3 and 0.5, strong if it was between 0.5 and 0.8, and very strong if it was above 0.8, according to the criteria proposed by Cohen [31]. The variables related to health-promoting behavior derived from this study were mixed with positive (+) and negative (−) effect variables. Therefore, in this study, when calculating the overall effect size and the effect sizes by each sub-domain, the correlation coefficient of the variables was converted into an absolute value for analysis. The individual effect size of each variable was analyzed in the direction of the original correlation coefficient (+ or −). For examples, the effect size of depression was  $ESr = -0.27$ , but it was converted into  $|-0.27| = 0.27$  to calculate the total effect size of a sub-domain 'activity related affect'. Trim and fill, fail-safe N, Egger's test, and funnel plots were used to analyze publication bias in the 50 included studies. Each study was sequentially removed from the sensitivity analysis of the articles included in the meta-analysis to confirm the change in effect size by a specific study [32].

#### Ethical consideration

The Institutional Review Board approved an exemption for the review of this study (IRB No. \*\*\*\* 2021-10-005-001).

## Results

#### Characteristics of the included studies

A total of 50 studies related to the health-promoting behaviors of Korean nurses were selected according to the selection criteria.

Seven (14.0%) papers related to nurses' health-promoting behaviors in Korea were published before 2005, seven (14.0%) between 2006 and 2010, 11 (22.0%) between 2011 and 2015, and 25 (50%) between 2016 and 2022. Regarding the tools used to measure the health-promoting behavior of Korean nurses, 29 studies (58.0%) used HPLP II, 11 studies (22.0%) used HPLP, four (8.0%) used the health-promoting lifestyle measurement tool, two studies (4.0%) used the preventive health behavior measurement tool against cancer, and one (2.0%) each used the nurses' health-promoting behavior measurement tool, the Yangsaeng measurement tool, Breslow Index, and the FANTASTIC Lifestyle tool (Table 1).

The number of participants in the studies ranged from 68 to 780. Among them, 34 studies (68.0%) included 68 to 249 participants, 15 (30.0%) included 250 to 499 (0.0%) included 500 to 749, and one (2.0%) included 750 to 1000 participants. The types of hospitals where the studies were conducted were classified based on Article 3 of the Medical Act. Twenty studies (40.0%) were conducted in general hospitals, 15 (30.0%) were in university hospitals, eight (16.0%) were in diverse healthcare settings, five (10.0%) were in hospitals, one (2.0%) was in a public health center and one (2.0%) was in a tertiary hospital. The number of hospitals (study sites) surveyed in the studies ranged from 1 to 25. Among them, 41 studies (82.0%) surveyed from 1 to 5, five (10.0%) surveyed from 6 to 10, three (6.0%) surveyed from 10 to 25, and one (2.0%) did not provide the number of hospitals.

#### Quality assessment of the included studies

All 50 studies selected for the systematic review in this study were correlation studies. The Quality Assessment and Validity Tool for Correlation Studies was modified and supplemented by Cummings et al. [28]. The researchers independently conducted a quality evaluation and checked for agreement. A consensus was made through meetings in the case of disagreement.

Regarding study design, all 50 were cross-sectional studies (100.0%). Fifty studies (100%) applied the non-probability sampling method. Regarding sampling methods, 33 studies (66.0%) had valid sample sizes, 38 studies (76.0%) recruited from more than one place, 50 studies (100.0%) guaranteed the anonymity of the participants, and the survey response rate was 60% or higher in 49



**Table 1** General Characteristics of the Studies Included in Systematic Review and Meta-Analysis (N = 50).

No.	Author, year	Participants	Study setting	Average length of clinical experience (yr)	Sample size	Measurement (author)	Related variable	Quality assessment
1	Bae et al., 2015	RN	Hospital		254	Preventive health behavior measurement tool against cancer (Kim & Kim, 2012)	Stress Perception of cancer occurrence risk	10
2	Bark et al., 2019	RN	General hospital		218	Health-promoting lifestyle tool (Park, 1995)	Resilience Psychological well-being	8
3	Cho et al., 2012	RN, CN, HN	General hospital		341	HPLP (Walker et al., 1987)	Organizational culture	8
4	Cho et al., 2016	RN, CN, HN, Team director	General hospital		170	HPLP II (Walker et al., 1995)	Job stress	9
5	Cho, 2021	RN, CN over unit manage	Hospital	7.25	138	HPLP II (Walker et al., 1995)	Emotional labor	9
6	Choi et al., 2013	RN	General hospital		194	HPLP II (Walker et al., 1995)	Psychological well-being Subjective health status	7
7	Choi et al., 2019	RN, CN	University hospital	9.24	110	HPLP II (Walker et al., 1995)	Nursing work environment Job stress	8
8	Choi et al., 2021a	RN, CN, HN	General hospital		160	HPLP II (Walker et al., 1995)	Social support Resilience	9
9	Choi et al., 2021b	RN	University hospital	7.6	148	HPLP II (Walker et al., 1995)	Social support	9
10	Choi et al., 2022	RN, CN	Diverse Healthcare Settings	6.15	137	HPLP II (Walker et al., 1995)	Job stress Resilience	10
11	Chung et al., 2002	RN, CN, HN	Diverse Healthcare Settings		201	HPLP (Walker et al., 1987)	Self-efficacy Job stress	9
12	Han et al., 2004	RN, CN	General hospital	4.6	249	HPLP II (Walker et al., 1995)	Hardiness Social support Self-efficacy Coping behavior	9
13	Hong, 2014	RN, CN, HN	Diverse Healthcare Settings		233	HPLP II (Walker et al., 1995)	Self-efficacy Emotional labor	8
14	Jang et al., 2018a	RN	University hospital		147	HPLP II (Walker et al., 1995)	Job stress Positive psychological capital Nursing work environment	8
15	Jang et al., 2018b	RN, CN, More than HN	General hospital		206	Health-promoting lifestyle (Park, 1995)	Emotional labor	9
16	Jang et al., 2019	RN	University hospital		236	HPLP II (Walker et al., 1995)	Spirituality	9
17	Jang et al., 2021	RN, More than CN	General hospital	5.3	256	HPLP II (Walker et al., 1995)	Organizational support	8
18	Jeon et al., 2007	RN	University hospital	6.8	319	HPLP (Walker et al., 1987)	Subjective health status Perceived benefit Perceived barrier Self-efficacy Social support Age Job experience	10
19	Jeong et al., 2018	RN	Diverse Healthcare Settings	5.48	285	HPLP II (Walker et al., 1995)	Subjective health status Job stress	10
20	Jung et al., 2021	RN, CN	General hospital		155	HPLP II (Walker et al., 1995)	Job stress Subjective health status	9
21	Kang, 2018	RN	General hospital		153	HPLP II (Walker et al., 1995)	Perceived fatigue Subjective health status	10
22	Kim et al., 2003	Public health nurses Hospital Nurses	Diverse Healthcare Settings		214	HPLP (Walker et al., 1987)	Happiness Perceived fatigue	9
23	Kim et al., 2005	RN	University hospital		311	HPLP II (Walker et al., 1995)	Subjective health status Body image	7

24	Kim et al., 2009	RN	General hospital	7.9	206	HPLP (Walker et al., 1987)	Perceived obesity BMI Subjective health status Depression Familial support Cholesterol Hemoglobin	8
25	Kim et al., 2010a	RN	University hospital		400	HPLP II (Walker et al., 1995)	Resourcefulness Subjective health status	9
26	Kim et al., 2010b	RN	University hospital		400	HPLP II (Walker et al., 1995)	Resourcefulness	9
27	Kim et al., 2010c	RN	Diverse Healthcare Settings		357	HPLP (Walker et al., 1987)	Subjective health status	7
28	Kim et al., 2014	RN More than CN	Diverse Healthcare Settings		195	Breslow Index (Breslow & Enstrom, 1980)	Job stress	5
29	Kim et al., 2015	RN	University hospital	11.76	177	HPLP II (Walker et al., 1995)	Sleep hours Age Job experience Drinking alcohol frequency Exercise frequency	8
30	Kim et al., 2018a	RN, CN, HN, Head of the nursing department	General hospital		135	HPLP II (Walker et al., 1995)	Perceived fatigue Subjective health status	9
31	Kim et al., 2018b	RN, CN, HN	General hospital	3.88	308	Preventive health behavior measurement tool against cancer (Kim & Kim, 2012)	Knowledge of cancer Attitude toward cancer	8
32	Kim et al., 2018c	RN	Public health center		436	HPLP II (Walker et al., 1995)	Perceived susceptibility Perceived seriousness Perceived benefit Perceived barrier Self-efficacy	10
33	Kim et al., 2019	RN	General hospital		157	HPLP (Walker et al., 1987)	Workplace bullying perception Physical symptoms Job stress	9
34	Kim et al., 2020a	RN, CN, More than HN	Hospital		227	HPLP II (Walker et al., 1995)	Job stress Subjective health status	10
35	Kim et al., 2020b	RN	General hospital		87	HPLP II (Walker et al., 1995)	E-Health Literacy	9
36	Kim et al., 1999	RN, CN, HN	University hospital		388	HPLP (Walker et al., 1987)	Self-efficacy Subjective health status	9
37	Kim, 2001	RN, CN, HN	University hospital		426	Health-promoting lifestyle (Park, 1995)	Job stress	8
38	Koo et al., 2018	RN	Diverse Healthcare Settings	7.1	195	HPLP II (Walker et al., 1995)	Emotional labor	8
39	Lee et al., 2014	RN	General hospital	4.38	193	HPLP II (Walker et al., 1995)	Depression Perceived fatigue	9
40	Lee et al., 2022	RN	University hospital		162	Measurement Tool for Health Promotion Behavior of Nurses (Kim, 2021)	Knowledge about COVID-19 Attitude toward COVID-19 infection Job stress Social support Self-efficacy	9
41	Lee, 1994	RN, CN, HN, Team director	General hospital		145	HPLP (Walker et al., 1987)	Self-esteem	8
42	Lee, 2008	RN	General hospital		780	Health-promoting lifestyle (Park, 1995)	Previous related behavior Subjective health status Self-efficacy Perceived benefit Perceived barrier Social support	9

(continued on next page)

Table 1 (continued)

No.	Author, year	Participants	Study setting	Average length of clinical experience (yr)	Sample size	Measurement (author)	Related variable	Quality assessment
43	Nam, 2007	RN	Hospital	17.2	68	HPLP (Walker et al., 1987)	Subjective health status	9
44	Oh et al., 2014	RN, CN, HN	General hospital	6.10	245	HPLP II (Walker et al., 1995)	Job stress Job stress compensation optimization strategy	9
45	Park et al., 2015	RN, More than CN	Hospital	8.16	131	YS-TOHP (Kim, 2004)	Happiness	9
46	Park et al., 2020	RN	University hospital		242	HPLP II (Walker et al., 1995)	Grit Subjective health status	9
47	Shin et al., 2021	RN	Tertiary hospital	8.5	139	HPLP II (Walker et al., 1995)	Self-efficacy Job experience	8
48	Son et al., 2011	RN	University hospital	8.16	91 (shift) 74 (non-shift)	FANTASTIC Lifestyle (Wilson & Gliska, 1984)	Subjective health status	10
49	Song et al., 2021	RN	University hospital		300	HPLP (Walker et al., 1987)	Perceived fatigue Depression	10
50	Yeun et al., 2011	RN	General hospital	336	HPLP II (Walker et al., 1995)	HPLP (Walker et al., 1987)	Self-efficacy Compassion fatigue Mood states Resourcefulness Subjective health status	10

Note. BMI = body mass index; HPLP = Health-promoting Lifestyle Profile; YS-TOHP = Yangaeng-Traditional Oriental Health Promotion.

studies (98.0%). In terms of measurements, 49 studies (98.0%) used tools with tested reliability, 49 studies (98.0%) used tools tested for validity, and 50 studies (100.0%) used self-reported variables related to health-promoting behaviors. Thirty-nine studies (78.0%) used health-promoting behavior measurement tools with internal consistency reliabilities of 0.70 or higher, and 28 studies (56.0%) used theoretical models/frameworks as guidelines. Regarding statistical analysis, 50 studies (100.0%) analyzed correlations between variables, and two studies (4.0%) dealt with outliers. In summary, in the quality evaluation of the included 50 studies, 10 studies (20.0%) were scored as high, with a score of 10 or more, and 40 studies (80.0%) were scored as medium, with a score of 5–9. No studies were evaluated as low, and no study was excluded through quality evaluation.

