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Impact of Nursing Interventions on Hospital Readmissions in Patients With Pulmonary Tuberculosis: A Quasi-Experimental Study

Sunpapoa, Chamlong [1]
; Na-Ek, Nat [2]
; Sommai, Areeya [3]
; Boonpattharatthiti, Kansak [4]
; Huynh, Nina S [5]
; Kanchanasurakit, Sukrit [6]
[1] Division of Internal Medicine, Department of Nurse, Phrae Hospital, Phrae, Thailand [2] Division of Social and Administration Pharmacy, Department of Pharmaceutical Care, School of Pharmaceutical Sciences, University of Phayao, Phayao, Thailand [3] Division of Ambulatory Care, Department of Pharmacy, Phrae Hospital, Phrae, Thailand [4] Department of Clinical Pharmacy, Faculty of Pharmaceutical Sciences, Burapha University, Chonburi, Thailand [5] Department of Pharmacy Practice, University of Illinois at Chicago College of Pharmacy, Chicago, USA [6] Division of Pharmaceutical Care, Department of Pharmacy, Phrae Hospital, Phrae, Thailand; Division of Clinical Pharmacy, Department of Pharmaceutical Care, School of Pharmaceutical Sciences, University of Phayao, Phayao, Thailand; Center of Health Outcomes Research and Therapeutic Safety (Cohorts), School of Pharmaceutical Sciences, University of Phayao, Phayao, Thailand; Unit of Excellence on Clinical Outcomes Research and IntegratioN (UNICORN), School of Pharmaceutical Sciences, University of Phayao, Phayao, Thailand; Unit of Excellence on Herbal Medicine, School of Pharmaceutical Sciences, University of Phayao, Phayao, Thailand

ABSTRACT (ENGLISH)

SummaryPurpose
Our study aimed to evaluate the effectiveness of the nursing care program on the incidence and rate of 28-day hospital readmissions among pulmonary tuberculosis (TB) patients.
Methods
We conducted a quasi-experimental study using a historical control (usual care) group. Patients diagnosed with pulmonary TB who received nursing interventions between January 28, 2021, and May 31, 2021, were categorized as an intervention group, whereas historical controls were selected from January 1, 2020, to December 31, 2020. The primary outcomes were the incidence and rates of hospital readmissions within 28 days due to TB-related complications. The secondary outcome was the change in knowledge and self-care behavior scores at discharge and 28 days postdischarge. Cox models were used to assess the intervention's impact on the incidence of hospital readmission. Rates of readmission were compared by the Poisson model. Both Cox and Poisson models were adjusted for age, sex, sputum smears at diagnosis, serum albumin level, and diabetes mellitus at baseline.
Results
Among 104 pulmonary TB patients included in the analysis (68 were in a historical control group and 36 were in an intervention group), 20 patients were readmitted due to TB-related complications. We found that our nursing care program resulted in a significant reduction in the incidence (adjusted hazard ratio was 0.16 [95% CI 0.03, 0.87]) and

the rate of hospital readmissions (adjusted incidence rate ratio was 0.22 [95% CI 0.06, 0.85]). Furthermore, nursing interventions significantly improved knowledge and self-care behavior scores with significant score retention at 28 days postdischarge.

Conclusions

The nursing care program can significantly decrease the incidence and rate of 28-day hospital readmission and improve knowledge and self-care behavior scores in pulmonary TB patients.

FULL TEXT

Introduction

Pulmonary tuberculosis (TB) is a major health problem worldwide, especially in developing countries [1,2]. According to the World Health Organization (WHO), TB affects more than 10 million people so far, leading to 1.5 million deaths globally [1]. Thailand is among the countries where the TB burden is stretched. In 2021, the estimated incidence of TB in Thailand was 42.6 per 100,000 population [3].

Although TB is a curable disease, treatment failure is still challenging as patients need to strictly adhere to a long treatment duration (i.e., at least 6 months of a standard regimen). Therefore, to improve the treatment success, multimodalities of patient care from multidisciplinary healthcare professionals are required. These modalities include (1) Directly Observed Therapy (DOT) program, (2) home healthcare and nutritional supporting program, (3) pharmacist monitoring program, and (4) a nursing care program [4–9].

The nursing care program aims to enhance patients' and caregivers' knowledge and improve treatment adherence. The program also proactively monitors patients' responses and treatment-related adverse events. The previous study showed that nurses' discharge planning programs could improve TB patients' knowledge and self-care behavior scores [10]. However, it is unclear whether these improved scores could be maintained during the next follow-up visit. Moreover, a previous randomized controlled trial had shown that empowering patients through nursing care programs can decrease the readmission rate in heart failure patients [11]. Nevertheless, no study directly examines the impact of nursing intervention on TB outcomes.

We conducted a quasi-experimental study using a historical control to investigate the effectiveness of a nursing care program on the incidence and rates (i.e., frequency within a specific period) of hospital readmissions within 28 days after hospital discharge among pulmonary TB patients. We also examined the change and retention of TB patients' knowledge and self-care behavior scores after receiving nursing interventions.

Methods

The report of this study followed the Transparent Reporting of Evaluations with Nonrandomized Designs (TREND) statement (Supplementary Table S1) [12].

Study design

This study implemented a quasi-experimental design using a historical control group to assess the effectiveness of a recently initiated nursing care program at Phrae hospital, Thailand. All pulmonary TB patients diagnosed and admitted to the hospital from January 28, 2021, onward would receive a nursing care program during hospitalization, upon hospital discharge, and at 28 days postdischarge. These patients were then categorized as an intervention group and were followed for a month later. The data of a historical control group was collected from pulmonary TB patients who were initially diagnosed and admitted from January 1, 2020, to December 31, 2020 (the period before the nursing program was initiated). We only considered the first readmission episode after the TB diagnosis for individuals with several hospital admissions.

Setting and participants

This research was conducted on a general medicine ward at Phrae hospital, a 500-bed secondary hospital in northern Thailand. Eligible participants were inpatient pulmonary TB patients diagnosed by physicians using WHO's criteria [13], based on clinical manifestations, chest X-ray, and laboratory values. We excluded patients who were (1) aged ≤18 years old at the time of pulmonary TB diagnosis, (2) not able to fluently communicate in Thai, or (3) not able to cooperate with the investigation. Moreover, individuals who died within 28 days postdischarge, lost to follow-

up, or had missing data in the electronic database were not included in the analysis.

Intervention: A nursing care program

The nursing care program consists of several proactive actions at three periods, including (1) during the hospital stay, (2) on hospital discharge day, and (3) at 28 days postdischarge. The multidisciplinary team, including registered nurses, infectious disease physicians, clinical pharmacists, and nutritionists, designed and developed this program. Details of the interventions given at each period are as follows:

During a hospital stay, the interventions included as follows:

- **1)** Administering medications with the directly observed therapy (DOT) program by registered nurses.
- **2)** Evaluating patients' treatment regimens and nutritional status by physicians, clinical pharmacists, and nutritionists.
- **3)** Assessing baseline scores of patients' knowledge and self-care behaviors using two questionnaires (pulmonary TB knowledge questionnaire and self-care behaviors questionnaire) by registered nurses.

The details of the questionnaire used in our study have been described elsewhere [10]. In brief, this questionnaire is a set of questions designed to assess a patient's knowledge of the etiology, signs and symptoms, route of transmission, treatment, and prevention of TB infection. Responders were assigned one point for each correct answer or zero points if-else. The total score ranged from zero (i.e., no knowledge at all) to ten points (i.e., excellent knowledge) (Supplement TableS2). According to the previous study, the content validity index (CVI) and the Kuder &Richardson 20 (KR-20) of the knowledge questionnaire were 0.90 and 0.71, respectively [10].

The self-care behavior questionnaire contains twelve questions designed to address patients' hygienic habits to control the transmission of TB. Responders were given 5 (regular), 3 (occasional), and 0 (never) points for each question. Thus, the total score ranged from 0 (i.e., no hygienic habits at all) to 60 points (i.e., fully corporate with hygienic habits) (Supplement TableS3). Additionally, the self-care behavior questionnaire showed an excellent content validity (CVI of 1.00) and a good reliability (Crombach's α of 0.82) from the previous work [10].

- **4)** Providing the information regarding the disease and the treatment to enhance patients' knowledge by registered nurses.
- **5)** Contact tracing and monitoring potential adverse drug reactions due to anti-tuberculosis therapy (e.g., hepatotoxicity or an allergic reaction) by registered nurses and clinical pharmacists.

Upon hospital discharge, the interventions included as follows:

- **1)** Assigning the home health care team to provide continuity of care and monitor patients at home.
- **2)** Re-assessing patient's knowledge and self-care behavior by registered nurses.
- **3)** Re-counseling patients about adverse drug reactions of anti-tuberculosis medications and emphasizing the importance of adherence to prescribed treatment.
- **4)** Educating caregivers on the DOT program.

At 28 days postdischarge, the interventions included as follows:

- **1)** Reassessing the patient's knowledge and self-care behavior through telehealth (conducted by registered nurses).
- **2)** Monitoring patients' clinical status and potential adverse drug reactions by registered nurses at a primary care unit.

•**3)**Reevaluating compliance to the DOT program at home by trained local village health volunteers.

Usual care

All pulmonary TB patients received usual care during admission on the general medicine wards. Using a multidisciplinary team consisting of physicians, clinical pharmacists, and registered nurses, all pulmonary TB patients received individualized anti-tuberculosis therapy, followed by close monitoring for potential adverse drug reactions. Registered nurses were responsible for assuring standard isolation protocol for patients, updating physicians of laboratory results, administering medications (without DOT program), and periodically monitoring patients' vital signs.

Data collection and data source

The usual care group's demographic and clinical data were retrospectively obtained from electronic health records. In addition, data of the nursing intervention group were collected prospectively from medical records. Comorbidities were identified using the 10th revision of the international classification of disease (ICD-10). Included comorbidities in this study were anemia (i.e., D59.4), type 2 diabetes mellitus (i.e., E11.0-E11.9), cerebrovascular accident (i.e., I61.0-I61.9, I62.0-I62.9, and I63.0-I63.9), human immunodeficiency virus (i.e., B20.0-B20.9, B23.0-B23.8, and B24.0), chronic obstructive pulmonary disease (i.e., J44.0-J44.9), and respiratory failure (i.e., J96.0-J96.9).

Outcomes

Our primary outcomes were the incidence and rates of hospital readmissions from TB-related complications within 28 days after being discharged from the first TB treatment in a hospital. The incidence of hospital readmission was calculated as the number of patients readmitted to the hospital due to TB-related complications within 28 days after being discharged from initial TB treatment, divided by the total patient-time of follow-up (person-days). The ratio of the incidence rate (hazard rate) in the nursing care program and usual care groups gives us the hazard ratio of hospital readmission. Meanwhile, the rates of hospital readmissions were the frequency of hospital readmission within 28 days after discharge from the initial TB diagnosis and treatment. The ratio of the rates between groups gives us an incidence rate ratio. The TB-related complications were defined as hospital readmission due to treatment failure or reported adverse drug reactions. Reasons for hospital readmission were obtained from medical records. The secondary outcomes were the change in scores of knowledges and self-care behaviors at hospital discharge and 28 days thereafter, which were measured only in the nursing care program group. All patients were followed for 28 days after hospital discharge. Their outcome data were obtained from medical records (if they had a hospital visit in the next 28 days) or a phone call (if they had no hospital visit in the next 28 days).

Statistical analysis

Since we included all eligible participants in the analysis, the sample size was not estimated. Additionally, we planned to perform power calculation, providing that unadjusted results were nonsignificant. We described and compared patients' characteristics between groups using descriptive and inferential statistics as appropriate. To examine the impact of nursing intervention on hospital readmissions within 28 days, we used a Cox-proportional hazards model to assess the incidence of the first readmission. Poisson model was used to explore rates of readmission within 28 days.

In both models, we performed serial adjustment as follows: (1) unadjusted model, (2) a model adjusting for age and sex, and (3) age and sex-adjusted model with further adjustment for sputum smear results at diagnosis, baseline albumin levels, and diabetes mellitus, which are the proxy of TB severity, patient's nutritional status, and patient's comorbidity that can significantly affect treatment outcome [14,15] and prognosis [16,17]. We also controlled for the follow-up time of individuals in the Poisson model to satisfy models' assumptions.

To ensure the validity of the Cox model, we performed a Schoenfeld residuals test and created log-minus-log plots to examine the proportional-hazards assumption. We also tested a goodness-of-fit of the Poisson model in which nonsignificant *p*-values (≥.05) from both deviance and Pearson statistics are required to ensure the appropriate use of Poisson regression with our data. Additionally, we analyzed each covariate's variance inflation factor (VIF) in fully adjusted models to test the multicollinearity.

Regarding the impact of the nursing care program on TB knowledge, patients receiving the nursing care program were asked to complete the questionnaire three times: at baseline (before teaching intervention), at hospital discharge (after teaching intervention), and at 28 days postdischarge. Scores at hospital discharge were then compared with baseline scores. We further compared scores retention as well. Paired t-test was used to analyze data since the distribution of mean differences was normally distributed. Moreover, to minimize the inflation of type-I error rate due to multiple comparisons, we used a Bonferroni adjusted significant *p*-value threshold at .008 (.05/6) and reported the corresponding 99.2% confidence interval [21].

All analyses were based on a complete-case approach with a two-sided alpha error of 5.0% using STATA version 16 (Stata Corp, LLC, College Station, Texas).

Ethical consideration

This quasi-experimental study was approved by Ethical Committee for Clinical Research at Phrae Hospital (No.34/2564). Inform consent was required for all patients who participated in the nursing care program group.

Results Characteristics of participants

We identified 115 pulmonary TB patients from January 1, 2020, to May 31, 2021. Six of 115 patients expired before 28 days postdischarge, 3 had missing data, and 2 were lost to follow-up. Among 104 patients included for analysis, 68 were in the usual care group, and 36 were in the nursing care program group (Figure 1). Baseline characteristics are presented in Table 1. The majority of participants were female (58.7%) with a mean age of 56.24 years old and a mean body mass index of 18.65 kg/m^2. Of these, 40.4% had sputum smear-positive +1, 63.5% never smoked, and 65.4% denied alcohol drinking history. We also observed that anemia (16.4%) and diabetes mellitus (24.0%) were among the most prevalent comorbidities.

Most of the characteristics were not statistically different between groups except gender, smoking history, alcohol drinking status, sputum smear results, and baseline albumin levels. Patients receiving the nursing care program majority were male (*p*-valuep-valuep-valuep-value = .002), compared to those in the usual care group (Table 1).

Hospital readmissions due to pulmonary TB-related complications within 28 days

Twenty patients were readmitted due to pulmonary TB-related complications within 28 days postdischarge. Of these, 16 patients were readmitted due to treatment failure, whereas 4 were readmitted due to adverse drug reactions from anti-tube-rculosis.

Patients receiving the nursing care program had a lower incidence of hospital readmission (HR, 0.19; 95% CI 0.04, 0.82). This finding remained consistent when adding age and sex to our analysis (HR, 0.18; 95% CI 0.04, 0.81) and even after combining age, sex, sputum smear at diagnosis, baseline albumin levels, and diabetes to the analysis (HR, 0.16; 95% CI 0.03, 0.87) (Table 2). Kaplan-Meier analysis confirmed that the nursing care program significantly lowered the incidence of hospital readmission due to pulmonary TB-related complications (Figure 2, *p*-value from log-rank test = .012). Additionally, the number needed to treat (NNT) to prevent one hospital admission was 4.78 (95% CI 3.02, 18.42) over 28 days of follow-up.

In terms of rates of hospital readmissions within 28 days, compared to patients in the usual care group, those receiving the nursing care program had lower rates of hospital readmissions (IRR, 0.27; 95% CI 0.08, 0.89). After adding age and sex into consideration, we found that the readmission rate was still lower in the nursing care group

than the usual care group (IRR, 0.26; 95% CI 0.08, 0.92). We also found similar findings after fully adjusting for potential confounders (IRR, 0.22; 95% CI 0.06, 0.85).

Knowledge and self-care behaviors

The knowledge and self-care behavior scores at baseline, upon hospital discharge, and 28 days postdischarge were shown in [Table 3]. We observed that nursing care programs significantly improved knowledge and self-care behavior scores at the time of hospital discharge compared with baseline (mean difference 2.22 [99.2% CI 1.21, 3.24], *p*-valuep-valuep-value = .330).

Furthermore, we observed a similar pattern of improvement in the self-care domain. The mean score was significantly increased by 11.67 points (99.2% CI 8.34, 15.00; *p*-valuep-valuep-value = .036).

Discussion

In this study, we evaluated the effectiveness of the nursing care program on hospital readmission, patient knowledge, and self-care behaviors among pulmonary TB patients. We showed that the nursing care program was significantly associated with the decrease in both incidence and rate of 28-day hospital readmission. Our patients in the nursing care program group showed significant improvement in knowledge and self-care behaviors with significant scores retention at 28 days postdischarge.

Compared to previous studies

After performing a systematic search from various databases (e.g., PubMed, Google Scholar, and Scopus), we could not find any studies examining nursing intervention's impact on clinical outcomes in pulmonary TB patients. Only a few studies have shown that educational intervention given to pulmonary TB patients can improve all aspects of knowledge, patients' satisfaction, and self-care behaviors [[10],[18]]. Comparing with the previous study of 30 TB patients in Thailand [[10]], we observed a relatively similar degree of improvement in the knowledge domain at hospital discharge (2.22 vs. 3.13). In contrast to the previous study, our patients had higher scores of self-care behaviors at hospital discharge (55.92 vs. 21.36). This comparison has a limitation as it is difficult to compare the outcome solely based on scores. Participants in our study reportedly had high baseline scores (44.25). It would be beneficial to observe growth rate and retention scores. However, we cannot assess this as the other study did not report baseline scores that could have offered an opportunity for comparison.

Explanations

Our proposed nursing care program contributed to the significant decrease in the incidence of 28-day hospital readmission due to several explanations. First, our interventions primarily sought to empower patients to improve their self-care behaviors. A previous randomized controlled trial had shown that empowering patients positively impacted clinical outcomes in heart failure patients [[11]]. Furthermore, a meta-analysis of trials and observational studies also showed the importance of patient-centered modalities as a key to successful TB treatment [[19]]. Second, evidence has been demonstrated that DOT delivery in the community, which is a part of our intervention, led to better outcomes for TB treatment than DOT delivery at the clinic [[19]]. Third, improving patient TB knowledge has positively affected the treatment completion rate, cure rate, and adherence [[19]]. Lastly, evaluation of nutritional status was incorporated as a part of the intervention program during hospital admission. Previous studies had shown the association between poor nutritional status and mortality rates in TB patients [[17],[20]].

Strengths and limitations

To the best of our knowledge, this study is among the first trial examining the clinical impact of nursing care programs in pulmonary TB patients in Thailand. We comprehensively investigated clinical (i.e., incidence and rates of hospital readmission due to TB-related complications within 28 days of admission) and surrogate endpoints (i.e., knowledge and self-care scores).

However, some limitations should be concerned. First, historical control might introduce bias due to changes in clinical practice over time, directly affecting hospital readmissions. It is worth noting that the guidelines for TB treatment in 2020 (usual care group) and 2021 (nursing care group) remained unchanged. Second, we did not randomize patients due to feasibility and ethical considerations. Nonetheless, as further protection against bias, the endpoints were adjusted for age, sex, sputum smears at diagnosis, baseline serum albumin levels, and diabetes mellitus. Importantly, due to the nature of the intervention, we cannot blind participants or investigators. This may lead to information bias and limit the causal inferences. Lastly, data collection was performed in only one setting. Thus, generalizability cannot be warranted.

Implications

Our study strongly supports the role of nurses as a key to improving clinical outcomes of pulmonary TB patients, and the nursing care program for pulmonary TB management should be widely adopted. Also, the impact of our proposed nursing care programs should be externally validated in other settings. Further study with a larger sample size may be needed to ensure the robustness of our findings.

Conclusion

Our nursing care program was significantly associated with the decrease in incidence and rate of 28-day hospital readmission due to pulmonary TB. In addition, patients receiving the nursing care program not only improved their knowledge and self-care behaviors but also continued to have knowledge retention over 28 days postdischarge. Therefore, we highly recommend implementing our nursing program in a clinical setting to improve the outcomes of pulmonary TB patients.

Abbreviations

DOT, Directly Observed Therapy; HR, hazard ratio; IRR, Incidence Rate Ratio; TB, Tuberculosis; VIF, Variance inflation factor; WHO, World Health Organization; CVI, Content Validity Index; KR-20, Kuder &Richardson 20

Ethical approval and consent to participate

All methods were performed in accordance with relevant guidelines and regulations. Our research received authorization from the Ethical Committee for Clinical Research of Phrae Hospital (No.34/2564). All patients in the intervention group have received the information about the study, and informed consent was obtained before study participation.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and analyzed during the study are available from the corresponding author upon reasonable request.

Author contributions

Chamlong Sunpapoa: Conceptualization, data curation, investigation, methodology, validation, writing-original draft, **Nat Na-Ek:** Conceptualization, formal analysis, methodology, writing-review and editing, **Areeya Sommai:** Conceptualization, writing-review and editing, **Kansak Boonpattharatthiti:** Data curation, **Nina S. Huynh:** Conceptualization, writing-review, editing and proofreading, **Sukrit Kanchanasurakit:** Conceptualization, data curation, formal analysis, methodology, validation, software, writing-original draft, writing-review and editing. All authors have read and approved the final manuscript.

Author statement

All authors meet the ICMJE authorship criteria.

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Conflict of interest

All authors declare no conflicts of interest.

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The authors thank the members of staff at Phrae hospital who helped with the trial at the study site.

Appendix A Supplementary data

The following are the supplementary data to this article.**Multimedia component 1**Multimedia component 1

Appendix A Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.anr.2023.06.002.

Characteristics	All participants (n = 104)	Usual care group (n = 68)	Nursing care group (n = 36)	p-value
Age, years (Mean ± SD)	56.24 ± 17.61	57.25 ± 17.17	54.33 ± 18.51	.424[a]
Female, numbers (%)	61 (58.7%)	51 (75.0%)	10 (27.8%)	<.001[b]
Weight, kg (Mean ± SD)	48.54 ± 10.46	49.78 ± 10.66	46.19 ± 9.79	.096[a]
Height, cm (Mean ± SD)	160.51 ± 8.80	161.16 ± 9.15	159.28 ± 8.08	.301[a]
BMI, kg/m^2 (Mean ± SD)	18.65 ± 3.94	18.85 ± 3.92	18.26 ± 3.99	.473[a]
Smoking status, numbers (%)				
Never	66 (63.5%)	58 (85.3%)	8 (22.2%)	<.001[b]
Ex-/Current-	38 (36.5%)	10 (14.7%)	28 (77.8%)	
Alcohol drinking, numbers (%)				
Never	68 (65.4%)	55 (80.9%)	13 (36.1%)	<.001[b]
Ex-/Current	36 (34.6%)	13 (19.1%)	23 (63.9%)	
Sputum smear results, numbers (%)				
+1	42 (40.4%)	30 (44.1%)	12 (33.3%)	.020[b]

+2	34 (32.7%)	16 (23.5%)	18 (50.0%)	.770[c]
+3	28 (26.9%)	22 (32.4%)	6 (16.7%)	
Albumin, g/dL (Mean ± SD)	2.49 ± 0.64	2.61 ± 0.73	2.28 ± 0.35	.002[d]
Intercurrent conditions, numbers (%)				
Anemia	17 (16.4%)	12 (17.7%)	5 (13.9%)	.622[b]
COPD	2 (1.9%)	1 (1.5%)	1 (2.8%)	1.000[e]
CVA	2 (1.9%)	1 (1.5%)	1 (2.8%)	1.000[e]
DM	25 (24.0%)	14 (20.6%)	11 (30.6%)	.258[b]
HIV	6 (5.8%)	5 (7.4%)	1 (2.8%)	.662[e]
Respiratory failure	5 (4.8%)	4 (5.9%)	1 (2.8%)	.657[e]

Outcomes	Usual care group (n = 68)		Nursing care group (n = 36)		Effect size[a] (95% CI)
Events	Event rate	Events	Event rate	Incidence of 28-day hospital readmission	
Unadjusted model	18[b]	10.72 (6.75, 17.02)[d]	2[c]	2.04 (0.51, 8.15)[d]	0.19 (0.04, 0.82)
Age and sex adjusted model					0.18 (0.04, 0.81)
Fully adjusted model					0.16 (0.03, 0.87)
Rate (frequency) of 28-day hospital readmission					
Unadjusted model	21	0.31 ± 0.55[e]	3	0.08 ± 0.37[e]	0.27 (0.08, 0.89)
Age and sex-adjusted model					0.26 (0.08, 0.92)

Fully adjusted model					0.22 (0.06, 0.85)

Testing domain	Baseline scores, Mean ± SD	Scores after receiving a nursing care program				Mean difference comparing between 28 days postdischarge and at hospital discharge (99.2% CI)[a]
At hospital discharge, Mean ± SD	Mean difference (99.2% CI)[a]	At 28 days postdischarge, Mean ± SD	Mean difference (99.2% CI)[a]	Knowledge	6.03 ± 1.68	8.25 ± 1.13
2.22 (1.21, 3.24)	8.00 ± 1.04	1.97 (1.28, 2.67)	−0.25 (−0.96, 0.46)	Self-care behaviors	44.25 ± 7.43	55.92 ± 2.30

DETAILS

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A Theory-Based, Technology-Assisted Intervention in a Hybrid Cardiac Rehabilitation Program for Patients with Coronary Heart Disease: A Feasibility Study

Mei Sin Chong [1]
; Janet Wing Hung Sit [1]
; Kai Chow Choi [1]
; Suhaimi, Anwar [2]
; Sek Ying Chair [1]
[1] The Nethersole School of Nursing, Faculty of Medicine, The Chinese University of Hong Kong, Hong Kong SAR, China [2] Department of Rehabilitation Medicine, University Malaya Medical Centre, Malaysia

ABSTRACT (ENGLISH)

SummaryPurpose
To assess the feasibility of a technology-assisted intervention in a hybrid cardiac rehabilitation program among patients with coronary heart disease.
Methods
This study was a two-arm parallel randomized controlled trial. Twenty-eight patients with coronary heart disease were randomly assigned to either the intervention group, receiving a 12-week technology-assisted intervention (*n* = 14), or the control group (*n* = 14), receiving usual care. Guided by the Health Belief Model, the intervention group received three center-based, supervised exercise training sessions, a fitness watch that served as a cue to action, six educational videos, and a weekly video call. The Self-efficacy for Exercise, exercise capacity, and Health Promoting Lifestyle Profile II were assessed at baseline and immediately post-intervention (12-weeks).
Results
Among the 28 patients who participated in this study, 85.7% completed the program, with a relatively low attrition rate (14.3%). The number of exercise training sessions accomplished by the participants in the intervention group was 51.27 ± 19.41 out of 60 sessions (85.5%) compared to 36.46 ± 23.05 (60.8%) in the control group. No cardiac adverse events or hospitalizations were reported throughout the study. Participants in the intervention group showed greater improvement in health-promoting behaviors when compared with the control group at 12 weeks. Within-group effects demonstrated improvement in exercise self-efficacy and exercise capacity among participants in the intervention group. A participant satisfaction survey conducted immediately post-intervention revealed that participants were “very satisfied” (23.1%) and “satisfied” (76.9%) with the technology-assisted intervention.
Conclusions
The findings demonstrated that technology-assisted intervention in a hybrid cardiac rehabilitation program was feasible and suggested to be beneficial in improving exercise self-efficacy, exercise capacity, and health promoting behavior among patients with coronary heart disease. A full-scale study is needed to determine its effectiveness in the long term.
Trial and protocol registration
ClinicalTrials.gov NCT04862351.
https://clinicaltrials.gov/ct2/show/NCT04862351.

FULL TEXT

Introduction

Cardiovascular diseases (CVDs) remain the leading cause of global mortality, with approximately 18 million people dying of CVDs each year, contributing to 32% of all deaths [1]. Cardiac rehabilitation (CR) is a comprehensive care model that includes structured exercise training, psychological support, and health education for patients with CVD such as coronary heart disease (CHD), heart failure, and those who underwent coronary revascularization [2]. According to the European Society of Cardiology, CR is classified as a class 1A recommendation [3]. Besides reducing long-term hospital readmissions by 52%, CR is associated with a 78% lower risk of death from all causes [4

]. Patients who participated in CR reported significantly improved exercise capacity, blood lipid profile, psychological outcomes, and quality of life [5]. Despite the benefits of CR, participation and adherence rates are relatively low, ranging between 31% and 43% and 36.7% and 84.6%, respectively [6]. A previous retrospective cohort study reported a dropout rate of 24% [7]. Based on a narrative review, the CR dropout rates were even higher in the middle-income countries, which could be up to 82% [8]. Several traditional barriers to CR have been identified in previous studies, including a lack of self-efficacy and perceived benefits of CR, access (distance and transportation), and travel or work conflicts [9,10]. Given there is a need to improve the participation and adherence to CR, it is time to develop an alternative approach using technologies to deliver CR especially in the midst of the COVID-19 pandemic, and investigate its feasibility in the real-world settings.

The COVID-19 pandemic has further reduced CR attendance and completion due to patients' fear of face-to-face attendance at health services and limited service access. In the early days of the pandemic, ambulatory and nonessential services were temporarily closed while CR programs were reduced or stopped, and recruitment of new patients was halted [11]. This phenomenon reinforced the urgent need to provide alternatives to conventional, center-based CR, such as home-based or hybrid (a combination of center-based and home-based) CR. A global survey suggested the need to support alternative models that provide CR programs outside of major institutions to reach a vast number of eligible patients [12]. There are several terminologies of technology-assisted interventions in CR including eHealth, telehealth/telemedicine, and mobile health (mHealth) [13]. The utilization of technology for CR delivery has been proliferating, and in recent years, previous studies have examined a web-based educational support intervention [14] and an exercise-based telerehabilitation program [15]. Both studies demonstrated positive patient outcomes. Hence, this is the time to focus more on CR delivery using technologies to boost utilization and promote its availability and accessibility to eligible patients. A previous mixed-methods study reported that the majority of patients with chronic diseases preferred combined in-person visits and telerehabilitation [16] Nevertheless, there is a lack of literature on hybrid CR programs. It would be interesting to examine the feasibility of a hybrid CR program, particularly during the COVID-19 pandemic, which may pose additional challenges to patients.

Although findings from the aforementioned studies that delivered technology-assisted interventions have shown promising results in the improvement of patient outcomes, they lacked interactive approaches (synchronous communication) and follow-up interventions (e.g., a weekly video/telephone call). Also, the feasibility of implementation in Southeast Asia, especially in a multicultural, high- middle-income country, is uncertain, and limited evidence is available on cardiac rehabilitation. This study aimed to explore the feasibility of a technology-assisted intervention in a hybrid cardiac rehabilitation (TecHCR) program among patients with CHD based on four key areas; implementation, practicality, limited-efficacy testing, and acceptability [17].

Methods Study design

This was a single site, two-arm, parallel randomized controlled trial (RCT).

Study setting

This study was conducted in an outpatient CR clinic of the largest teaching hospital in Malaysia. On average, 25 patients with CHD were referred to the phase II CR program per month. The study recruitment was conducted from March to May 2021 with a 12-week post-intervention assessment, and registered with the U.S. National Library of Medicine, ClinicalTrials.gov (Registration Number: NCT04862351).

Participants and sample

A consecutive sampling method was used to recruit participants for this study. A list of eligible patients was obtained from the outpatient CR clinic on a weekly basis. The eligible patients were approached at the Non-invasive Cardiology Clinic after their exercise stress test. Study inclusion criteria were: 1) adults ≥18 years old; 2) clinically diagnosed coronary heart disease; 3) treated with thrombolytic therapy or percutaneous coronary intervention (PCI) or revascularization surgery; 4) stratified into low or moderate risk for cardiac events by a rehabilitation medicine physician based on clinical assessments and exercise stress tests as per American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) guidelines; 5) own a smartphone with Internet access; 6) literate; 7) understand English or Malay language; 8) return home for living after hospital discharge; and 9) medically stable,

referred to the CR program and able to give informed consent to participate in this study. Exclusion criteria included: 1) participating in other studies; 2) comorbidities such as dementia, impaired hearing or vision, or psychiatric illness that might affect their ability to participate in the CR program; and 3) pre-existing mobility problems that prevent them from exercising.