*Theoretical framework for the analysis of variables related to health-promoting behaviors*

Recent meta-analyses have been conducted by categorizing variables based on theoretical models to elaborate and increase the explanatory power of the theory used [33,34]. When a meta-analysis is conducted based on nursing theories, a more reliable interpretation is possible through empirical verification of the theory.

Therefore, this study categorized the related variables into the sub-domains of the Health Promotion Model (HPM) of Pender [6] according to their characteristics (Figure 2A). Pender's Health Promotion Model was used in this systematic review and meta-analysis because 80% of the included studies used HPLP and HPLP II, which are health promotion behavior measurement tools, and Pender's Health Promotion Model provided a paradigm for the development of HPLP measurement tools [35]. It is necessary to classify the relevant variables of studies according to each sub-domain of Pender's Health Promotion Model, and identify the effect sizes of these variables on nurses' health-promoting behaviors. Existing studies on nurses in Korea have selected only some variables and focused on ensuring the individual relationships between these variables rather than verifying all concepts included in Pender's model [18,19]. Thus, it is necessary to comprehensively analyze the results of previous studies based on Pender's model, a representative theory related to health promotion.

Therefore, this research team reviewed the theoretical definitions of relevant variables and measurement tools to classify and categorize them according to Pender's model. Through several meetings, the relevant variables were categorized according to the characteristics of each sub-domain of the model. For example, resilience, subjective health status, emotional labor, job stress, resourcefulness, and psychological well-being were classified as personal psychological factors among the sub-domains of Pender's model, and social support was classified as an interpersonal influence.

*Overall effect size of the studies*

When calculating the overall effect size, 50 individual studies were set as the unit of analysis to maintain an assumption of independence. As a result of the analysis,  $I^2 = 91.5\%$  [ $Q = 573.82, p < .001$ ], showing a high level of heterogeneity, and a random effect model was used for the analysis. The overall effect size was 0.30 [95% confidence interval (CI): 0.26 to 0.33], indicating a moderate effect level.

*Effect sizes of sub-domains of health-promoting behaviors*

For the effect sizes of the sub-domains of health-promoting behaviors, individual variables with two or more cases ( $k \geq 2$ )

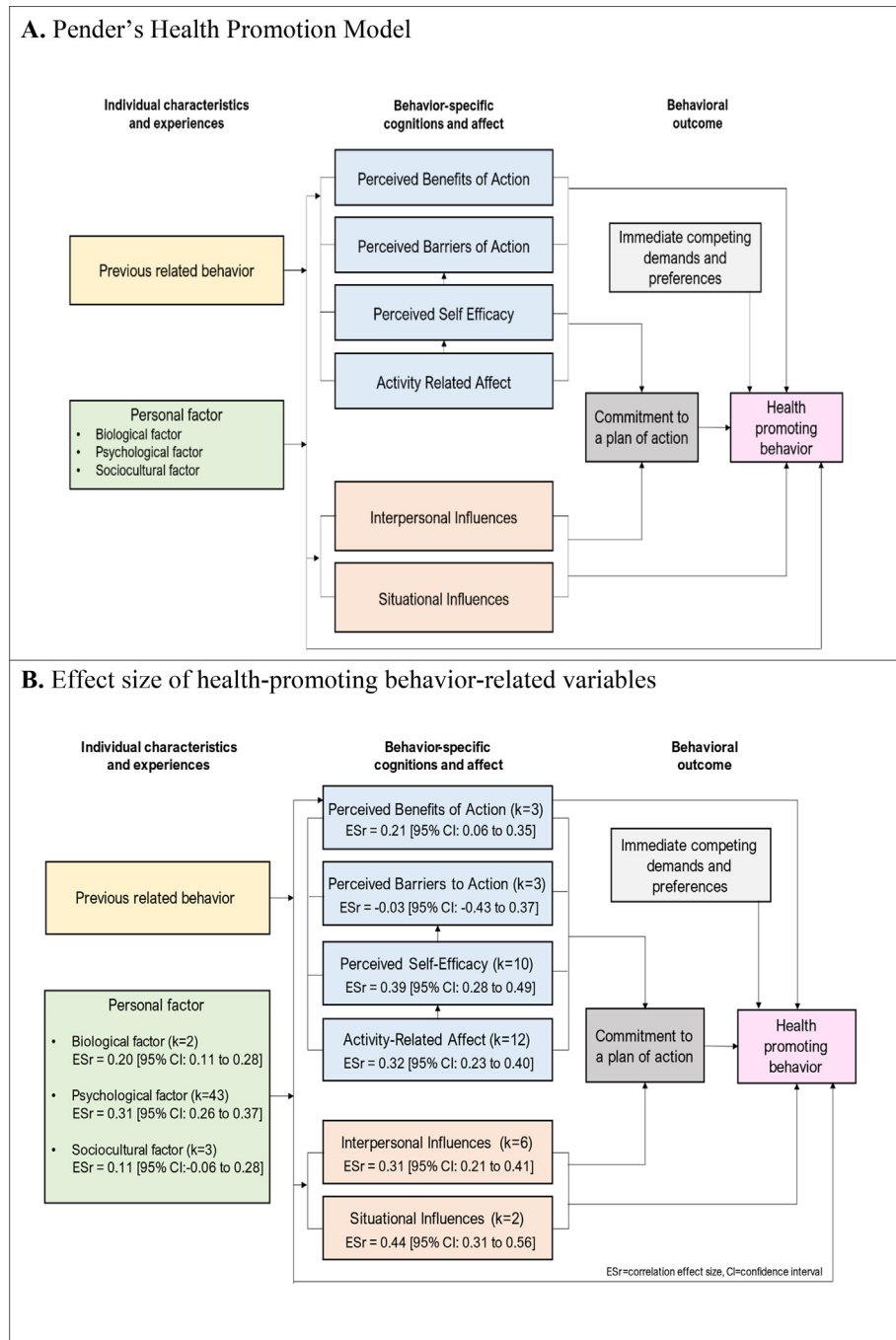


Figure 2. Health Promotion Model and Effect Size of Related Variables.

were selected and categorized into sub-domains of Pender's Health Promotion Model (Table 2, Figure 2B). However, previous related behavior, commitment to a plan of action, and immediate competing demands and preferences were excluded from the meta-analysis because there were no corresponding studies (k = 0).

1) Personal biological factors

One variable of age included two cases, with an effect size of 0.20 (95% CI: 0.11 to 0.28), indicating a modest effect size with statistical significance (Figure 3A).

2) Personal psychological factors

A total of six variables, including subjective health status, job stress, emotional labor, resilience, resourcefulness, and psychological well-being, with 43 cases, were included. As a result of the analysis, the effect size was 0.31 (95% CI: 0.26 to 0.37), indicating a moderate effect size with statistical significance (Figure 3B). Among the variables included, resilience (ESr = 0.62, 95% CI: 0.44 to 0.75) and psychological well-being (ESr = 0.50, 95% CI: 0.42 to 0.57) had strong effect sizes, and subjective health status (ESr = 0.29, 95% CI: 0.22 to 0.35), job stress (ESr = -0.22, 95% CI: -0.32 to -0.13), and

**Table 2** Effect Size of Individual Variables.

Health promotion variables	Related variables	k	n	ESr	95% CI		p	Heterogeneity		
					lower	upper		I <sup>2</sup>	Q	p
Personal biological factors	Age	2	496	0.20	0.11	0.28	<.001	0.0	0.04	.842
Personal psycho-logical factors	Subjective health status	17	4,695	0.29	0.22	0.35	<.001	84.2	101.17	<.001
	Job stress	14	2,685	−0.22	−0.32	−0.13	<.001	84.3	82.89	<.001
	Emotional labor	4	772	−0.20	−0.26	−0.13	<.001	0.0	0.24	.971
	Resilience	3	515	0.62	0.44	0.75	<.001	87.5	15.98	<.001
	Resourcefulness	3	1,136	0.45	0.41	0.50	<.001	0.0	0.36	.837
Personal socio-cultural factor	Psychological well-being	2	412	0.50	0.42	0.57	<.001	0.0	0.29	.589
	Length of clinical experience	3	635	0.11	−0.06	0.28	.199	78.4	9.25	.009
	Perceived benefits of action	3	1,535	0.21	0.06	0.35	.008	88.7	17.65	<.001
	Perceived barriers to action	3	1,535	−0.03	−0.43	0.37	.878	98.5	134.30	<.001
	Perceived self-efficacy	10	3,310	0.39	0.28	0.49	<.001	91.9	110.90	<.001
Activity-related affect	Perceived fatigue	6	860	−0.30	−0.38	−0.21	<.001	45.3	9.13	.104
	Depression	4	564	−0.27	−0.46	−0.07	.010	83.5	18.20	<.001
	Happiness	2	284	0.45	0.35	0.54	<.001	0.0	0.06	.810
	Social support	6	1,818	0.31	0.21	0.41	<.001	78.9	23.75	<.001
Situational influences	Nursing work environment	2	257	0.44	0.31	0.56	<.001	37.1	1.59	.208

Note. CI = confidence interval; ESr = correlation effect size; K = number of cases; n = number of participants.

emotional labor (ESr = −0.20, 95% CI: −0.26 to −0.13) had modest effect sizes. All results were statistically significant.

### 3) Personal sociocultural factors

The length of clinical experience variable included three cases, with an effect size of 0.11 (95% CI: −0.06 to 0.28), which was not statistically significant (Figure 3C).

### 4) Perceived benefits of action

The variable of perceived benefit included three cases. The effect size was 0.21 (95% CI: 0.06 to 0.35), indicating a modest effect size, which was statistically significant (Figure 3D).

### 5) Perceived barriers to action

The variable of perceived barrier included three cases. The effect size was −0.03 (95% CI: −0.43 to 0.37) and was not statistically significant (Figure 3E).

### 6) Perceived self-efficacy

The self-efficacy variable included 10 cases. The effect size was 0.39 (95% CI: 0.28 to 0.49), indicating a moderate effect size, and was statistically significant (Figure 3F).

### 7) Activity-related affect

Three variables—perceived fatigue, happiness, and depression, included 12 cases, with a moderate effect size of 0.32 (95% CI: 0.23 to 0.40), which was statistically significant (Figure 3G). Two variables—happiness (ESr = 0.45, 95% CI: 0.35 to 0.54) and perceived fatigue (ESr = −0.30, 95% CI: −0.38 to −0.21), showed moderate effect sizes.

### 8) Interpersonal influence

One variable, social support, included six cases with a moderate effect size of 0.31 (95% CI: 0.21 to 0.41), which was statistically significant (Figure 3H).

### 9) Situational influence

The nursing work environment variable included two cases, with an effect size of 0.44 (95% CI: 0.31 to 0.56), indicating a statistically significant effect size at a moderate level (Figure 3I).

### Risk of bias

The trim and fill analysis was performed to confirm the publication bias of the 50 studies and showed an effect size of 0.25 [95% CI: 0.21 to 0.29] after adding nine studies to correct asymmetry to symmetry. However, it was still significant, as 0 was not included in the 95% confidence interval (Supplementary Appendix 3). The fail-safe N analysis showed that 27,751 studies were required for the effect size to be insignificant ( $p > \alpha$ ), and Egger's regression analysis result was not significant [intercept = 1.54, SE = 1.12,  $p$ -value (2-tailed) = .176], indicating no publication bias.

### Sensitivity analysis

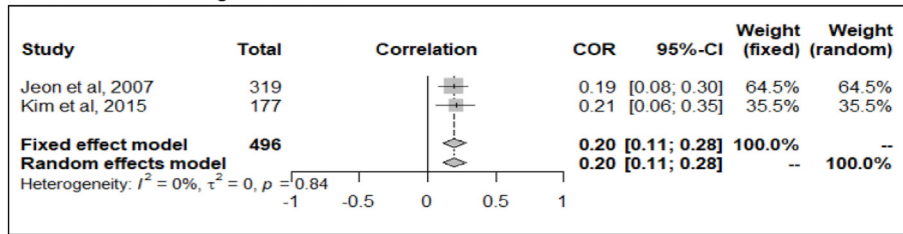
Stable results without significant differences in the effect size of each sub-domain were found in the sensitivity analysis of variables according to Pender's sub-domains, even after each study was sequentially removed (Supplementary Appendix 4).

## Discussion

Previous research on nurses' health-promoting behaviors has primarily focused on specific variables, providing valuable insights in individual areas. However, this study takes a more integrative approach to synthesize these findings and provide a comprehensive understanding of the factors that influence these behaviors. By conducting a systematic review and meta-analysis, drawing on diverse studies [10,12,18,19], we aim to bridge this gap and offer a holistic view. A review of literature from 2016 to 2022, accounting for half of the selected studies, shows increasing interest in this area. However, most research has been conducted in general or university hospitals, highlighting a gap in understanding nurses' health behaviors in non-hospital settings. The analysis of the tools used to measure nurses' health-promoting behaviors in the 50 studies found that 22.0% of the studies used the HPLP developed by



**A. Personal biological factors**



**B. Personal psychological factors**

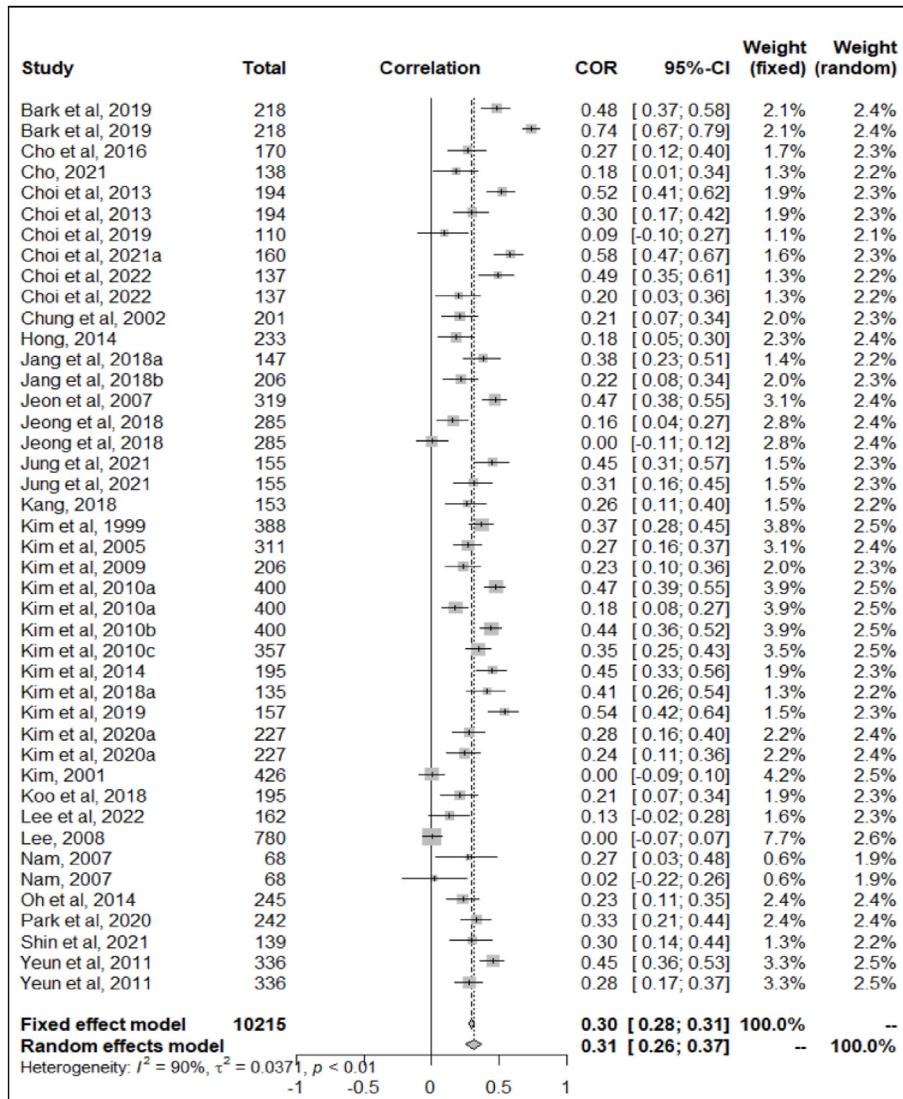


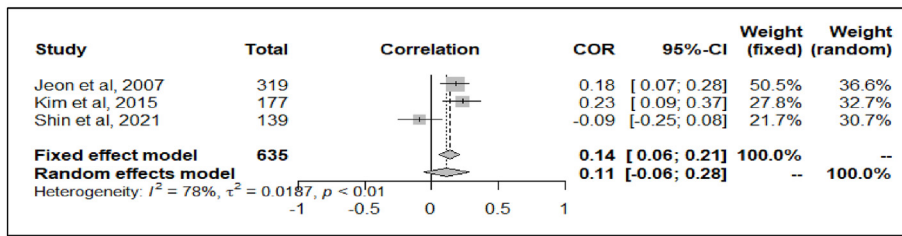
Figure 3. Forest Plots of Health-Promoting Behavior-Related Variables.

Walker et al. to target adults in another country, not Korea [36], and 58.0% of the studies used HPLP II, a revision of the HPLP [37], which was used by 80.0% of the studies included in the meta-analysis in this study. Four studies (8.0%) used Park's [38] tool, which was developed in Korea, with verified validity and reliability. Its validity and reliability in measuring nurses' health-promoting behaviors were verified [39]. This analysis highlights the importance of tailoring research approaches to better suit the nursing field's evolving nature. It is recommended that future studies prioritize the development and utilization of measurement tools that are

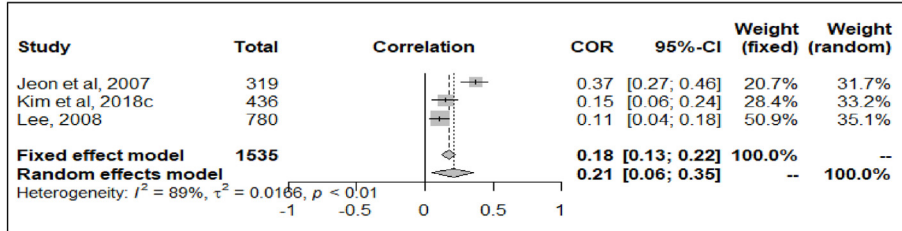
specifically designed to reflect the unique job characteristics and working environments of nurses. These tools could be informed by Pender's Health Promotion Model, ensuring they are aligned with contemporary trends and the specific needs of this professional group.

A discussion focusing on the sub-domains and individual variables with large effect sizes in each sub-domain in the meta-analysis in this study follows. Among the nine sub-domains in this study, situational influence had the largest effect size, which was moderate effect size according to Cohen's standards [31].

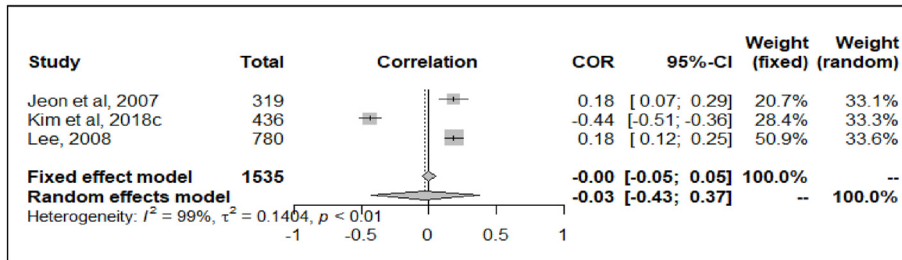
C. Personal sociocultural factors



D. Perceived benefits of action



E. Perceived barriers to action



F. Perceived self-efficacy

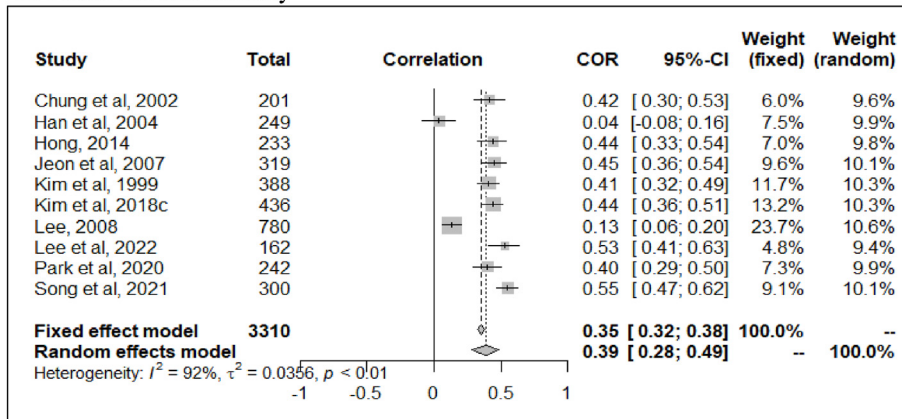
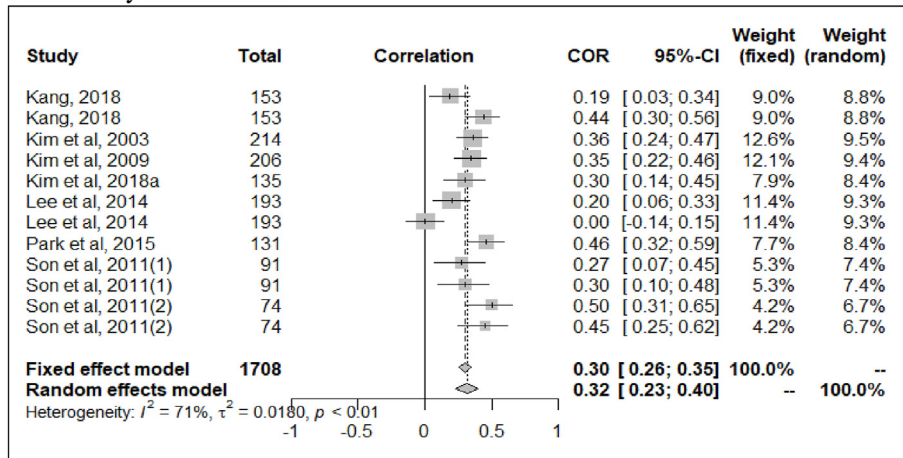


Figure 3. (continued).