As suggested by Julious et al. [18], a sample size of 12 participants per group in a 2-arm parallel trial is adequate to preliminarily estimate effect sizes for the size planning of a full-scale trial. Further allowing for some attrition, we aimed to recruit a total of 28 participants (14 participants per study group).

Randomization, allocation and blinding

Consented participants were randomly allocated to either the intervention group (TecHCR, *n* = 14) or control group (usual care, *n* = 14) in a 1:1 ratio based on computer-generated random codes. Allocation was concealed by using sequentially numbered, opaque, and sealed envelopes. Due to the nature of the study, participants were unable to be blinded to the group allocation but were strongly advised against disclosing the group assignment to other patients. The outcome assessor was blinded to group allocation and study hypotheses.

Theoretical framework

A theoretical framework may guide the design of interventions and increase the probability of successful outcomes [19]. Only about one-third of the included studies in a recent systematic review used behavior change theory, with a lack of description of the theoretical framework integrated into the intervention components [13]. A review by Timlin et al. [20] mentioned that poor theory application to intervention design and fidelity might explain the inconclusive effectiveness of an intervention.

The Health Belief Model (HBM) was chosen in this study as this model has yielded significant results in research, and the six constructs (perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cues to action, and self-efficacy) are suitable to be included in a framework for developing short-term and long-term behavioral change interventions [21]. A scoping review identified that both perceived barriers and perceived benefits were the strongest predictors of health behaviors [22]. HBM has been used as a framework in previous CR studies to guide the implementation of an educational support intervention through a web link [14] and examine the motivation and barriers to attending a CR maintenance program [23]. The primary concepts of HBM include accepting the diagnosis, believing that the condition may have serious consequences, and believing that the susceptibility or severity of the condition may be reduced by a course of action [24]. To make a change in behavior, an individual must have a change in belief; they need to recognize the risks and consequences of a condition, as knowledge alone is inadequate to make behavioral changes [25]. Once an individual has made behavior changes, motivation is maintained through self-efficacy, which provides self-regulation of behavior [26]. Evidence suggests that HBM constructs could be applicable in the development of behavioral change interventions. Therefore, HBM may be suitable to underpin the intervention design to promote behavioral changes in a hybrid CR program that provides a transition from face-to-face, center-based CR to home-based CR. Table 1 presents the details of the development of the TecHCR intervention based on the HBM constructs.

Control group

Participants randomized to center-based CR (CCR) had the usual care for 6 or 8 sessions at the outpatient clinic depending on their stratified risk category (6 sessions for low risk and 8 sessions for moderate risk) as per hospital policy during the pandemic, including 1-hour individualized exercise training and 1-hour occupational therapy. Each exercise training session consisted of a 10-minute warm-up, 30 minutes of moderate-intensity exercise and a 10-minute cool down supervised by a physiotherapist. End-of-session education [e.g., symptoms to watch out for during exercise, Rating of Perceived Exertion (RPE) scale] and feedback were provided by the physiotherapist. The exercise prescription was based on age, stress test results, and exercise tolerance, with each participant having an individualized target heart rate while exercising at home. All participants were encouraged to exercise for ≥30 minutes at least five days/week (150 minutes/week) of moderate intensity, following the guidelines from the World Health Organization [27]. For the occupational therapy, participants received education on topics including stress and anxiety management, time management, sleep hygiene, and relaxation techniques, and relaxation

sessions. Both participants in the control and intervention groups received a daily log (checklist with exercise and dietary practices) to balance the psychological effect.

Intervention group

The principal investigator (an experienced nurse) would demonstrate how to use a wearable technology (a fitness watch), upload the exercise data, and sign in to the video call application with each recruited participant, followed by a return demonstration. Participants received three sessions of usual care at the outpatient clinic scheduled for Week 1, Week 3, and Week 12. Each session consisted of 1 hour of individualized exercise training and 1 hour of occupational therapy. The first two (Week 1 and Week 3) supervised exercise training sessions were intended to prepare the participants to be able to exercise in a home environment, allowing the transition of exercise training from the center to home. The third session (the last session, Week 12) was to recap the previous sessions and act as a closure of the exercise training sessions for phase II CR before entering maintenance phase III CR. Participants were asked to wear the fitness watch to record their heart rate, exercise frequency, and duration during the exercise training at home. The exercise training data were synced to the Zepp App by each participant. Simultaneously, the data were automatically pulled into the UMFit website, allowing the principal investigator to review the exercise data on a weekly basis. Over 12 weeks, participants received a weekly video call that lasted for approximately 30 minutes each for the following purposes: 1) to strengthen participants' self-efficacy in recommended health behaviors, 2) to improve perceived benefits, 3) to enhance problem-solving skills (i.e., how to improve perceived barriers), and 4) to provide reinforcement for positive changes 4). From Week 1 to Week 6, participants received a weekly audio-visual educational video via a messaging application (a total of six videos). Technical support was provided to the participants in the TecHCR group. First, the principal investigator ensured the participants knew how to use the technologies by assessing their demonstrations. If participants encountered any technological issues, they were able to get support via telephone call, text messaging, or video call.

Measurements

1. Implementation

The implementation was assessed by examining the recruitment process within a specified period with data such as the number of eligible patients for screening, the number of patients randomized into the intervention and control groups, reasons for declining participation, and the number of follow-ups. To determine whether the study protocol could be executed as planned, the attrition rate and treatment adherence were assessed. Treatment adherence was defined as a percentage of the total exercise sessions accomplished by the participants [28]. In total, each participant should have 60 exercise training units, considering a recommended exercise schedule of 5 days/week × 12 weeks. For participants in the CCR, the number of supervised exercise training sessions at the outpatient clinic was recorded, and daily log exercise entries were counted. The exercise data for each participant in TecHCR was extracted from the UMFit website, and daily log exercise entries were counted.

1. Practicality

One of the outcomes of interest in practicality is to explore the adverse effects on the target participants [17]. Based on a nationwide survey by Saito et al. [29], adverse events associated with CR were defined as incidents (e.g., unstable angina, acute myocardial infarction, cardiac arrest, mortality, stroke, and severe musculoskeletal injury) that happened during exercise or within 24 hours after an exercise session. In this study, participants were required to report any adverse events throughout the program. Data related to adverse events (i.e., reasons for outpatient visits or hospital admissions) were also collected from the patient's electronic medical record.

1. Limited-efficacy testing

An intervention in a feasibility study will be tested in a limited way, including with limited statistical power or a shorter duration of follow-up [17]. In this study, limited-efficacy testing was performed on the following outcomes; exercise

self-efficacy, exercise capacity, and health-promoting behavior, specifically looking at the intended effects and effect size estimation at 12-week follow-up.

The primary outcome for this study was exercise self-efficacy, which significantly predicted the initiation of exercise and its maintenance [30]. The secondary outcomes were exercise capacity and health-promoting behavior.

Exercise self-efficacy was measured by Bandura's 18-item exercise self-efficacy scale (ESE) to assess the perceived self-efficacy to get oneself to perform an exercise routine regularly [31]. For the English version, each item is rated from 0 representing “cannot do at all” to 100 representing “highly certain can do”, with a higher score indicating a higher level of self-efficacy. It has a high internal consistency, with a Cronbach's α of 0.95 in a CR setting [32]. The Malay version of ESE has a significant factor loading of more than 0.40 and an intra-class correlation of 0.99 [33]. For this study, we quantified the response of each item following the Malay version, a 5-point response scale from 1 “not at all confident” to 5 “extremely confident”. The current study showed good reliability of ESE with a Cronbach's α of 0.98.

The exercise capacity was assessed by the metabolic equivalent of task (MET), determined by an exercise stress test with modified Bruce Protocol, conducted at the non-invasive cardiology laboratory by a rehabilitation medicine physician and a trained technician. One MET equals 3.5 ml of oxygen/kg (body weight)/minute, the consumption of oxygen while sitting at rest [34]. In our study, a treadmill (T-2100, GE Case Stress System V6.73) was used for the exercise stress test with a modified Bruce Protocol. According to the guidelines by the American College of Sports Medicine [35], Stage 1 to Stage 3 (3 minutes for each interval) of the protocol has a constant speed of 1.7 mph and the grade (inclination) increases by 5%; from Stage 4 onwards, both speed and grade increase every 3 minutes and the test will be terminated when the patient reaches volitional exhaustion. During the test, participants had continuous real-time 12-lead ECG and heart rate monitoring. The participant's blood pressure was measured before, at the last 45 seconds of each stage, immediately post-exercise stress test, and every 2 minutes thereafter [35]. The MET was automatically recorded by the treadmill controller based on its speed and grade [36]. Higher METs indicate higher exercise capacity.

The Health Promoting Lifestyle Profile II (HPLP II) was used to measure participants health-promoting behaviors. It consists of six subscales: health responsibility, self-actualization, physical activity, interpersonal relationships, nutrition, and stress management, with a 4-point response scale of 1 (never), 2 (sometimes), 3 (often), and 4 (routinely) [37]. The mean shall be used as the overall score for the 52-item scale as well as the mean of each subscale to maintain the 1–4 metric of item responses. Both the English and Malay versions of HPLP II have shown high internal consistency, with the α coefficients for the subscales ranging from 0.793 to 0.872 [37] and 0.737 to 0.878 [38], respectively. A CR-related study used this instrument to measure one of its outcomes [39]. The current study demonstrated good reliability with a α coefficient of 0.97.

1. Acceptability

Acceptability of the program focused on the perceived satisfaction among targeted participants related to the intervention. A self-reported program satisfaction survey by Chiang [40] was adopted and used to determine the acceptability of the TecHCR intervention among the participants. It consists of five statements on participant perceptions of TecHCR intervention, including TecHCR design, program duration, relevance of the educational information, performance of the intervener, and overall satisfaction with TecHCR. This instrument is based on a 5-point Likert scale, from a scale of 1 = “very unsatisfied”, 2 = “unsatisfied”, 3 = “neutral”, 4 = “satisfied”, and 5 = “very satisfied”.

Procedure

Assessments were conducted at two time points: [baseline (T0) and 12-week, immediate post-intervention (T1)]. All participants completed the sociodemographic and clinical data questionnaires on, exercise self-efficacy, exercise capacity, and health-promoting behaviors at T0 before randomization. The sociodemographic and clinical data of the participants, including age, gender, marital status, educational level, employment status, monthly household income, smoking status, comorbidities, current medications, distance from home to the CR center (kilometer), transportation mode, were obtained from the electronic medical record and a self-reported structured questionnaire. After 12 weeks (T1), data were collected during the post-intervention exercise stress test appointment, including exercise self-efficacy, exercise capacity, health promoting behavior, treatment adherence, adverse events, and a program satisfaction survey.

Data analysis

IBM SPSS 25 (IBM Crop. Armonk, NY) was used to perform the statistical analyses. As this feasibility study had a relatively small sample size and a 12-week follow-up, there was no missing data detected, but those who dropped out were not included in the final analysis. Skewness and Q-Q plots were assessed to check the normality assumption. The baseline sociodemographic and clinical characteristics were described using mean and standard deviations for continuous variables, and frequencies and percentages for categorical variables. Homogeneity of baseline characteristics between the TecHCR and control groups was assessed using the Fisher's exact test for categorical variables and the Mann-Whitney U test for continuous variables. Statistical comparisons were performed within and between groups to describe the outcome variables across time points (T0 to T1) using the Wilcoxon signed rank test and Mann-Whitney test, respectively. The change in each outcome (T1 − T0) was compared between groups and used for effect size estimation. Following the recommendation by Tijssen and Kolm [41] for pilot studies with small sample sizes, the main focus of the outcome analysis was effect size estimations rather than their significance multiplicity correction was therefore not performed. Hedges' g effect sizes and their 95% confidence intervals for the outcomes were calculated using the online calculator: https://www.psychometrica.de/effect_size.html. All the statistical tests involved were two-sided with level of significance set at 0.05.

Ethical considerations

Ethical approvals were obtained from the Joint Chinese University of Hong Kong-New Territories East Cluster Clinical Research Ethics Committee (Reference Number: 2020.621) and University of Malaya Medical Centre-Medical Research Ethics Committee (Reference No. 202117-9674). Prior to randomization, written informed consent was sought from each participant. Assurance was provided to participants that their identity and personal data would be kept confidential. Participants were informed that they had the right to withdraw from the study at any time without affecting their treatment in the study setting. If the findings demonstrate effective intervention outcomes, the TecHCR may be provided to participants in the control group after the completion of the main study.

Results

Table 2 summarizes the baseline characteristics of the participants. The mean age of participants was 54.6 ± 12.6 vs. 58.4 ± 13.6 years (range 35–74) and predominantly male (96.4%) with only one female participant. Most of them were married (92.9%), with more than half of the participants having secondary school education (57.1%) and self-driving from home to the CR center (64.3%), with a distance between 5 and 40 kilometers. Four participants were stratified into moderate-risk groups (1 participant vs. 3 participants). The majority of the participants were diagnosed with hypertension (78.6%) and dyslipidemia (89.3%). Out of 28 participants, 67.9% had PCI. Over half (64.3%) of the participants in TecHCR had a family history of CHD. TecHCR and control groups were generally homogeneous regarding baseline characteristics, except that the latter had a low proportion of participants using beta-blockers. In

view of the small sample size, no further adjustment was made to the statistical analysis.

1. Implementation

Among the 67 patients screened for eligibility, 35 were excluded as they did not fulfill the inclusion criteria. Out of the 32 patients who were invited to participate in the study, four declined due to a lack of interest in participating. Twenty-eight patients (87.5%) agreed and consented, with 14 participants in each arm of the study. Among the participants (N = 28) who completed the baseline assessment (T0), a total of four were lost to follow-up during the 12-week program. Three participants from the TecHCR dropped out due to fear of attending face-to-face supervised exercise training during high daily COVID-19 cases (n = 1), were diagnosed with COVID-19 (n = 1), and left to work abroad (n = 1), and one participant from the CCR dropped out due to fear of attending the outpatient, center-based CR appointments (n = 1), representing an attrition rate of 14.3%. At 12-weeks, a total of 24 participants completed the study, with 11 and 13 participants in the TecHCR and CCR, respectively (Figure 1).

The treatment adherence of participants is shown in Table 3. Participants from TecHCR who completed the post-intervention assessment (n = 11) accomplished 51.27 ± 25.22 exercise training sessions (85.5%), in the range between 12 and 84 exercise training sessions within the 12 weeks of intervention. However, only 9 out of 11 participants (81.8%) in the TecHCR group performed at least 150 minutes of exercise each week. Two participants who were unable to perform the targeted duration of exercise per week provided reasons, including 1) the unavailability of a conducive environment for exercise due to the closure of parks and 2) a lack of time due to work commitments. Completers in the TecHCR attended all video call sessions except for one participant who had to be contacted five times using telephone calls due to work. Thirteen participants from CCR who completed the post-intervention assessment performed 36.46 ± 25.03 exercise training sessions (60.5%), in the range between 10 and 84 exercise training sessions. Seven out of 13 participants (53.8%) in the control group performed at least 150 minutes of exercise per week. Reasons for failing to achieve exercise duration in a week were similar to those in the intervention group, including a lack of motivation.

1. Practicality

No adverse events were reported by the participants or found in the patient's electronic medical record. Unrelated to the interventions, one of the participants in the TecHCR group was diagnosed with COVID-19 positivity in the midst of the program and chose to discontinue the program while serving home quarantine.

1. Limited-efficacy testing of TecHCR on exercise self-efficacy, exercise capacity, and health-promoting behavior.

Table 4 presents the results of limited-efficacy testing in the study. The results of the Wilcoxon signed rank test indicated that TecHCR had a significant within-group effect over the 12-week course of study in exercise self-efficacy, exercise capacity, and health-promoting behavior. In addition, the Mann-Whitney test showed a significant improvement in health-promoting behavior in TecHCR when compared with CCR (Hedges' g effect size = 1.04, 95% CI: 0.19 to 1.90, p = 0.007). However, no differences on exercise self-efficacy (Hedges' g effect size = 0.47, 95% CI: −0.35 to 1.28, p = 0.323) or exercise capacity (Hedges' g effect size = 0.17, 95% CI: −0.64 to 0.97, p = 0.132) were detected between groups.

1. Acceptability

Table 5 shows that the majority of the participants (69.2%) were very satisfied, and the remaining (30.8%) were also satisfied (30.8%) with the intervention design. Participants were either very satisfied (23.1%) or satisfied (53.8%) with the duration of the program, but 23.1% reported being neutral. More than half of the participants (53.8%) were very satisfied with the relevance of the educational information, and 61.5% were very satisfied with the performance

of the intervener. Overall, the participants were very satisfied (23.1%) and satisfied (76.9%) with the TecHCR program.

Discussion

Our findings suggest that technology-assisted intervention, including supervised exercise training sessions (three times at the center), a wearable technology (a fitness watch), educational videos, and telecoaching (a weekly video call), is feasible. Given the fact that this study was conducted during the COVID-19 pandemic and the non-invasive cardiology clinic only conducts the exercise stress test for patients referred to CR once a week, recruitment proceeded smoothly, with only four out of 32 eligible patients rejecting participation. In recent years, much attention has been paid to improving CR among underrepresented groups, especially women, with meta-analyses reporting significantly lower referral rates among women when compared with men [42]. Despite our study setting providing automatic referral to CR for all eligible patients, the number of females with CVD in Malaysia was lower than the males; amongst the individuals who had undergone PCI, only 17% of them were females [43]. Therefore, it was not surprising that there were only two female, eligible patients during our recruitment period; one female participant consented while another female declined our invitation to participate in the study due to a lack of interest in participating in a trial.

Overall, the completion rate of our study was a notable 85.7%. This is comparable to the results of a recent RCT by Batalik et al. [28], which demonstrated a completion rate of 91% in a 12-week home-based telerehabilitation. With respect to treatment adher-ence, our TecHCR group showed greater exercise training adherence when compared to the center-based CR program (85.5% versus 60.5%). A recently published systematic review revealed that nine out of 14 included studies demonstrated greater treatment adherence among patients who had digital interventions compared to conventional CR [44]. In contrast, a meta-analysis by Chong et al. [13] reported that no significant differences in treatment adherence were found between home-based/hybrid CR and center-based CR. These previous results were rather inconclusive. A possible explanation of our desirable findings is that the HMB constructs of “external cues to action” and “self-efficacy,” which were delivered through wearable technology (a fitness watch) and telecoaching (weekly video call), may in part account for the treatment adherence. Indeed, Odnoletkova et al. [45] reported that nurse-led telecoaching promotes health behavior changes that are aligned with the goals set by the patients.

Regarding practicality, we found no adverse effects reported by both groups in our study, suggesting TecHCR can be safely implemented among non-high-risk cardiac patients, even in elderly patients. A recent study on smartphone-based telemonitored exercise showed no occurrence of serious complications or adverse events throughout the study period [46]. According to Sanchis-Gomar et al. [47], there may be potential adverse events related to exercise training triggered by exercise intensity and physiological demands in certain individuals. In our study, precautions during exercise (i.e., measuring the intensity of physical activity with RPE and when to seek immediate medical attention) were emphasized to the participants in both groups. Hannan et al. [48] highlighted the lack of data collection on adverse events in CR studies with a specific protocol. Heindl et al. [49] suggested that future research should look into detailed reporting on patient assessment and home inspection before the commencement of exercise training in the home environment. This creates opportunities to identify the gaps in home-based exercise and improve measures to minimize the risks of adverse events before translating the evidence into clinical practice.

In this present study, results on the limited-efficacy testing were desirable. We observed a significant improvement in health-promoting behavior with a large effect size (g = 1.04) following the intervention. Similarly, a recent RCT that delivered the eHealth approach in CR also demonstrated significantly improved the health-promoting behavior at 12-

week post-intervention [39]. Zafari Nobari et al. [50] reported that a healthy lifestyle empowerment program significantly improved the health-promoting behavior of patients with coronary bypass graft surgery. From the viewpoint of promoting a healthy lifestyle, TecHCR provided educational videos on topics related to physical activity and exercise, a healthy diet, stress management, and smoking cessation. Together with these videos, our telecoaching was intended to motivate participants to adopt healthy behavioral changes. These components of TecHCR might have contributed to improving perceived health promoting behavior among the participants. Although there was no statistical evidence in favor of TecHCR on exercise self-efficacy and exercise capacity, both showed relatively greater improvement than those of CCR. Smarz et al. [51] suggested that other than exercise dose, intensity, and adherence, the improvement of exercise capacity is also influenced by several potential, factors such as both cardiac and non-cardiac-related factors and comorbidities. Future research may examine exercise capacity based on stratification by comorbidity. Also, as the present study is a pilot study with a relatively small sample size, a larger sample size may be required to statistically detect significant differences in both exercise self-efficacy and exercise capacity.

Successful implementation of an intervention in a real-world, clinical setting requires acceptability. Our study highlights the acceptability of TecHCR among participants from a wide range of ages, including older adults aged 60 years and above. All the participants in the TecHCR group were satisfied with the overall program, with three participants rating the program as “very satisfied” and 10 participants rating it as “satisfied”. We believe that this could be due to the fact that our participants were able to use the technologies throughout the program. A national survey by the Department of Statistics Malaysia [52] showed the vast majority of individuals had access to the Internet (96.8%) and mobile phone (98.7%), which allows additional options for patients other than the usual center-based CR. Of note, several barriers to adopting technology in CR among older adults include physical barriers such as visual and fine motor skills and technological anxiety [53]. In order to minimize the technical challenges during the present study, we assisted participants in the TecHCR group to install the apps upon recruitment and ensured they knew how to operate the fitness watch and apps by return demonstration. Taking into consideration of possible barriers among the older adults, our intervention was carefully planned to reduce complexity of the integrated technologies. We included a fitness watch that has a simple, user-friendly interface, educational videos that were sent to participants' messaging apps, and a weekly video call using Google Meet with a secured password. More than half of the participants were satisfied with the duration of the program. As of now, there is no identified optimal duration for a CR program, and it varies across countries. An explanation might be that the duration of 12 weeks might allow participants to achieve their optimal outcomes (i.e., physical function) as reported by Morrin et al. [54], and this could enhance their satisfaction. The majority of the participants in the current study reported being very satisfied with the relevance of the educational information. Gomez-Perez et al. [55] recommended contents that are useful, easy to understand, eye-catching, and well-designed. In our opinion, the audio-visual educational videos in the study were not only attention-grabbing with the use of colors and voice-over for the contents, but they also enabled participants to know more about CR, their disease, and other important components of CR, including exercise, diet, smoking cessation, and stress management. To the best of our knowledge, no previous studies have reported patient satisfaction with a nurse-led CR program as an outcome. Nonetheless, previous studies reported high levels of satisfaction among patients with primary care provided by nurse practitioners [56,57]. One possible explanation of our findings could be due to the nurse-patient rapport. We indirectly built the rapport through the weekly video call over 12 weeks. Communication is the cornerstone of patient-centered care, and effective communication skills are associated with improved patient satisfaction [58].

According to Bowen et al. [17], feasibility studies allow researchers to determine the applicability of the interventions

and whether adjustments are needed to make them more applicable in practice, as these issues have to be solved before actual implementation. Crucially, our findings provide invaluable insights, showing that TecHCR can be potentially implemented in future research with a larger sample size. Despite a small sample size, the TecHCR was well accepted, creating potential equitable access to hybrid CR in the future. This innovation may be an alternative to facilitate the sustainability of the CR program in the midst of the pandemic. Besides, the integration of HBM in the intervention development may aid in the successful implementation of the intervention and improve patient outcomes.

Our study has several strengths and limitations. This study had substantially high completion and treatment adherence rates in the TecHCR group, with strategies such as proactive and timely technical support and video calls to enhance participant engagement through frequent positive reinforcement and problem-solving. Our participants aged between 35 and 74 years old, suggesting that the feasibility of TecHCR is not limited to younger participants who are deemed to be more technology savvy. However, this study was underpowered to detect statistical significance; a large-scale trial with a longer duration of follow-up is required to examine the effectiveness of the TecHCR on the outcome variables. Although the exercise capacity was objective data, other self-reported outcomes might be subject to social desirability bias. To the best of our knowledge, there is no available data on the reliability of MET measured by the treadmill used, which could be one of the limitations of the study. Another limitation included the lack of qualitative data on participant experience that could provide rich descriptions. Future research may consider an open-ended interview to yield in-depth responses from participants on their experiences and opinions about the program. Also, several internet connection problems caused disruptions in video call sessions. An assessment of the types of internet connections needs to be taken into consideration. Due to the nature of this study, participants in the intervention group were expected to have basic Internet skills to use the fitness watch and mobile applications. The findings might not be generalizable to patients who are not able to use the technologies independently.

Contemporary CR programs that included patient education and exercise training were established in developed countries as early as the 1970s [59]. The COVID-19 pandemic has pushed forward the implementation of alternative models such as hybrid or home-based CR. However, limited literature is available on the CR situation in developing countries or Southeast Asia. Due to limited resources, the pilot study was conducted in a country situated in Southeast Asia which might not be able to represent the whole region. Nonetheless, the findings of the current study will be able to provide insights to policymakers and health care providers in supporting the development of CR programs, particularly in developing countries.

Conclusion

The findings of this study demonstrate that theory-based TecHCR is feasible among the low- to moderate-risk cardiac patients referred to phase II CR. A high overall satisfaction rating for the program further supports the idea that TecHCR was acceptable among participants in the intervention group. The results of limited-efficacy testing demonstrated positive improvements in exercise self-efficacy, exercise capacity, and health-promoting behavior among patients in the TecHCR group. A full-scale RCT with a longer follow-up is warranted to provide more conclusive estimates of the benefits of TecHCR.

Ethical approvals

Ethical approvals were obtained from the Joint Chinese University of Hong Kong-New Territories East Cluster Clinical Research Ethics Committee (Reference Number: 2020.621) on and University of Malaya Medical Centre-Medical Research Ethics Committee (Reference No. 202117-9674).

Author contributions

CMS, JSWH and CSY contributed to the concept and design of this pilot study. CMS provided the intervention and AS contributed in the recruitment and supervision of intervention. CMS and CKC completed the analysis and interpreted the results. CMS, JSWH, CKC, AS and CSY drafted and revised manuscript. All authors read and approved the final version of manuscript.

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Conflict of interest

None declared.

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Health Belief Model construct	Objectives	Content	Delivery mode	Component	Technological devices and software used
Perceived susceptibility and severity	To provide educational support with accurate information about cardiovascular risk factors, the consequences of the disease, and recommended action.	•Educational content includes:1)Heart disease2)Cardiovascular risk factors3)Effects of a poor diet4)Effects of stress5)Effects of smoking	Asynchronous	Electronic learning	Smartphone and instant messaging app (WhatsApp)
Perceived benefit	To provide information on the benefits of a recommended healthy lifestyle and diet.	•Educational content includes:1)Benefits of exercise for the heart2)Benefits of a healthy diet3)Benefits of quitting smoking4)Benefits of stress management	Asynchronous	Electronic learning	Smartphone and instant messaging app (WhatsApp)

To provide positive reinforcement to portray the positive benefits of adopting health behavior changes	•Congratulate the participant on his/her achievement (e.g., achieved target heart rate, reduced intake of sugar)•Check with the participant on his/her perception of adopting health behavior changes (e.g., “So far, how you feel after starting to exercise regularly?” “Did you notice the changes in your body with health diet and regular exercise?”•Affirm the positive feedback from the participant.	Synchronous	Telecoaching	Smartphone/laptop, and video communication service app (Google Meet).	Perceived barrier
To facilitate problem-solving strategies in patients to overcome barriers to adopting health behavior changes	•Assess the potential barriers and facilitators in adopting health behavior change (e.g., “What could be the factors prevented you from achieving the exercise frequency?”)•Facilitate the participants to think of the possible ways of overcoming the barriers (e.g., “Now, let's think of some alternatives. What do you think about indoor exercises?”)	Asynchronous	Electronic learning	Smartphone/laptop, and video communication service app (Google Meet).	Cues to action

The heart rate and exercise duration data on the fitness watch act as the biofeedback strategy that will be used as an external trigger.	•The fitness watch provides synchronous exercise data on the watch and Zepp App, allowing participants to monitor their exercise.•The fitness watch vibrates once the participant achieves certain goals such as 10000 steps.	Synchronous and Asynchronous	Wearable technology Telemonitoring	Commercial fitness watch and health monitor app (Zepp App) Note: participants have to sync the exercise data onto the health monitor app and researchers will receive the data on the UMFit website.	To provide feedback and advice as external cues for participants to activate the recommended health actions
•Review the exercise data for the past 7 days.•Recap the goals set for the past 7 days.•Remind the participant the importance of achieving the recommended health actions.	Synchronous	Telecoaching	Smartphone/laptop, and video communication service app (Google Meet).	Self-efficacy	To build participant's beliefs about his/her ability to adopt health behavioral changes by using incremental goal setting strategies

Characteristics	Intervention (n = 14) n (%)	Control (n = 14) n (%)	p
Age (years)[a] [range: 35–74]	54.6 (12.6)	58.4 (13.6)	.608[b]
Gender			
Men	13 (92.9)	14 (100.0)	.999[c]
Women	1 (7.1)	0 (0)	
Ethnicity			.999[c]
Malay	8 (57.1)	8 (57.1)	

Chinese	4 (25.0)	3 (21.4)	
Indian	2 (14.3)	3 (21.4)	
Occupation			.454[c]
Employed	4 (28.6)	7 (50.0)	
Unemployed	3 (21.4)	1 (7.1)	
Home maker	1 (7.1)	0 (0)	
Retired	6 (42.9)	6 (42.9)	
Monthly household income (RM)			.999[c]
<5000 (<US$ 1220)	9 (64.3)	10 (71.4)	
≥5000 (≥US$ 1220)	5 (35.7)	4 (28.6)	
Marital status			.481[c]
Married	14 (100.0)	12 (85.7)	
Single/divorced/married	0 (0)	2 (14.3)	
Education			.999[c]
Primary	0 (0)	1 (7.1)	
Secondary	8 (57.1)	8 (57.1)	
Tertiary	6 (42.9)	5 (35.7)	
Driving to cardiac rehabilitation center	11 (78.6)	7 (50.0)	.423[c]
Distance from home to rehabilitation center (kilometres)[a] [range: 5–40]`	19.0 (12.3)	16.8 (8.6)	.361[b]
Coronary family history	9 (64.3)	5 (35.7)	.257[c]
Smoking status			
Never	7 (50.0)	4 (28.6)	.239[c]

Former smoker	7 (50.0)	7 (50.0)	
Current smoker	0 (0)	3 (21.4)	
AACVPR risk category			.596[c]
Low	13 (92.9)	11 (78.6)	
Moderate	1 (7.1)	3 (21.4)	
Hypertension	13 (92.9)	9 (64.3)	.165[c]
Dyslipidemia	12 (85.7)	13 (92.9)	.999[c]
Diabetes	7 (50.0)	6 (53.8)	.999[c]
Percutaneous coronary intervention	10 (71.4)	9 (64.3)	.999[c]
Coronary artery bypass graft surgery	4 (28.6)	4 (28.6)	.999[c]
Medication			
Antiplatelet	14 (100.0)	14 (100.0)	–
Nitrates	3 (21.4)	1 (7.1)	.596[c]
Beta-blocker	14 (100.0)	7 (50.0)	.006[c]
ACE inhibitors/Angiotensin receptor blocker	8 (57.1)	8 (57.1)	.999[c]
Calcium channel blocker	9 (64.3)	3 (21.4)	.678[c]
Statin	14 (100.0)	14 (100.0)	–

Treatment adherence	Control (n = 13)	Intervention (n = 11)

Mean (SD)	(%)	Mean (SD)	(%)	Exercise training sessions (range: 0–60)
36.46 (25.03)	60.5	51.27 (25.22)	85.5	Exercise duration (minutes/week) (achieved ≥150 minutes/week)

Outcome variables	Control	Intervention	Between group comparisons

Baseline measurement (T0) (n = 14)	Immediate post intervention (T1) (n = 13)	p (within-group comparison)[a]	Baseline measurement (T0) (n = 14)	Immediate post intervention (T1) (n = 11)	p (within-group comparison)[a]	Hedges' g effect size (95% CI)[b]	p (between-group comparison)[a]	Exercise self-efficacy (ESE)
38.1 (12.1)	45.5 (11.0)	.003	47.5 (20.6)	59.5 (15.9)	.012	0.47 (−0.35, 1.28)	.323	Exercise capacity (MET)

7.3 (2.3)	8.6 (2.7)	.058	8.6 (2.1)	10.0 (2.3)	.008	0.17 (−0.64, 0.97)	.132	Health promoting behavior (HPLP II)

	Very satisfied	Satisfied	Neutral	Unsatisfied	Very unsatisfied
n (%)	n (%)	n (%)	n (%)	n (%)	Intervention design
9 (69.2)	4 (30.8)	0 (0)	0 (0)	0 (0)	Duration
3 (23.1)	7 (53.8)	3 (23.1)	0 (0)	0 (0)	Relevance of information
7 (53.8)	6 (46.2)	0 (0)	0 (0)	0 (0)	Performance of intervener

8 (61.5)	5 (38.5)	0 (0)	0 (0)	0 (0)	Overall satisfaction of the program

DETAILS

Subject:	Occupational therapy; Patients; Behavior; Telemedicine; Cardiac stress tests; Intervention; Pandemics; Hospitals; Cardiovascular disease; Feasibility; Rehabilitation; Heart; Education; Cardiology; Clinical outcomes; Fitness training programs; COVID-19
Business indexing term:	Subject: Feasibility
Identifier / keyword:	technology; hybrid; cardiac rehabilitation; coronary heart disease
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Educational Program with Text Messaging for Community-Dwelling Patients with Hypertension: A Pilot Randomized Controlled Trial

Tam, Lon [1]
; Eliza Mi Ling Wong [2]
; Cheung, Kin [3]
[1] School of Nursing, The Hong Kong Polytechnic University, Hong Kong SAR, China; The Nethersole School of Nursing, Faculty of Medicine, The Chinese University of Hong Kong, Hong Kong SAR, China [2] School of Nursing, Tung Wah College, Hong Kong SAR, China [3] School of Nursing, The Hong Kong Polytechnic University, Hong Kong SAR, China

ABSTRACT (ENGLISH)

SummaryPurpose
Controlling blood pressure minimizes the risk of cardiovascular events among patients with hypertension. Despite regular follow-ups, the hypertension management for patients aged ≥45 years is limited as evidenced from a decreased control rate. This pilot study aimed to test a theory-guided educational program for community-dwelling patients with hypertension.