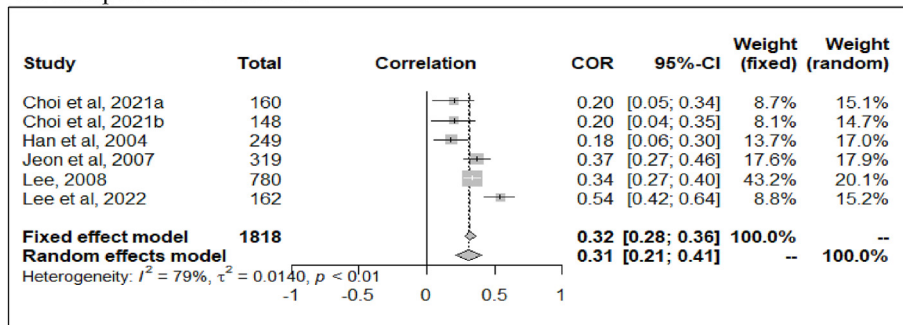
According to the meta-analysis, the nursing work environment variable was found to be the most significant sub-domain, indicating that a positive perception of the work environment is associated with an increased health-promoting behavior among nurses. Improving aspects of the nursing work environment, such as involving nurses in hospital affairs, establishing nursing foundations for quality care, ensuring adequate staffing and resources, promoting collegial nurse-physician relations, and providing strong

leadership and support for nurses, can lead to better health-promotion behaviors among nurses. These findings suggest that by prioritizing the improvement of the nursing work environment, positive impacts can be made on the health-promotion behaviors of nurses. Previous research has shown that improving work environments can reduce job dissatisfaction, burnout, and turnover intentions [40]. Furthermore, studies have found a positive correlation between job enjoyment and physical activity levels [11].

**G. Activity-related affect**



**H. Interpersonal influences**



**I. Situational influences**

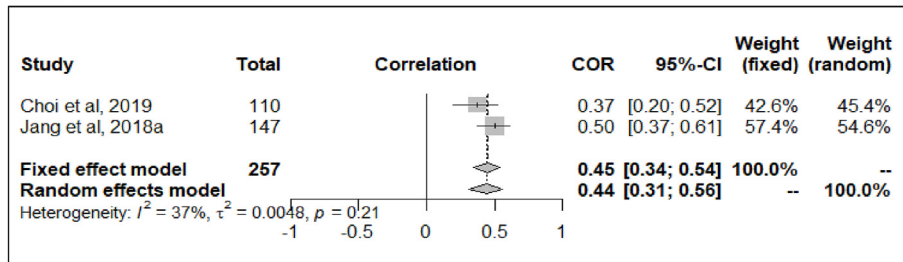


Figure 3. (continued).

Consequently, nurses' satisfaction with their work environment can enhance their interest in personal health. However, challenges such as shift work, night shifts, and intense workload are identified as barriers to health-promoting practices [5,7–9]. Efforts like the pilot project to improve nurses' shift work systems in Korea [41] underscore the national recognition of the work environment's impact on nurses' health behaviors. Future legislative and policy enhancements are anticipated to continue positively influencing these aspects.

The sub-domain with the second largest effect size was perceived self-efficacy and it is one of the main concepts of social cognitive theory, which is the basis of the Health Promotion Model. The higher the level of self-efficacy, which is the confidence that one can successfully perform an action, the more successful a health promotion action can be [6,19]. Nurses are experts in healthcare with abundant related knowledge and experience, so the confidence that they can perform health-promoting activities for themselves may have led to

the high level of self-efficacy in this study. This supports the results of previous studies [9], confirming that self-efficacy is a factor that promotes nurses' health-related behaviors. Therefore, strategies to increase nurses' self-efficacy must be included when planning an intervention program for nurses.

The sub-domain with the third largest effect size was activity-related effects. According to Pender [6], the higher the positive emotions, the higher the performance rate of health-promoting behaviors. The results of this study also showed that higher happiness levels, which is a positive emotion, were associated with lower perceived fatigue and depression, which are negative emotions, and higher planning and execution rates of health-promoting activities. There were six studies on perceived fatigue and health-promoting behaviors, four on depression, and two on happiness, so further research on the effect of nurses' emotions, such as depression and happiness, on health-promoting behaviors is necessary.

The two sub-domains with the fourth largest effect sizes were personal psychological factors and interpersonal influences. Personal psychological factors had a moderate effect size with statistical significance. This is similar to previous studies reporting that job stress was an obstacle to health-promoting behaviors, such as healthy eating habits, through a literature review of nurses [7,9]. Among the variables included in the sub-domain analysis, resilience showed the largest effect size among all 16 individual variables. Resilience is the ability to respond positively and cope successfully, even in stressful situations [42]. In this study, resilience showed the largest effect size. However, only three studies were included in the meta-analysis, so additional research is necessary to verify the effect of resilience on nurses' health-promoting behaviors. Among the 16 individual variables with two or more cases in this study, the variables with an effect size of 0.5 or more were resilience and psychological well-being, which were included in the personal psychological factors sub-domain, indicating that it is necessary to first consider the levels of these psychological factors to improve nurses' health-promoting behaviors. However, the individual's psychological state is essential for their will to be converted into action, and the support system or obstacles surrounding them affect the actual performance of the action. Therefore, it is necessary to evaluate previous related behavior, commitment to a plan of action, and immediate competing demands and preferences presented in Pender's model but not yet identified. Interpersonal influences, which showed the same effect size as personal psychological factors, included social support. According to Pender [6], family members, peers, and caregivers are essential sources of interpersonal influences, and their social support can increase or decrease the performance of health-promoting behaviors. The culture of the units where nurses work was reported to influence health-promoting behavior [7], and interactions with peers on a diet or performing exercise positively or negatively affected nurses' eating habits [9]. These results suggest that positive support and communication from colleagues or managers are essential to successful health-promoting behaviors in nurses. Previous studies [10,18] reported that support from nursing managers and positive peer relationships with doctors were positively related to nurses' health-promoting behaviors, which supports the results of this study that found a significant effect size of social support on health-promoting behavior. Therefore, future research on nurses' social support should use a theoretical framework for more scientific and systematic analysis to identify various support systems required by nurses and consider ways to improve them.

Perceived benefit of action had the sixth highest effect size. In a systematic review [17] of 136 studies that provided interventions to improve physical activity, stress, and dietary habits for nurses, various interventions improved physiological indicators and the physical and mental health of nurses, showing the benefits of health-promoting behaviors. Therefore, when providing interventions for nurses, it is necessary to remind them of the importance and benefits of health promotion, even if they are already health experts, and to present positive and exemplary models leading them to actual actions [43]. In other words, if nurses recognize that health-promoting behavior will bring benefits beyond behavioral improvement, the level of motivation will be further improved, and their efforts and strategies for health promotion will be strengthened.

In this study, it was found that two of the nine sub-domains examined, sociocultural factors and perceived barriers of action, did not show significant effect sizes. Sociocultural factors encompass a wide range of factors such as race, society, economic status, education, and other related factors. Perceived barriers of action refer to practical obstacles that may be anticipated in performing health behaviors, such as inconvenience and high costs [24]. In

future research on nurses' health-promoting behaviors, it would be beneficial to include further investigation into these areas.

Literature review [22,23] on studies that used Pender's Health Promotion Model as a theoretical framework simply listed individual studies reporting the relationship between some variables of interest and the perceived barrier. However, this study is significant because the integrated effect size of health-promoting behavior and perceived barrier and its significance were presented through a meta-analysis. In Pender's Health Promotion Model, a perceived barrier is considered an essential factor affecting the establishment of action plans and reducing health-promoting activities [24]. Still, it was not significant in this study. This is different from the results of previous studies, which showed that health-promoting behaviors decreased when there was a lack of dining facilities in medical institutions or when it was difficult to access healthy food [7] for financial or time reasons [8]. Therefore, more details, such as work type, hospital size, and nurse-patient ratios, should be analyzed when more related studies are available. Individual sociocultural factors, a non-significant sub-domain in this study, should also be examined in future research if studies that identify the relationship between variables such as clinical experience and salary level and the health-promoting behaviors of nurses are accumulated.

#### *Implication for practice and research*

We have recommendations for nursing education, research, practice, and policy based on the results of this study. First, we suggest preparing a systematic support plan and related curriculum for the health promotion of nursing students and nurses in nursing education. Second, we suggest conducting more studies to confirm effect sizes on sub-domains that could not be analyzed because the number of cases was less than two or there were insufficient previous studies on related variables through a meta-analysis. Conducting a meta-analysis or meta-path analysis by applying the Health Belief Model or Information–Motivation–Behavioral Skills Model (IMB model), which is actively used in the field, in addition to Pender's Health Promotion Model applied in this study is also recommended. Third, when operating a health promotion intervention program targeting nurses in nursing practice settings, personal psychological factors, perceived self-efficacy, activity-related affect, interpersonal influences, and situational influences that showed a moderate effect size in this study should be included. Finally, when developing policies for nurses, including improvement plans for nurses' health maintenance and promotion and finding the results of nurses' health-promoting behaviors on variables related to the individual, job, and organizational levels are suggested.

#### *Limitation*

This research presents a limitation due to its selection of nurse participants from a single country, potentially restricting the generalizability of its findings across nurses with varied cultural and healthcare system experiences. To enhance the external validity of future studies, it is recommended to broaden the participant criteria to encompass nurses from diverse countries, thereby incorporating a wider range of cultural and healthcare system backgrounds.

#### **Conclusions**

This study categorized health-promoting behavior-related variables into the nine sub-domains of Pender's Health Promotion Model. The effect size of situational influences was the largest. Next, the effect sizes of the six sub-domains were significant in the order of perceived self-efficacy, activity-related affects, personal



psychological factors, interpersonal influences, perceived benefits of action, and personal biological factors. In contrast, the effect sizes of personal sociocultural factors and perceived barriers to action were insignificant. The results should be confirmed in further research after more studies on variables related to this sub-domain are accumulated. Resilience and psychological well-being showed large effect sizes among the 16 individual variables in this study. Therefore, various international nursing organizations should closely consider these variables and conduct systematic efforts across the nation to increase the health-promoting behaviors of nurses.

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### Conflict of interest

The authors declared no conflict of interest.

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### Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.anr.2024.04.007>.

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## Review Article

## Barriers and Facilitators to Medical Help-seeking in Rural Patients with Mental Illness: A Qualitative Meta-synthesis

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## SUMMARY

**Purpose:** Numerous barriers hinder individuals with mental illness from seeking medical assistance in rural regions, yet a comprehensive understanding of these challenges remains elusive. This meta-synthesis aims to understand the barriers and facilitators in medical help-seeking among rural individuals with mental illness.

**Methods:** We systematically searched seven databases [PubMed, CINAHL, Medline (OVID), PsycINFO (OVID), Cochrane, Embase, and ProQuest] in May 2023 and included the studies if they reported the barriers or/and facilitators to seek healthcare in rural patients with mental illness. We conducted hand search and citation search on Google Scholar for literature supplements. Thematic analysis was employed.

**Results:** The study included 27 articles reporting on the barriers and facilitators to seeking medical help in this population from 2007 to 2023. We ultimately identified themes at three levels: navigating the terrain of vulnerability and empowerment (the individual with mental illness), navigating the terrain of external environment (the external environment) and connectivity within the healthcare ecosystem for mental health (the health service system).

**Conclusions:** We must design more effective strategies to improve mental healthcare access for rural patients, considering cultural nuances and health service utilization patterns. This requires a multi-level approach, tailored to the unique needs of diverse populations.

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## Introduction

Mental illness is a global public health issue [1], affecting millions of people's mental health worldwide and is one of the leading causes of disability and morbidity worldwide [2]. It may seriously affect these patients' quality of life, including their physical, social, and emotional aspects. The study has shown that overcoming a series of barriers when seeking medical help is the experience of most mental illness patients [3,4]. Exploring this can be a sensitive and complex topic for them, often accompanied by particular challenges of social self-stigmatization and negative perceptions

[5,6]. Due to these difficulties and challenges, patients cannot access medical services on time. It may delay patients' disease diagnosis and treatment, affecting their recovery and happiness satisfaction and significantly increasing social burden and risk [7].

The study showed that medical health has a wide gap in rural–urban areas [8]. Almost all rural–urban differences in health staffing, service financing, and legal coverage occur in the rural population. Data showed that half of the world's population lives in rural areas. However, only 23.0% of health workers globally work in rural areas and 63.0% of rural people lack access to medical help, compared with 33.0% of the urban population [9]. Mental illness are widespread in urban and rural areas alike, but due to many factors such as limited medical resources, there are many barriers to medical treatment in rural areas, resulting in medical service utilization rates being much lower than in cities [10]. Therefore, we need to understand fully the barriers and facilitators of rural people with mental illness from seeking medical help. This will allow the design of future interventions to expand the accessibility and availability of rural mental health services.

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Most existing studies have explored this topic from a single perspective of patients, caregivers, and other stakeholders but still require systematic examination to synthesize these different perspectives [11,12]. The aim of this review is to examine the barriers and facilitators to seeking health help for rural people with mental illness by synthesizing findings from included studies. The following two issues are mainly discussed in this paper: (1) What are the barriers and facilitators of medical help-seeking for people with mental illness in rural areas from multiple levels of stakeholder perspective? (2) What guidance and recommendation can be provided for future clinical practices and research from the combined results of these studies?

## Methods

### Study design

We have conducted a qualitative meta-synthesis, and the study protocol had been registered in PROSPERO (international prospective register of systematic reviews) in June 2023 (Registration number: CRD42023429680). Meta-synthesis is increasingly recognized as an effective way to inform appropriate medical health interventions [13]. This systematic review was undertaken following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) [14] and the Enhancing Transparency in Reporting the Synthesis of Qualitative Research [15].

### Search strategies

Peer-reviewed journal articles in English were identified by searching databases [PubMed, Medline (OVID), PsycINFO (OVID), CINAHL, Cochrane, Embase, and ProQuest] from inception to May 2023. The search strategy was pre-designed and developed for PubMed. The full database search strategy is in eAppendix 1 in the Supplement. In this review, the participants were people with

mental illness or other stakeholders; the phenomenon of interest was the experience of people seeking medical help, the context was rural, and the type of study was qualitative. Additionally, we conducted hand search and citation search on Google Scholar for literature supplements.

### Study selection and quality appraisal

All search results were imported into EndNote X9 software and independently selected for research by LHZ and YBC researchers. When there were any disagreements, they had a critical discussion and discussed them with a third researcher.

Inclusion criteria were the following: (1) qualitative studies with qualitative components; (2) a sample of mental illness patients in rural settings (including mental illness, schizophrenia, anxiety, depression, bipolar disorder, and borderline personality disorder.); (3) studies that described barriers or facilitators to seeking medical help; (4) published in English.

Exclusion criteria were the following: (1) non-rural patients with mental illness; (2) instead of describing the barriers or facilitators to patients' medical help-seeking; (3) apart from the aforementioned mental disorders and their types, such as postpartum depression (maybe their service strategies are different from others); (4) studies not written in English, no peer review and grey literature. The selection process and results follow the PRISMA system reporting guidelines (Figure 1).

The quality of included studies was appraised by the Critical Appraisal Skills Programme – Qualitative Research Checklist [16]. The two authors evaluated independently and consulted with other team members on differences.

### Data extraction and synthesis

The extracted data included author, year of publication, country, research aims, participants' age and gender, recruitment strategies,

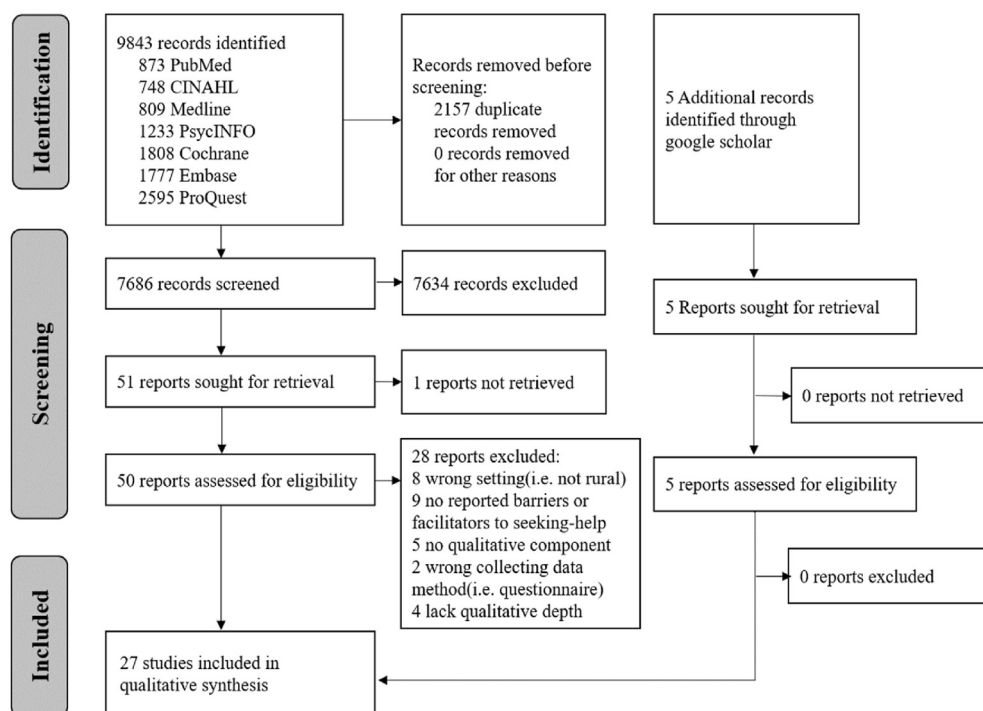


Figure 1. PRISMA Flow Diagram.

Note. PRISMA = Preferred Reporting Items for Systematic Reviews and Meta-Analyses

**Table 1** Data Extraction.

Author (year)	Country	Research aims	Participants (n)	Age Gender	Recruitment strategy	Type of mental illness and mental illness severity	Research design Data collection Data analysis
Abayneh (2017)	Ethiopia	To explore barriers to, and facilitators of, service user/caregiver involvement in rural Ethiopia to inform the development of a scalable approach	Mental health service users (n = 13), caregivers (n = 10), heads of primary care facilities (n = 8), and policymakers/planners/service developers (n = 8)	2 participants were aged ≤25 years 21 participants were aged >25 years Female = 11	Purposive sampling	Schizophrenia, schizoaffective disorder, bipolar disorder, depressive disorder with psychotic features major depressive disorder Other not reported	Phenomenology interviews Thematic analysis
Angdembe (2017)	Nepal	To better understand a comprehensive mental health approach	Working at the policy level, workers at health facility level, community level members, and service users (n = 95)	Average age of 47.68 years Female = 49	Purposive sampling, snowball sampling	No reported severe mental disorders	Formative qualitative interviews, focus groups Framework analysis
Braathen (2013)	South Africa	To study access to health services for vulnerable populations	A woman with mental disorder and her family (n = 7)	65 years Not reported	Not reported	Not reported	Grounded theory Interviews Grounded theory analysis
Byrne (2017)	Australia	To describe significant barriers to the provision of quality mental health services in rural and regional locations	Peer workers (n = 13)	Not reported Female = 8	Purposive sampling	Not reported	Grounded Theory Interviews Grounded theory analysis
Chilale (2017)	Malawi	To identify factors that influence healthcare help-seeking behaviors and possibly identify barriers that may exist between service users and service providers	Clients recovering from mental health problems and carers (six homogeneous groups of a maximum of eight participants)	All participants were aged >18 male-to-female client ratio of 1:1, Caregivers: Mostly women over 40 years	Purposive sampling	Schizophrenia, bipolar affective disorder Mentally stable	Exploratory phenomenology Focus groups Thematic analysis
Collins (2009)	Australia	To investigate barriers to help-seeking for mental health concerns	Adults (n = 16)	Ranged 36–75 years Female = 11	Maximum variation sampling, snowball sampling	Depression, psychosis, anxiety Not reported	Qualitative study Interviews Thematic analysis
De Silva (2017)	Australia	To explore GPs' experience and views on which factors influence access to mental health services for mild to moderate depression	General practitioners (n = 10)	Not reported Female = 2	Purposive sampling	Depression Mild-moderate	Qualitative study Interviews General inductive approach
Esponda (2022)	UK	To investigate factors that influenced engagement in a primary care mental health service program	Patients with common mental disorders (n = 30)	Ranged 18–60 years Female = 28	Purposive sampling	Depression, anxiety Not reported	Qualitative study Interviews Framework analysis
Goodwin (2007)	Australia	To explore the theme of systemic barriers to participation	Relatives or friends (no reported)	Not reported	Posters, flyers, press advertisements, and conferences	Not reported	Qualitative study Focus groups Content analysis
Goodwin (2008)	Australia	Psychiatric nurses' views about systemic barriers to participation and the potential of education	Nurses (n = 30)	Not reported	Purposive sampling	Not reported	Explorative qualitative Focus groups Content analysis

(continued on next page)