Methods
Sixty-nine patients with hypertension aged ≥45 years and having high blood pressure (>130/80 mmHg) were recruited in this two-arm pilot randomized controlled trial. Participants in the intervention group underwent a program guided by the Health Promotion Model, whereas those in the control group received usual care. Data were collected at baseline, week 8, and week 12 and used to assess the blood pressure, pulse pressure, self-efficacy, and adherence to hypertension management. Data were analyzed using a generalized estimating equation based on the intention-to-treat principle. Process evaluation was conducted to assess the feasibility and acceptability of the educational program.

Results
The results obtained using the generalized estimating equation revealed that the educational program led to

reduction in the systolic blood pressure (β = −7.12, *p* = .086) and pulse pressure (β = −8.20, *p* = .007) and to improve self-efficacy (β = 2.61, *p* = .269) at week 12. The program had a small-to-moderate effect on the reduction of systolic blood pressure (effect size = −0.45) and pulse pressure (effect size = −0.66) and self-efficacy (effect size = 0.23). The participants were highly satisfied with the educational program.

Conclusions

The educational program was found to be feasible and acceptable and may be incorporated into current hypertension management practices at the community level.

Trial registration

ClinicalTrials.gov with identifier: NCT04565548.

FULL TEXT

DETAILS

Subject:	Clinical trials; Data collection; International organizations; Health education; Pilot projects; Blood pressure; Intervention; Lifestyles; Hypertension; Text messaging
Location:	China; Macao
Identifier / keyword:	blood pressure; health education; hypertension; mhealth; self-efficacy
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Benefits of Music Intervention on Anxiety, Pain, and Physiologic Response in Adults Undergoing Surgery: A Systematic Review and Meta-analysis

Ho Yeon Lee [1]
; Nam, Eun Sook [2]
; Chai, Gong Ju [3]
; Doo Myung Kim [4]

[1] Doowon Technical University, Department of Nursing, Anseong, Republic of Korea [2] Kangwon National University, College of Nursing, Chuncheon, Republic of Korea [3] Hallym Polytechnic University, Department of Nursing, Chuncheon, Republic of Korea [4] Andong Science College, Department of Nursing, Andong, Republic of Korea

ABSTRACT (ENGLISH)

SUMMARYPurpose

Evidence on factors influencing the variations of music’s effect on anxiety and pain in surgical patients is unclear. We aimed to elucidate the effects of music intervention on anxiety and pain throughstudy characteristics.

Methods

We conducted a search on the PubMed, CINAHL, Embase, Cochrane, and Web of Science databases from March 7 to April 21, 2022, for randomized controlled trials (RCTs) for the effect of music intervention on anxiety, pain, and physiological responses in surgical patients. We included studies published within the last 10 years. We assessed the risk of bias in the study using the Cochrane risk of bias tool for randomized trials and performed meta-analyses using a random-effects model for all outcomes. We used change-from-baseline scores as summary statistics and computed bias-corrected standardized mean differences (Hedges'g) for anxiety and pain outcomes and mean

differences (MD) for blood pressure and heart rate.

Results

Of the 454 records retrieved, 30 RCTs involving 2280 participants were found to be eligible. Music intervention was found to be superior to standard care in reducing anxiety (Hedges' g = −1.48, 95% confidence interval: −1.97 to −0.98), pain (Hedges's g = −0.67, −1.11 to −0.23), systolic blood pressure (MD = −4.62, −7.38 to −1.86), and heart rate (MD = −3.37, −6.65 to −0.10) in surgical patients. The impact of music on anxiety and pain relief varied significantly depending on the duration of the intervention. The largest effect was observed in interventions lasting between 30 and 60 minutes, with a decrease in anxiety and pain.

Conclusions

Music intervention is an effective way to reduce anxiety, pain, and physiological responses in surgical patients. Future reviews examining the influence of different types of surgery on the effects of music would add to the body of knowledge in this field. This study has been registered on the International Prospective Register of Systematic Reviews (PROSPERO) under the number CRD42022340203, with a registration date of July 4, 2022.

FULL TEXT

DETAILS

Subject:	Physiology; Music; Anxiety; Surgery; Blood pressure; Intervention; Research design; Pain; Data collection; Systematic review; Meta-analysis; Narcotics; Heart rate; Bias
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Psychoneuroimmunological Markers of Psychological Intervention in Pediatric Cancer: A Systematic Review and New Integrative Model

Idyatul Hasanah [1]
; Nursalam, Nursalam [2]
; Krisnana, Ilya [2]
; Ramdani, Wawan F [3]
; Haikal, Zikrul [4]
; Tita Rohita [5]

[1] Faculty of Nursing, Airlangga University, Surabaya, 60115, Indonesia; Nursing Department, STIKES Yarsi Mataram, 83115, Indonesia [2] Faculty of Nursing, Airlangga University, Surabaya, 60115, Indonesia [3] Center for Woman, Family, and Disaster Studies, Universitas Aisyiyah Yogyakarta, Indonesia [4] Surgery Department, Faculty of Medicine, Universitas Mataram, 83125, Indonesia [5] Nursing Department, Faculty of Health Sciences, Galuh University, Ciamis, 46251, Indonesia

ProQuest document link

ABSTRACT (ENGLISH)

SUMMARYPurpose

Pediatric cancer is a serious problem and still becomes a global challenge today. Various complex stressors due to diagnosis, disease symptoms, and various side-effects from the treatment that children with cancer undergo will cause problems in the child's psychoneuroimmunological aspects. Psychological interventions designed to modulate the stress response include psychoneuroimmunological markers. Unfortunately, there is little evidence to support the

effect of psychological interventions on psychoneuroimmunological markers. This systematic review aims to assess the effectiveness of psychological interventions on psychoneuroimmunological markers in children with cancer and to provide a new integrative model for further research.

Methods

This systematic review uses four main databases (Scopus, PubMed, ScienceDirect, and ProQuest). The guideline used Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA). Selecting articles used the Rayyan application. The quality study was conducted using Joanna Briggs Institute (JBI)'s critical appraisal tools. The data were analyzed using the population, intervention, comparison, outcome, and study design (PICO) Synthesis based on similarities and differences in study characteristics to interpret the results.

Results

The search results in this systematic review found 1653 articles, 21 of which matched the predetermined inclusion and exclusion criteria. Most of the designs used were randomized controlled trials (57.1%). Massage therapy was the most common type of psychological intervention (14.2%). Almost half of the studies measured psychological responses (38.0%), and psycho-physiological responses (42.9%), and only a small proportion assessed the effectiveness of psychological interventions on neuroimmunological markers in pediatric cancer.

Conclusions

We recommend the use of psychological interventions as an additional intervention in managing psychoneuroimmunological markers of pediatric cancer. This study offers a new integrative model demonstrating the interaction between stress and psychological intervention involving neuroendocrine and immune mechanisms. However, future researchers need to test all domains of these new integrative models. This will reveal the complex interactions among these components and understand their relevance to health outcomes.

FULL TEXT

Introduction

Cancer ranks as the second most prevalent cause of mortality among children aged 1 to 14 years, following accidents. According to available data, it is projected that around 1040 children below the age of 15 in the United States will experience mortality due to cancer in the year 2023 [1]. Multiple empirical studies have indicated that the well-being of children and their families can be adversely affected by diseases and adverse effects associated with different forms of cancer treatment, including chemotherapy, radiation therapy, surgery, and bone marrow transplants [1–4]. The administration of the treatment can exacerbate the symptoms of heightened distress that are commonly linked to the adverse effects of the treatment and its toxic properties [5]. In addition to the physical manifestations of the disease and the adverse effects of the treatment regimen, pediatric cancer patients are subjected to an extensive period of hospitalization, which may elicit a range of emotional responses including fear, anger, and sadness [6]. According to previous research, children and adolescents diagnosed with cancer often describe experiencing both physical and psychosocial transformations resulting from their therapeutic interventions. Additionally, they frequently encounter stigmatization from others and express a strong desire to regain a sense of normalcy that they had prior to their illness [4].

The majority of pediatric patients diagnosed with cancer encounter at least one distressing symptom, with a significant proportion experiencing at least one highly distressing symptom [7]. According to prior studies, a significant majority of children undergoing cancer treatment exhibit various symptoms, including reduced appetite (87.0%) and pain (86.0%) [8]. Additionally, these children commonly experience fatigue, nausea, vomiting, and sleep disturbances [5,9,10]. A range of factors can contribute to the occurrence of stressful conditions in children. This finding is consistent with prior scholarly investigations, which elucidate that children diagnosed with cancer exhibit notable indications of anxiety, stress, and depression [11]. The presence of symptoms related to anxiety, stress, and depression during the course of treatment has the potential to adversely impact the overall quality of life experienced by individuals [12].

Numerous scholarly sources elucidate the significant advancements witnessed in the domain of pediatric cancer treatment and supportive care in recent decades. As a result, the current 5-year survival rate for pediatric cancer

exceeds 80.0% [13]. This assertion is corroborated by additional research studies which have documented favorable outcomes among a significant number of pediatric cancer survivors subsequent to their treatment. Nevertheless, the majority of subgroups encountered psychological distress and a decline in health-related quality of life [14]. There exists a significant body of evidence within the cancer population that establishes a correlation between psychological stress and a decline in immune function [15]. The impact of psychological distress on the hyperactivity of the hypothalamic-pituitary-adrenal (HPA) axis has been recognized, leading to disruptions in the integration of neurohormonal and immunological processes [13,16–18]. The occurrence of psychological stress prompts communication between the brain and the immune system, thereby exerting an influence on immune function. The bidirectional communication between the immune system and the brain is facilitated through reciprocal pathways. Both directions are associated with the progression of diseases. This becomes particularly pertinent in cases where the psychological stress persists over an extended period of time, or when there is a chronic activation of the immune system. In both scenarios, there is a decrease in both physical and mental activity, which has the potential to contribute to the development and progression of illness and disease [18,19].

The psychoneuroimmunological perspective is derived from the integration of psychological distress and the body's biological conditions [19]. Psychoneuroimmunology (PNI) is a discipline that investigates the impact of the interplay between psychological, neural, and immunological mechanisms on both human health and behavior [20–22]. Additional scholarly literature elucidates that PNI is a discipline that exhibits a strong interconnection with stress regulation, the intricate interplay between human behavior, and the intricate functioning of the nervous, endocrine, and immune systems [20–23]. This discipline encompasses the comprehension of the impact that thoughts, emotions, and behaviors can exert on the immune response and overall well-being [20–22]. In the field of pediatric oncology, research on psychoneuroimmunology (PNI) aims to elucidate the interplay between psychological factors, the nervous system, and the immune response, as well as their impact on cancer pathology and therapeutic interventions [24,25].

Several interventions have been devised to assist pediatric cancer patients in managing psychoneuroimmunological markers, with psychological interventions being one such approach. Nevertheless, there exists a lack of consensus regarding the precise delineation of the terminology associated with psychological intervention. According to a meta-review conducted by Hodges et al. [26] states that the description of the terms of intervention that are often used in research are ‘psychosocial’, psychological, psychotherapy, nonpharmacological, behavioral, supportive, psychoeducational, psychosomatic, psychiatric, and noninvasive. Hoffman et al. [27] define psychological interventions as a method or strategy used to manage a person's physical, psychological, and neurocognitive response interventions. These interventions can be categorized into various approaches, including relaxation techniques, distraction techniques, cognitive behavioral therapy (CBT) strategies, mindfulness-based stress reduction, acceptance and commitment therapy, cognitive therapy functional, health coaching, biofeedback, education, and counseling.

There is a growing body of research focused on cancer survivors, which indicates that a range of psychological interventions have the potential to mitigate psychological distress, enhance coping mechanisms, and positively impact immune function by influencing the neuro-endocrine and immune systems [24]. The existing body of literature has extensively documented the correlation between psychological stress and cancer across different age groups. Nevertheless, the existing body of literature indicates a scarcity of empirical support regarding the impact of psychological interventions on psychoneuroimmunological markers, specifically within the context of pediatric cancer. The utilization of psychoneuroimmunological markers to identify the physiological reactions of the body can serve as a prospective objective measure in evaluating the efficacy of psychological interventions in the context of pediatric cancer [28].

This review aims to provide empirical evidence regarding the efficacy of psychological interventions in modulating the psychoneuroimmunological system in pediatric cancer patients. Furthermore, this review presents an integrative framework that offers a comprehensive understanding of the interplay between pediatric cancer, psychological intervention, and the intricate processes involved in nervous system development. This framework allows for the

evaluation of the impact on children's psychoneuroimmunological markers as a means of assessing these novel pathways. This systematic review aims to contribute to the advancement of interventions by providing a comprehensive overview of the integration of biopsychosocial factors, psychological interventions, and PNI in the context of pediatric cancer. The objective of this systematic review is to evaluate the efficacy of psychological interventions in modulating psychoneuroimmunological markers among pediatric cancer patients.

Methods

The guideline used to conduct this systematic review is The Preferred Reporting Items for Systematic Review and Meta-analysis (PRISMA) [29]. This systematic review has been registered with PROSPERO with registration number CRD42023392169.

Inclusion and exclusion criteria

The selection and search criteria used inclusion and exclusion criteria. The inclusion criteria include: (1) using PICOS (population, intervention, comparison, outcome, and study design). P (Population), means the study must involve children aged 0 to 18 years who suffer from cancer, I (intervention), is the use of all types of psychological interventions (we replicate the definition provided by Hoffman et al. [27] by defining psychological intervention as one of the following approaches: all kinds of relaxation techniques, all kinds of distraction technique, cognitive behavioral therapeutic strategies, mindfulness based stress reduction, acceptance and commitment therapy, cognitive functional therapy, health coaching, biofeedback, education, and counseling), C (comparison), is the control group or comparison group that is not psychological intervention, O (outcome), means studies include an analysis of at least one psychoneuroimmunological response in the form of a psychological responses (there is a feeling that someone feels like stress level, depression level, anxiety level, fear, fatigue level, quality of sleep, and quality of life that is measured by using a questionnaire); physiological responses (an individual response physically characterized by an increase heart rate, pulse, blood pressure, pain level, appearance nausea, vomiting, and fever); and neuroimmunological response (the body's response to stimuli involving the central nervous system (CNS) and the immune system that is measured by one of the saliva, hair, blood, or urine tests such as cortisol, leukocytes, cytokines, immunoglobulins and other immune responses). Study design (S) is all types of quantitative research; (2) the year of publication is the last ten years, between 2013 and 2022; (3) the articles taken are published in English. The exclusion criteria are (1) protocol studies, conference presentations, editorials, review articles, case reports, and case series, qualitative research, applied or development designs; (2) Studies involving molecular indicators or DNA; and (3) studies combining psychological intervention therapy with pharmacological intervention (use of drugs).

Search strategy

Reviewers scanned academic databases from the study commencement date from December 2022 to February 09, 2023. Searches were performed on four databases (Scopus, PubMed, ScienceDirect, and ProQuest). The minimum standard for searching the literature in a systematic review is minimally using a combination of 4 main databases [30]. The consequence of using these four main databases is that researchers will produce fewer search results, and there is a possibility of missing relevant references. However, in this systematic review, we also use Google Scholar to minimize the possibility of missing relevant references. In general, researchers consider combining four main databases equipped with Google Scholar to provide efficient results in this systematic review.

The main search term is “psychological intervention” combined using the Boolean “AND/OR” with terms related to “psychological and physiological responses” and “neuroimmunological markers”. Then the related term “children with cancer” was added. The author defines synonyms with the keyword as follows: (“Paediatrics” OR “Child” OR “childhood” OR “Children” OR “Adolescent” OR “teen” OR “teenagers”) AND (“cancer” OR “pediatric cancer” OR “childhood cancer” OR “neoplasm”) AND (“psychology” OR “psychological” OR “Psychological programs” OR “Psychological intervention” OR “psychotherapeutic” OR “psychotherapy”) AND (“Psychoneuroimmunology” OR “Psychoneuroimmunology responses” OR “psychology” OR “Physiology” OR “neurology” OR “endocrinology” OR “immunology” OR “Biological Markers” OR “Biomarkers” OR “cortisol” OR “leukocyte” OR “Cytokines” OR “lymphocytes” OR “immunoglobulins” OR “interleukins” OR “anxiety” OR “distress” OR “stress” OR “pain” OR “Fatigue” OR “Heart rate” OR “blood pressure” OR “respiratory rate” OR “body temperature” OR “blood oxygen”).

Full search strategies for all resources can be seen in supplementary Appendix 1.

Selection of study

All authors (IH, NN, IL, WFR, ZH, and TR) scanned academic databases. Then we conduct the process of selecting articles. Four reviewers (IH, WFR, ZH, and TR) used Rayyan's intelligent systematic review to select articles. Rayyan is a web and mobile app for systematic reviews. Rayyan proved effective in conducting a systematic review and has significant potential to lighten the load of reviewers [31]. Articles filtered from the four main databases were entered into the Rayyan application. The total number of studies from this initial database search found 1,652 articles (898 from the main database and 754 from the auxiliary database). These articles were then checked, and the duplicates were removed.

IH, WFR, ZH, and TR independently reviewed the titles and abstracts yielded by this comprehensive search and subsequently selected articles based on the predetermined inclusion and inclusion criteria. Titles and abstracts were screened to include articles that first referred to psychological interventions and then had any terms related to PNI responses (as listed in the search terms above). We found 34 relevant studies from the main database and independently read them in full text. Then, disagreements between reviewers were resolved by consensus or by the decision of a third independent reviewer. A level of consensus of 80.0% or higher was considered to represent strong agreement [32]. Finally, 21 studies were included in this systematic review (13 articles from the main database and eight articles from the supplementary database (Figure 1).

Data extraction, analysis, and synthesis

Data were taken from each article that met the inclusion criteria. The data extraction process uses a Microsoft Excel sheet. All articles were read, and all authors extracted the data independently. Then, any discrepancies were discussed and resolved consensually. When differences could not be resolved, a third opinion would be sought, which might prove unnecessary. Given the apparent heterogeneity among studies in the type of psychological intervention, length of intervention, and study design, a meta-analysis was impossible. Thus, we only conducted a narrative review of the findings. Analysis using PICO Synthesis. The stages of the synthesis process begin with identifying the characteristics of the study (Population, Intervention, Comparison, Outcome, and study design) in each article obtained, then grouping them based on the Cochrane Handbook for Systematic Reviews [33].

Risk of bias and study quality

The authors identified study quality by considering the risk of bias. This assessment aims to assess a study's methodological quality and determine the extent to which a study has overcome possible biases in its design, implementation, and analysis. To identify the risk of bias, this systematic review uses The Joanna Briggs Institute (JBI) Critical Appraisal tools following the research design [34]. Each research design has different questions. Researchers must assess the articles that have been selected. The scoring results come from the scoring results from the percentage, which is ≥ 75% = Good, 50–75% = Fair, and 35].

Model development

This study offers a new integrative model that shows the interaction between several factors affecting stress levels, which can be observed through neuroendocrine and immune mechanisms. Meanwhile, this integrative model also demonstrates how psychological interventions can modulate the effects of these various factors on neuroendocrine and immune mechanisms, ultimately influencing health outcomes. The conceptual framework of this new integrative model was created based on the conceptual framework of the biopsychosocial model [36] integrated with the field of PNI [19] and the results of this systematic review (Figure 2).

The biopsychosocial model is structured by several domains, including psychosocial, biological, and health behaviors, stress, psychological interventions, neuroendocrine and immune system mechanisms, and health outcomes. The biopsychosocial model describes the interaction among the factors that influence the stress of a person's life. Those factors encompass psychosocial, biological, and health behaviors that lead to susceptibility (or resistance) to disease, onset, disease symptoms, disease development, exacerbation, recovery, and quality of life through the process of involving neuroendocrine and immune mechanisms. Meanwhile, health psychological interventions are regarded to modulate the effects of these various factors on neuroendocrine and immune

mechanisms, which in turn will influence health outcomes. The indicators for each domain refer to the results of a literature search and this systematic review's results.

The new integrative model shows the integration between the biopsychosocial model in the domain of neuroendocrine mechanisms and the immune system and psychoneuroimmunology (PNI). PNI is a field of medical science that examines the relationship between psychological stress and physiological processes in the body. The mind, nervous, endocrine and immune systems have a reciprocal relationship anatomically and biochemically [19]. PNI in the new integrative model is organized into four domains: psychology, physiology, neuroendocrinology, and immune systems. The indicators for these four domains are compiled based on our results in this systematic review. In the psychological intervention domain, the authors arrange the types of psychological interventions in the new integrative model according to the results of the author's synthesis in this systematic review. Based on the biopsychosocial model, the domain of psychological intervention consists of cognitive behavioral stress management (CBSM), relaxation, hypnosis, meditation, emotional disclosure, adherence-based interventions, sleep hygiene, exercise, social support groups, psychotherapy, imagery, distraction, behavioral pain management, yoga, massage, biofeedback, drug/alcohol prevention/rehabilitation, psychotherapy, and behavioral conditioning. All of these interventions can be used in any type of disease or condition. However, the types of psychological interventions set in the integrative model framework are the psychological interventions that can be used in children with cancer, considering that this systematic review was carried out on the population of children with cancer.

Results Study characteristic

The author obtained 1653 articles through all the specified databases. Studies that met the inclusion criteria in this systematic review were 21 articles. A description of the percentage of study characteristics obtained is shown in Table 1.

Based on the table above shows that most of the designs used were randomized controlled trials 12 (57.1%). At the same time, the types of psychological interventions used vary widely. The most common type of psychological intervention was massage therapy 3 (14.2%). Almost half of the studies measured psychological responses 8 (38.0%), and psycho-physiological responses 9 (42.9%), and only a small proportion assessed the effectiveness of psychological interventions on neuroimmunological markers in pediatric cancer.

Risk of bias and study quality

Almost all studies included in this systematic review (n = 18) have a study quality category as “Good” with a score above 75.0% using the Joanna Briggs Institute (JBI) critical appraisal so that all studies can be carried out synthesis analysis (see Table 2).

Impact of psychological intervention

From searching several scientific-based data, 21 studies illustrated that psychological interventions positively impacted psychoneuroimmunological responses in children with cancer. Based on this review, the author divides the impact of psychological intervention into two themes, including: (1) psychological responses (e.g., pain, anxiety, stress/distress, mood, fear, fatigue, depression, sleep quality, quality of life, and other psychological responses) and physiological responses (e.g., fever, pain, nausea, vomiting, blood pressure, heart rate, and other physiological responses); (2) psycho-physio and neuroimmunological marker (e.g., cortisol, NK cell, B lymphocytes, CD4+ T lymphocytes, CD8+ T lymphocytes, IgM antibodies, IgA antibodies, α-amylase, and another neuroimmunological marker).

1. Impact of psychological interventions on psychological and physiological responses.

Almost all of the research in this systematic review assesses the effectiveness of psychological interventions on psychological responses (stress/distress, fear, anxiety, fatigue, depression, decreased sleep quality, and quality of life) and physiological responses (blood pressure, heart rate, pain, nausea, vomiting, and fever). Nine studies assessed the effectiveness of interventions on psycho-physiological responses [37–45] and eight studies only assessed psychological responses but did not assess children's physiological responses [46–52].

Based on these studies, some studies show insignificant results. The psychological intervention in the form of

MEDiPORT was reported to have no significant effect on the level of pain felt by children with cancer who underwent needle insertion. MEDiPORT is a 3-foot-tall humanoid robot (NAO hardware produced by Softbank Robotics and MEDi software produced by RxRobots. The robot is self-standing, able to walk, has hands that can self-adapt and grip, has eyes with light emission diodes, and has two speakers and four microphones to detect and project sounds. The robot can be programmed using a proprietary software development kit [37]. In addition, other studies have reported that massage therapy in adolescents with cancer undergoing hospitalization shows no significant changes in anxiety, mood, or fatigue from before to after the intervention [49]. This review shows that all studies that measure psychological responses use questionnaires. The questionnaires used varied, but most of the psychological problems assessed were the child's level of anxiety, mood, fear, and distress/stress level. At the same time, the physiological response is assessed through symptoms such as pain, nausea, vomiting, fever, and changes in vital signs such as blood pressure and heart rate. Measurement of pain level and assessment of symptoms such as nausea and vomiting in all studies used a questionnaire. Meanwhile, measuring vital signs such as blood pressure and heart rate uses standard tools. Diastolic and systolic blood pressure and heart rate in this study were used to measure children's physiological stress. Research has found that measuring physiological responses is always accompanied by assessing psychological responses using a questionnaire.

1. Impact of psychological intervention on the psycho-physio-neuroimmunological marker.

Based on this review, we found that there was one article that only assessed the effectiveness of psychological interventions on neuroimmunological markers [53], one article assessing psycho-neuroimmunological markers [54], one article assessing physio-neuroimmunological markers [24], and one article assessing psycho-physio-neuroimmunological markers [55].

Based on this review, music therapy is one of the psychological interventions used to manage neuroimmunological responses. Music therapy does not statistically affect cortisol levels but clinically shows a positive effect in reducing cortisol levels. The study suggested that the results that were not statistically significant could be caused by several things, including the small sample size, the range of results for measuring cortisol levels that were too far apart, the homogeneity of clinical conditions and levels of stress exposure, environmental factors, and the time and duration of therapy music that is too long [53]. Meanwhile, a study by Lopes Junior et al. (2020) reported that the clown intervention positively impacted cortisol levels but did not impact α-amylase levels in children with cancer. Future research should focus on a specific tumor type, have homogeneous samples, and use a more detailed investigation with robust statistical analyses. Future studies could also identify pediatric cancer inpatient profiles most likely to benefit from this type of intervention regarding age, gender, frequency of clown visits, and follow-up period [54]. In addition, a related study was also conducted in the UK and found that pediatric patients with leukemia who underwent PNI-based psychological interventions had a strong correlation between improvements in several key immune markers and a more satisfactory evolution of various clinical aspects of the disease, symptomatic treatment, and quality of life [24]. Quasi-experimental research conducted in Taiwan also identified the effectiveness of therapeutic play on changes in psychological, physiological, and neuroendocrine aspects. This study reports that therapeutic play interventions can reduce anxiety, heart rate (HR), and cortisol scores before External beam radiotherapy (EBRT) in children with brain tumors [55]. A summary of the studies can be seen in Table 3.

Development of a new integrative model

The following illustrates a new integrative model that explains the relationship between the biopsychosocial model, PNI, and psychological intervention in children with cancer. Based on the results of a systematic review and the incorporation of several theoretical concepts, the development of this new integrative model is divided into four

domains, including.

1. Factors that affect stress (Box A-C)

Based on the biopsychosocial model, the factors influencing a person's stress condition include psychosocial, biological, and health behavior. Psychosocial processes (Box A) are factors that influence a person's interpretation and response to stressors which include individual differences (e.g., the child's personality model, coping strategies used, and perceptions of illness); mood (e.g., feeling of helplessness, anxiety levels, and stress levels); resources (e.g., social support, care-giver's coping strategies, care-giver's degree of psychological distress); other (stress reactivity). Biological factors (Box B) are factors that influence a person's response to a stressor, including genetics, gender, age, diagnosis of cancer, type of cancer, physical symptoms, medical treatment, repeat invasive procedures, and repeat hospitalization. Health behaviors/lifestyle factors (Box C) are factors that influence a person's response to a stressor, e.g., quality and quantity of sleep, healthy diet, exercise, and treatment adherence. The indicators for each psychosocial, biological, and health behavior domain refer to previous literature, which discusses the factors that influence stress regulation in children with cancer [[23]].

1. Stress

Stress is a person's inability to cope with perceived threats to one's mental, physical, emotional, and spiritual well-being, resulting in physiological responses and adaptations [[56]]. All cancer patients experience distress due to the diagnosis, effects of the disease, or treatment being undertaken [[57]]. Life stress (Box D) can be acute or chronic. Acute stress lasts minutes to hours, and chronic stress lasts months to years [[19]]. Acute and chronic stress will affect the stress response through psychoneuroimmunological markers (psychological responses, neuroendocrine and immune markers) (Box E).

1. Psychological interventions

Psychological interventions (Box F) are designed to modulate the stress response and promote health behaviors by teaching individuals more adaptive methods of dealing with perceived stress. Psychosocial interventions are useful for treating stress-related disorders and can influence the course of chronic disease [[58]]. Based on the results of this review, we identified 18 types of psychological interventions used to manage psychoneuroimmunological markers in children with chronic illness, including MEDiPORT cognitive-behavioral arm, animal-assisted therapy, virtual reality, music therapy, massage therapy, clown intervention, make-a-wish intervention, mandala drawing, cognitive behavioral therapy, deep breathing, pet therapy, hypnosis, touching, relaxation-guided imagery, humor therapy, interactive therapeutic play education program, play therapy, and sleep hygiene.

1. Neuroendocrine and immune mechanisms

Neuroendocrine and immune system mechanisms in the biopsychosocial model suggest integration from the field of psychoneuroimmunology (PNI). Box F shows the bidirectional communication of PNI, which is the mechanism that occurs in a two-way interaction between the neuroendocrine and immune axes that mediates the relationship between biobehavioral factors (Box A–D). PNI is divided into four domains: psychology, physiology, neuroendocrinology, and immunology. The indicators for all domains are compiled based on the results of this systematic review. Based on the results of our systematic review, the psychological system domain is assessed through several indicators such as anxiety, fear, stress/distress, mood, sleep disorder, resilience, fatigue, and depression. The physiology domain is evaluated through indicators such as blood pressure, heart rate, fever, and pain. The authors found no studies in this systematic review that assessed the neurological system through neurological markers such as dopamine, epinephrine, norepinephrine, β-endorphins, or other markers. Meanwhile,

in the endocrine system domain, the indicators assessed were cortisol, and the immune system indicators assessed included: Natural killers (NK), B lymphocytes, CD4+ T lymphocytes, CD8+ T lymphocytes, IgM IgA antibodies, IgA antibodies, and α-amylase).

Table 3 provides a brief description of the new integrative model.