Table 1 (continued)

Author (year)	Country	Research aims	Participants (n)	Age Gender	Recruitment strategy	Type of mental illness and mental illness severity	Research design Data collection Data analysis
Hailemariam (2016)	Ethiopia	To explore barriers to initial and ongoing engagement of people with severe mental disorders (SMD) in rural Ethiopia	Service users in treatment ( $n = 10$ ) and carers ( $n = 7$ ), People with SMD never accessed care ( $n = 3$ ) and caregivers ( $n = 7$ ), people with SMD who had initiated treatment ( $n = 4$ ) and Caregivers ( $n = 8$ ) Additional interviews ( $n = 11$ ) Stakeholders ( $n = 33$ )	All participants were aged >18 Female = 19	Purposive sampling	Not reported severe	Phenomenology study interviews, focus groups Thematic analysis
Hailemariam (2017)	Ethiopia	To inform delivery of a new primary care-based mental health service in rural Ethiopia by identifying potential barriers to equitable access to mental healthcare and strategies to overcome them	Primary care providers, faith community representatives, college students, administrators, and families ( $n = 50$ ) Aboriginal men, carers, and those involved in service delivery ( $n = 17$ )	Ranged 25–65 years Female = 17	Purposive sampling	Not reported	Formative qualitative Interviews Framework analysis
Haynes (2017)	America	To understand mental health, mental health treatment, and barriers to treatment	Primary care providers, faith community representatives, college students, administrators, and families ( $n = 50$ ) Aboriginal men, carers, and those involved in service delivery ( $n = 17$ )	All participants were aged >18 Female = 28	Snowball sampling	Not reported	Qualitative study Interviews Principles of grounded theory
Isaacs (2013)	Australia	To explore the help-seeking behavior of Aboriginal men who are mentally unwell in a rural Victorian community	Aboriginal men, carers, and those involved in service delivery ( $n = 17$ )	Ranged 25–65 years Female = 2	Snowball sampling, purposive sampling	Not reported	Qualitative description Interviews Thematic analysis
Kasa (2023)	Ethiopia	To explore the preferences for healthcare and its determinants among mentally ill patients	Key informants, mental health stakeholders ( $n = 26$ )	Ranged 20–55 years, average age of 37.92 years Female = 12	Purposive sampling	Not reported	Ethnographical study Focus groups, interviews Thematic analysis
Kitchen (2013)	America	To investigate depression treatment preferences and anticipated service use	Adults ( $n = 16$ )	Ranged 56–63 years, average age of 59 years Female = 8	Chain sampling	Depression Not reported	Qualitative methods Interviews Thematic analysis
Mabunda (2022)	Brazil	To explore the CHWs perception of psychosis and their experiences and beliefs about the factors that might enable or hinder care-taking for patients with psychosis	Community health workers ( $n = 79$ )	Average age of 38.81 years Female = 51	Purposive sampling	Not reported	Qualitative study Focus groups Thematic analysis
Mokwena (2021)	South Africa	To determine the reasons for treatment defaulting	Treatment defaulter ( $n = 21$ )	Ranged 19–45 years, Average age of 35 Female = 10	Purposive sampling	Schizophrenia, major depressive disorder Not reported	Explorative qualitative Interviews Thematic analysis
Muhorakeye (2021)	East Africa	To investigate these barriers to mental health service utilization in depth	Patients with mental disorders ( $n = 10$ )	Ranged 18–59 years, Average age of 41 Female = 4	Convenience sampling	Anxiety disorders, psychosomatic disorders, schizophrenia, depression, epileptic, substance use disorder, dual diagnosis Not reported	Qualitative method Interviews Thematic analysis
Reddy (2014)	South India	To explore factors that preclude patients and their families' access to psychiatric treatment	Patient, family-related ( $n = 16$ )	Average age of 40.06 Female = 7	Case finding	Schizophrenia Not reported	Qualitative method Interviews Content analysis

Roberts (2020)	UK	To identify and describe self-reported barriers that contribute to this “treatment gap” in a rural district in central India	Screening positive for depression and their relatives ( <i>n</i> = 50)	Ranged 18–70 years, Average age of 42.3 Female = 21	Purposive sampling	Depression Moderate, moderately severe	Qualitative study Interviews Framework approach
Robinson (2012)	America	To determine the experience of patients and family members who are dealing with mental illness in rural communities.	Patients and family members ( <i>n</i> = 44)	Not reported	Snowball sampling	Not reported	Qualitative study Focus groups Immersion/ crystallization technique
Snell-Rood (2017)	America	To understand women’s experiences of depression broadly and their effects on the use of conventional treatments for depression	Low-income women ( <i>n</i> = 28)	Ranged 20–66 years Female = 28	Purposive sampling	Depression Moderate to severe	Qualitative study Interviews Directed content analysis
Speed (2013)	America	To examine the lived experiences of rural African Americans accessing and utilizing mental health services	Rural African Americans with mental illness ( <i>n</i> = 9)	Average age of 30 Female = 7	Purposive sampling, snowball sampling	Bipolar disorder Depression No reported	Phenomenology study Interviews Phenomenological analysis method
Van Rooyen (2019)	South Africa	To explore and describe experiences of persons living with severe and persistent mental illness and those of their families in respect of mental health services	Mental illness and their family members ( <i>n</i> = 29)	Patients: ranged 30–40 years Others not reported	Convenience sampling, Purposive sampling	Schizophrenia Severe and persistent	Qualitative, descriptive, and exploratory research Interviews Thematic analysis
Vayro (2023)	Australia	To identify and understand the personal factors that act as barriers and facilitators to mental health help-seeking in farming populations	Farmers ( <i>n</i> = 10), partners ( <i>n</i> = 10), and general practitioners ( <i>n</i> = 8)	All participants were aged >18 Farmers: ranged 43–70 years Partners: ranged 29–64 years Female = 16	Snowball sampling	Not reported	Explorative qualitative Interviews Thematic analysis
Wang (2023)	China	To describe and document the experiences of people with schizophrenia during the delayed treatment in rural China	Patients ( <i>n</i> = 13)	Average age of 34, ranged 21–53 years Female = 6	Purposive sampling	Schizophrenia Not reported	Phenomenology study Interviews Thematic analysis

Note. CHW = community health worker

mental illness type and severity, study design, data collection, and analysis (Table 1).

The papers were imported to the qualitative data management software (NVivo 14). Thomas and Harden's thematic analysis approach was used to guide the meta-synthesis [13]. The purpose of this analysis is to synthesize the experience of seeking help for schizophrenia in rural areas. As thematic analysis enables the analysis, organization, and detailed description of data, it allows authors to gain in-depth insights into the themes and patterns present in the data during the analytical process, and this data-driven approach enables results to be strongly supported in the data [17]. Firstly, the first author partially extracted, then repeatedly browsed, and coded the data from the included studies. The extracted data pertained to experiences of seeking professional help for rural schizophrenia and was predominantly presented through participant quotations. This approach was adopted based on the belief that such a method would more directly explore the participants' potential meanings. Then, the second author randomly checked at least 10%, and if they disagreed, they discussed it with the other authors. After coding all the studies, the first and second authors developed descriptive topics and generated analytical topics.

In the final stage of generating analytical themes, the research team identified emerging themes broadly consistent with the Anderson's health service use behavior model level [18]. After subjecting the generated subthemes to critical discussion, they have been assigned to the health service use behavior model (individuals with mental illness, external environment, and health service system). At the appropriate levels, we identified the factors that facilitate or hinder help-seeking behavior. This model [18] was decided to be used because it can be applied to the health service utilization behavior of the whole population and provides an analytical framework with high theoretical value and practical significance for analyzing the medical behavior of different people [19]. All the authors actively participated in the whole analysis and synthesis process.

#### *Researcher reflexivity and trustworthiness*

All authors have a nursing academic background and experience in mental, psychological, and qualitative research. The reliability of the research is ensured through four areas: credibility, reliability, confirmability, and transferability [20]. The included studies underwent rigorous peer review, and the qualitative research's good-quality assessment (see eAppendix 2 in the Supplement) confirmed the credibility of the results. Reliability is obtained through the analysis of research data methods and the presentation of results. The thematic analysis we employed is a prevalent method in recent qualitative health psychology, capable of analyzing the facilitators and barriers of a particular experience. Moreover, we selected descriptive citations from the literature to support the themes of the articles. This further provides readers with the opportunity to review the research results, demonstrating the confirmability of the study. Among the 27 studies included, participants from various countries, cultures, and identity backgrounds were involved. The integration of these studies allows readers to assess the potential applicability of the research results, reflecting the transferability of the study. We engaged in critical reflective discussions, analyzing only participants' quotations to minimize the impact of pre-existing ideas and experiences on the results. All researchers were actively involved in the process of data screening, extraction, and integration to improve the validity of the review results.

## **Results**

We identified 9,848 articles through 7 databases and Google Scholar searches, 55 full-text articles were read, and 28 were excluded (Figure 1). Finally, 27 [7,10–12,21–43] articles met the inclusion criteria for this review and reported quality appraisal results in eAppendix 2 in the Supplement. Studies were conducted in Australia ( $n = 7$ ), America ( $n = 5$ ), Africa and Ethiopia ( $n = 4$ ), the UK ( $n = 2$ ), Nepal, Malawi, Brazil, South India, and China ( $n = 1$ ).

#### *Quality appraisal*

All 27 included studies were in good quality, scoring at least 7 out of 10 Critical Appraisal Skills Programme (CASP) items. One (3.7%) study did not describe the recruitment strategy; ten (37.0%) studies did not describe the relationship between researchers and participants; and four (14.8%) studies did not describe the consideration of ethical issues. All 27 studies were analysed qualitatively due to the methodological quality.

#### *Demographic characteristics of the research results*

There were 739 participants (not including two articles that do not report the number of participants). Participants in the included studies ranged from about 18 to 75, and most were women. Studies reported various participants, including mental health service users, caregivers, friends, peer workers, general practitioners, nurses, community health workers, primary care providers, faith community representatives, agriculture, teachers, college students, administrators, and other stakeholders. Thirteen studies did not report the type of mental illness, and most did not report the severity of mental illness (Table 1).

#### *Methodological characteristics*

The 27 included studies used different qualitative research designs: 5 phenomenological studies, 3 grounded theory studies, 1 ethnographical study, the other 4 studies only reported exploratory qualitative research, 2 formative qualitative pieces of research, and 12 qualitative research studies with no specific methodology. Nineteen studies used interviews to collect data, 5 used focus groups, and three reported both. For data analysis, thematic analysis was most commonly used in 13 studies, content analysis in 4 studies, framework approach in 4 studies, grounded theory in 3 studies, phenomenology in 1 study, immersion/crystallization method in 1 study, and general inductive method in 1 study (Table 1).

#### *The results of meta-synthesis*

Our meta-synthesis revealed the barriers and facilitators to seeking medical help for rural people with mental illness: individual factors, external environmental factors, and health service system factors (Figure 2).

#### *Navigating the terrain of vulnerability and empowerment Vulnerability in seeking help*

*Resource scarcity and survival priorities.* Fifteen studies [7,10–12,23,27,29–31,34,36,39–41,43] have highlighted that patients face a tug-of-war between their mental health needs and the practical demands of life, especially in rural areas where economic hardship and the need to secure basic resources take precedence. Several participants have indicated the necessity of maintaining continuous work to prevent the risk of hunger, "I am too busy" [10].