Discussion Effectiveness of psychological interventions on the psychological and physiological responses in children with cancer

The utilization of psychological interventions in the management of mental health among pediatric oncology patients holds promise for enhancing both psychological and physical health outcomes. A total of nine studies were conducted to evaluate the efficacy of various interventions, including animal-assisted intervention, cognitive behavioral therapy, virtual reality, massage therapy, mandala drawing, the home-based multimodal symptom-management program, and mindfulness-based stress reduction, in terms of their impact on psychological and physical responses [37–45]. Three out of nine studies indicated that psychological interventions did not yield statistically significant outcomes in terms of the psychological and physiological responses observed in children diagnosed with cancer. The statistical analysis conducted in a study indicates that there is no significant evidence to support the effectiveness of massage therapy in managing the physiological and psychological responses of children diagnosed with cancer [43]. Moreover, the utilization of the MEDiPORT humanoid robot for the purpose of mitigating procedural pain and distress in pediatric cancer patients yielded comparable outcomes in both the control and intervention groups [37]. The study found that the home-based multimodal symptom-management program was effective in reducing fatigue among participants. However, there was no significant difference observed between groups in terms of reducing nausea and vomiting, pain, mucositis, and anxiety [42].

Out of the nine studies examined, six of them indicated that various psychological interventions, including animal-assisted intervention, cognitive behavioral therapy (CBT), virtual reality, mandala drawing, and mindfulness-based stress reduction (MBSR), have been found to be effective in managing the psychological and physiological responses experienced by children diagnosed with cancer. This aligns with a prior systematic review conducted in the United Kingdom in 2017. The review indicated that a total of nine studies demonstrated statistically significant enhancements in psychological outcomes. The aforementioned findings suggest that psychological interventions have demonstrated efficacy in diminishing anxiety, physical symptoms, depressive symptoms, and enhancing overall quality of life [59].

Several other studies have documented the efficacy of psychological interventions, particularly those that employ more targeted and specific approaches. Animal-assisted therapy has been successfully utilized across different age groups and for various disease diagnoses. For instance, it has been employed in the context of pediatric surgery for children [60]; as well as for children diagnosed with Post-Traumatic Stress Disorder (PTSD) [61]; and those receiving treatment in acute care pediatric settings [62]. Contrary to the aforementioned viewpoint, Feng et al. [63] conducted a systematic review that found no significant impact of animal-assisted therapy on anxiety, depression, stress, and heart rate among hosptialized children and adolescents. In the field of psychology, CBT has emerged as a prevalent intervention technique. This approach has been modified to cater to various age groups, including children, adolescents, adults, couples, and families. The cognitive aspect of CBT focuses on mitigating exaggerated and negative thoughts related to pain, while the behavioral component involves implementing relaxation techniques and activating coping behaviors [64,65] Psychological intervention has been found to have an impact on brain mechanisms, leading to a decrease in both pain and anxiety experienced by individuals. According to existing scholarly works, various aspects of successful psychological intervention may be corroborated by alterations in neural circuitry. These alterations are typically characterized by decreased activation and/or diminished

hyperconnectivity in brain regions associated with pain processing, emotion, and cognitive control [64].

According to the review, a total of eight studies exclusively evaluate the efficacy of psychological interventions in managing the psychological reactions exhibited by children diagnosed with cancer [46–52,66]. Seven out of the eight studies presented in this analysis have indicated that psychological interventions possess considerable potential in effectively managing psychological responses among children. Additional empirical evidence has also documented the positive impact of psychological interventions on the psychological responses of children with various conditions. For instance, studies have shown the effectiveness of music therapy in children undergoing surgery and those with asthma [67,68]; virtual reality (VR) therapy in children with sickle cell disease and those undergoing surgery [69,70]; pet therapy for children undergoing hospitalization [71]; hypnosis in children with cancer, in children with burns, and children with Crohn's disease [72–76]; parental touch followed by music therapy in critically ill children [77]; relaxation-guided imagery in children undergoing surgery [78]; humor therapy in children with atopic dermatitis [79]; interactive therapeutic play education program for children undergoing surgery [80]; and play therapy in children undergoing elective surgery and in children undergoing liver transplantation [81–84]. Certain studies have the potential to be grounded in empirical evidence, as they demonstrate that psychological interventions have a notable impact on the management of psychological reactions, thereby enhancing the overall quality of child healthcare [46]. The implementation of psychological interventions presents cancer patients with a comprehensive approach to healthcare, potentially safeguarding the overall physical and psychological welfare of individuals diagnosed with cancer [85].

According to a study conducted on children with cancer, approximately one out of every eight studies revealed no statistically significant alterations in anxiety, mood, or fatigue levels following the implementation of psychological intervention through massage therapy [49]. Nevertheless, this finding contradicts the conclusions drawn from previous systematic reviews, which demonstrated the efficacy of massage therapy in effectively mitigating stress levels among children receiving palliative care in hospital settings [86,87]. Massage therapy has been found to have beneficial effects on various pediatric conditions. The aforementioned factors encompass a range of issues affecting preterm infant growth, psychological well-being, gastrointestinal functioning, painful conditions such as burns and sickle cell disease, muscle tone disorders like cerebral palsy and Down syndrome, as well as chronic illnesses including diabetes, asthma, cancer, and HIV [88].

Effectiveness of psychological interventions on the psycho-physio-neuroimmunological markers in children with cancer

The current body of research examining the efficacy of psychological interventions on psycho-physio-neuroimmunological markers in pediatric populations, particularly those diagnosed with cancer, remains relatively scarce. Based on the findings of this comprehensive systematic review, it was determined that a mere four out of the total of 21 studies examined in this analysis focused on the evaluation of psycho-physio-neuroimmunological markers. In this investigation, the efficacy of psychological interventions on neuroimmunological markers was examined in one study [53]. Additionally, another study focused on psychoneuroimmunological markers [54], while a separate study explored physio-neuroimmunological markers [24]. Furthermore, a study was conducted to investigate the impact of psychological, physiological, and neuroimmunological factors on markers [55].

A single study was identified that exclusively evaluated the neuroimmunological response. According to the study, music therapy has a statistically significant impact on neuroimmunological markers, specifically salivary cortisol levels. This study elucidated the clinical impact of music therapy on the reduction of cortisol levels [53]. This finding aligns with the findings of Finn &Fancourt [89] who conducted a review and observed that 13 out of the 33 biomarkers tested exhibited changes following exposure to music. One of the biomarkers that has been extensively examined is

cortisol, a stress hormone. Approximately half of the clinical studies conducted have indicated that listening to music has a stress-reducing impact. Several other biomarkers that have been examined are also components of biological stress pathways, suggesting that the primary mechanism by which music impacts us biologically is through the modulation of the stress response.

The previous literature has provided a description of the mechanism by which music therapy regulates cortisol levels. The auditory perception of music elicits neural responses in the hypothalamus, subsequently triggering the release of endorphins through the activation of the pituitary gland [56,90]. Endorphins, which are endogenous opiates similar to morphine, serve as the body's innate analgesics and possess the ability to mitigate the impact of stressful conditions by modulating cortisol levels [56,90]. According to previous studies, psychological interventions, including animal-assisted activities, have not shown statistically significant effects on salivary cortisol levels and C-reactive protein (CRP) in children who are hosptialized [91]. An additional discovery pertains to the impact of psychological interventions on the levels of noradrenaline and cortisol, while the levels of adrenaline remain unaffected. The intervention had a discernible impact on adrenaline levels exclusively within a time frame of 6-8 days following surgery in patients undergoing Coronary Artery Bypass Graft (CABG) procedures [92].

Three studies were identified that aimed to evaluate the neuroimmunological markers as well as the physical and psychological responses in pediatric patients diagnosed with cancer. The aforementioned studies have documented that various psychological interventions, such as clown intervention, therapeutic play, and psychoeducational intervention, yielded favorable outcomes in terms of physical, psychological, and neuroimmunological indicators in pediatric cancer patients. These indicators include cortisol levels, α-amylase levels, CD8+ T cells, B cells, natural killer (NK) cells, serum immunoglobulin A (IgA), and immunoglobulin M (IgM) [24,54,55]. The implementation of clown intervention has demonstrated efficacy in the management of psycho-physio-neuroimmunological markers among pediatric cancer patients. Nevertheless, the findings of this review exhibit notable disparities when compared to previous research. According to a previous conducted by Ding et al., it was found that clown intervention has a positive impact on distress levels, duration of crying following a medical procedure, and length of hospital stay. Nevertheless, the study findings did not reveal any statistically significant disparity in cortisol levels [93,94]. In contrast, there has been limited research conducted on the efficacy of therapeutic play. No comparable studies evaluating the efficacy of therapeutic play on psycho-physio-neuroimmunological markers were identified by researchers. Nevertheless, according to William et al. [95] it was found that children who underwent therapeutic play intervention exhibited reduced levels of state anxiety scores during both the pre-operative and post-operative periods. In addition, psychoeducation interventions have been implemented in patients undergoing multidrug therapy (MDT) treatment. The research findings indicated that psychoeducation was successful in enhancing spiritual response, perception, stigma, and anxiety, while also reducing cortisol levels [95].

Various psychological interventions have been documented for the management of psycho-physio-neuroimmunological markers. The study conducted by Chang et al. examines the efficacy of psychological interventions, specifically the Laughing Qigong program (LQP), in adolescent patients who are undergoing hospitalization. LQP is an integrative approach that combines the practices of qigong and laughter techniques, emphasizing the interplay between the mind and body. This study examined both neuroimmunological responses, specifically cortisol levels, as well as their impact on physical responses, including heart rate and heart rate variability, and psychological responses, such as mood states, self-esteem, self-efficacy, and depression [96]. In 2021, a study conducted in Peru yielded similar findings, indicating the positive impact of providing augmented reality books on the management of psychological and neuroimmunological responses. The evaluation of emotional stress and neuroimmunological markers in hosptialized children involved the utilization of the Weisz visual analogue

scale to assess psychological responses, alongside the measurement of cortisol levels. This study was unable to provide evidence supporting the hypothesis that reading augmented reality books resulted in a greater reduction of salivary cortisol levels compared to reading a standard book among children who were hosptialized. In addition, it has been found that augmented reality (AR) books have a positive impact on reducing emotional stress, as measured by the Weisz visual analogue scale [97].

Additional psychological interventions encompass the utilization of storytelling, which has been observed to exert an influence on both physiological responses and neuroimmunological markers. Specifically, this intervention has been found to elevate oxytocin levels while concurrently reducing cortisol and pain levels in children undergoing treatment in intensive care units (ICU) [98]. In the realm of psychological interventions, it has been observed that mindfulness-based stress reduction (MBSR) techniques have proven to be advantageous, resulting in notable enhancements in both psychological and biological aspects, including endocrine and immunological markers [99,100]. The existing body of literature pertaining to the neural underpinnings of psychological interventions in cancer patients is currently insufficient, necessitating additional investigation. A study conducted in the Netherlands in 2022 elucidates the mechanisms underlying psychological intervention in the regulation of psychoneuroimmunological responses. According to the study, psychological interventions administered to individuals with cancer have the potential to influence cortical and subcortical brain activity. These changes align with the brain regions associated with distress responses [85].

A new integrative model

Within the specific context of individuals diagnosed with cancer, the prevalence rate of psychological distress is observed to be four times greater compared to the general population. This heightened prevalence of psychological distress is frequently associated with inferior outcomes. Furthermore, a number of cellular and molecular studies have provided evidence supporting the intricate signaling networks influenced by chronic stress-induced psychological distress in the context of cancer development [101]. The experience of receiving a diagnosis, the effects of the disease, and the treatment process can elicit distress among individuals diagnosed with cancer [57]. The correlation between the specific cancer diagnosis of patients and the levels of physical distress, emotional distress, and depressive symptoms has been found to be statistically significant [102]. Furthermore, it should be noted that the administration of the treatment may lead to an exacerbation of the symptoms associated with heightened distress, as indicated by previous research [5]. Cancer survivors are at the greatest risk of developing endocrine disorders over time when they undergo cancer treatments involving radiation in major endocrine organs, including the hypothalamus, pituitary, thyroid, and gonads [13]. The immune system of an individual can be impacted by disorders within the endocrine system [18,56].

In addition to the diagnostic process, the presence of illness, or the administration of treatment, which are known stressors for pediatric cancer patients, a study conducted in Ohio, United States, elucidates that children with cancer experience stress in various domains. These domains include (a) disruptions in daily functioning and roles, such as missing school or falling behind in academic work, being unable to engage in previously enjoyed activities, frequent visits to hospitals or clinics, and concerns about the well-being of family and friends; (b) physical manifestations resulting from treatment, such as feelings of sickness or nausea, anxieties regarding changes in appearance, and discomfort or pain arising from medical procedures; and (c) uncertainties surrounding the nature of cancer, including difficulties comprehending medical explanations, confusion regarding the concept of cancer, and apprehensions about future outcomes [103].

The regulation of the neuroendocrine and immune systems can be influenced by a range of stressors, leading to potential impacts on the health outcomes of children. The impact of stress on immune function is exacerbated, while

on the other hand, psychological interventions have the potential to regulate neuroendocrine activity and improve immune system functioning. However, there is limited knowledge regarding the extent to which children with cancer can achieve immunological recovery. The intricate nature of stress-induced factors in pediatric cancer patients and the limited amount of scholarly research examining potential mediating mechanisms, such as the impact of stress and psychological interventions on the immune system. Therefore, future research can employ this novel integrative model framework to manipulate the variables of psychological interventions, thereby facilitating the examination of direct effects on the immune response. The investigation of interventions that are most well-received by pediatric cancer patients is a fundamental aspect of immune effect preservation, thus necessitating additional scholarly inquiry in this domain.

There exist certain limitations to this review. Due to the diversity observed in the psychological interventions employed, the age range of the children included, the study design implemented, and the instruments utilized for outcome assessment, the feasibility of conducting a meta-analysis was precluded. Moreover, while the utilization of the JBI for evaluating bias in this review is comprehensive and adheres to explicit criteria, the individual assessment of studies by each author remains subjective. In order to enhance the comprehensiveness and validity of future research, it is recommended that subsequent investigations incorporate post-intervention evaluations to elucidate the enduring ramifications of the intervention. Additionally, it is crucial to account for the homogeneity of various indicators, including but not limited to gender, type of psychological intervention, type of cancer treatment, stage of cancer, type of instrument employed, methodologically appropriate sample size, and objective tools to assess bias. By considering these factors, researchers can obtain results that are more robust and reliable. Further research is required to comprehensively evaluate the effectiveness of psychological interventions in terms of their impact on neurobiological processes and clinical outcomes. The examination of the associations between observed neurobiological alterations and clinical outcomes is crucial in order to comprehend the potential neural activity changes that may be responsible for the clinical impact of an intervention [85]. The lack of clarity surrounding the terminology used in psychological interventions poses a potential limitation in this review, as it may hinder the identification of additional pertinent studies. When conducting further research, it is imperative to carefully select keywords that are more specific in order to avoid overlooking relevant studies.

Despite the presence of certain limitations, this review possesses several notable strengths. First, it stands as one of the pioneering evidence-based interventions that evaluates the efficacy of psychological interventions on psychoneuroimmunological markers in pediatric cancer patients. Second, it introduces a novel integrative model that can aid healthcare professionals in making informed clinical decisions. This model offers a comprehensive and holistic depiction of the various factors that impact stressful conditions in children with cancer. Furthermore, it provides insights into the mechanisms through which psychological interventions influence physical, psychological, and neuroimmunological markers in this population. It is imperative for future researchers to thoroughly investigate the various integrative models, encompassing psychosocial factors, biological factors, health behaviors, neuroendocrine and immune system mechanisms, and disease outcomes. This examination should be conducted using a longitudinal design to comprehensively address the intricate interplay among these components and to gain a comprehensive understanding of their significance in relation to health outcomes. Psychological intervention is a viable evidence-based treatment option that can be employed by healthcare professionals in the field of nursing, particularly in the context of pediatric patients diagnosed with cancer. This intervention encompasses educational initiatives, counseling sessions, and training programs, all aimed at enhancing the overall well-being of children grappling with cancer. The findings of the study also emphasize the importance of nurses being aware that psychological intervention is a crucial aspect of providing comprehensive and high-quality nursing care for children

with cancer. Consequently, the outcomes of this review may serve as valuable input for relevant stakeholders to incorporate psychological interventions into the nursing curriculum, thereby facilitating the enhancement of nursing students' skills during their collegiate education.

Conclusion

This review shows that many studies have identified the effectiveness of psychological interventions on psychological and physiological responses. However, research assessing the impact of psychological interventions on neuroimmunological markers is still very limited. This systematic review shows that psychological interventions positively impact psychoneuroimmunological markers in children with cancer. So, we recommend the use of psychological interventions as an additional intervention in pediatric cancer. This study offers a new integrative model demonstrating the interaction between several factors that influence stress in children with cancer through neuroendocrine and immune mechanisms. Meanwhile, this integrative model also shows how psychological interventions can modulate the effects of these various factors on neuroendocrine and immune mechanisms, ultimately affecting health outcomes. In addition, little literature evaluates possible mediation pathways, such as the effect of psychological interventions on the neuroendocrine system and the immune system, so this new integrative model framework can be utilized. Future researchers need to test all of these new integrative models, including factors that influence stress in children with cancer, modify psychological interventions, and evaluate their mechanisms on the neuroendocrine and immune systems. This will reveal the complex interactions among these components and understand their relevance to health outcomes.

Authors Contribution

IH: Do Conceptualization, Methodology, Resources, Data Curation, Writing - Original Draft, Writing - Review &Editing. NN: Supervision, Methodology, Investigation, Validation; IK: Do Supervision, Validation, Investigation, Data Curation; WFR: Validation, Formal analysis, Investigation, Data Curation, Writing - Original Draft; ZH: Project administration, Supervision; TR: Project administration, Data Curation.

Data Availability Statement

The authors confirm that the data supporting the findings of this study are available within the article and/or its supplementary materials.

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Conflict of interest

The authors declare no conflicts of interest concerning the publication of this paper.

Ethical approval

This research is not research involving humans or animals, so the authors do not require ethical approval.

Appendix A Supplementary data

The following are the Supplementary data to this article.Multimedia component 1Multimedia component 2

Appendix A Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.anr.2023.07.001.

Component	Characteristic	(n = 21)	Percentage (%)
Study design	Randomized controlled trial	12	57.1
Nonrandomized controlled trial	9	42.9	Intervention type
Psychosocial intervention	1	4.8	Mediport cognitive-behavioural arm
1	4.8	Animal-assisted interventions	2
9.5	Virtual reality	1	4.8
Music therapy	1	4.8	Massage therapy
3	14.2	Clown intervention	1
4.8	Make a wish intervention	1	4.8
Mandala drawing	1	4.8	The home-based multimodal symptom-management program
1	4.8	Integrated experiential training program with coaching	1
4.8	Adventure-based training	1	4.8

Cognitive behavioral therapy	1	4.8	Psychological intervention base psychoneuroimmunology
1	4.8	Therapeutic play	1
4.8	Mindfulness-based stress reduction	1	4.8
Art therapy (drawing, painting and ceramic art)	1	4.8	Drawing and writing technique
1	4.8	Outcome	Psychological responses
8	38.0	Neuroimmunological markers	1
4.8	Psychological and physiological responses	9	42.9
Psychological responses and neuroimmunological markers	1	4.8	Physiological responses and neuroimmunological markers
1	4,8	Psycho-physio-neuroimmunological marker	1

Studies Included Randomised Control Trial (RCT) (13 Item Question)	

No	Author	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Total score	Category
1	(Jibb et al., 2018)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	13/13	100.0% (Good)
2	(McCullough et al., 2018)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	13/13	100.0% (Good)
3	(Gerçeker et al., 2021)	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	N	Y	11/13	84.6% (Good)
4	(Shoshani et al., 2016)	Y	Y	Y	N	N	Y	Y	Y	Y	Y	Y	N	Y	10/13	76.9% (Good)
5	(Gürcan and Atay Turan, 2021)	Y	Y	Y	Y	N	N	Y	Y	Y	Y	Y	Y	N	10/13	76.9% (Good)
6	(Lam et al., 2018)	Y	Y	Y	N	Y	Y	Y	Y	N	Y	Y	Y	Y	11/13	84.6% (Good)
7	(Jacobs et al., 2016)	N	N	Y	N	Y	N	Y	Y	Y	Y	Y	Y	Y	9/13	69.0% (Fair)
8	(Li et al., 2018)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	13/13	100.0% (Good)
9	(Zhang et al., 2019)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	13/13	100.0% (Good)

10	(Hsiao et al., 2019)	Y	Y	N	N	N	N	Y	Y	Y	Y	Y	Y	Y	9/13	69.0 % (Fair)
11	(Cheng and Tan, 2021)	Y	Y	N	N	N	N	Y	Y	Y	Y	Y	N	N	7/13	53.8 % (Fair)
12	(Liu et al., 2019)	Y	Y	N	N	N	Y	Y	Y	Y	Y	Y	Y	Y	10/13	76.9 % (Good)
Studies Included Non-Randomized Control Trial (Non RCT) (9 Item Question)																
No	Author	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9					Total score	Category
13	(Hasanah et al., 2020)	Y	Y	Y	N	Y	N	Y	Y	Y	-	-	-	-	7/9	77.0 % (Good)
14	(Genik et al., 2020)	Y	Y	Y	Y	Y	N	Y	Y	Y	-	-	-	-	8/9	88.8 % (Good)
15	(Lopes-Junior et al., 2020)	Y	Y	Y	N	Y	N	Y	Y	Y	-	-	-	-	7/9	77.0 % (Good)
16	(Cheng and Tan, 2021)	Y	Y	Y	Y	Y	Y	Y	Y	Y	-	-	-	-	9/9	100.0 % (Good)
17	(Çelebioğlu et al., 2015)	Y	Y	Y	Y	Y	N	Y	Y	Y	-	-	-	-	8/9	88.8 % (Good)

18	(Altay et al., 2017)	Y	Y	Y	N	Y	N	Y	Y	Y	-	-	-	-	7/9	77.0 % (Good)
19	(Patil et al., 2021)	Y	Y	Y	Y	Y	N	Y	Y	Y	-	-	-	-	8/9	88.8 % (Good)
20	(Silva and Osó Rio, 2018)	Y	Y	Y	N	Y	N	Y	Y	Y	-	-	-	-	7/9	77.0 % (Good)
21	(Chacin-Fernández et al., 2019)	Y	Y	Y	Y	Y	Y	Y	Y	Y	-	-	-	-	9/9	100.0 % (Good)

No	Author, year	Country	Design	Sample Size (N) Age Mean ± SD/Median (Mean-Max)	Participant and setting	Type of intervention	Instrument	Outcome	Result

Intervention group age	Control group age	Intervention group	Control group	Psychological and physiological responses	Psychoneuroimmunological markers	1	(Hsiao et al., 2019)	Taiwan	Quasi-Experimental	n = 7 Age: 0–18 years mean ± SD 0.65 ± 0.27	n = 6 Age: 0–18 years mean ± SD 4.81 ± 2.75	Patients with acute lymphoblastic leukemia (ALL) or acute myeloid leukemia (AML) aged <18 years who underwent BMP and lumbar puncture (n = 13)

Psycho-social interventions consisting of preparation and cognitive behavioral interventions	Without psychosocial interventions	Observational Scale of Behavioral Distress (OSBD-R)	Distress level	–	The mean age at diagnosis of leukemic was 6.6 years (range: 3–11 years). Fifteen patients were diagnosed with acute lymphoblastic leukemic, and 3 were diagnosed with acute myeloid leukemic. The mean OSBD-R total score in the 7 patients with psychosocial intervention was significantly lower than the mean score in the 6 patients without intervention (0.65	2	(Jibb et al., 2018)	Canada	Randomized controlled trial	n = 19 Age: 4–9 years mean ± SD 2.6 ± 3.5	n = 21 Age: 4–9 years mean ± SD 3.5 ± 3.9	Pediatric patients aged 4 to 9 years with cancer who underwent needle insertion (n = 40)

					vs 4.81, pZ0.002). Pre- and post-psychosocial interventions for BMA and LP behavioral disorders were evaluated for the remaining 5 patients. Consistently, there was a significant decrease in the OSBD-R score after the intervention (3.04 vs. 7.81, pZ0.025)							

MEDiPORT cognitive-behavioral arm (robot using evidence-based cognitive-behavioural interventions) or active distraction arm (robot dancing and singing)	No control group	1. Face Pain Scale—Revised (FPS-R)	1.Pain level	–	Overall, MEDiPORT and this study were acceptable to the participants. There was no significant difference in pain intensity between arms (P = .68), but there was less pressure during the procedure on the distracted arm. No differences between groups were observed for the fear and distress subscale (P = .012).	2.The Children's Fear Scale (CFS)	2.Degree of fear	3.Behavioral Approach-Avoidance Scale (BAADS)	3.Distress level	3	(McCullough et al., 2018)	USA

Randomized controlled trial	n = 60 Age: 3–17 years mean ± SD 8.9 ± 4.5	n = 46 Age: 3–17 years mean ± SD 8.1 ± 4.6	Newly diagnosed cancer patients, aged 3 to 17 years (n = 106)	Animal-assisted interventions	standard care	1.The State-Trait Anxiety Inventory™	1.Anxiety level	–	Children in both groups experienced a significant decrease in anxiety (P < .001). However, there were no significant differences between groups over time at any of the observed measures.	2.Pediatrica Quality of Life Inventory	2.Blood pressure and heart rate	3.Child blood pressure and heart rate

4	(Gerçeker et al., 2021)	Turkey	Randomized controlled trial	n = 21 Age: 6–17 years mean ± SD 2.4 ± 1.8	n = 21 Age: 6–17 years mean ± SD 5.3 ± 1.8	Hematology-oncology pediatric patients undergoing port with Huber needle aged >6 to <17 years (n = 42)	Virtual reality	standard care (without VR)	1.Wong-Baker Faces Pain Rating Scale	1.Pain level	–	Patient self-reported pain scores in the VR and control groups were 2.4 ± 1.8 and 5.3 ± 1.8, respectively. This study found statistically significant differences between groups in pain scores ($p < .001$). Statistically significant differences were found between groups according to self-reported and parental fear and anxiety scores after the procedure. Self-

												reported fear scores in VR and control groups were 0.8 ± 0.9, 2.0 ± 1.0, self-reported anxiety scores were 2.9 ± 2.0, 5.4 ± 2, respectively 0 ($p < .001$).
2.Children's Anxiety Meter	2.Level of anxiety	3. Child Fear Scale	3.Degree of fear	5	(Hasanah et al., 2020)	Indonesia	Pre-experimental study	n = 30 Age: 6–18 years median (min-max) Children: 0.00 (9.35–3.18) Adolescent: 0.54 (2.47–3.95)	None	Pediatric patients with leukemia aged 6–18 years who undergoing IV line insertion (n = 30)	Music therapy	no control group

ELISA	–	Cortisol levels	Cortisol levels before and after music therapy each had a median (min–max) of 4.14 (0.25–9.89) and 3.47 (0.16–15.31). The median difference in cortisol levels was 0.67 ng/ml	6	(Genik et al., 2020)	Canada	Pre-post single group pilot study	n = 8 Age: 8–18 years mean ± SD 14.57 ± 2.51	None	Pediatric patients aged 8–18 years with cancer (n = 8)	Massage therapy	no control group

			. This ≥0.05 ng/ml change indicates the clinical effect of music therapy on cortisol levels. Although music therapy did not significantly affect salivary cortisol levels (p = .99), this stud									

			y rev eale d a clini cal effe ct of mus ic ther apy in red ucin g corti sol leve ls.									

1.PainSquad App	1.Pain level	–	All participants rated the MT intervention as acceptable and agreed that the intervention helped muscle pain (Mean = 4.80; Median = 5.00/5; range: 4–5; SD = 0.45), reduced anxiety/stre	2.Faces Pain Scale-Revised (FPS-R)	2.Degree of fear	3.Children's Fear Scale (CFS).	3.Quality of life	7	(Lopes-Junior et al., 2020)	Brazil	Quasi Experimental	n = 16 Age: 6–14 yeas rs mean ± SD 11.4 ± 3.44

			ss (Mean = 4.40; Median = 4, 00/5; range: 4–5; SD = 0.55), helped relax (Mean = 5.00; Median = 5 .00/5; range: 5; SD = 0.00), and significantly increased their QOL overall (Me									

			an = 4.60; Median = 5.00/5; range: 4–5; SD = 0.55).									

none	Pediatric patients with cancer undergoing chemotherapy aged 6–14 years (n = 16)	Clown intervention	no control group	1.High sensitivity enzyme-linked immunosorbent assay kit	1.Stress level	Levels of salivary cortisol and α-amylase	Compared to baseline measurements, total psychological stress and fatigue levels improved after the clown intervention at the +4 h collection time point (P = .003 and P = .04, respectively). Salivary cortisol showed a significant decrease after the clown intervention at +1, +9, and +13 h collection time points (P < .05); however, α-	2.Child Stress Scale-ESI	2.Quality of life	3.PedsQL Multidimensional Fatigue Scale.	8	(Shoshani et al., 2016)

							amylase levels remained unchanged					

Israel	Randomized controlled trial	n = 32 Age: 5–12 years mean ± SD 10.13 ± 3.51	n = 31 Age: 5-12 years mean ± SD 10.67 ± 4.71	Pediatric patients aged 5–12 with early diagnosis of cancer (n = 63)	Make a wish intervention	waiting list control group without make a wish intervention	1.The Brief Symptom Inventory-18 (BSI)	1.Level of distress	–	Children in the intervention group showed significant reductions in general distress (d = 0.54), depression (d = 0.70), and anxiety symptoms (d = 0.41), improvement in health-related quality of life (d = 0.59),	2.The Global Severity Index (GSI)	2.Depression

										expectation (d = 0.71), and positive affect (d = 0.80) and there was no significant change in other measures in the control group.		

3.PedsQL	3.Level of anxiety	4.The Positive and Negative Affect Schedule for Children (PANA	4.Quality of life	5.Herth Hope Index (HHI)	6.The Life Orientation Test-Revised (LOT-R)	9	(Gürcan and Atay Turan, 2021)	Turkey	Randomized controlled trial	n = 30 Age: 12–17 years mean ± SD 14.26 ± 1.79	n = 30 Age: 12–17 years mean ± SD 13.56 ± 1.67	Adolescent patients with cancer aged 12–17 years who are hospitalized (n = 60)

		S-C)										

Mandala drawing	routine care only	Anxiety and Depression Scale and Memorial Symptom Assessme	1.Levels of anxiety and depression	–	Anxiety and depression scores decreased significantly in the intervention group, compared to the control group, after 5 days of intervention, F(1.57) = 28.9, p < .01, η2 = 0.337. Similarly, psychological symptom scores decreased significantly in the intervention group, compared to the control group, F(1.57) = 69.7, p < .001, η2 = 0.550).	2.Psychological symptoms	10	(Cheng and Tan, 2021)	Singapore	Randomized controlled trial	n = 25 Age: 10–18 years mean ± SD 13.9 ± 2.4	n = 25 Age: 10–18 years mean ± SD 13.4 ± 2.6

		n t S c a l e										

Pediatric patients with cancer aged 10–18 who are undergoing chemotherapy (n = 50).	The home-based multimodal symptom-management program	usual care	Memorial Symptom Assessment Scale 10–18 and the State Anxiety Scale for Children.	1.Symptoms	–	Between-group comparisons showed that the intervention group had significantly reduced fatigue over time (P < .05). However, no differences were found with respect to nausea and vomiting, pain, mucositis, and anxiety between groups. Both children and parents reported positive experiences with symptom management programs.	2.Anxiety	11	(Çelebioğlu et al., 2015)	Turkey	Quasy experimental	n = 12 Age: 4–15 yeas mean ± SD 7.66 ± 3.86

n = 13 mean ± SD 8.00 ± 3.31	Pediatric patients aged 4–15 years in children with cancer (n = 25)	massage therapy	standard treatment (without massage therapy)	Analog visual scale	Pain and anxiety levels	–	When the pain and anxiety levels of the pre-test and post-test groups were compared, no statistically significant difference was found (P > .05). It was determined that the pain and anxiety levels in the experimental group decreased significantly. This study provides preliminary evidence for the effectiveness of massage in children in reducing pain and anxiety	12	(Lam et al., 2018)	China	Randomized controlled trial	n = 37 Age: 9–18 years mean ± SD 12.8 ± 2.5

							arising from intrathecal therapy or bone marrow aspiration.					

n = 33 Age: 9–18 years mean ± SD 12.5 ± 2.5	Pediatric patients with cancer aged 9–18 years (n = 70)	Integrated experiential training program with coaching	placebo interventions	1.The Chinese version of the Fatigue Scale (Cancer-related fatigue)	1.Fatigue level	–	The experimental group reported significantly lower levels of cancer-related fatigue, higher levels of physical activity and physical activity self-efficacy, greater right and left grip strength, and better quality of life than the control group at 9 months.	2.The Chinese University of Hong Kong Physical Activity Rating for Children and Youth	2.Physical activity	3.Pediatric Quality of Life Inventory cancer module v. 3.0 (Quality of life)	3.Quality of life	13

(Jacobs et al., 2016)	Washington DC	Randomized controlled trial	n = 18 Age: 12–21 years mean ± SD 15.5 ± 2.6	n = 16 Age: 12–21 years mean ± SD 16.0 ± 2.5	Adolescent patients aged 12–21 with cancer who are hospitalized for at least 4 consecutive days.	Massage therapy	waitlist control (without massage)	1.Sleep was measured with actigraphy	1.Sleep quality	–	The results showed that there was no significant change in anxiety, mood or fatigue from pre to post intervention. However, there was a trend toward increased night time and	2.Fatigue Scale Adolescent

											overall sleep in the intervention group compared to standard care, but no between-group differences on patient-reported outcome measures (2.3, P = .049).	