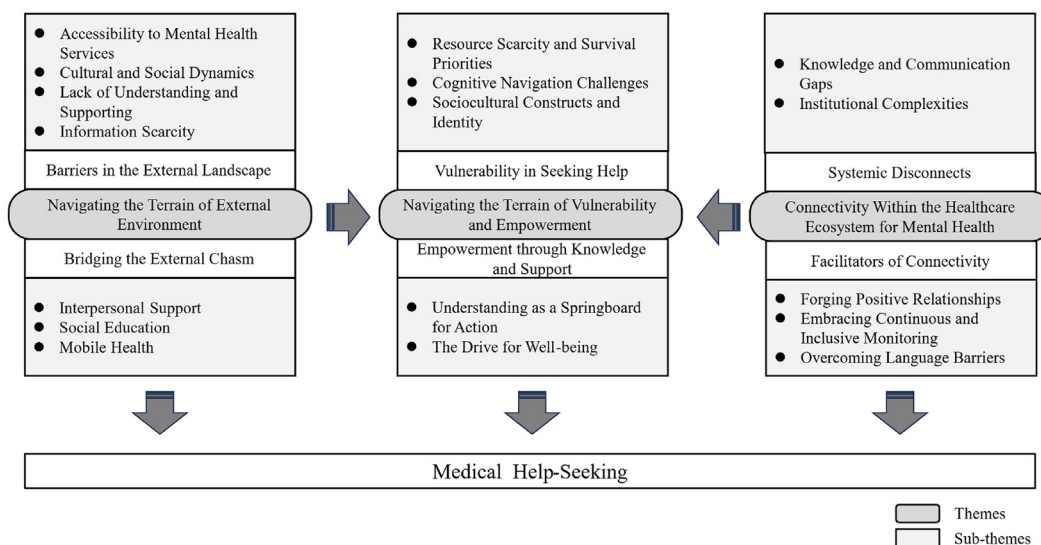


Figure 2. The Barrier and Facilitator to Medical Help-seeking.

Others were compelled to forsake medical treatment owing to indigence, “Some people returned to their homes with their prescription paper without buying the medication” [31]. Moreover, financial limitations also hindered access to healthcare services, with participants revealing, “We were unable to travel far and obtain treatment due to financial constraints and there was no money to spare on treatment” [39].

**Cognitive navigation challenges.** In 22 studies [7,10,11,21–23,25–27,30–41,43], individuals with mental illness often struggle with health literacy and confront complications linked to the intrinsic nature of their mental conditions, which hampers their ability to seek and adhere to treatment. As Wang [7] reported, “I didn’t think my symptoms were serious, so I bought some hypnotics at the village pharmacy”. Similarly, Muhorakeye and Biracyaza [38] found, one participant said, “I only knew other people’s disease like malaria and I just used to look at people who are sick. I didn’t have any thoughts about mental health conditions” Most patients are sceptical about treatment for their disease, specifically related to their barriers to seeking help. “I’m scared to death to try [antidepressants]—because I see so many people that are on it are just zonked out”, said Snell-Rood of Hauenstein [41]. Furthermore, the complications of abnormal brain function of mental illness itself may make it difficult for patients to seek medical help. “Disabled people can do this since they are physically disabled. But mentally ill person faces difficulty on the main part of thinking” [21].

**Sociocultural constructs and identity.** Fifteen studies [7,11,21,26,30,31,33–37,39–41,43] collectively examined the distinct characteristics of individuals in rural areas compared to their urban counterparts. In rural settings, deep-seated gender norms and identity-related expectations create obstacles that particularly impact women’s access to care, “families prefer putting women in chain than taking them for treatment” [30] and men’s willingness to seek help, “I don’t need help. Just go and be a man and stuff” [33], further compounded by instability in living situations, “I was away visiting relatives in Dubai. I overstayed. I left my hospital card at home” [37].

#### Empowerment through knowledge and support

**Understanding as a springboard for action.** Nine studies [7,10,25,27,31,34–36,41] propose that knowledge of the illness and

an appreciation of the benefits of treatment equip individuals with the power to take action, breaking the cycle of helplessness. As emphasized in the study by Wang [7], one patient underscored the significance of knowledge, asserting, “I need to know more about my illness so that I can recognize the symptoms at first” Numerous studies demonstrate that engagement with mental health services can yield multiple benefits, as suggested by the following quotations: “It [my health] improved after the treatment” [31] and “It [involvement] can also help protect people with mental health problem from any abuse and maltreatment. Their [service users and caregivers] participation could also mean that the professional can get needed information from them about their need and situation” [21]. Some participants broached issues related to social recognition and integration, noting, “—but now he has been re-integrated into the family and community” [25].

**The drive for well-being.** This theme emerged in seven studies [7,10,25,27,31,35,41]. The fundamental urge to alleviate suffering and enhance quality of life serves as a motivator to engage with mental health services, with personal and familial well-being as critical incentives. One patient stated, “I was very constant with my [attendance], and whatever date the doctor said, I would be there. Because I wanted to get out of there. It is not nice to be sad, or angry, or anxious, or scared” [27]. Some participants reported that their utilization of mental health services to alleviate symptoms was driven by a commitment to their children: “Being healthy is important to me, I never want my kids to feel that I am too sick in the head to take care of them” [10].

#### Navigating the terrain of external environment

**Barriers in the external landscape accessibility to mental health services.** Irrespective of participant characteristics, all 13 studies [7,10–12,22–25,29–31,39,42] identified that a significant divide exists between the need for mental health services and their availability in rural areas. One patient lamented, “—there isn’t counseling available [in this town]” [11]. Concurrently, the unique characteristics of rural areas and geographical constraints impede the professional growth opportunities for peer workers. There is a scarcity of long-term service providers, compelling patients to seek aid in distant cities. “Because there is no psychiatrist who can be seen on a

permanent and regular basis, she had opted out of mental healthcare in her area in favour of driving 1.5 h to the city for treatment" [25]. Moreover, the "physical distance" rural patients must traverse to receive services poses a significant challenge, as stated by Byrne and Happel [24]. "It takes me an hour to get here. For our clients [consumers of the service] it's a real problem. If you live in [name removed], which is another hour south of the nearest mental health units, it's two hours to get here if you want to visit a loved one. So it's a big issue for us." Furthermore, the lack of convenient transportation in rural areas exacerbates the accessibility issues of mental health services: "There's not really any good public transport here—if you don't have a car it's pretty hard, and if you can't afford fuel it's pretty hard, and that's a big problem here" [12].

**Cultural and social dynamics.** Twenty-three studies [7,10–12,21,22,25–27,30–36,39–43] have revealed that enduring cultural attitudes towards mental illness creates a veil of stigma and misunderstanding that can suppress help-seeking behavior. For instance, beliefs such as "mental illness is an affliction of evil spirits" and "Traditional spiritualists have the power and gift to banish demonic spirits like 'Setana [the devil],' 'Buda [the evil eye],' and 'Jinni [the evil spirit],' which are responsible for impaired mental functions" [34]. The social stigma associated with such illnesses serves as a psychological barrier, "I'm not going to go to that place, then be labelled". If you go there, you'll be labelled as mental or something" [33]. Furthermore, some participants noted that despite the government's initiation of numerous aid programs for the impoverished, these programs may not reach individuals from vulnerable castes, thereby inhibiting them from seeking medical treatment. A patient from a general caste remarked, "We are Thakur by caste [general caste] so that's why we don't get any benefits" [40].

**Lack of understanding and supporting.** Sixteen studies [7,21,22,25–27,30,31,33,36–42] indicate that a dearth of comprehension and support from families, peers, and society, coupled with social stigma, deter individuals with mental illnesses from seeking medical aid. These impediments are notably associated with interventions rooted in family and societal structures. "After marriage, her brothers did not show any concern about their sister and they neglected her treatment" [39]. Some participants acknowledged that empathizing with the emotional and mental state of an individual with mental illness is challenging, "Only she can know about it—I don't know what she thinks in her mind and what she doesn't think" [40]. Social isolation exacerbates the difficulties encountered by individuals with mental illnesses when seeking medical help. "I just wouldn't tell them that I had mental disorder [depression] because they would say, 'Get away from me! You're mentally ill.'" [38].

**Information scarcity.** Eleven studies [7,22,26,30,33–36,38,42,43] propose that the comprehension of mental illness and mental health service information by patients and their caregivers is pivotal in seeking appropriate medical aid. The majority of these studies highlight the deficiency in health-related information pertaining to mental health education. This is encapsulated in the following quote: "Definitely a lack of education in the general community", "You never see anything advertised" [26]. This issue can be traced back to the insufficient mental health education information provided by the external environment, including communities or society at large. Moreover, individuals in rural areas often lack an in-depth understanding of potential mental illness symptoms and the available services and treatments. This lack of knowledge can impede their ability to seek help, and they may not even comprehend the services and treatments at their disposal: "If you're not told about how to go about getting that help you just don't know where to go obviously" [26].

#### *Bridging the external chasm*

**Interpersonal support.** Ten studies [11,22,25,27,28,31,33,36,38,39] underscore that family members, peers, and residential communities serve as significant catalysts for discussions related to mental illness and professional health services. It is often advantageous for a patient experiencing symptoms to engage in dialogs with close family members before seeking professional assistance. These are the individuals who are readily accessible to the patient and whom they trust due to familiarity. As some participants reported, "Family has a big role. Family should have supportive feelings for their ill member. Mental problems can be cured if there is good coordination between family members and their ill member" [22]. Furthermore, many studies posited that peers can exemplify positive behavior for patients. As reported by Hailemariam et al. [31], "Seeing someone recover is the key driver of seeking treatment". Some participants indicated that community workers can offer valuable assistance to patients. For instance, "As for my community, I, as a CHW, have to help those people who do not understand that the illness can be treated at the hospital, advise the ladies or the families to take the person with that disability to hospital, in order to get better ... " [36].

**Social education.** Nine studies [11,22,26,27,34–36,39,43] propose that the provision of relevant psychological support or health education from the external environment may exert a positive influence on patients. The majority of these studies assert that education is a critical step towards enhancing disease awareness and mental health literacy. As articulated by some participants, "I also think educating the community on just being mentally healthy, just educating and letting them know it's not a weakness but it's about a chemical imbalance and some things you can't help. Try to help them with coping skills and educate them" [32].

**Mobile health.** One study [22] suggests that the potential of mobile health technology presents an innovative pathway to overcome traditional barriers. As some participants articulated, "It will be feasible if people are able to use it. The documented cases can be easily searched and viewed. It will make the work of diagnosis much easier. If the people are able to use it then it will turn out to be a good idea" [22]. By leveraging digital platforms, mHealth can streamline the delivery of mental health assistance, information, and support to under-resourced areas.