2.Fatigue level	3.The State Trait Anxiety Scale, State Portion	3. Level of anxiety	4.Behavioral, Affective and Somatic Experiences Scale Revised, Parent-Report and Child-Report (BASES)	4.Moods	14	(Li et al., 2018)	Hongkong	Randomized controlled trial	n = 117 Age: 9–16 years mean ± SD 12.8 ± 1.9	n = 105 Age: 9–16 years mean ± SD 12.5 ± 2.6	Pediatric patients with cancer aged 9–16 years (n = 222)	Adventure-based training

placebo interventions	Fatigue Scale–Child (FS–C)	fatigue level	–	The experimental group showed statistically significantly lower levels of cancer–related fatigue (P < .001), higher levels of self-efficacy (P < .001) and physical activity (P < .001), and better quality of life (P < .01) than the control group at 12 months.	15	(Zhang et al., 2019)	China	Randomized controlled trial	53 cases were from the children aged from 8 to 12 years old and 46 cases from 13 to 18 years old. mean ± SD Not mentioned	53 cases were from the children aged from 8 to 12 years old and 46 cases from 13 to 18 years old. mean ± SD Not mentioned	Pediatric cancer patients receiving chemotherapy aged 8–18 years (n = 106)	Cognitive behavioral therapy

routine psychological care	The Conner–Davidson Resilience Scale (CD-RISC) and depression anxiety stress scale (DASS)	Resilience, stress and anxiety levels	–	Before the intervention, there was no significant difference in the psychological adjustment abilities between the 2 groups (P > 0.05 for all). After the intervention, the total CD-RISC score was significantly higher (56.09 ± 7.29 vs 44.75 ± 5.40), while the depression score (4.57 ± 2.94 vs 7.25 ± 4.25), anxiety (5.83 ± 3.07 vs 8.66 ± 4.92), stress (7.51 ± 4.33 vs 11.17 ± 4.25)	16	(Chacin-Fernández et al., 2019)	UK	Non-randomized, open-label clinical trial	n = 16 Age: 5–15 years mean ± SD 10.1 ± 0.9	n = 10 Age: 5–15 years mean ± SD 9.8 ± 1.2	Pediatric patients with leukemia undergoing chemotherapy (n = 26)	Psychoneuroimmunology-based psychological interventions.

				were clearly lower in the CBT group than in the control group ($P < 0.05$ for all). Additionally, the reduction in negative mood scores in children with a yolk sac tumor was most pronounced in the CBT group.								

psychoeducation in relation to their treatment and disease,	1.Immunological evaluation using flow cytometry and immunoturbidimetry	1. Duration of signs and symptoms (Fever and Pain)	Immune markers	Psychoneuroimmunology-based interventions improve immune markers (CD8+ T, B, and natural killer cells, serum immunoglobulin A, and immunoglobulin M) and quality of life, while shortening the duration of fever and the use of antipyretics, antibiotics, analgesics, and respiratory therapy. Immunity markers correlate with clinical conditions. Thus, psychoneuroimmunology-based	-Natural killers (NK)	-B lymphocytes	-CD4+ T lymphocytes	-CD8+ T lymphocytes	-IgM IgA antibodies	2.Quality of Life was assessed using the QoL Questionnaire in Pediatric Oncology.	2.Duration of administration of pain therapy, antibiotics and antipyretics	-IgA antibodies

				interventions can reduce hospital costs and improve patient well-being								
17	(Altay et al., 2017)	Turkey	Quasi-experimental design	n = 30 Age: 9–16 years mean ± SD 2.56 ± 267	Without control group	Pediatric patients with cancer who are undergoing treatment aged 9–16 years (n = 30)	Drawing and writing technique	no control group	The State Anxiety Inventory	anxiety level	–	A lower State Anxiety Inventory score indicates lower anxiety after the intervention (36.86 ± 4.12 compared to before (40.46 ± 4.51) ($p < .05$).

18	(Patil et al., 2021)		Quasi-experimental design	n = 15 Age: 7–12 years Not mentioned mean ± SD	n = 15 Age: 7–12 years Not mentioned mean ± SD	Pediatric patients with cancer aged 7–12 years (n = 30)	art therapy (drawing, painting and ceramic art)	routine therapy	Perceived stress scale dan Hamilton anxiety rating scale (HAM-A)	Stress and anxiety	–	The effect of art therapy in the experimental group showed a significant difference in mean post-test stress and anxiety scores (p = .00069 and p = 0.000642) compared to controls. Comparison of anxiety scores with all types of cancer showed a significance of p = .010 in the experimental group compared to the controls in the post-test

19	(Liu et al., 2019)	China	Randomized controlled trial	n = 46 Age: 10–21 years mean ± SD 15.9 ± 5.2	n = 45 Age: 10–21 years mean ± SD 16.2 ± 4.9	Pediatric patients with osteosarcoma aged 10–21 years (n = 91)	Mindfulness-based stress reduction	routine therapy (no psychological intervention)	1.Wong-Baker Faces Pain Rating Scale (WBRS)	1.Pain level	–	There were no significant differences in sociodemographic and clinical parameters between the intervention and control groups. The intervention program significantly alleviated the psychological and physiological complications in patients with osteosarcoma. Specifically, this study revealed that 8 weeks of the combined MBSR/MT intervention effectivel

												y reduced pain and anxiety scores and improved sleep quality in patients.
2.The Hamilton Anxiety Rating Scale (HAM-A)	2.Anxiety level	3. The Pittsburgh Sleep Quality Index (PSQI)	3.Sleep quality	20	(Tsai et al., 2013)	Taiwan	Quasi-experimental design	9 patients aged 3–12 years (median = 8.12 years)	10 patients aged 3–14 years (median = 8.9 years)	Brain tumor patients, aged 3–15 years (n = 19)	Therapeutic play	general medical procedures

The Beck Youth Anxiety Inventory dan Faces Anxiety Scale	1.Anxiety level	Salivary cortisol concentration	The study group had significantly lower anxiety, HR and cortisol scores and expressed fewer negative emotions than the control group before External beam radiotherapy (EB	2.Heart rate	21	(Silva and Osó Rio, 2018)	Italy	Quasi-experimental design	n = 24 Age: 6–12 years mean ± SD 8.58 ± 1.98	none	Pediatric patients with a diagnosis of solid tumor aged 6 to 12 years (n = 24)	Animal assisted therapy

			RT).									
no control group	1.Child Stress Symptoms Inventory	1. Stress	-	This study reported reductions in pain (p = .046, d = −0.894), irritation (p = 0.041, d = −0.917), stress (p = .005; d = −1.404) and a trend toward improvement in depressive symptoms (p = .069; d = −0.801).	2.Quality of Life Evaluation Scale	2.Pain	3.Child Depression Inventory	3.Mood	4.Adapted Brunel Mood Scale: Faces Pain Scale	4.Anxiety, depression	5.AAT Assessment Questionnaire	5.Quality of life

DETAILS

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Increased Parasympathetic Activity as a Fall Risk Factor Beyond Conventional Factors in Institutionalized Older Adults with Mild Cognitive

Impairment

Suh, Minhee

ABSTRACT (ENGLISH)

SummaryPurpose

This study aimed to investigate autonomic nervous function during the orthostatic challenge and its relationship with depression and fall, and to elucidate fall-associated factors, including autonomic function, executive function, and depression among institutionalized older adults with mild cognitive impairment (MCI).

Methods

This study employed a descriptive cross-sectional design. Fall experiences in the current institutions were researched. Heart rate variability (HRV) during the orthostatic challenge was measured. Executive function was evaluated using the semantic verbal fluency test and clock drawing test. Depression was assessed using the Geriatric Depression Scale.

Results

Of the 115 older adults, 17 (14.8%) experienced falls in the current institution. None of the HRV indices during the orthostatic challenge showed any significant changes except for the standard deviation of normal RR intervals (p = .037) in the institutionalized older adults with MCI. None of the HRV indices was significantly related to the depressive symptoms. Multivariate logistic regression analysis showed that normalized high frequency on lying was independently associated with falls (OR = 1.027, p = .049) after adjusting for other conventional fall risk factors although executive function and depressive symptoms were not significant factors for falls.

Conclusions

Institutionalized older adults with MCI were vulnerable to autonomic nervous modulation, especially to sympathetic modulation, during the orthostatic challenge, which was not associated with depressive symptoms. As increased resting parasympathetic activity seemed to play a key role in association with falls, autonomic nervous function assessment should be considered for fall risk evaluation.

FULL TEXT

Introduction

Falls are one of the major adverse events that lead to negative consequences such as unintentional injuries and death in older adults [1]. Although nurses are making tremendous efforts to prevent falls among institutionalized older adults, 50.2% of institutionalized older adults still suffered from falls for a year, an average of 1.3 falls per 1.57 persons [2,3]. As institutionalized older adults are deconditioned with multiple chronic diseases and on various medications, special attention is needed to consider their physiological state for fall risk factors. However, there is a lack of literature considering the underlying physiological conditions in institutionalized older adults.

Mild cognitive impairment (MCI) is a clinical entity characterized by slight cognitive impairment without functional dependence [4], which is associated with 1.53 times higher odds of fall-related injury [5]. Further, older adults with MCI have reported reduced executive function [6]. Executive function—a cognitive subdomain—is an important mediating factor between visual acuity and postural stability, especially in cognitively impaired older adults [7], and is an important factor for daily life activities [8]. Recent studies have shown that executive function is a key cognitive domain involved in gait or postural control [9,10] and is closely related to falls in community-dwelling older adults [11]. As institutionalized older adults with MCI are more likely to have pronounced executive dysfunction, it is necessary to investigate their executive function as a risk factor for falls in institutionalized older adults.

In addition to cognition, autonomic dysfunction can be considered a risk factor for falls in older adults. With

increasing age, the overall ability of cardiac autonomic modulation declines constantly [12]; consequently, blood pressure regulation reduces [13], which, in turn, causes hypotensive episodes and falls [14]. A previous study also reported that autonomic dysfunction is common in patients with MCI [15]. Moreover, as institutionalized older adults with MCI have several chronic diseases and take various medications, including antihypertensives and antidepressants, they may be subject to the exaggerated risk of orthostatic intolerance and falls. Thus, their autonomic nervous function during orthostatic challenge should be assessed and evaluated in association with falls. Depression has also been suggested as a risk factor for falls in community-dwelling older adults although there are some controversies in institutionalized adults. In a meta-analysis, the authors demonstrated that depressive symptoms were significant predictors of falls [16], whereas Susilowati et al. [17] found no significant relationship between depressive symptoms and falls among institutionalized older adults. Furthermore, considering a recent meta-analysis showing that heart rate variability (HRV) was found to be reduced among depressed older adults [18], HRV may mediate between depressive symptoms and falls. Therefore, it is necessary to examine depressive symptoms and HRV in relation to falls in institutionalized older adults.

This study aimed to investigate the autonomic nervous function during the orthostatic challenge and to explore the involvement of depressive symptoms in autonomic nervous function. This study also aimed to elucidate the associations between autonomic nervous function, cognitive function, including the executive function domain, and depressive symptoms with falls among institutionalized older adults with MCI.

Methods Study design and participants

This descriptive cross-sectional study investigated autonomic nervous function during the orthostatic challenge using HRV to explore the involvement of autonomic nervous function in depressive symptoms and analyzed associations of autonomic nervous function, cognitive function, and depressive symptoms with falls. The conceptual models of this study were illustrated in Figure 1.

A convenience sample of 115 institutionalized older adults aged ≥65 years was recruited from four regional geriatric hospitals in South Korea from July 2017 to February 2020. Older adults with the following characteristics were included: those who complained of decreased memory in answering the question, “Do you feel like your memory is becoming worse?” [19]; who did not have dementia with scores greater than 1.5SD below the mean on the Mini-Mental Status Examination for Dementia Screening (MMSE-DS) score regarding age, gender, and education as suggested by a previous study [20]; who could communicate and walk around by themselves or with little assistance from one caregiver; who had been institutionalized for more than 1 week. Older adults with current arrhythmias on the EKG were excluded. The participant selection process was illustrated in Figure 2.

Based on Long's suggestion for a regression model with binary outcomes of at least 10 cases per estimated parameter [21], the minimum number of participants required for this study was 90, with the expectation of nine predictors included in the regression model.

Study measures

General characteristics such as years of education, marital status, subjective financial status, smoking, and drinking were obtained via interviews. Clinical information, including age, gender, admission date, and diagnosed disease information, was acquired from medical records.

Fall and fall risk

A fall was defined as an event that resulted in a person coming to rest inadvertently on the ground, floor, or any other such lower level with or without injury [22]. Fall experience in the current institution was assessed with the question, “Have you fallen in the current institution?” Fall situations when the fall occurred in current institutions were also asked. Fall experience and fall situations in the current institutions were verified by caregivers at patients’ bedsides to ensure the reliability of patient responses. Further, fall risk was assessed using the Bobath Memorial Hospital Fall Risk Assessment Scale Short Form (BMFRAS-SF) [23]. It has four items: past fall history, level of physical activity, number of fall risk factors, and number of fall-risk-increasing medications. Each item has a 4-point scale ranging from 0 to 3, with a total score of 12. Individuals with a score greater than 5 are considered to have a high fall risk [23]. It has been shown to have a good sensitivity of 86.7% and a specificity of 67.9% [23].

Heart rate variability

For autonomic nervous system function, HRV was measured using Heart Rhythm Scanner 3.0 (Biocom Technologies, Poulsbo, USA) [24] in the participants' room. HRV was measured between 9 a.m. and 11 a.m. to minimize bias from HRV diurnal variation. Caffeine, nicotine, and alcohol intake were restricted from 12 h before the measurement to evaluate HRV accurately. Further, three-channel electrocardiogram electrodes were attached to the inner part of both wrists to measure HRV. It was measured for 5 min in the participant's lying position after 5 min of rest, and for another 5 min in their sitting position after 5 min of resting, as 5 min are believed necessary for adjustment to the posture [25].

The software Heart Rhythm Scanner 5.4.1. version (Biocom Technologies, Poulsbo, USA) was used, developed according to standards and mathematical procedures set forth by the European Society of Cardiology and the North American Society of Pacing and Electrophysiology. HRV was analyzed both in the time domain—the standard deviation of the normal RR intervals (SDNN), root mean square of the differences between adjacent RR intervals (RMSSD)—and the frequency domain—normalized high frequency (nHF), normalized low frequency (nLF), and LF/HF ratio—on each of the two measurements. SDNN is the index of the heart's response to changing workloads and was measured in milliseconds, with higher SDNN indicating better cardiac response to changing workloads [26]. RMSSD is the primary time-domain measure used to estimate vagally mediated changes reflected in HRV, with higher RMSSD indicating greater activity of parasympathetic nervous system [27]. nLF indicates the contribution of the low frequency in the total power, excluding the contribution of very low frequency (VLF), and reflects sympathetic activity dominantly. nHF indicates the contribution of the high frequency in the total power, excluding the contribution of VLF, and is mediated almost entirely by parasympathetic nerve activity. The LF/HF ratio verifies the balance between sympathetic and parasympathetic nervous activities.

Orthostatic hypotension

Orthostatic hypotension (OH) was defined as a decrease in systolic blood pressure (SBP) of at least 20 mmHg or a decrease in diastolic blood pressure (DBP) of at least 10 mmHg within 3 min of standing from a supine position [25]. To evaluate OH, brachial BP was measured using an electronic sphygmomanometer (HEM-907, Omron, Kyoto, Japan). After the participants rested for 5 min in the lying position, brachial BP was measured. Subsequently, the participants sat on the bed, and brachial BP was measured within 3 min.

General cognitive function and executive function

The Mini Mental Status Examination for Dementia Screening (MMSE-DS) was used to evaluate overall cognitive function [20]. The MMSE-DS comprises 19 items, including tests of orientation, attention, memory, language, and visual-spatial skills. The total score was 30, with higher scores indicating better cognitive function.

Executive function, one of the cognitive domains, is defined as complex cognitive abilities that enable the identification of goals, mental planning, behavior organization, and planning actions to achieve these goals [28]. To evaluate executive function, the semantic verbal fluency (VF) test and clock drawing test (CDT) were used. VF reflects multiple dimensions of executive function of the frontal and temporal lobes, and starts to be damaged from the beginning of Alzheimer disease [29]. For the VF test, participants were asked to speak as many names as possible in an animal category for 1 min; subsequently, the number of correct animal names was counted with higher counts indicating better executive function [30]. The CDT evaluates cognitive abilities, including auditory and visual comprehension, concentration, visuospatial abilities, abstract conceptualization, and executive control [31]. For CDT, participants were asked to draw a clock on paper and mark a specific time on it. The Rouleau scoring system was used to calculate the CDT score [32]. The total score ranges from 0 to 10, with higher scores indicating better executive function.

Depressive symptoms

Depressive symptoms were evaluated using the 15-item Geriatric Depression Scale Short Form (GDS-SF) [33]. Each item has a binary response format (yes/no), with scores ranging from 0 to 15. A higher score indicates more severe depressive symptoms. Depression was considered present when the score was equal to or greater than 6. The Korean version of the GDS-SF has been shown to have good validity [34]. The Crombach's α of the GDS-SF was .80

previously [35], and .82 in this study.

Procedures and ethical considerations

This study was approved by the institutional review board of Inha University (Approval No. 161118-1AR). To recruit participants, the researcher contacted the directors of four regional geriatric hospitals conveniently selected to receive approval for data collection. The directors extracted the names of older adults who met the inclusion criteria and provided the list to the researcher. The researcher then visited the patients to explain the study purpose and procedure and obtain written consent from each participant. The patients were given time to consider participation or discuss it with their family. When necessary, the researcher explained the study purpose and procedure to their family via phone call or in person. The older adults who voluntarily decided to participate in this study were included. Subsequently, a research assistant measured HRV and orthostatic BP, and assessed general information and depressive symptoms via one-on-one interviews for approximately 40 min. Clinical information, including diseases diagnosed and medication taken, was collected by reviewing participants' electronic medical records. Participants who completed all procedures were given a small gift as a reward.

Before visiting the participants, three research assistants were educated on data collection protocols over an hour in advance. In addition, they visited four participants together to observe data collection procedures in the beginning and coordinated the details of the protocols through discussion with the others to ensure reliability.

Statistical analysis

All statistical analyses were performed using IBM SPSS Statistics 25 for Windows (IBM, Armonk, USA). All continuous variables were first assessed for normality using the Shapiro–Wilk test. In descriptive statistics, the mean with standard deviation and median with interquartile range were demonstrated for variables with normal distribution and those without it, respectively. The paired *t*-test and Wilcoxon signed-rank test were used to compare HRV indices during the orthostatic challenge. Because the changes in HRV indices during the orthostatic challenge did not show normal distribution, ranked ANCOVA was used to compare changes in HRV during the orthostatic challenge adjusted for antidepressant medication with presence of depression. For ranked ANCOVA, the residuals of ranked changes in HRV indices during orthostatic challenge adjusted for antidepressants use were calculated, which was analyzed depending on the presence of depression using ANOVA. For univariate analyses for association between study variables and fall experience in the current institutions, chi-square tests, *t*-test, and the Mann-Whitney U test were used. Multiple logistic regression was used to identify the influence of cognitive function, autonomic nervous function, and depression on falls, including age, sex, and other fall risk factors with *p* value 36,[37]]. The level of statistical significance was set at *p* **Results**

One hundred and fifteen older adults participated in this study. The mean age of the participants was 78.0 years old (SD = 8.20), and 73 (63.5%) were female ([Table 1]). The median education years was 7 years with the interquartile range of 6, and 34 (29.5%) reported themselves in poor financial status. Most participants did not smoke or drink. The average duration of admission was 302.0 days. The most common disease diagnosed was hypertension (40.1%), followed by musculoskeletal diseases (24.5%) such as arthritis and osteoporosis.

Among the 115 participants, 17 (14.8%) had experienced falls in the current institutions ([Table 1]). Further, 49 (40.8%) were classified into the high fall risk group based on the BMFRAS-SF. While the median scores of the MMSE-DS and CDT were 23.0 and 8.0, respectively, the mean score of the VF test was 8.51. Moreover, 92 participants (80.0%) had depression, with a GDS≥6.

For HRV during the orthostatic challenge, SDNN significantly increased from 18.50 millisecond to 20.30 millisecond ($p = .037$) ([Table 2]). nHF decreased from 46.9% to 41.6%, while nLF increased from 54.5% to 58.9%, which was not significant. The other HRV indices showed no significant changes during the orthostatic challenge. None of the HRV indices was significantly related to the presence of depression ([Table 2]).

In univariate analyses, older adults with fall experience in current institutions were significantly younger than those without fall experience ($p = .041$) ([Table 3]). The MMSE-DS score ($p = .008$) and VF score ($p = .036$) were significantly higher in older adults with fall experience in current institutions than in those without it. However, the CDT score was lower in older adults with fall experience in current institutions although the difference was not significant. Among

HRV indices, nHF on lying was significantly higher in older adults with fall experience in current institutions than in those without it (p = .047). There were no significant differences in high fall risk assessed on BMFRAS-SF, presence of OH, and presence of depression between older adults with fall experience in current institutions and those without it.

In the multivariate logistic regression analysis, age, sex, and factors with p values less than .10 were included. Only nHF on lying was independently associated with falls (OR = 1.03, 95%CI: 1.000–1.055 p = .049) ([Table 3]). The Hosmer–Lemeshow goodness of fit was not significant (χ^2 = 9.019, p = .341), indicating adequate model fit.

Discussion

This study was conducted to investigate the autonomic nervous function during the orthostatic challenge using HRV measurement, explore the involvement of autonomic nervous function in depressive symptoms, and elucidate the association of cognitive function, including executive function, autonomic nervous function, and depressive symptoms, with falls.

In this study, surprisingly, older adults who experienced falls in current institutions were the ones with higher MMSE-DS scores, better VF, and younger age. This result contradicts the prior finding that cognitive impairment and older age have also been shown to be intrinsic risk factors for falls [38]. The first thing to be considered is that the participants have received general fall preventive care in current institutions; the healthcare personnel have already taken care of those with lower cognition and older age. Second, older adults with older age and lower cognitive functions may have refrained from walking around to have a lower chance of falling. Mendes da Costa et al. [39] pointed out that older adults with older age restricted their activity more than those with younger age owing to fear of falling. Lastly, older age and lower general cognitive ability may not increase risk of falls in institutionalized older adults with MCI. A recent meta-analysis study by Hopkins et al. [40] showed that fall-related factors were physical performances such as gait and dual-tasking ability, rather than age or general cognitive function, in older adults with MCI, consistent with the finding that the association of age and cognitive ability with falls disappeared in the multivariate analysis. Furthermore, they addressed that there were no effective fall intervention programs to reduce falls for MCI patients in previous studies. Therefore, another strategy focusing on physical performance training and cognitive training targeting for dual-task ability or working memory are needed for healthcare personnel to prevent further falls among institutionalized MCI older adults with relatively higher cognitive function and younger age.

All of the participants had significantly increased SDNN upon sitting, which is an appropriate transition to increased cardiac reactivity. However, the increase in nLF and decreased nHF during the orthostatic challenge did not reach a significant level, indicating attenuated sympathetic/parasympathetic modulation. This is consistent with a previous study [41], which addressed autonomic dysfunction in both sympathetic and parasympathetic modulation among community-dwelling older adults with MCI. Although sympathetic modulation is believed to play an important role in postural control [42] and maintained in some healthy older adults [43], notably, a smaller increase in nLF was prominent among the institutionalized older adults with MCI in this study. Thus, it seems that the institutionalized older adults with MCI were vulnerable to sympathetic modulation with a reduced capacity to accelerate cardiac function during the orthostatic challenge. Failing to redistribute autonomic balance during the orthostatic challenge has also given rise to diminished quality of life [44]. Therefore, more attention should be paid to autonomic dysfunction in institutionalized older adults with MCI.

When exploring HRV in relation to falls, however, it was nHF on lying that was significantly higher in older adults with fall experience in current institutions than in those without fall experience although its significant level was somewhat marginal. In addition, its influence outweighed that of cognitive function and others on fall experience in current institutions. This is somewhat different from the study of Razjouyan et al. [45] who suggested that nHF was low in patients with a high fall risk. This discrepancy may be due to the fact that most participants in the previous study were adults and young older adults. As parasympathetic modulation appeared to be maintained during the aging process, whereas other HRV indices were reduced [46], parasympathetic modulation in older adults might be preserved more than sympathetic modulation, which contributes to fall occurrence. Indeed, LF/HF in the prior study was approximately 3.8, which is much greater than 1.3 in this study. Moreover, institutionalized older adults may be

on medications that reinforce parasympathetic activity and weaken sympathetic activity, such as antidepressants and various antihypertensives. Thus, increased parasympathetic activity during lying likely plays a key role in the occurrence of falls in institutionalized older adults. On the other hand, there was no significant difference in the presence of OH between older adults with fall experience in current institutions and those without it. There have been controversies regarding OH as a significant risk factor for falls [47]. A recent meta-analysis reported that OH was associated with time to fall incidence, not with fall occurrence itself [48], in line with the findings of this study. Considered together, autonomic nervous function assessment based on HRV is likely more sensitive than OH assessment for evaluating fall risk in institutionalized older adults with MCI.

In this study, depressive symptoms were not associated with falls. This is contrary to a prior result that depression increased the risk of falls in community-dwelling older adults [49]. This may be because of the severity of the depressive symptoms. The participants in the prior study were relatively low depressed, with a prevalence of depression of only 10.0% and free-living in community settings. However, in the study [49], 86.4% of older adults were depressed, with a GDS >5. Further, Kamińska, Brodowski, and Karakiewicz [50] suggested there was no difference in depressive symptoms between fallers and nonfallers, but depressive symptoms were involved in the number of falls. Therefore, depressive symptoms seem to have little relevance to fall occurrence in institutionalized older adults with severe depression.

In addition, depressive symptoms were not related to changes of HRV during orthostatic challenge in this study, whereas Luo et al. [51] addressed reduced HRV function in older adults with depression. This difference might come from the type of antidepressant medications that were taken by some depressive older adults. Some of prior studies addressed antidepressant agents from different classes may differentially impact HRV, addressing tricyclic antidepressants decrease HRV and selective serotonin reuptake inhibitors do not or do so to a lesser extent [52,53]. In this study, taking antidepressants was adjusted but type of antidepressants was not, which may lead to the inconsistency. Because the involvement of antidepressants in HRV alterations in depressive patients is still somewhat debatable, further research is needed to investigate the different effect of antidepressants on HRV in older adults with depression.

This study has certain limitations. First, fall occurrence was retrospectively investigated in a small number of older adults who experienced falls. Prospective research with larger sample sizes is needed to follow up fall occurrence to identify contributing factors to falls in the future. Second, the measurement of HRV was as short as 5 min and performed only once. However, as HRV measurement for 5 min was reported to be stable compared to that for 24 h [54] and performed in a relatively consistent time frame, it would be worthy of being accepted. Third, the effects of medications could not be controlled for HRV although those were controlled for falls. Further research is needed to determine the types of antidepressants, antihypertensives, and other cardiac medications that affect autonomic nervous activity. Finally, we cannot help pointing out missing variable bias because only seven predictors were included in the final logistic regression model, which may lead to no predictor except for the one marginally significant factor, nHF on lying.

Conclusion

In this study, fall experience in current institutions was significantly associated with younger age and better cognitive function. Therefore, another strategy is needed for healthcare personnel to prevent further falls among MCI older adults with younger age and higher general cognitive function. Further, institutionalized older adults with MCI had attenuated sympathetic/parasympathetic modulation, and higher nHF on lying was independently associated with fall experience in current institutions. Thus, parasympathetic function based on HRV assessment should be considered as a significant factor for evaluating fall risk. Depression was not significantly associated with HRV or falls. In the future, studies with prospective fall follow-up in a large population considering medications, and their effects on a relationship between depression and HRV are needed.

Conflict of interest

The authors declare no conflict of interest.

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Appendix A Supplementary data

The following is the supplementary data to this article:**Multimedia component 1**Multimedia component 1

Appendix A Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.anr.2023.05.001.

Variables		n (%)
Age (years)	Mean (SD)	78.00 (8.20)
Gender	Men	42 (36.5)
Women	73 (63.5)	Education years
Median (IQR)	7.00 (6.00)	Marital status
Married	45 (39.1)	Widowed
65 (56.5)	Single	3 (2.6)
Divorced	2 (1.7)	Subjective financial status
Good	8 (7.0)	Average
73 (63.5)	Poor	34 (29.5)
Smoking	Never	80 (69.6)
Previous smoker	34 (29.5)	Current smoker
1 (0.9)	Drinking alcohol	Previous drinker
59 (51.3)	Never	53 (46.1)
Sometimes	3 (2.6)	Admission duration (days)
Mean (SD)	302.04 (146.83)	Underlying illness diagnosed[a]
Hypertension	77 (40.1)	Musculoskeletal disease

47 (24.5)	Stroke	34 (17.7)
Cancer	16 (8.3)	Kidney disease
9 (4.7)	Parkinson disease	9 (4.7)
Fall experience in current hospitals	Yes	17 (14.8)
No	98 (85.2)	Fall situation (n = 17)
Losing one's balance	5 (29.4)	Losing one's footing
4 (23.5)	Changing position	3 (17.6)
Walking on stairs	3 (17.6)	Others
2 (11.8)	Fall risk score	High risk
49 (40.8)	Low risk	66 (57.4)
Previous fall for 1 year	Yes	41 (35.7)
before admission	No	74 (64.3)
MMSE-DS	median (IQR)	23.00 (8.75)
Verbal fluency	mean (SD)	8.51 (4.07)
Clock drawing test	median (IQR)	8.00 (5.00)
Depressive symptoms	median (IQR)	7.00 (3.00)
Yes (≥6)	92 (80.0)	No (<6)
23 (20.0)	Orthostatic hypotension	Yes
14 (12.2)	No	101 (87.8)

HRV during orthostatic challenge		median (IQR)	Z[a]	p	Residuals of changes in HRV during orthostatic challenge[c] mean (SD)	Depression		Z	p
Yes (n = 92)	No (n = 23)	SDNN (millisecond)	Lying	18.50 (19.10)	−2.09	.037	△ in SDNN	−1.82 (26.52)	7.30 (24.96)
1.616	.286	Sitting	20.30 (23.95)						
	RMSSD (millisecond)	Lying	12.60 (26.10)	−0.49	.628	△ in RMSSD	−0.32 (26.77)	1.29 (28.51)	0.034
.855	Sitting	12.70 (24.90)							
nHF (%), mean (SD)	Lying	46.9 (23.83)	1.99[b]	.050	△ in nHF	0.96 (26.77)	−3.77 (26.48)	0.762	.386

Sitting	41.6 (22.97)								nLF (%), mean (SD)
Lying	54.5 (23.76)	−1.59[b]	.114	△ in nLF	1.53 (26.65)	−5.98 (26.34)	0.301	.586	Sitting
58.9 (22.65)								LF/HF (a.u)	Lying
1.20 (2.10)	−0.66	.510	△ in LF/HF	2.36 (25.83)	−9.44 (34.58)	1.742	.192	Sitting	1.40 (2.60)

Variables		Univariate analysis					Multivariate analysis	
Fall experience in current hospitals, n (%)		Mann-Whitney's U or χ^2	p	Fall experience in current hospitals, Yes			Yes (n = 17)	No (n = 98)
Exp(B)	CI	p	Age, mean (SD)		74.29 (7.16)	78.62 (8.23)	2.04[a]	.044
0.98	0.896–1.080	.735	Gender	Men	6 (35.3)	36 (36.7)	0.01	.915

–	–	–	Women	11 (64.7)	62 (63.3)			1.29
0.324–5.091	.721	Education years, median (IQR)		9.00 (6.00)	9.00 (6.00)	812.00	.765	–
–	–	Admission duration		792.50 (1180.75)	311.00 (896.00)	22.00	.282	–
–	–	Previous fall before admission	Yes	8 (47.1)	33 (33.3)	1.20	.274	–
–	–	No	9 (52.9)	65 (66.7)			–	–
–	Fall risk	High risk	13 (76.5)	52 (53.1)	3.23	.060[b]	5.23	0.992–27.542
.051	Low risk	4 (23.5)	46 (46.9)			–	–	–
MMSE-DS, median (IQR)		26.50 (4.75)	22.00 (15.00)	504.00	.008	1.10	0.919–1.321	.293
Verbal fluency, mean (SD)		10.41 (4.00)	8.19 (4.01)	−2.12[a]	.036	1.04	0.816–1.329	.744
Clock drawing test, median (IQR)		7.50 (4.00)	8.00 (9.00)	624.00	.424	–	–	–
Depressive symptoms	Yes	13 (76.5)	79 (80.2)	0.13	.748	–	–	–

No	4 (23.5)	19 (19.8)			–	–	–	Orthostatic hypotension
Yes	1 (5.9)	13 (13.1)	0.72	.689[b]	–	–	–	No
16 (94.1)	85 (86.9)			–	–	–	Heart rate variability	
SDNN (millisecond) median (IQR)	Lying	18.00 (27.40)	20.30 (19.00)	609.50	.956	–	–	–
Sitting	21.60 (34.03)	20.70 (25.05)	548.50	.552	–	–	–	RMSSD (millisecond)
Lying	12.00 (34.90)	12.60 (23.30)	597.50	.861	–	–	–	median (IQR)
Sitting	13.90 (38.48)	12.80 (20.55)	450.00	.112	–	–	–	nHF (%), mean (SD)
Lying	58.69 (22.07)	44.92 (23.89)	−2.01[a]	.047	1.03	1.000–1.055	.049	Sitting

39.96 (25.35)	41.82 (22.37)	0.29[a]	.774	–	–	–	nLF (%), mean (SD)	Lying
48.31 (24.92)	55.67 (23.76)	1.09[a]	.277	–	–	–	Sitting	60.03 (25.37)
58.77 (22.14)	−0.20[a]	.843	–	–	–	LF/HF (a.u), median (IQR)	Lying	1.00 (2.20)
1.30 (2.10)	552.00	.529	–	–	–	Sitting	1.15 (2.20)	1.80 (2.80)
553.50	.586	–	–	–	Constant		–	–

DETAILS

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Outcomes of Emergency Trauma Patients After the Implementation of Web Application Operating Systems

Pearkao, Chatkhane [1]
; Potisopha, Wiphawadee [1]
; Wonggom, Parichat [1]
; Jumpamool, Apinya [2]
; Apiratwarakul, Korakot [3]
; Lenghong, Kamonwon [3]
[1] Department of Adult Nursing, Faculty of Nursing, Khon Kaen University, Khon Kaen, Thailand [2] Department of Nursing Administration and Research, Faculty of Nursing, Khon Kaen University, Khon Kaen, Thailand [3] Department of Emergency Medicine, Faculty of Medicine, Khon Kaen University, Khon Kaen, Thailand

ABSTRACT (ENGLISH)

SUMMARYPurpose

Trauma has significant impacts on the livelihoods and well-being of patients. Prompt emergency, medical, and nursing care is the key to reducing mortality rates. Digital platforms have become important for patient care. This research aimed to evaluate patient outcomes after implementing a novel web application operating system in trauma care.

Methods

A descriptive comparative study was conducted on trauma patients. The patients were divided into two groups: those who used the developed application (n = 70) and those who did not (n = 70). The patients' characteristics, the time of the trauma team's arrival at the emergency department (ED) and the length of stay in the ED, and patients' outcomes were collected from electronic medical records and the application database. A statistical analysis was performed to evaluate this data. Sixty registered nurses who used the application completed the survey on the feasibility of the application.

Results

The activated trauma intervals for the non-application-used group and the application-used group were 5.0 ± 1.1 and 3.1 ± 0.4 minutes, respectively (p = .010). The length of stay in the ED for the non-application-used group and the application-used group were 30.1 ± 5.1 and 18.3 ± 6.2 minutes, respectively. A high level of agreement confirms the feasibility of the application.

Conclusions

This application improves patient outcomes in terms of length of stay. This mobile application can improve the cooperation and communication and efficacy of the trauma care team.

FULL TEXT

Introduction

Trauma injury is a major cause of death globally, especially in lower- and middle-income countries [1]. The primary cause of trauma is road traffic accidents [1]. Road traffic accidents are becoming an increasingly more severe global problem. In 2018, the World Health Organization stated that according to the most recently available data, the number of road traffic crashes that resulted in death had increased to 1.35 million people worldwide per year and accounted for an average of 3,700 people per day [2]. The death rate was mostly due to accidents involving cars (29.0%), followed by motorcycles (28.0%), bicycles and pedestrians (26.0%), and other road users (17.0%). In Thailand, the number of road deaths was ranked the ninth highest in the world and the overall first in Asia and the ASEAN region [2]. The estimation currently stands at 32.7 deaths per 100,000 population or an average of 22,491 deaths per year (60 daily) [3–5]. As the Office of Transport and Traffic Policy and Planning report in 2020 indicates,

most accidents were caused by motorcycles (74.4%), followed by cars (12.3%), pedestrians (7.6%), cyclists (3.5%), and other road users (2.3%) [6]. Statistics information from the Strategy and Planning Division of the Office of the Permanent Secretary, the Ministry of Public Health 2018-2019 and the ThaiRSC Accident Information Center all confirm that road accident deaths increased steadily in 2020 [3–5]. Accidents have tremendous impacts on the physical, emotional, and overall state and quality of life. The major causes of death for trauma patients are excessive blood loss, airway obstruction or ineffective breathing, and severe brain injury [7]. The first hour is crucial in saving lives, and having a prompt emergency care system in place is essential [8].

The first and arguably the most important step in the response for injured patients is to screen and classify the injured patient rapidly and accurately to manage and deliver prehospital care, select a suitable hospital, and transfer important patient information to the destination hospital where the patient is transported to [9]. In practical situations, emergency medical service (EMS) providers use the radio to talk to command-and-control centers that pass along information to a healthcare provider at the emergency department (ED). However, there are a number of limitations to the strictly verbal communication used in EMS situations that often result in miscommunication. The impact of miscommunication between healthcare providers during treatment in time-sensitive emergencies may lead to delays and other negative patient outcomes. In the ED, the priority is to screen and provide care for injured patients promptly and accurately, especially in the first hour, known as the “Golden Hour” [10]. In many hospitals in Thailand, registered nurses work in both the EMS unit and the ED. Nurses have played an important role in initial assessment, monitoring, coordination, preparation of equipment, and nursing records. Thus, nurses’ competencies in rapid and accurate emergency response and nursing implementation are critical [11].

Currently, technology plays an important role in solving communication problems. The use of web applications has been demonstrated to reduce documentation time, improve patient outcomes, increase self-triage, and lead to a recommendation to call an emergency center [12, 13]. Therefore, the development of web application tools for injured patients on mobile devices used by healthcare providers, particularly nurses, is needed on a larger scale. This application can provide lifesaving information about injured patients from EMS field crews and relay it to the hospital. This information will support healthcare provider decisions according to the pathological problems and will reduce the incidents of miscommunication. This platform can promptly provide the trauma team before the patient's arrival at the ED and help the emergency healthcare providers better prepare for these patients.

The development of a web application needs to consider the characteristics of its end-user, including registered nurses in the targeted hospitals. The codesign concept is a creative and participatory process that involves a diverse group of stakeholders to explore, develop, and test an intervention for a shared challenge [14]. The greatest strength of applying the codesign process is that an app is likely to be acceptable by potential users and be technically feasible to implement in real-world settings [15]. Therefore, codesign and collaboration between healthcare professionals and app developers are recommended for developing all digital solutions.

The primary objective of this study was to compare the activated trauma team interval, length of stay, and clinical patient outcomes in the ED between before and after the web application has been implemented. This study also aimed to determine the feasibility of the web application in terms of user satisfaction.

Methods Design and setting

This study was a descriptive comparative study conducted in trauma patients who received prehospital services from EMS teams at Khon Kaen province, Thailand during a six-month period from July to December 2021. This hospital is a level I trauma center in Northeastern Thailand, which has an average of roughly 800 to 1000 EMS operations of trauma patients per year.

Web application

The web application was developed to aid healthcare providers, especially nurses in the EMS unit and the ED, in providing care for trauma patients following the standard practice guideline. The initial content of the app was created by trauma and emergency care experts following the practice guidelines of the Advanced Trauma Life Support (ATLS) guidelines, 10th edition. An in-depth interview with five experts in trauma care, consisting of one emergency physician, two nursing instructors, and two emergency accident department nurses, was conducted to

review the scientific content and accuracy of the context body. The content validity index (CVI) was verified to be 0.90. Afterward, the web application was developed by app developers using React Java Script Code for its ability to distribute the app on online platforms via smartphones and tablets. Subsequently, the content and design consistency of the web application prototype was reviewed by three experts in computer engineering. The CVI was 0.87.

The final web application operating system (Figure 1) contained the following key elements: a primary survey and a secondary survey for common traumatic problems, including prehospital care, multiple injuries, traumatic brain injury, and shock. This application allowed healthcare providers to record patients' vital signs, clinical conditions, and nursing care. Additionally, this application also displayed practices for patients with mild traumatic brain injury.

Study sample

This study focused on adult trauma patients during the stated period. Patients taken to other hospitals or dead-on-arrival were excluded. The patients were divided into two groups by EMS providers: patients in situations where this application was used and patients in situations where it was not used. The sample size was calculated using the G*Power software (Version 3.1.9.6) based on an α-value of 0.05, a power of 0.80, and an effect size of 0.5 for the independent t-test based on Cohen's recommendation [16]. The medium effect size was applied in this study due to the fact that there was no similar study in Thailand and a similar previous study showed a high effect size of 1.10 [23], resulting in a too-small calculated number of participants. The minimum predicted sample size was 64 patients per group. Concerning the missing data of around 10.0%, we recruited 70 patients per group.

The feasibility of this application was evaluated by 60 registered nurses who used the web application. Inclusion criteria were registered nurses having at least 1 year of working experience in the emergency department and willing to participate in the project.

Measurement

The interval for activating the trauma team was defined as the time from when EMS providers notified the trauma team of the case until the time when the trauma team arrived at the ED. The length of stay in the ED was defined as the time when patients arrived at the ED through the time when they were discharged from the ED. The time utilized for this study was determined by two synchronized clocks that were found within the command-and-control center and the ED. Patient outcomes included shock index (SI), Glasgow coma score (GCS), and oxygen saturation at the time before discharge from the ED. The SI is calculated by dividing the heart rate by the systolic blood pressure, with the accepted normal range of 0.5–0.9. A greater SI (>1.0) indicates a deteriorating hemodynamic state and shock [24]. The patients' characteristics consisted of gender, age, mechanism of injury, organ injury, the emergency severity index, and the area of injury.

The application utilized was defined as the nurses' perception of the possibility of using the web application. The questionnaire was adapted from previous research on surveys measuring satisfaction with smart phone applications [11]. The possibility of using the web application questionnaire consists of 10 Likert scale items that refer to the app's design, audio, visual quality, content, usefulness, and user-friendliness. The CVI was 0.92. The Cronbach's α of this the web application scale was 0.94. The mean score of each item was interpreted into five levels of agreement: least agreed (1.00–1.50), slightly agreed (1.51–2.50), moderately agreed (2.51–3.50), highly agreed (3.51–4.50), and extremely highly agreed (4.51–5.00) [17].

Ethical considerations

This study was carried out in compliance with the Declaration of Helsinki's principles and Good Clinical Practice recommendations. The study was approved by the Khon Kaen University Ethics Committee for Human Research (HE642124). Requirement for informed consent from the patients was waived since all identifiers were removed from the obtained data to ensure confidentiality. Written informed consent was obtained from all registered nurses.

Data collection

The data consisting of characteristics of patients, the time of trauma team arrival at the ED, the time of patients receiving nursing care, and the length of stay in the ED were all acquired from electronic medical records and the database from the application. The data were extracted and put into Microsoft Excel, and the duplicate data entry

was completed by two independent investigators who were not associated with the treatment team. At the end of the six-month trial period, we distributed the survey to users to assess the feasibility of this web application and explore the direction to further improvements.

Data analysis

All data were recorded in Microsoft Excel 2016, and statistical analyses were performed using IBM SPSS 2017 for Windows, version 28.0. Descriptive statistics for the approximately normally distributed numerical variables were presented as mean (standard deviation) and N (percent) for categorical variables. Independent sample t-tests were used to compare the two groups' differences in terms of activated trauma interval and length of stay in the ED. Chi-square test was applied to compare the categorical variables, including SI, GCS, oxygen saturation, and patients' characteristics. A p value of

Results

Data from 140 participants were collected. The characteristics of patients in both groups were familiar. More than a half of participants in this study were male. Most of them were aged between 18 and 60 years. The most common mechanism of injuries was traffic accidents. Most severity assessments according to the Emergency Severity Index were in level 2, as shown in [Table 1].

The activated trauma interval for the non-application-used group and the application-used group were 5.0 ± 1.1 minutes and 3.1 ± 0.4 minutes (p = .010), respectively ([Table 2]). Lengths of stay in ED for the non-application-used group and the application-used group were 30.1 ± 5.1 minutes and 18.3 ± 6.2 minutes, respectively.

The number of EMS providers using this application was 60 participants. Users' perception of the possibility of using the web application of the nursing practice guidelines in the ED settings was demonstrated in [Table 3].

Discussion

The web application was developed to facilitate emergency staff communication for trauma patients. This study aimed to evaluate the outcome of patients after implementing these applications in the nursing care system. The results of this study show that implementing this new application could considerably reduce patient care time.

In regards to the time the trauma team took to arrive at the ED after notification from the EMS (the activated trauma interval), our study found that patients who applied this application took less time than the group that did not. This is consistent with previous studies [9,15,17] which demonstrated that smartphone applications improve teamwork and communication and enhanced the safety and efficiency of trauma care delivery. The reason may be due to the fact that EMS providers who use this application can transfer real-time patient information to the ED staff and trauma team without obstacles resulting from verbal miscommunication. Not only was there a time reduction, but a previous study also demonstrated that the electronic documentation captured more data elements, especially the time of team activation, the primary assessment, and the arrival time of the attending physician, than the paper documentation [18].

Our study demonstrated that patients' length of stay in the ED was shorter in the group that implemented this application. This may be due to one of the parts of this application containing trauma nursing care guidelines that can help EMS providers, ED staff, and trauma teams to evaluate and manage patients early and provide accurate emergency nursing care following ATLS guidelines. However, this study did not explore any details in the diagnosis or ED disposition delay. The next step should be to particularize the impact of this web application on each step of care. Furthermore, the use of portable devices allows nurses to record patient care assessments and nursing practice in real-time rather than on paper, which may reduce the time required for nursing documentation [19]. Our findings were consistent with those of a prior study conducted in Greece, which found that using electronic documentation decreased the time between admission and completion of planned care, the total length of stay in the ED, and the time between completion of care and discharge from the ED [20].

In terms of patient outcomes, our study found that patients in the application group had more clinical improvement than patients in the comparison group, especially in the case of oxygen saturation because both EMS providers and the ED team could deliver oxygen to patients faster by performing nursing care following the guideline in this application. However, the SI and GCS did not improve in this group. A study in Thailand partially supported

these findings that using the multisystem trauma care guideline for nurses improved clinical outcomes, particularly the SI and oxygen saturation [21]. This may be due to the nature of trauma patients' conditions that needed more advanced care, especially where surgery was required. This was consistent with previous studies [22, 23, 25–27], which demonstrated the utility of medical applications in smartphones that are widely used in health care and show improvement in the overall clinical practice.

Users who participated in the project expressed their opinions on the web application used to record patient data in accordance with the conceptual framework of the nursing process, which is comparable to following the guidelines of nursing care for emergency trauma patients. It was found that the mean score was very high, indicating that the web application could actually be used and was reliable, particularly to closely monitor changes in injured patients and provide timely care and assistance. The assessment of nursing practices in trauma patients was analyzed to adjust for nursing diagnosis to be appropriate for the injured patient continuously. This is consistent with the study of Zhang et al. [28], which established a guideline to assist injured persons in the framework of ATLS for the assessment of life-threatening symptoms in trauma patients in the first phase (Primary Assessment) and Phase II (Secondary Assessment), thus, enabling patients to receive standardized care and deliver the patient outcomes in a positive direction [29–33]. In addition, the recording of nursing activities in the operating system web application also helps to systematically build and store the database. Nurses can use the data to analyze for continuous improvement and can print out documents as evidence of nursing records that save time as opposed to writing redundant records [19]. However, users can record more important patient information that is specific to each patient.

Limitations

The study's limitations were (1) data collection from a single EMS team and single level of EMS personnel, who may have a different perspective on the studied population compared to other organizations. As a result, the generalizability of the study's findings is limited. Future research with a larger number of participants, across multi-centered settings, should be implemented to address these issues. (2) This study did not demonstrate the patient outcomes related to patient mortality or intensive care admissions. Moreover, this study did not analyze the severity of trauma patients that may interfere with the results of this study. To address this concern, the evaluation of the web application in improving other clinical patient outcomes is needed in the future. (3) The unstable quality of the internet signal may cause delays in some cases and should be concerned during using the web application.

Conclusions

Developing nursing practice guidelines for emergency trauma patients on the platform of a web application is useful for EMS providers and staff members who work in the emergency department. The results reflect that this application has a high likelihood of improving the trauma patient care processes, especially in the areas of communication, knowledge, and coordination between teams. Additionally, the nurse's perception supported the possibility of using the web application in the ED settings. This web application should be introduced to targeted hospitals and be implemented in several clinical settings.

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Author contributions

Conceptualization: CP, PW, WP, AJ. Data curation: CP, WP. Formal analysis: CP, WP. Funding acquisition: CP. Methodology: CP, PW, WP, KA, AJ. Project administration: CP. Visualization: PW, WP, KL. Writing - original draft: CP, PW, KL. Writing - review &editing: PW, CP, WP. All authors have read and agreed to the published version of the manuscript.

Conflict of interest

The authors declare that there are no conflicts of interest.

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the collection of valuable operational data.

Category	Non-application-used n = 70(%)	Application-used n = 70(%)	p-value
Gender			.620
Men	38 (54.3)	37 (52.9)	
Women	32 (45.7)	33 (47.1)	
Age (years)			.582
18–60	56 (80.0)	58 (82.9)	
>60	14 (20.0)	12 (17.1)	
Mechanism of injury			.510
Traffic accident	56 (80.0)	58 (82.9)	
Falls, slips, trips	10 (14.2)	7 (10.0)	
Assaults	2 (2.9)	3 (4.2)	
Struck by objects	2 (2.9)	2 (2.9)	
Emergency severity index			.486
Level 1	32 (45.7)	30 (42.9)	
Level 2	38 (54.3)	40 (57.1)	
Area of injury			.512
Head	39 (55.7)	37 (52.9)	
Abdomen	38 (54.3)	37 (52.9)	
Chest	34 (48.6)	32 (45.7)	
Extremities	22 (31.4)	20 (28.6)	

Patient outcomes	Non-application-used n = 70(%)	Application-used n = 70(%)	p-value
Activate trauma interval, Mean (SD) (min)	5.02 (1.07)	3.10 (0.42)	.010
Length of stay in the ED, mean (SD) (min)	30.10 (5.10)	18.31 (6.20)	.012
Shock Index			.262
<1.0	48 (68.6)	54 (77.1)	
1.00–1.09	7 (10.0)	4 (5.7)	
1.10–1.49	10 (14.3)	8 (11.4)	
>1.49	5 (7.1)	4 (5.7)	
Oxygen saturation			<.001
>94	44 (62.9)	64 (91.4)	
≤94	26 (37.1)	6 (8.6)	
Glasgow coma score			.624
13–15	47 (67.1)	48 (68.6)	
9–12	9 (12.9)	8 (11.4)	
<9	14 (20.0)	14 (20.0)	

Possibility	Mean	SD	Level of agreement
1. The web application can be used to record the nursing care of trauma patients	4.25	0.72	High
2. The process of the web application is clear and reliable	4.21	0.69	High
3. The web application uses plain language and is easy to understand	3.98	0.74	High
4. The web application is easy and convenient to use	4.03	0.71	High

5. Using a web application reduces nursing recording information time	4.06	0.86	High
6. The web application can help in caring for injured patients	4.15	0.70	High
7. The web application is suitable for use in practical work	3.98	0.74	High
8. Using a web application is more cost-effective	4.01	0.74	High
9. The use of web applications will be effective for patients	4.08	0.71	High
10. The use of web applications satisfies my colleagues and me	4.13	0.79	High
Overall mean score	4.09	0.74	High

DETAILS

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Validity and Reliability of the Korean Version of the Paternal Postnatal Attachment Scale

Choi, Yookyung
; Suk-Sun, Kim

ProQuest document link

ABSTRACT (ENGLISH)

S U M M A R YPurpose

The study aimed to translate the Paternal Postnatal Attachment Scale (PPAS) into Korean and to evaluate the validity and reliability of the Korean version of the PPAS (K-PPAS).

Methods

The PPAS was translated, back-translated, and reviewed by 12 experts and 5 fathers following the World Health Organization's guideline. A convenience sample of 396 fathers with infants in their first 12 months participated in this study. For construct validity, an underlying factor structure and model fit was assessed with an exploratory and

confirmatory factor analysis. Convergent and discriminant validity and reliability of the K-PPAS were evaluated.

Results

The construct validity of the K-PPAS with 11 items was identified by two-factor structures: healthy attachment relationship, and patience and tolerance. The final model fit was shown acceptable with the normed chi-square = 1.94, comparative fit index = .94, Tucker–Lewis index = .92, root mean square error of approximation = .07, and standardized root mean square residual = .06. This model had acceptable convergent and discriminant validity for each construct with the values of the composite reliability and heterotrait–monotrait ratio at a satisfactory level. Discriminant validity with known groups showed that fathers with no postnatal depression had significantly higher scores on the K-PPAS than those with postnatal depression. Cronbach's α and McDonald's omega coefficient of the K-PPAS was .84 and .83.

Conclusions

The K-PPAS would be beneficial to measure postnatal attachment among fathers with infants aged 12 months or younger in Korea. However, further studies are suggested to evaluate the applicability of the scale considering the various family structures, such as single or foster parents and multicultural families that exist within the Korean population.

FULL TEXT

Introduction

A father-infant attachment emerges as an important mechanism in raising a child and influences the biological, psychological, and social aspects of a child's development [1]. From biological aspects, a secure attachment in infants has been associated with stimulating an infant's brain growth and development and allowing strong emotional immunity to form, making them more tolerant to stress [1]. Also, a positive paternal attachment in the early infant phase of childrearing greatly influences the child's later cognitive development [2], and these children also grew up to exhibit fewer behavioral problems, including emotional symptoms, conduct problems, hyperactivity, peer relationship problems, and prosocial behavior [3]. In contrast, the children of fathers with disengaged interactions even at 3 months of age were to manifest early behavioral problems such as aggression, rebellion, and hyperactivity [4].

Many scholars in pediatric and child psychology suggest that maternal and paternal roles in caregiving are separate systems from the evolutionary perspective [5]. When comparing both parents, mothers as the primary caregiver spend more time with their children even in the case of both parents having to work full time [6]. Previous studies had mainly addressed maternal attachment to a child's developmental outcomes as mothers were considered to be a more influential figure to children. However, the growing interest in fathers' involvement in childrearing has become an increasing trend with nuclear families and dual-income households being more prevalent in Korea [7]. Women's participation in the workforce might have led to changes in the perceptions of fathers and mothers sharing parenting and housework [8]. With this transition, recent studies have explored the role of Korean fathers as caregivers and their impact on children's development [9,10].

Although recent studies have highlighted the importance of paternal involvement in early attachment with their infants [11,12], evidence concerning paternal attachment towards an infant was less examined in comparison to maternal attachment due to a limited number of valid assessment tools available in Korea [13]. Several maternal attachment measures varying from self-report questionnaires to observational approaches have been translated into Korean, such as the Maternal Postnatal Attachment Scale [14], Maternal Attachment Inventory [53], and Attachment Q-sort [15].

However, only one scale, the Paternal Attachment Scale (PAS) [16], has been available to assess paternal attachment in infancy in Korea. The PAS [16] is developed from the father's perspective to describe the involvement with his neonate, who refers to a child aged under 28 days [17]. It is a self-report measure of 35 items with seven subscales, which assess traits such as absorption, preoccupation, and interest exhibited in fathers who have formed bonds with their newborns. Often the term “infant” has been used interchangeably with the term “neonate” regarding paternal attachment in Korea. While the PAS measures paternal attachment in neonates, it has been referred to and

used in previous studies to describe paternal attachment in infants [18,19], which is an unsuitable usage of the tool for fathers of infants as old as 24 months [17]. Moreover, the use of the PAS in cross-cultural studies may also be limited with its measuring concepts developed and addressed in Korean. Hence, to accurately assess the correct age group of the infants, tools that assess mother-infant attachment were used by modifying words such as “mother” to “father” [20]. Nonetheless, this is still inadequate because mothers and fathers develop attachments differently [21]. Therefore, a tool that specifically assesses father-infant attachment more accurately with infants correctly termed is in need.

On the other hand, the Paternal Postnatal Attachment Scale (PPAS) [22] consists of 19 items with 3 subscales that measure the affective and cognitive part of paternal attachment by considering the subjective experience of a father in forming an attachment with his infant up to 12 months. The formation of a father's attachment with an infant up to 1-year-old has been considered a crucial developmental milestone for infants [11], as the growth and development of major functional networks occur within the first year of life [23]. Likewise, according to Bowlby [24], the sensitive period for the development of infant attachment is from 6 to 24 months. In contrast to the PAS, the PPAS properly captures the crucial period in which infants develop an attachment with their fathers, and a further assessment has proven it to be an acceptable measure for paternal attachment with infants that are 24 months old [25]. Thus, regardless of the terms of age used in the original study, the PPAS has been shown to assess the important developmental period of attachment across infancy. Moreover, because it has been used in many studies worldwide and was translated and adapted for use across diverse cultures with good validity and reliability to the original scale [26–28], it can also be used in cross-cultural studies. In light of the aforementioned gap in the postnatal field, a cross-culturally validated tool like the PPAS that evaluates attachment between fathers and infants of ages up to 12 months is required in Korea.

Hence, the aim of this study is to translate and adapt the PPAS into Korean and examine the validity and reliability of the Korean version of the PPAS (K-PPAS). The results of this study will provide a foundation for future research measuring and understanding Korean fathers’ attachment to their infants.

Methods Study design

In this validation study, a cross-sectional study was applied to evaluate the validity and reliability of the Korean version of the PPAS. The PPAS was translated into Korean following the four phases of the guideline of the World Health Organization: forward and back translation, cultural adaptation with an expert panel, content validity, and pretesting and cognitive interviewing [29]. The psychometric properties of the translated version of the PPAS were examined among Korean fathers. Permission to use and translate the PPAS was acquired by the copyright holder prior to this study.

Translation process Forward and back translation

Firstly, two independent pediatric nurses, who are fluent in both Korean and English, translated the PPAS into two initial versions. These two initial versions were synthesized into one version by reviewing and resolving any inadequately translated expressions or concepts with an initial team of experts, comprising a professor, a researcher from the department of psychiatric mental health nursing, and three pediatric nurses with clinical experience of more than 6 years. The synthesized version was back translated into an English version by a bilingual professor in pediatric nursing, who has studied and worked in the United States.

Cultural adaptation with expert panel

A panel of 6 experts consisted of the initial team of 5 experts in the previous phase of forward and back translation and the bilingual professor in pediatric nursing. They ensured cultural and conceptual equivalence and reconcile any discrepancies between the back translated and the original. The panel agreed on maintaining item 1 (“When I take care of my child, I get bored or annoyed”) as the words “annoyance” and “irritation” used in the original tool were difficult to distinguish in general terms used in Korean. They also discussed to keep the change of item 13's response from “Neither” to “I don't care about the amount of time that I spend with my child” as the original option was unable to adequately convey the meaning needed for a person to answer a question. However, the panel suggested that consistency in response options for the scale should be needed for less confusion, and all back translated items were adapted into a 5-point Likert scale. After a consensus was reached within the panel of experts,

the preliminary version of the tool was produced from this process.

Content validity

The final confirmation of the scale was assessed independently by a panel of 7 different experts with three professors and two researchers from the department of pediatric nursing and two senior pediatric nurses with more than 10 years of clinical experience. Experts were asked to evaluate each item on a 4-point Likert scale (1 = not relevant, 2 = item needs some revision, 3 = relevant but needs minor revision, and 4 = very relevant). The values of the item-level content validity index for each item and the scale-level content validity index based on the average method above .78 and .90, respectively, were considered adequate for content validity [30].

Pretesting and cognitive interviewing

The pretesting of the preliminary version of the K-PPAS was carried out using a purposive sampling method to recruit 5 fathers who have infants in their first 12 months. These participants were first-time fathers, with mean age of 34.60 (SD = 5.86) years. All of them were married with undergraduate degrees and worked full-time earning middle-class income. Interviews were performed to probe about the clarity of words or expressions used in questions. No problems were raised regarding clarity and comprehension of all items, and hence, a final version of the K-PPAS was created.

Setting and Samples

The survey for this study was conducted through online childrearing communities in Korea. Convenience sampling was adopted to recruit fathers. The inclusion criteria were as follows: fathers aged 18 to 65 with infants in their first 12 months and have no problem communicating and answering questionnaires written in Korean, and have given a statement of consent prior to the study. A total of 396 fathers participated in this study, excluding four fathers who provided incomplete and inconsistent responses to survey questionnaires. To assess the construct validity of the scale, the necessary sample size for factor analysis was suggested as a minimum of 10 participants per item for exploratory factor analysis (EFA) and 200~300 participants for confirmatory factor analysis (CFA) [31]. Based on this, the data sample size was appropriate to conduct the factor analysis.

Ethical Considerations

The current study was conducted after receiving ethical approval from the Institutional Review Board at Ewha Womans University (Approval no. ewha-202203-0045-01). Participants were all informed about this study, and consent was gathered before commencing data collection.

Instruments

The PPAS [28] is a self-report measure that assesses the emotional responses of fathers to their infants during the first year of life in relation to the father-to-infant attachment. It comprises 19 items grouped in three subscales: patience and tolerance (PT) (8 items), pleasure in interaction (7 items), and affection and pride (4 items). Each item is scored with two to five response options. The score in the questionnaire ranges from 19 to 95, with a higher score indicating greater father-infant attachment. The PPAS has demonstrated adequate construct validity and reliability, and Cronbach's α coefficient ranged from .78 to 81 in the original study.

The K-Edinburgh Postnatal Depression Scale (EPDS) [32] translated from the original EPDS [33] is administered to assess postnatal depression. This 10-item scale is scored on a 4-point rating with a higher score indicating a greater level of postnatal depression. Cronbach's α coefficient of the K-EPDS and the EPDS was .84 and .87, respectively. As paternal depression is conceptually differentiated from father-infant attachment [34], the K-EPDS was used to examine discriminant validity.