#### *Connectivity within the healthcare ecosystem for mental health Systemic disconnects*

**Knowledge and communication gaps.** Nineteen studies [7,11,12,21–28,31–33,35,37,38,41,42] indicate that the challenge starts with the foundational issue of healthcare professionals' lack of mental health training and awareness, which leads to diminished patient trust. As one participant noted, "My concern is that the general practitioners, you know, they're not trained. They don't have that mental health background" [11]. In rural primary medical institutions, staff deficiencies in knowledge could result in delayed referrals, thereby impeding patients' access to professional medical assistance. One participant shared, "He (village doctor) did not say exactly what the disease was, and only gave me some sleeping pills" [7]. This barrier is amplified in rural settings, where the scarcity of specialized knowledge places sufferers at a disadvantage from the onset of their healthcare journey, "no one ever told them what was wrong with Pumla or what had happened to make her ill" [23].

**Institutional complexities.** Twenty-one studies [7,10–12,21,22,24–33,37,38,40–42] suggest that the mental health service system's inherent complexity, marked by inefficient organization and poor intercomponent communication, discourages patient engagement. One participant lamented, "The system is just crazy. It's designed for people who don't have jobs. It's not convenient at



all" [10]. Patients and caregivers alike find themselves navigating a labyrinth characterized by long wait times, fragmented services, and a conspicuous lack of cohesiveness that should ideally support their journey towards better mental health. Van Rooyen and Topper [42] quoted a participant's experience: "This takes a long time before a person gets help. You have to sit in a long queue with so many patients, and the sisters will take a long time to help you." A caregiver underscored the communication gap between psychiatric services and emergency services, stating, "It's usually the police that attend when there's a crisis and yet there's no information passed from the police to psych services" [28]. Issues with the service system's management were also reported. One participant reflected, "I think we've got a long way to go in terms of running meetings and services that are consumer and carer friendly" [29].

#### *Facilitators of connectivity*

*Forging positive relationships.* Six studies [12,27,28,36–38] indicate that the importance of nurturing positive interpersonal relationships between patients and healthcare providers emerges as a critical facilitator. It underscores the need for empathy, understanding, and a patient-centered approach in healthcare interactions, which can significantly enhance patient satisfaction and engagement. "The nurses were exceptionally caring and inclusive. Their interaction with us, and my son, was commendable. I found that I could contact him [the nurse] at any time. The experience was not only easy but also wonderful" [28]. Consequently, the vital role played by fostering harmonious relationships between patients and medical staff should not be overlooked in the delivery of healthcare services.

*Embracing continuous and inclusive monitoring.* Three studies [12,31,36] emphasize implementing continuous monitoring strategies, such as home visits by mental health professionals, is highlighted as an effective method for bridging the gap between rural communities and mental health services, "I guess some sort of outreach service would be fantastic, and if mental health services had mental health professionals that could actually go to people's houses and see them in that context and prescribe for them and manage them as a unit, that would be really good" [12]. It underscores the importance of a proactive and inclusive approach to mental healthcare that prioritizes regular follow-ups and personalized care plans.

*Overcoming language barriers.* Two studies [28,33] highlight recognizing the importance of language proficiency among healthcare providers, especially in linguistically diverse regions, emphasizes the need for a healthcare system that is accessible, inclusive, and sensitive to the cultural and linguistic context of its patients, "We have to use interpreter service, which is pretty cumbersome and hard to use. Sometimes those people fall through the cracks" [12]. Therefore, healthcare professionals who understand the local language are often better positioned to grasp patients' needs and concerns. They can provide meaningful feedback, facilitate discussions, and thus enhance patients' receptivity to professional assistance.

## **Discussion**

This meta-synthesis systematically reviews 27 studies on the factors that act as facilitators and barriers to seeking medical help for people with mental illness in rural areas. Barriers and facilitators are reflected across three levels: the individual level of mental illness, the external environment level, and the mental health service system level. These factors are often attributed to and interact across these levels.

#### *Individuals with mental illness*

When considering the factors that influence patients' help-seeking behaviors, it is vital to recognize that the characteristics of the environment and resources are not sufficient to account for entry or non-entry into the service system. Researchers must also consider the underlying mechanisms by which individual consumers seek medical help.

Firstly, individual barriers to correctly identifying illness and seeking professional help depend on the patient's knowledge, beliefs, and attitudes about mental illness and medical services. Symptoms of mental illness are blurred when distinguishing from physical symptoms (for example, irritability, difficulty sleeping, sadness, and fatigue, to name a few.); patients may not be able to take appropriate coping styles and may be less willing to seek help [27]. However, patients who know more about their disease and perceive that they will gain enough benefit from seeking help will increase their willingness to seek help [7,31].

Secondly, our findings suggest that some intersectional attributes of rural patients may limit patients' ability to seek help. For example, gender restricts women's normal help-seeking after illness and makes it difficult for dominant males to seek help when they are self-reliant [30,33].

Additionally, the patient's own possible conditions, such as poverty and time factors, may disrupt the normal behavior mode, making the road to seeking medical help fraught with obstacles [21,31,33,42]. However, this review found that patients' aspirations for their health needs outweighed these barriers to seeking medical help [7,27].

#### *External environment*

Our study suggests a lack of access to medical services and information resources in the external environment, a finding that aligns with a recent systematic review [44]. When patients develop symptoms, the relatively limited availability of resources and services often forces them to travel to another town, potentially leading to delays in seeking help from medical services [11]. A literature review reported the feasibility and acceptability of emerging mHealth and eHealth interventions for patients with mental illness [45]. The current review indicates that the accessibility and effectiveness of services for people with mental illness can be enhanced through mHealth technology, supplementing existing research in this area.

Mental illness is often stigmatized [38,39]. Lack of external understanding and support (for example, from peers, neighbors, and the community) can leave patients feeling isolated, and they are subjected to discrimination and ridicule by those around them, reducing their motivation to seek medical help [22]. At the family and community level, this review identifies active family involvement in services and the provision of community knowledge and education as facilitators for discussing patient medical help-seeking.

Additionally, our review finds that traditional cultural beliefs in rural areas often lead individuals to seek help from religion or village elders as a coping mechanism for stress [34,40]. This approach is inconsistent with the views of modern medicine. Therefore, cultural perception differences should be considered in designing interventions to promote medical help for people with mental illness in rural areas.

#### *Health service system*

The findings of this review also highlight several factors within the mental health service system that both present barriers to and

facilitate discussions about seeking medical help for people with mental illness. Our review found that patients and their families emphasize particularly the potential role of personal relationships between professional staff and themselves. Good relationships may enhance their experience of seeking and thus facilitate patients' help-seeking behavior [43]. Regular training and briefing of healthcare staff should be strengthened to overcome the professional staff's lack of knowledge and communication skills [21,22]. Previous studies also support this finding [46]. In addition, this review highlighted the importance of mental health staff knowing or being fluent in the local language, similar to the research of Al Shamsi et al [47] on language barriers in healthcare.

The review found that patients and families were less motivated to seek help when they perceived the service system as complex and challenging to access and when their lack of understanding of it was inconsistent with their views [10]. The review also indicated significant issues with communication and liaison between services. The study by Goodwin and Happell [28] argues that all services should be interconnected, although these are not emerging findings [48]. The continuity of care is highly valued by many participants in rural areas, and it is seen as strength of rural services [28]. Continuous monitoring of patients can optimize resource allocation and improve the efficiency and effectiveness of medical services, corroborating and complementing previous research [49].

The results of this review reveal that there are barriers and facilitators affecting their behavior in individuals with mental illness, external environment, and service system, and they are more common in individuals with mental illness and external environment levels. It is worth noting that we cannot deny that a great deal of work has been done on mental health. Still, the review revealed a common thread across nearly all studies: patients' unfamiliarity with mental illness and health services, lack of social support, and stigma are important factors preventing patients from seeking medical help. This does not undermine the significant work that has been done in mental medical help; it underscores the possibility that these barriers may arise from a combination of factors. Therefore, future interventions should take into account the unique characteristics of patients in rural environments, adopt multiple perspectives, and form close connections with the external environment and service system.

Despite modest successes in mental health medical services coverage and utilization, gains have been less pronounced in many low-income countries [31]. Therefore, more extraordinary efforts are needed. So far, practical measures to address these problems have tended to employ strategies of centralizing public knowledge of mental health medical services delivery. It aims to reduce disease stigma and encourage patients to seek medical help as early as possible [50]. This strategy may benefit some patients but does not significantly improve patient willingness to seek medical help, possibly because it does not take into account the inherent rural context such as the patient's living conditions or cultural beliefs. Approaches to improving patient service utilization can be more effective when decision-makers and service providers integrate their strategies with theoretical models and local constraints. Where the strategies implemented are not adapted to the local context in this way, the conclusions drawn in this review suggest that, even with considerable effort, some local people with mental illness still face many challenges in seeking medical help from health services.

Challenges can exist for a variety of reasons, including various factors such as the limitations of the patient's own conditions and the lack of corresponding health medical resources. We need an in-depth analysis of facilitators and hindrances at different levels to help patients seek medical help more accurately. There is a need to

provide education on specific needs, highlight potential benefits of participating in services, and encourage patients and their families to seek medical help. Moreover, peer support is also critical, and patients who benefit from services can share their experiences, which may motivate other patients to seek help. At the same time, mobile technology can make up for the incoordination of urban and rural resources and help patients obtain medical services in a timely and effective manner.

Training of professionals is also necessary to enhance their knowledge, language, and communication skills. Often, these individuals may not be fully equipped to assess and recognize a patient's symptoms, potentially leading to misdiagnosis and delayed treatment, which could undermine patient trust. By providing appropriate training to doctors and nurses, we aim to enhance their ability to communicate effectively with patients and encourage patients to seek medical help actively.

Unfortunately, some studies did not adequately consider the relationship between researcher and participants, and several did not consider ethical issues. Future qualitative research in this field should follow qualitative research reporting guidelines to improve the methodological quality of the research.

### Strengths and limitation

The strength of this study is that the participants included in the study are stakeholders from different occupations, countries, and cultural backgrounds. To our knowledge, it is the first systematic and comprehensive review of qualitative research in the field that uses rigorous thematic analysis to identify multi-level factors and provide reference information for future interventions. The limitations of this synthesis include the potential for reporting bias in the studies. The study only included literature published in English, and we could not review the experiences of people with mental illness seeking medical help in non-English-speaking cultures. The inclusion criteria for the study favored patients with more common psychiatric disorders, leading to the exclusion of unselected patients, which may also limit the study. Differences in the methodological quality and rigor of the included studies could affect the overall quality of our synthesis. Lastly, different countries have different definitions of rural areas and different healthcare systems and resources available, which could be a limitation of this study.

### Conclusion and recommendation

The combined results of this qualitative research-based meta-analysis provide new insights into barriers and facilitators of seeking medical help for people with mental illness in rural areas. We reveal these factors' complexity and multifaceted nature, which may provide more valuable assistance for future interventions. Inadequate awareness of mental illness, limited access to help-seeking and stigmatized environments, as well as staff competencies hinder individuals' likelihood of seeking medical help. To address the multifaceted and complex help-seeking challenges of rural mental illness patients, interventions at different levels need to be considered comprehensively, and approaches to develop rural mental illness management consistent with different cultural backgrounds and health service use behavioral mechanisms need to be explored. This may require further research in the future to better understand barriers and facilitators of medical help-seeking among rural mentally ill patients.

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## Conflict of interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

## Ethics approval

Not applicable.

## Patient consent

Not applicable.

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## Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.anr.2024.04.010>.

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