Data Collection

This study recruited participants from online childrearing communities throughout April 2022. Prior to conducting data collection, consent from the administrators of online childrearing communities was obtained with a clear explanation regarding the study's purpose. The details of this study and a URL to the online survey were posted on each permitted online community. Participants were informed that their responses would remain anonymous and confidential, and assured of their right to refuse or withdraw their consent at any stage of this study without any consequences. A statement of consent was obtained from all participants before the survey began by allowing only

those who have pressed “I consent” to continue onto the questionnaires. A gift voucher was given upon the completion of the questionnaires.

Data Analysis

The data were analyzed using IBM SPSS 28.0 and SPSS AMOS 28.0 programs (IBM Corp., Armonk, NY, USA). For the item analysis, means, standard deviations, skewness (35] and item-total correlations (≥.30) were assessed [36]. Construct validity was evaluated with EFA and CFA. The data collected were divided randomly to perform the EFA (n = 190) and CFA (n = 206). To determine the underlying factor structure, principal axis factoring with varimax rotation was used in the EFA [37]. The Kaiser–Meyer–Olkin (KMO >.60) and Bartlett's test of sphericity (*p* 38]. The optimum number of factors was extracted in accordance with an eigenvalue of 1 or above the elbow represented in a scree plot [37]. Items with loading onto their primary factors of .40 or above, alternative factors of .30 or below, and having a loading difference of .20 between their primary and alternative factors were considered acceptable [38]. For model fit verification, the CFA was performed with normed chi-square (χ2/df), comparative fit index (CFI), Tucker–Lewis index (TLI), root mean square error of approximation (RMSEA), and standardized root mean square residual (SRMR). The model fit was evaluated using the following criteria: χ2/df ≤ 3, CFI and TLI ≥.90, RMSEA ≤.08, and SRMR ≤.06 [39,40].

Convergent validity and discriminant validity for each construct in the model were evaluated using the values of the composite reliability (CR) and heterotrait–monotrait ratio with the CFA data set [41,42]. Discriminant validity with known groups was assessed with the scores determined from the K-EPDS [32], comparing the scores of the postnatal depressed (K-EPDS ≥10) and the normal (K-EPDS 41].

Results Sample Characteristics

The sample consisted of 396 fathers with data distributed randomly to have necessary sample sizes for both the EFA and CFA. The mean age of the total sample was 34.07 (SD = 3.86). The majority of fathers were married (98.7%) and living together with someone (97.7%). Most were first-time fathers (83.3%), and slightly more than half of the children were male (50.5%). Other characteristics of the fathers and their children are shown in Table 1.

Item Analysis

The results of the item analysis are shown in Table 2. The skewness and kurtosis of each item of the initial 19-item K-PPAS ranged from –.87 to .30 and –.49 to 1.83, respectively, meeting the criteria for normality. No items were additionally deleted with the initial item-total correlation coefficients ranging from .30 to .71.

Content Validity

The item-level content validity index value for each item was above .78, with all items scoring 1.00 except .85 for item 8; however, still demonstrated excellent content validity for 11 items [30]. The scale-level content validity index based on the average method value scored .99, with the above recommended value of .90 [30], also satisfying the criterion for good content validity, and thus all items were retained.

Construct Validity

Both EFA and CFA were performed to determine underlying factor structures that might exist as cultural adaptation and confirm any possibilities for reclassifying the items from the original PPAS. The KMO was .89, and Bartlett's test of sphericity was χ2 = 1559.02 (*p* 38] were considered in addition to content coherence with the original scale [22]. As a result, items 10, 12, 13, 14, 15, 16, 18, and 19 were deleted.

EFA was performed again with a final 11 items, resulting in a KMO of .84 and Bartlett's test of sphericity of χ2 = 790.95 (*p* 22] that accounted for 45% of the total variance, and meeting the total variance criteria of 40-60% [39, 43]. The percentages of the variance explained by each factor are presented in Table 2. Factor 1 was labeled “healthy attachment relationship (HAR)” (items 3, 4, 5, 7, 8, 9, and 11) and factor 2 was labeled “PT’” (item 1, 2, 6, and 17). Factor loadings of all the 11 items ranged from .49 to .84, with each factor consisting of more than three items (Table 2).

Based on the result of the EFA, the assumption of multivariate normality was tested by calculating Mardia's coefficient of multivariate kurtosis before conducting maximum likelihood estimation for CFA. The value of Mardia's coefficient multivariate kurtosis and the critical ratio was 110.91 and 47.07, which was greater than the threshold

criteria of the multivariate kurtosis 44]. Thus, multivariate normality was not met, and the Bollen-Stine bootstrap [45] method using recommended 250 bootstrap samples was applied [46]. The initial fit indices of the two-factor structure were Bollen-Stine bootstrap p = .056, χ2/df = 2.85, CFI = .87, TLI = .83, RMSEA = .10, and SRMR = .07. The initial model showed a poor fit to the data with CFI, TLI, RMSEA, and SRMR not meeting the criteria for good fit indices [39, 40]. The modification index (MI) values were inspected, and the covariance modification between error terms could significantly improve the initial model fit. The MI values of 3.84 or above suggested a need for model improvement [39]; however, a threshold of 10 was used for greater efficiency [44]. After considering the items' content and MI values, the initial model was revised by setting the covariance of the error term to item 6 and 17 (MI = 30.41), and the fit indices of the new model were Bollen-Stine bootstrap p = .291, χ2/df = 2.12, CFI = .92, TLI = .89, RMSEA = .07, and SRMR = .06. This model fit was improved than the initial model, but TLI of .89 still suggested a poor fit. The covariance of the error term was additionally set to items 4 and 5 (MI = 10.20), and the fit indices of the revised model were Bollen-Stine bootstrap p = .422, χ2/df = 1.94, CFI = .94, TLI = .92, RMSEA = .07, and SRMR = .06 (Table 3). The difference in the CFI value between model 1 and model 2 indicates a substantial improvement in the model fit. Additionally, the final model showed a better model fit than model 2 [35]. The fit indices of this revised model were improved substantially compared with the initial model by having all the criteria met for fit indices: χ2/df ≤ 3; CFI and TLI ≥.90, RMSEA ≤.08, and SRMR ≤.06 [39, 40]. The final model was confirmed (Figure 1). As shown in Table 2, the standardized factor loadings of all the 11 items in the final model ranged from .30 to .80, with all factor loading coefficients reaching significance (p .50 is ideal in CFA. However, the results were considered acceptable and in agreement given that each loading coefficient was statistically significant (p 39]. In addition, the revised model revealed to have adequate convergent validity for each construct in the model with the CR values of the two factors as .81 and .65 (Table 2), meeting the criterion of CR > .60 [41]. Discriminant validity was also supported by the heterotrait–monotrait ratio of .66, meeting the criterion of 42].

Discriminant Validity (known groups)

The results of the discriminant validity using known groups are shown in Table 4. The group of fathers with no postnatal depression (K-EPDS p p –5.77, p **Reliability**

Cronbach's α coefficient for 11 items of the K-PPAS was .84, with .81 and .85 for the subscales of HAR and PT, respectively. The McDonald's omega coefficient for the scale was .83 and for the subscales of HAR and PT was .81 and .85. An acceptable internal consistency of the K-PPAS was demonstrated with the result of all coefficient values above .70.

Discussion

In this study, the PPAS was culturally adapted into Korean and had its psychometric properties evaluated among 396 Korean fathers with infants up to 12 months old. The results revealed that the 11-item K-PPAS had acceptable validity and reliability to assess the construct of father-infant attachment in Korea. The use of this tool may contribute to gaining knowledge and supporting further studies on father-infant attachment to bring about positive outcomes in an infant's later development.

The two-factor structure of 11-item K-PPAS was identified by conducting factor analysis: healthy attachment relationship, and patience and tolerance. This result was not consistent with the three-factor structure of the original PPAS (“patience and tolerance”, “pleasure in interaction”, and “affection and pride”) [22], as well as the 15-item Spanish [26] and 18-item Turkish [28]. On the other hand, compared to the three-factor, the findings in this study were similar to the two-factor structure in the 16-item Portuguese version (“quality of attachment” and “patience and tolerance”) [27]. One of the reasons for these differences in the factor structure may be due to not performing CFA in the original study to support its structure and items [26]. The absence of CFA may leave how well the proposed factor structure fits with observed data unexplored [32]. However, cultural differences may have also influenced the inequivalent number of factors and item placements. Therefore, it is advised to use the K-PPAS after careful consideration.

One strength of this study is that both EFA and CFA were performed to validate the factor structure among 396 fathers with infants, who were randomly divided into two data, one for EFA and the other for CFA. The results

showed a total of 11 items after removing 8 items (10, 12, 13, 14, 15, 16, 18, and 19) from the original 19-item PPAS. Consistent with this study by conducting both factor analyses, the Spanish version had 4 items (6, 8, 9, and 15) and the Turkish version had 1 item (16) omitted. Although item deletion happened in all studies above, it was incomparable with the findings of this study as the cultural context was not dealt with as one of its reasons. In contrast, the cultural context was dealt with as having contributed to all 8 item deletions in this study as low parental responsibilities were observed in Korean fathers, who believe that being involved in childrearing is important but still perceive themselves to be in assisting roles in childrearing [47]. The Confucian culture, which has deeply rooted in the Korean society, influenced a physical and psychological gap to form between the Korean men and women [48]. This has typically made Korean fathers to be the financial providers of their families and lacked opportunities to be involved with their children [49]. Likewise, with a majority of Korean fathers in this study holding a job, conflict in the work-life balance may have also influenced responses to be inconsistent with these items. Therefore, characteristics such as being apart from one's infant (item 10, 12, and 14), balancing time spent on one's infant and for oneself (item 13 and 18), feeling affectionate (item 15), accepting the infant as one's own (item 16), and being patient (item 19) may have differed from the study's participants.

The K-PPAS has two subscales of “HAR (7 items)” and “PT (4 items)”, which differed from the original PPAS consisting of three subscales: “PT (8 items)”, “pleasure in interaction (7 items)”, and “affection and pride (4 items)”. The “HAR” subscale is a combination of items from the “pleasure in interaction” and “affection and pride” subscales of the original PPAS and contains similar items of the “quality of attachment” and “quality of bonding” from the Portuguese and Spanish versions, respectively. While these translated versions focus on the aspect of “quality”, the K-PPAS emphasizes the “healthy” part of attachment, the quality, and nature of the actual relationship between the parent and infant that is formed from repetitive nurturing behaviors involving interaction and affectionate touches [50]. These characteristics of a healthy attachment relationship between the father and infant include being attentive to the infant's needs with warmth and care and having conversational interactions and positive attitudes [51]. Likewise, item 8 (“I try to involve myself as much as possible in childrearing”), included only in the K-PPAS, captures the aspect of a healthy attachment relationship representing a father's active involvement with his infant. This demonstrated the difference between the two translated versions' subscales and the “HAR” of the K-PPAS, as not only this subscale assesses the father's capability of childrearing but also their will to maintain healthier attachment relationships with their infants.

The second subscale of the K-PPAS represents the degree of PT that fathers have when interacting with their infants [22]. The 4 items (1, 2, 6, and 17) of this subscale were in correspondence to the “patience and tolerance” subscale of the original PPAS, the Turkish, and Portuguese versions. This may suggest that “PT’ represents a common quality among fathers despite cultural differences. Fathers’ high level of PT to infants help them become more engaged as a father and cope with difficult situations in parenting [52], which in turn may promote father-infant attachment. The cultural context of low parental responsibilities in Korean fathers [47] and having low paid paternity leave [53] may have contributed to low factor loading on item 17, as some fathers may not be involved enough with their children to feel like they have given up on things. However, item 17 was retained for the importance it would have in the near future as the current trend of Korean fathers' involvement in childrearing [7] and more paid leave entitlements being available for fathers [53] may affect perceptions and parenting practices among Korean fathers. Moreover, the discriminant validity using known groups demonstrated that discrimination existed between nondepressed and postnatal depressed fathers in relation to attachment formed with their infants. The finding was similar to the systematic review examining the use and performance of father-child relationship tools [34], in which nondepressed fathers formed a higher level of attachment with their infants than depressed fathers. Fathers with postnatal depression are shown to have more withdrawn parental behaviors and are less involved in interacting with their infants [54]. Hence, this may suggest that further studies are in need to interpret this occurrence of depressed fathers during the postnatal period in association with the attachment towards their infants.

The present study had some limitations. First, the K-PPAS was culturally adapted by applying a 5-point Likert scale to all items of the original PPAS, which is from a 2- to 5-point Likert scale. This resulted in difficulty in comparing this

study's findings with other studies due to items' response options all being modified. Second, test-retest reliability to investigate the internal consistency of the K-PPAS was unable to be performed because online surveys have difficulty in gathering the same participants. Thirdly, an online survey has made it difficult to examine any physical, psychological, and social problems in fathers and infants that could interrupt the formation of father-infant attachment prior to the study. Future research should consider this in the exclusion criteria. Lastly, other influences including cultural differences may be suggested as the reason behind the inconsistency of the number of factors between the K-PPAS, the original, and the other translated versions. Hence, future studies should be performed to further examine the psychometric properties and application of the K-PPAS in a broader Korean population considering the various family structures and cultural diversity that exist within the Korean population.

Conclusion

The 11-item K-PPAS adapted from the original PPAS for the assessment of the father-infant attachment in the postnatal period consists of two aspects: “healthy attachment relationship” and “patience and tolerance”. However, inconsistencies in the structure compared to the original scale could have occurred with cultural differences, and thus, it is recommended to carefully consider all the necessary aspects when using the K-PPAS in the Korean population.

Conflicts of interest

There are no conflicts of interest and ethical adherence of this manuscript, and the authorship belongs to Yookyung CHOI and Suk-Sun KIM.

Ethical approval

The study was approved by the Institutional Review Board of Ewha Womans University (ewha-202203-0045-01). All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee.

Acknowledgments

This article is based on a part of the first author's master thesis from Ewha Womans University.

	Characteristics	Categories	Total (n = 396)	EFA (n = 190)	CFA (n = 206)
			Mean ± SD or n (%)	Mean ± SD or n (%)	Mean ± SD or n (%)
Father	Age (years)		34.07 ± 3.86	34.44 ± 3.98	33.72 ± 3.71
	Marital status	Unmarried	5 (1.3)	2 (1.1)	3 (1.5)
		Married	391 (98.7)	188 (98.9)	203 (98.5)
	Educational level	High school or less	24 (6.0)	11 (5.8)	13 (6.3)
		College/university	325 (82.1)	173 (91.0)	152 (73.8)
		Graduate or above	47 (11.9)	6 (3.2)	41 (19.9)
	Job status	Yes	382 (96.5)	181 (95.3)	201 (97.6)

		No	14 (3.5)	9 (4.7)	5 (2.4)
	Family structure	Alone	9 (2.3)	3 (1.6)	6 (2.9)
		Nuclear family	353 (89.1)	181 (95.3)	172 (83.5)
		Parents/parents-in-law	33 (8.3)	6 (3.1)	27 (13.1)
		Others	1 (0.3)		1 (0.5)
	Planned pregnancy	Yes	319 (80.6)	148 (77.9)	171 (83.0)
		No	77 (19.4)	42 (22.1)	35 (17.0)
	Number of children	First	330 (83.3)	160 (84.2)	170 (82.5)
		Second	60 (15.2)	28 (14.7)	32 (15.5)
		Third or more	6 (1.5)	2 (1.1)	4 (2.0)
	Childrearing (hours)	Weekdays	3.65 ± 2.36	3.67 ± 2.65	3.63 ± 2.06
	Childrearing (hours)	Weekends	8.68 ± 4.30	7.99 ± 4.08	9.32 ± 4.42
	Childrearing support	None	125 (31.6)	74 (38.9)	51 (24.8)
		Parents/parents-in-law	243 (61.4)	99 (52.7)	144 (69.8)
		Others	28 (7.0)	17 (8.4)	11 (5.4)
Child	Age (months)		8.47 ± 2.77	8.61 ± 2.51	8.33 ± 2.99
	Gender	Men	200 (50.5)	95 (50.0)	105 (51.0)
		Women	192 (48.5)	93 (48.9)	99 (48.0)
		Twins or more	4 (1.0)	2 (1.1)	2 (1.0)
	Gestational age (weeks)		37.19 ± 3.55	37.08 ± 3.53	37.29 ± 3.58
	Birth weight (grams)		3069.35 ± 368.09	3127.32 ± 396.74	3146.47 ± 375.41

Factors	Item no.	Mean ± SD	ITC	EFA (n = 190)				CFA (n = 206)		CR
Initial factor structure		Final factor structure		FL	p	1	2	1	2	Healthy attachment relationship
Item 3	3.98 ± 0.75	.59	.50	.31	.49	.28	.64	<.001	.81	Item 4
3.53 ± 0.83	.39	.58	.00	.65	−.03	.48	<.001		Item 5	3.68 ± 0.72
.48	.62	.08	.72	.06	.61	<.001		Item 7	3.87 ± 0.85	.59
.60	.28	.59	.28	.64	<.001		Item 8	3.96 ± 0.71	.55	.61
.20	.69	.18	.58	<.001		Item 9	3.56 ± 0.89	.46	.49	.15
.49	.17	.67	<.001		Item 10	3.45 ± 0.87	.30	.31	−.07	
				Item 11	3.99 ± 0.64	.65	.65	.34	.54	.29
.66	<.001		Item 12	3.96 ± 0.76	.57	.49	.37			
		Item 13	3.96 ± 0.74	.65	.59	.37				

	Item 14	4.07 ± 0.71	.71	.55	.50					
Item 15	4.13 ± 0.73	.69	.55	.48						Item 16
3.95 ± 0.80	.65	.55	.45						Item 19	3.58 ± 0.76
.39	.36	.22						Patience and tolerance	Item 1	3.68 ± 0.87
.58	.10	.81	.11	.84	.80	<.001	.65	Item 2	3.85 ± 0.9	.60
.13	.81	.18	.79	.68	<.001		Item 6	3.70 ± 0.98	.56	.18
.70	.19	.72	.43	<.001		Item 17	3.65 ± 1.00	.50	.11	.68
.16	.64	.30	<.001		Item 18	3.05 ± 0.97	.31	.12	.35	
					Eigenvalue (%)			34.09	7.78	35.40
12.84					Cumulative (%)			34.09	41.88	35.40

Modified model	Bollen-Stine bootstrap (p)	Absolute fit index	Incremental fit index

χ2/df	RMSEA	SRMR	CFI	Difference value of CFI	TLI	1	.056
2.85	.10	.07	.87		.83	2	.291
2.12	.07	.06	.92	.05	.89	Final	.422

Factors	Known group Validity Mean (SD)		t(p)	Cohen's d
Normal group (K-EPDS <10)	Depressed group (K-EPDS ≥10)			Healthy attachment relationship
16.57 (2.09)	13.00 (3.18)	–12.01 (<.001)	1.40	Patience and tolerance
28.13 (3.88)	25.65 (4.50)	–5.77 (<.001)	0.60	K-PPAS

DETAILS

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What Frequency of Ankle Pump Exercise is Optimal to Improve Lower Limb Hemodynamics? A Systematic Review and Network Meta-analysis

Wang, Xin [1]
; Tang, Rongsong [2]
; Zhang, Heli [3]
; Li, Fan [4]
; Wang, Jing [2]
; Li, Baohua [2]

[1] Institute of Sports Medicine, Peking University Third Hospital, China [2] Nursing Department, Peking

University Third Hospital, China [3] Department of Rehabilitation Medicine, Peking University Third Hospital, China [4] Department of Neurosurgery, Peking University Third Hospital, China

ABSTRACT (ENGLISH)

SummaryPurpose

Ankle pump exercises (APE) have been widely used in clinical practice. However, best practices for APE have not been established. Recognize the most effective frequency of APE for improving lower extremity hemodynamics and establish recommendations in clinical practice.

Methods

Therefore, a systematic review and network meta-analysis (NMA) was performed according to PRISMA-NMA. Six English databases (Pubmed, Medline, CINAHL, Embase, the Cochrane library and ProQuest) and four Chinese databases (CNKI, Wanfang, VIP and Sinomed) were searched. Randomized controlled trials (RCTs) and quasi-experimental studies investigating the effects of different frequencies of APE on lower limb hemodynamics published before July 2022 were included. The reference list was also searched. Seven studies (one RCTs and six quasi-experimental studies) were included in the systematic review and five studies (one RCTs and four quasi-experimental studies) were included in the NMA. The risk of bias was assessed using the Cochrane and Joanna Briggs Institute tools. The NMA was performed using the R software (version 4.2.1) and OpenBUGS (version 3.2.3).

Results

The results of the NMA showed that a frequency of every 3–4 s the most effective in improving lower extremity hemodynamics (P =.85), followed by every 1–2 s (P = .81), every 5–6 s (P=.32) and less than every 10 s (P =.02). Subgroup analysis failed to find a difference between healthy participants and those with unilateral total hip arthroplasty or fracture (MD = −0.23, 95% CI-5.92 to 4.61).

Conclusions

Consequencely, for adult patients, with or without lower extremity disease, a frequency of every 3–4 s can be recommended as the optimal frequency of APE in clinical care practice.

Registered number on PROSPERO

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FULL TEXT

Introduction

Ankle pump exercise (APE), an exercise performed through plantar flexion and dorsiflexion of the ankle joint, promotes venous blood return to the lower extremities by contracting and relaxing the calf muscles [1,2] and is recommended as an effective method for preventing venous thromboembolism (VTE) [3–5]. In addition, APE improves calf muscle pump function and reduces venous stasis, which is beneficial in patients with chronic venous insufficiency (CVI) and venous leg ulcers (VLUs) [6,7]. However, the most effective frequency of APE has not been determined [8,9].

Traditional APE recommends holding plantarflexion and dorsiflexion for 10 s at a time, which corresponds to a frequency of 3 beats/min [8]. However, faster APE frequencies have recently been found to be more effective in accelerating blood flow velocity in the lower extremities, ranging from 6 to 100 beats/min [8–14]. Validating the most effective frequency for APE is difficult due to the wide range of frequencies and inconsistent results. There are no evidence-based studies to aid decision-making in clinical practice.

Traditional meta-analysis methods compare only two frequencies at a time, making it difficult to answer the question of which frequency is most effective [15]. Network meta-analysis (NMA), a technique that compares multiple treatments simultaneously in a single analysis by combining direct and indirect evidence [16], may be more appropriate for determining the best APE frequency from a variety of different frequencies.

Therefore, the objectives of this systematic review were to [1] recognize the most effective frequency of APE for improving lower extremity hemodynamics through an NMA and [2] establish recommendations for the frequency selection of APE in clinical care practice.

Methods Registration

This systematic review and NMA is based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA-NMA) guidelines for extended reporting of NMAs [17]. The study protocol has been registered and updated on PROSPERO, an international systematic review prospective registry (ID: CRD42022349365).

Search strategy

Six English databases (Pubmed, Medline, CINAHL, Embase, the Cochrane library, and ProQuest) and four Chinese databases (CNKI, Wanfang, VIP, and SINOMED) were searched. The search strategy was established based on the PICOS tool: (P) population: adults (age ≥18 years) treated with APE; (I&C) interventions and comparators: different frequencies of APE; (O) outcomes: lower extremity hemodynamics; (S) studies: randomized controlled trials (RCTs) and quasi-experimental studies. For example, on Medline, search for “AB (ankle pump exercise or functional *training* or functional *exercise* or ankle motion or ankle plantarflexion or ankle valgus) and AB (frequency or number) and AB (lower extremity hemodynamics or blood flow rate or blood volume or venous blood return)". In addition to the database search, the reference lists of included studies were screened according to the inclusion criteria.

Inclusion criteria

RCTs and quasi-experimental studies conforming to the aforementioned PICOS, published by July 2022, written in English or Chinese, and peer-reviewed were included regardless of sample size. The frequency of APE was defined as any description that could indicate the number of APEs per minute or the interval between APEs. Low limb venous flow velocities, i.e., the velocity of blood in a specific vein, were used to measure lower limb hemodynamics and were assessed by a digital color Doppler ultrasound diagnostic system. For example, the time-averaged maximum flow velocity in the femoral vein is approximately 12.7 to 13.6 cm/s in the head-up position at rest [18, 19].

Study selection

Two independent reviewers (X.W. and R.S.T.) screened the retrieved articles through Endnote X9 literature management software. Study selection consisted of three stages, evaluating articles in terms of title, abstract, and full text, respectively. Any disagreements were resolved through discussions between two reviewers or a third reviewer (B.H.L.). If necessary, a broader team meeting will be held to resolve disagreements.

Data extraction

A standardized data extraction form was used with two independent reviewers (X.W. &R.S.T.) to record data, including authors, year of publication, country, study design, study setting, sample size, population, intervention, measurements, funds, and differences in low limb venous flow velocity before and after APE.

Quality appraisal

Two independent reviewers (X.W. and R.S.T.) assessed the quality of eligible studies. For RCTs, the Cochrane Handbook version 5.2.0, which contains 13 items to assess the risk of bias (ROB), was used. The 13 items assessed performance bias, detection bias, attrition bias, and reporting bias, and assessed whether there were systematic differences in the care provided, outcome assessment, loss of participants between comparison groups, and the presence of selective reporting [20]. Trials were also categorized into three levels based on the presence of ROBs described in 13 items: high risk (five or more), moderate risk (three or four), and low risk (two or less). For quasi-experimental studies, the Joanna Briggs Institute (JBI) quality assessment tool, which consists of nine items, was used to assess ROB in multiple ways [21]. After discussion by the study team, studies that measured comparative outcomes in an inconsistent and unreliable manner were excluded.

Data analysis

Descriptive analyses included trials, characterized by different APE frequencies, and summarized the contribution to the overall evidence. Considering the similar and varying frequencies of APE, which can be supervised with a timer in order to facilitate in clinical practice, we classified APE into five frequencies (less than every 10 s, every 5–6 s,

every 3–4 s, every 1–2 s, and greater than every 1 s) according to their intervals. Raw group data were combined into five frequencies, calculated from the mean, standard deviation (SD), and number of participants. To control for homogeneity, only studies that selected femoral vein velocity as an outcome were included in the NMA. Meanwhile, the SEM was converted to SD by counting the number of participants. The Bayesian method was used as a statistical method for NMA [22], and it was performed by the "gemtc" package of R software (version 4.2.1) and OpenBUGS (version 3.2.3) [23]. Markov chain Monte Carlo (MCMC) simulation is a tool for Bayesian inference. In this study, we chose the consistency model and set the number of Markov chains to four with parameters set to n.adapt = 20,000, n.iter = 50,000, and thin = 1, which is the conventional setting for NMA [16]. Sensitivity analysis forest plots were examined for homogeneity analysis, while I2 > 50% was defined as having heterogeneity. Fixed-effects and random-effects models were selected based on I2 (I2

The network plots show a direct comparison between the frequencies of APEs, while the edge thickness of the connected nodes implies the amount of data. MCMC simulations and convergence states are tested by trace and density plots, Gelman–Rubin statistical plots, and potential size reduction factors (PSRF).

Forest plots allow the graphical comparison of effect sizes by frequency of APE by NMA. The results are summarized as mean difference (MD) and 95% confidence interval (CI). Also, the surface under the cumulative ranking curve (SUCRA) was used to prioritize the different frequencies of APE. Subgroup analysis was used according to whether the participants were healthy or not. If 10 or more studies were included in the NMA, funnel plots were generated to assess publication bias.

Results Literature selection

A total of 805 studies were initially identified. However, 451 studies were removed due to duplication, three studies were included from other sources, and 454 studies proceeded to title and abstract review. Following title and abstract review, nine studies proceeded to full text review. One study was excluded because it did not meet the inclusion criteria, and one study was excluded because we were unable to find the full text. Finally, seven studies were included [8–14]. The detailed process is shown in Figure 1.

Characteristic of included studies

The characteristics of the included studies are shown in Table 1. These studies were conducted in China (n = 4) and Japan (n = 3). Two studies recruited only men, while one study recruited only women, and the other studies recruited participants of all genders. The majority of included studies were conducted at universities or research institutions (71.4%, 5/7), and two studies were conducted in hospitals (28.6%). A total of 456 participants were included, ranging from 10 to 307, with a median sample size of 29 (IQR 10 to 63). The included participants included 337 healthy participants, 92 patients with unilateral total hip arthroplasty, and 30 patients with fractures. We combined 12 frequencies into the 5 previously described frequencies (Appendix II). A total of 411 participants were included less than every 10 s, 411 participants were included every 5–6 s, 90 participants were included every 3–4 s, 138 participants were included every 1–2 s, and 35 participants were included every 1 s or more. All studies reported outcomes for low limb venous blood flow velocity. One study reported the percentage of calf muscle hyperemia after APE, and six studies reported the velocity of lower extremity veins. Four studies reported blood flow velocity in one lower extremity vein, one study reported two lower extremity veins, while one study reported three lower extremity veins. Also, five studies reported on the velocity of blood flow in the common femoral vein, two studies reported on the velocity of blood flow in the popliteal vein, one study reported on the velocity of blood flow in the deep femoral vein, and one study reported on the velocity of blood flow in the external iliac vein, with three studies selecting the peak velocity of blood flow as the outcome and three studies selecting the average velocity of blood flow. The intervention time of APE ranged from 1 min to 5 min. A total of 12 different frequencies of APE were compared (Appendix I).

Risk of bias assessment

One RCT and six quasi-experimental studies were included. The ROB in the RCT was low in all domains except allocation bias, which was assessed as high. In the quasi-experimental study, the ROB was high for participant homogeneity and complete follow-up, while the other domains were assessed as low risk. Full details on the ROB

assessment are reported in Appendix III.

Network meta-analysis for lower limb hemodynamics

Five studies with a combined total of 421 participants measured the velocity of the femoral vein (Table 1). In the absence of direct and indirect comparisons between more than once per second and other frequencies were excluded in the NMA. Figure 2 shows NMA plots examining the effect of four different frequencies of APE. Frequencies of once every 3–4 s and once every 1–2 s were found to be more effective compared to frequencies of less than once every 10 s (MD = 10.00, 95% CI 5.40–15.00; MD = 9.90, 95% CI 5.70–14.00). The frequencies of once every 3–4 s and once every 1–2 s were also found to be more effective compared to once every 5–6 s (MD = 7.30, 95% CI 2.60–12.00; MD = 7.00, 95% CI 2.80–11.00) (Figure 3), with the same results. No other significant differences in lower extremity hemodynamics could be found among the different frequencies of APE. Considering direct and indirect comparisons, a frequency of every 3–4 s had the best effect on improving lower extremity hemodynamics (*p* score = .85). Detailed results for APE frequency prioritization are presented in Table 2. In addition, subgroup analysis failed to find a difference between healthy participants and those with unilateral total hip arthroplasty or fracture (MD = −0.23, 95% CI −5.92 to 4.61), while the difference between studies conducted in China and Japan was also not significant (MD = 14.87, 95% CI −69.55 to 105.90).

The results of the homogeneity analysis showed that heterogeneity was clearly present (Appendix IV). The results of the nodal analysis confirm that there is no inconsistency in the model ($p > .050$) (Appendix V). The trace plots, density plots, and Gelman–Rubin statistical plots showed that MCMC simulations and convergence were in good condition, while PSRF converged to 1 (Appendices VI–VII). Also, publication bias was not assessed because fewer than 10 studies were included.

Discussion

To confirm the most effective frequency of APE and establish evidence-based recommendations for clinical practice, an NMA was conducted. A literature search identified 805 studies, and after removing duplicates, applying inclusion criteria, and completing a critical appraisal, seven studies were included for analysis. After direct and indirect comparisons of the NMA, evidence from different frequencies of APE was integrated, and the most effective frequency of the NMA was identified.

As an effective exercise to improve lower extremity hemodynamics [5], APE is popular in clinical care practice in patients lying in bed to prevent thrombosis [3,4]. However, although some studies have focused on the frequency selection of APE, there is no consensus on the frequency of APE. Therefore, there is a need to explore the most effective frequency of APE to guide clinical practice and improve the clinical outcomes of APE.

The results of the NMA showed that a frequency of every 3–4 s had the best effect on improving lower extremity hemodynamics, meaning that a frequency of every 3–4 s performed better than a frequency of every 1–2 s. This is quite different from previous studies, which found that faster APE performed better for improving lower extremity hemodynamics [11,13]. This may be because a single contraction of normal calf muscles can expel 60–90 ml of blood [24], whereas faster frequency APE can accomplish more contractions at the same time. Therefore, faster frequency APE can expel more blood at the same time. However, slower frequency of APE can increase the contraction force of calf muscles, which can promote more efficient venous blood return [11]. Thus, Toya et al found that a frequency of once every 4 s had a similar effect on lower limb hemodynamics as exercise without rest [9].

Our findings provide evidence-based recommendations for the frequency selection of APE in clinical practice, and patients will achieve the best clinical outcomes with APE at a frequency of every 3–4 s. Meanwhile, previous studies have found that APE every 3–4 s at 15–20 beats per minute has less post-exercise fatigue comparing to 60 beats per minute and 3 beats per minute [8,11], suggesting that APE every 3–4 s is clinically feasible and easily adhered to. However, our study still contains some limitations. First, most of the included studies were quasi-experimental studies, and all participants in these studies experienced all sets of different frequencies [8–14]. Although the effect of APE on lower extremity hemodynamics is transient and participants experiencing multiple frequencies of APE at different times do not lead to inaccurate results, more RCTs are still needed. Moreover, all included studies were conducted in Asia, and there is a lack of data from other continents. We also searched Chinese local data, while the

lack of local data of other countries. Third, the sample size of the included studies was limited. With the exception of one study with 307 participants, the number of participants in the other studies ranged from 6 to 63, which may increase the risk of false positive results in primary studies.

Conclusion

In this study, we provided evidenced-based recommendations for the clinical practice and standardization of APE through the NMA. APE every 3–4 s at 15–20 beats per minute is most effective in improving lower extremity hemodynamics with less post-exercise fatigue and should be recommended for widespread implementation in clinical practice.

Funding

None.

Conflict of interest

The authors declare that they have no conflict of interests.

Acknowledgments

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Appendix ASupplementary data

The following is the supplementary data to this article.**Multimedia component 1**Multimedia component 1

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.anr.2023.03.001.

Studies	Country	Study design	Research setting	N	Populations	Interventions	Original measurement mean (SD/SEM)	Post-combination frequencies Δ mean (SD)	Fund
Kagaya et al., 1991	Japan	Quasi-experimental study	Research Institute of Physical Fitness	6	Physically active women aged 21–22 years	Extend the ankle joint to 100°, then relaxed to return it to 90°, at frequencies of 20, 40, 60, 80, and 100 contractions/min	Post-exercise hyperemia of calf muscle 20 times/min:43.9 ± 5.3(SEM)% 40 times/min:44.3 ± 5.8 (SEM)% 60 times/min:53.6 ± 3.8 (SEM)% 80 times/min:47.4 ± 5.9 (SEM)% 100 times/min:60.9 ± 4.3 (SEM)%	Once every 3–4 s: 43.9 ± 12.98% Once every 1–2 s: 48.95 ± 12.38% More than once every 1 s: 54.15 ± 13.96%[s]	Not mentioned

Toya et al., 2016	Japan	Quasi-experimental study	University	10	Men without a history of cardiovascular diseases	Repeated dorsiflexion and plantarflexion with different frequencies: 15 times/min, 30 times/min, and 60 times/min.	Peak systolic velocity in the common femoral vein Baseline: 19.9 ± 1.9 cm/s 4 s rest exercise: 72.1 ± 10.4(SD)cm/s 2 s rest exercise: 61.0 ± 15.7(SD)cm/s no rest exercise: 73.7 ± 13.5(SD)cm/s	Once every 3–4 s: 52.2 ± 3.34 cm/s Once every 1–2 s: 47.45 ± 4.99 cm/s	Not mentioned
Nakayama et al., 2016	Japan	Quasi-experimental study	Rehabilitation department of a single private hospital.	29	Patients with unilateral total hip arthroplasty	Three different frequencies of active ankle movement: 40, 60, and 80 contractions per minute.	Mean velocity of blood flow in the profunda femoris Baseline: 11.9 ± 5.2(SD)cm/s 40 times/min: 20.2 ± 9.2(SD)cm/s 60 times/min: 29.4 ± 14.4(SD)cm/s 80 times/min: 26.0 ± 11.5(SD)cm/s	Once every 1–2 s: 12.90 ± 2.57 cm/s More than once every 1 s: 14.1 ± 2.34 cm/s[a]	None

Li et al., 2020	China	Quasi-experimental study	Third Hospital of Hebei Medical University	30	Patients with non-lower limb fracture/patients with limb fracture	Ankle pump exercise with different frequencies: 6 times/min, 10 times/min, 30 times/min, and 60 times/min.	Time-averaged mean velocity (TAMV) of the common femoral venous blood flow patients with non-lower limb fracture: Baseline: 19.82 ± 3.86(SD)cm/s 6 times/min: 34.84 ± 8.30(SD)cm/s 10 times/min: 36.03 ± 9.60(SD)cm/s 30 times/min: 43.15 ± 9.12(SD)cm/s 60 times/min: 52.36 ± 11.69(SD) cm/s Patients with lower limb fracture: Baseline: 16.98 ± 3.01(SD)cm/s 6 times/min: 22.20 ± 4.96(SD)cm/s 10 times/min: 24.01 ± 5.78(SD)cm/s 30 times/min: 29.20 ± 7.05(SD)cm/s 60 times/min: 35.75 ± 9.28(SD)cm/s	Patients with non-lower limb fracture: Baseline: 19.82 ± 3.86 cm/s Less than once every 10 s: 13.96 ± 1.75 cm/s Once every 5–6 s: 17.24 ± 1.73 cm/s Once every 1–2 s: 28.18 ± 2.16 cm/s Patients with lower limb fracture: Baseline: 16.98 ± 3.01 cm/s Less than once every 10 s: 5.22 ± 1.06 cm/s Once every 5–6 s: 7.03 ± 1.19 cm/s Once every 1–2 s: 15.50 ± 1.70 cm/s	Yes

Zhao Huanli et al., 2020	China	Quasi-experimental study	Fourth Clinical Medical College of Yangzhou University	63	Patients after unilateral total hip arthroplasty	Maximum plantar flexion and dorsiflexion of the ankle with different frequencies: 6 times/min, 12 times/min, 15 times/min, 20 times/min, 30 times/min, and 60 times/min.	Peak flow velocity of femoral vein of lower extremity Baseline: 29.17 ± 3.02(SD)cm/s 6 times/min: 36.20 ± 4.68(SD)cm/s 12 times/min: 39.22 ± 5.44(SD)cm/s 15 times/min: 42.14 ± 6.14(SD)cm/s 20 times/min: 48.93 ± 6.31(SD)cm/s 30 times/min: 52.59 ± 6.79(SD)cm/s 60 times/min: 34.71 ± 5.73(SD)cm/s	Less than once every 10 s: 7.03 ± 0.64 cm/s Once every 5–6 s: 10.05 ± 0.78 cm/s Once every 3–4 s: 16.37 ± 0.97 cm/s Once every 1–2 s: 14.48 ± 1.39 cm/s	Yes

Zhou Shanshan et al., 2020	China	Quasi-experimental study	First Hospital of Nanjing Medical University	11	Healthy men	Ankle pump exercise with different frequencies: 5 times/min, 10 times/min, and 15 times/min.	Peak flow velocity of femoral vein Baseline: 33.55 ± 5.67 (SD)cm/s 5 times/min: 45.45 ± 4.95(SD)cm/s 10 times/min: 52.55 ± 4.08(SD)cm/s 15 times/min: 56.09 ± 7.66(SD)cm/s Peak flow velocity of popliteal vein Baseline: 27.36 ± 5.46(SD)cm/s 5 times/min: 31.82 ± 4.90(SD)cm/s 10 times/min: 41.64 ± 5.67(SD)cm/s 15 times/min: 42.55 ± 8.30(SD)cm/s	Less than once every 10 s: 12.54 ± 2.07 cm/s Once every 5–6 s: 19.00 ± 2.11 cm/s Once every 3–4 s: 21.73 ± 3.25 cm/s	Yes

Li et al., 2022	China	RCT	Hospital	307	Healthy adults	Ankle pump exercise with different frequencies: 3 times/min and 30 times/min.	Mean velocity of external iliac vein: Baseline: 21.36 ± 8.13(SD)cm/s 3 times/min: 25.49 ± 9.21(SD)cm/s 15 times/min: 25.98 ± 8.96(SD)cm/s Mean velocity of femoral vein: Baseline: 16.21 ± 6.56(SD)cm/s 3 times/min: 19.18 ± 6.96(SD)cm/s 15 times/min: 18.98 ± 6.63(SD)cm/s Mean velocity of popliteal vein: Baseline: 13.06 ± 5.02(SD)cm/s 3 times/min: 15.12 ± 5.76(SD)cm/s 15times/min: 15.12 ± 5.27(SD)cm/s	Less than once every 10 s: 2.97 ± 0.55 cm/s Once every 3–4 s: 2.77 ± 0.53 cm/s	Yes

Frequency of APE	p score	Ranking
Less than once every 10 s	.02	4
Once every 5–6 s	.32	3
Once every 3–4 s	.85	1
Once every 1–2 s	.81	2

DETAILS

Subject:	Ankle; Veins &arteries; Hemodynamics; Software; Flow velocity; Clinical medicine; Blood; Systematic review; Quasi-experimental methods; Bias; Statistical analysis; Exercise
Identifier / keyword:	ankle; exercise therapy; network meta-analysis; systematic review; venous thromboembolism
Publication title:	Asian Nursing Research; Seoul
Volume:	17
Issue:	2
Pages:	53-60
Publication year:	2023
Publication date:	May 2023
Section:	Review Article
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ISSN:	19761317
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Source type:	Scholarly Journal
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ProQuest document ID:	2819645569
Document URL:	https://www.proquest.com/scholarly-journals/what-frequency- ankle-pump-exercise-is-optimal/docview/2819645569/se-2?accountid=211160
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Incidence and Risk Factors for Radiotherapy-Induced Oral Mucositis Among Patients With Nasopharyngeal Carcinoma: A Meta-Analysis

Li, Juejin [1]
; Zhu, Chuanmei [2]
; Zhang, Yun [1]
; Chang, Guan [1]
; Wang, Qi [1]
; Ding, Yuxin [1]
; Hu, Xiaolin [1]
[1] Department of Nursing, West China Hospital, Sichuan University/West China School of Nursing, Sichuan University, PR China [2] Outpatient Department, West China Hospital, Sichuan University, PR China

ABSTRACT (ENGLISH)

SUMMARYPurpose
To evaluate the incidence and identify the risk factors for radiotherapy-induced oral mucositis among patients with nasopharyngeal carcinoma.
Methods
A meta-analysis was conducted. Eight electronic databases (Medline, Embase, Cochrane Library, CINAHL Plus with Full Text, Web of Science, China National Knowledge Infrastructure, Wanfang Database, and Chinese Scientific Journals Database) were systematically searched from inception to 4 March 2023 for relevant studies. Study selection and data extraction were conducted by two independent authors. The Newcastle–Ottawa scale was used for quality assessment among the included studies. Data synthesis and analyses were performed in R software package version 4.1.3 and Review Manager Software 5.4. The pooled incidence was calculated using proportions with 95% confidence intervals (CIs), and the risk factors were evaluated using the odds ratio (OR) with 95% CIs. Sensitivity analysis and predesigned subgroup analyses were also conducted.
Results
A total of 22 studies published from 2005 to 2023 were included. The results of the meta-analysis showed that the incidence of radiotherapy-induced oral mucositis was 99.0% among nasopharyngeal carcinoma patients, and the incidence of severe radiotherapy-induced oral mucositis was 52.0%. Poor oral hygiene, overweight before radiotherapy, oral pH < 7.0, the use of oral mucosal protective agents, smoking, drinking, combined chemotherapy, and the use of antibiotics at early treatment stage are risk factors for severe radiotherapy-induced oral mucositis. Sensitivity analysis and subgroup analyses also revealed that our results are stable and reliable.
Conclusions

Almost all patients with nasopharyngeal carcinoma have suffered from radiotherapy-induced oral mucositis, and more than half of patients have experienced severe oral mucositis. Facilitating oral health might be the key focus of reducing the incidence and severity of radiotherapy-induced oral mucositis among nasopharyngeal carcinoma patients.

Registration number

CRD42022322035.

FULL TEXT

Introduction

Nasopharyngeal carcinoma is the most common type of otorhinolaryngeal carcinoma, with 133354 new cases and 80008 deaths in 2020 [1]. Due to the deep-seated anatomic location and high sensitivity to ionizing radiation, radiotherapy is the mainstay treatment modality for patients with nasopharyngeal carcinoma. The radiotherapy techniques have progressed from conventional two-dimensional radiotherapy to 3D conformal radiotherapy and then to intensity-modulated radiotherapy over time. The locoregional control and survival have been enhanced by the parallel improved dosimetric properties [2]. Despite improvements in the radiotherapy techniques, the ongoing and intensive irradiation that is required might still cause the normal tissues around the tumor to suffer from a series of acute and chronic radiation toxicities, which lead patients to experience various treatment-related problems and poor quality of life [3]. Radiotherapy-induced oral mucositis is the most frequent and distressing radiation complication, with an incidence ranging from 85.0% to 100.0% among patients with head and neck cancer during therapy [4,5]. Great attention to this unpleasant complication is needed.

Radiotherapy-induced oral mucositis refers to erythematous and painful ulcerative lesions of the oral mucosa and is observed in patients who are treated with radiotherapy combined with or without chemotherapy [6]. The main symptoms of oral mucositis may range from mild discomfort and erythema to painful erythema, and edema and ulcerations [7]. The presence of severe radiotherapy-induced oral mucositis can have detrimental effects on patients' daily functioning and quality of life: unable to eat, drink, and talk due to painful ulceration, ultimately leading to weight loss, nutritional deficiencies, secondary infections, extended length of hospital stay, and increased associated economic costs [8]. What is worse, severe radiotherapy-induced oral mucositis might lead to dose reduction and treatment interruption, which could adversely affect the treatment effects and disease prognosis [9]. At present, the optimal prevention and treatment regimens for radiotherapy-induced oral mucositis are unclear [10]. Although a range of treatments have been used for oral mucositis, such as palifermin, growth factor, cryotherapy, and low-level laser treatment, no treatment is fully effective [11]. Active precaution for a complication beforehand is much easier and cheaper than treating it, and preventive strategies directed towards the risk factors for oral mucositis might effectively decrease the incidence of these complications [12]. Therefore, it is urgent and necessary to determine the risk factors and accordingly develop targeted preventive measures of radiotherapy-induced oral mucositis among patients with nasopharyngeal carcinoma.

Currently, studies on radiotherapy-induced oral mucositis are mainly interventional studies that focus on symptom treatment and the effectiveness of these treatment measures [8,13]. There are only a small number of studies exploring the risk factors for radiotherapy-induced oral mucositis, and the limited studies are mostly focused on patients with head and neck cancer (such as oral cancer and oropharyngeal cancer) [14,15]. Although originating from similar cell or tissue lineages, nasopharyngeal carcinoma is distinctly different from other epithelial head and neck cancers [2]. In addition, the results of existing limited studies are inconsistent. For instance, Xu et al. [16] included 166 patients with nasopharyngeal carcinoma and found that smoking, poor oral hygiene, oral pH less than 7.0, and chemotherapy were risk factors for radiotherapy-induced oral mucositis. Dong et al. [17] explored the risk factors among 116 patients and found that smoking, oral pH less than 6.5, concurrent chemotherapy, and oral irradiation dose more than 32 Gy might contribute to the development of radiotherapy-induced oral mucositis. In addition, the incidence of severe radiotherapy-induced oral mucositis has varied in different studies, with a range from 30% to 100% [18,19]. To the best of our knowledge, no study has systematically explored the incidence and risk factors for

radiotherapy-induced oral mucositis and its incidence among patients with nasopharyngeal carcinoma. Therefore, the objectives of our study are to (1) identify the incidence of radiotherapy-induced oral mucositis among patients with nasopharyngeal carcinoma, (2) explore the possible risk factors for severe radiotherapy-induced oral mucositis in nasopharyngeal carcinoma patients, and (3) provide evidence-based references for developing targeted preventive measures of radiotherapy-induced oral mucositis.

Methods

This meta-analysis was registered with International Prospective Register of Systematic Reviews (http://www.crd.york.ac.uk/PROSPERO), and it was performed and reported according to the updated Preferred Reporting Items for Systematic Review and Meta-analyses (PRISMA2020) guidelines [20].

Eligibility criteria

Two authors independently screened and selected all literature. Studies were included if they met the following inclusion criteria: (1) participants were patients diagnosed with nasopharyngeal carcinoma, aged over 18 years, and received radiotherapy; (2) the exact diagnostic criteria for radiotherapy-induced oral mucositis were available; (3) the incidence or risk factors for radiotherapy-induced oral mucositis were reported; (4) the research types were observational including cross-sectional studies, case-control studies, and cohort studies; and (5) the study language was English or Chinese. The exclusion criteria were as follows: (1) studies did not provide complete data; (2) the full-text of the study was unavailable; and (3) studies were conference abstracts, dissertations, study protocols, and duplicate reports.

Data sources and search strategies

Eight electronic databases, including Medline, Embase, Cochrane Library, CINAHL Plus with Full Text, Web of Science, China National Knowledge Infrastructure (CNKI), Wanfang Database, and Chinese Scientific Journals Database (VIP), were searched from inception to 4 March 2023 for all possible literature. The search strategies were established by using medical subject headings (MeSH) terms, text word searches, and Boolean calculation searches (see supplemental material Table 1). For instance, in Medline of Ovid, the search terms were as follows: Nasopharyngeal neoplasms [Mesh] or “nasopharyngeal neoplasms” or “nasopharynx cancer” or “nasopharyngeal cancer” or “nasopharynx neoplasms” or “nasopharyngeal carcinoma” or NPC OR (nasopharynx [Mesh] or nasopharynx or nasopharyngeal or nasopharyngitis * or rhinopharyngitis * or choanae) and (neoplasms [Mesh] or carcinoma* or cancer* or neoplasm* or tumor* or tumour* or malignancy* or onco*)), and “radiation-induced oral mucositis” or “radiotherapy oral mucositis” or RTOM or ((radiotherapy [Mesh] or radiotherapy* or irradiation* or “radiation therapy”) and (Stomatitis [Mesh] or “oral mucositis” or stomatitis or stomatitides or oromucositis or oromucositides or (oral and (mucositis [Mesh] or mucositis or mucositides or mucosa inflammation). Additionally, the searches were limited to human adults, published in English or Chinese. The reference lists of the relevant studies were also screened for potentially relevant articles.

Study selection and data extraction

The reference management software EndNote X9 was used for data management. After removing duplicates, two authors independently screened the titles and abstracts of all citations in accordance with the inclusion and exclusion criteria. Then, the full-texts of citations were retrieved when considered potentially relevant by either investigator. Each article was evaluated by two independent authors for final study inclusion based on the eligibility criteria. The reference lists of the included studies were also screened for additional possible studies. Disagreements during the selection process were resolved by discussion or consultation with the third author.

Two independent authors extracted relevant data from the included studies using predesigned data collection forms. The following data were collected: the study author, date of publication, study site, study design, sample size, number of female and male patients, mean age, cancer stage, treatment regimen, diagnostic criteria, incidence of radiotherapy-induced oral mucositis, and assessed risk factors.

Quality assessment

Quality assessment was conducted by two independent authors. No cross-sectional studies were included in this study, and the quality of case–control studies and cohort studies was assessed using the Newcastle–Ottawa scale [

[21]. The scale evaluated the quality of the study from three domains: selection of subjects, comparability of study groups, and ascertainment of the exposure or outcome. The total score of the scale ranges from 0 to 9, with scores of 0–3, 4–6, and 7–9 indicating low, moderate, and high quality of each study, respectively.

Data synthesis and analysis

We used R software package version 4.1.3 and Review Manager Software 5.4 for the heterogeneity test and quantitative data synthesis. Heterogeneity among the included studies was evaluated using Cochrane's Q statistic, and the I^2 statistic and *p* value were used to assess the degree of heterogeneity. $I^2 \leq 50\%$ and a *p* value > .050 were regarded as indicating low heterogeneity and a fixed effect model was used to pool the results; otherwise, a random effect model was used to obtain more conservative pooled results. The incidence of radiotherapy-induced oral mucositis was presented as the proportion with 95% confidence intervals (CIs) and analysed using the Freeman-Turkey double-arcsine transformation random-effects model [22] in R software package version 4.1.3. The risk factors of severe radiotherapy-induced oral mucositis were determined by odds ratio (ORs) with 95% CIs in Review Manager Software 5.4. A two-sided *p* value less than .050 was used to indicate a statistically significant difference. In addition, predesigned subgroup analyses were performed according to the study characteristics and the different severities of oral mucositis. A sensitivity analysis was also conducted to test the stability and reliability of the pooled results of incidence and risk factors. Finally, a funnel plot and Egger's linear regression (*p*

Results

Study selection

Our study selection process is presented in Fig. 1. A total of 1453 records were retrieved from eight electronic databases. After removing the duplicates (*n* = 392), another 1020 records were excluded according to the titles and abstracts because the participants were not patients with nasopharyngeal carcinoma (*n* = 148), the studies were not related to radiotherapy-induced oral mucositis (*n* = 536) nor to its risk factors (*n* = 49), and the studies were non–observational studies (*n* = 284), protocol (*n* = 1), and conference abstracts (*n* = 2). Next, the full-texts of 41 citations were retrieved and evaluated based on the eligibility criteria, and 21 studies were excluded for the reasons presented in Fig. 1. Finally, another two records were identified from citation searching were included, a total of 22 studies [16–19,23–40] were included in our systematic review and meta-analysis.

Characteristics of the included studies

Table 1 presents the characteristics of the included studies. The 22 included studies all were observational studies, 12 of which were prospective cohort studies, five was a retrospective cohort study, and another five studies were case–control studies. All these studies were published between 2005 and 2023, and they were from China (*n* = 20), Italy (*n* = 1), and Japan (*n* = 1). The sample size of the included studies ranged from 22 to 1674, and the total sample size was 4507. The mean ages of all the participants ranged from 46.3 to 64.3 years old. Most studies (*n* = 17) included all stages of patients with nasopharyngeal carcinoma, one study included patients at stage, one study included patients at stage T3-4NxM0 or TxN2-3M0 following the Union for International Cancer Control (2010), and three studies included only locally advanced patients (stage). All participants were treated with radiotherapy alone or combined with chemotherapy. The diagnostic criteria of radiotherapy-induced oral mucositis varied in these included studies, grade 2 or above was defined as severe radiotherapy-induced oral mucositis. Specifically, 10 studies [17,23,24,27,28,33,35,38–40] used the Radiation Therapy Oncology Group criteria of acute effects for mucous membranes to assess the grade of oral mucositis. Five studies [16,18,30,32,36] used the World Health Organization oral mucositis grading scale to evaluated the severity of oral mucositis. Five studies [19,25,26,31,34] used the Common Terminology Criteria for Adverse Events to assess the oral mucositis grade. Two studies [29,37] did not report the details of the assessment tool for oral mucositis.

Quality of the included studies

All the included studies were evaluated using the Newcastle–Ottawa scale, and the results are presented in Table 1. Nineteen studies [16–19,24–28,30–32,34–40] were rated as having high quality and low risk of bias, and another three studies [23,29,33] were rated as having moderate quality and moderate risk of bias. In addition, the funnel plots and Egger's linear regression indicated that there was no significant publication bias (*p* = .224) in these included studies (see supplemental material Fig. 1).

Meta-analysis Incidence of radiotherapy-induced oral mucositis

A total of 20 studies with 4135 participants were included in the quantitative meta-analysis, and the incidence of radiotherapy-induced oral mucositis ranged from 50% to 100%. In detail, 16 studies reported that all the participants experienced radiotherapy-induced oral mucositis with an incidence of 100%. In addition, four studies [24, 33, 35, 37] reported that the incidences of oral mucositis were 98%, 90%, 84%, and 50%, respectively. As a high level of heterogeneity (I^2 = 97%, *p* Fig. 2) showed that the incidence of radiotherapy-induced oral mucositis was 99% (95% CI: 96% to 100%).

A sensitivity analysis was performed using a one-study-out method to test the stability and reliability of the pooled results. The pooled estimated incidence of radiotherapy-induced oral mucositis did not change significantly, ranging from 99% (95% CI: 96–100%) to 100% (95% CI: 99–100%) (see supplemental material Fig. 2).

Subgroup analysis

The results of the subgroup analysis showed that the incidences of mild and severe radiotherapy-induced oral mucositis were 46% (95% CI: 36–55%, I^2% = 97%) and 52% (95% CI: 43–61%, I^2% = 98%), respectively (Fig. 3). In addition, the subgroup analyses conducted based on the participant characteristics (gender, cancer stage, and treatment regimen) and study characteristics (study design, study language, sample size, and diagnostic criteria) showed that there were no significant differences no matter the participant and study characteristics (see supplemental material Table 2).

Risk factors for severe radiotherapy-induced oral mucositis

Of the 22 included studies, 17 studies [16, 17, 19, 23, 24, 27, 29, 31–40] reported at least one risk factor that was available for data synthesis, and another five studies [18, 25, 26, 28, 30] did not report relevant data for meta-analysis. The potential risk factors from the included studies were categorized into demographic factors (gender and age), health-related factors (such as BMI, weight loss, oral pH, diabetes, cancer stage, and oral hygiene), and lifestyle-related factors (such as smoking and drinking). Among these factors, nine factors (oral hygiene, oral pH, the use of oral mucosal protective agents, smoking, drinking, overweight before radiotherapy, combined chemotherapy, and the use of antibiotics at early treatment stage, and diabetes) from 14 studies had data that could be used for quantitative meta-analysis. The pooled results showed that poor oral hygiene (OR = 4.78, 95% CI: 2.56–8.91), oral pH Fig. 4).

Discussion

To our knowledge, this is the first meta-analysis to estimate the incidence and to explore risk factors for radiotherapy-induced oral mucositis among patients with nasopharyngeal carcinoma. Most of the included studies in our review were from China, which resulted from the extremely uneven geographical global distribution, with more than 70.0% new cases per year are in East and Southeast Asia [2]. High rates of nasopharyngeal carcinoma have long been observed in the population of Southern China, with an age-standardized rate (world) of 3.0/100000 [2, 41], and accounting for almost a half of nasopharyngeal carcinoma patients worldwide [42]. Although nasopharyngeal carcinoma is relatively uncommon compared with other cancers, it remains a significant public health problem in East and Southeast Asia [43]. Based on the comprehensive search strategy from eight electronic databases and systematic review of relevant studies, our study results provided evidence-based references for developing targeted preventive measures of radiotherapy-induced oral mucositis among patients with nasopharyngeal carcinoma.

Incidence of radiotherapy-induced oral mucositis

The pooled results of the meta-analysis revealed that almost all patients with nasopharyngeal carcinoma have experienced oral mucositis during the radiotherapy process, with a pooled incidence of 99.0%, and more than half (52.0%) of patients suffered from severe oral mucositis, which is as high as that among patients with head and neck cancers [6, 44]. On the one hand, the persistent and concentrated high-dose irradiation can inevitably induce acute and chronic toxicity reactions including radiotherapy-induced oral mucositis [2] in spite of the modern advances in radiotherapy technology. On the other hand, currently, the consistent and targeted assessment tools for oral mucositis are insufficient [45], nurses are unable to evaluate radiotherapy-induced oral mucositis comprehensively during clinical practice, which might cause inadequate attention and underestimation of the severity of oral mucositis among patients with nasopharyngeal carcinoma. In addition, consistent with other countries in the world, patients with nasopharyngeal carcinoma in China usually are treated with outpatient radiotherapy, which means they were

inaccessible to systemic and structured professional care and support compared to the inpatient setting [46], such as basic oral care, oral health education, and coping skills for oral mucositis. Thus, patients with nasopharyngeal carcinoma often suffer from high incidence of radiotherapy-induced oral mucositis, and it is urgent and necessary to pay more attention to nasopharyngeal carcinoma patients and take effective measures for the early identification and prevention of oral mucositis during their treatment process.

To test the reliability and stability of pooled results and explore the potential sources of heterogeneity, we also conducted subgroup analyses on the basis of participant characteristics (gender, cancer stage, and treatment regime) and study characteristics (study design, study language, sample size, and diagnostic criteria). The results showed that the incidence of radiotherapy-induced oral mucositis was similar within subgroups, which suggested that the results were stable and reliable, but there might be other possible sources of heterogeneity among these included studies. For example, the sample sources and age groups varied among the different studies, which might contribute to the high heterogeneity of our study.

Risk factors for severe radiotherapy-induced oral mucositis

This study identified eight significant risk factors for severe radiotherapy-induced oral mucositis among patients with nasopharyngeal carcinoma, including poor oral hygiene, oral pH less than 7.0, the use of oral mucosal protective agents, overweight before radiotherapy, smoking, drinking, combined chemotherapy, and the use of antibiotics. Poor oral hygiene, oral pH less than 7.0, and the use of oral mucosal protective agents are three oral health-related risk factors for severe radiotherapy-induced oral mucositis, among which poor oral hygiene is the most significant risk factor. Previous studies also showed that the status of oral health and hygiene is a risk factor for radiotherapy-induced oral mucositis [47]. However, it was reported that 64.4% of patients who received radiotherapy had poor oral hygiene, and the proportion of poor oral hygiene was much higher among patients with oral mucositis (69.1%) than among patients without oral mucositis (42.9%) [48]. Oral health, starting with good oral hygiene, is essential for patient wellness, and providing oral health education and prevention interventions to promote good oral hygiene can prevent infection by oral bacteria and consequently could reduce the risk and severity of oral mucositis [49,50,58]. In addition, previous studies have already identified that the use of oral mucosal protective agents and interventions promoting the oral pH to shift from an acidic to alkaline could enhance oral protection against mucositis and decrease the susceptibility to oral mucositis among patients [51,52]. Thus, preventive strategies are needed to target facilitating oral health during and even prior to radiation treatment to decrease the risk and severity of oral mucositis among patients with nasopharyngeal carcinoma [50].

Unsurprisingly, smoking and drinking were two other risk factors for severe radiotherapy-induced oral mucositis. A previous study [53] conducted among patients with head and neck carcinoma also revealed that smoking was a risk factor for radiotherapy-induced oral mucositis. Although drinking was not identified as a risk factor in previous studies, alcohol use is one of the leading risk factors for a range of diseases and injury conditions, and there is even a causal relationship between them [54]. As common lifestyle-related risk factors, further targeted strategies and interventions are needed to reduce the utilization of tobacco and alcohol among patients.

This meta-analysis showed that overweight before radiotherapy was a risk factor for radiotherapy-induced oral mucositis, which was inconsistent with Saito et al. [55] who reported significant association between low BMI and oral mucositis. However, as oral mucositis might lead to anorexia, dysphagia, and low BMI during radiotherapy, it is difficult to confirm whether low BMI caused oral mucositis, or the oral mucositis resulted in low BMI. For our result, a previous study [56] has identified the significant correlation between overweight and poor oral conditions, and the possible mechanism is that adipose tissue could cause increased levels of IL-6, IL-8, and TNF- α, resulting in raised leukocytes, which might activate systemic inflammation. Therefore, overweight status before radiotherapy also might be the focus for preventing severe oral mucositis.

Our study showed that concomitant chemotherapy and the use of antibiotics at early treatment stage were treatment-related risk factors for radiotherapy-induced oral mucositis. Although identified as a potential protective factor of oral mucositis, the use of antibiotics at early treatment stage for prevention oral mucositis was not recommended by any guidelines to be used in the prevention of oral mucositis, and caution is needed for antibiotic

utilization among patients [57]. Moreover, due to the toxicity of chemotherapeutics, patients who receive radiotherapy combined with chemotherapy can be definitely more prone to experiencing severe oral mucositis [58], and more attention is needed to patients who receive chemoradiotherapy when providing preventive measures of oral mucositis.

Limitations

Some limitations should be considered when interpreting the results: (1) due to the inconsistent characteristics among the included studies, high heterogeneity existed in our study; (2) some potential risk factors were not available for meta-analysis because they were reported in less than three studies, or reported with incomplete data; and (3) due to the geographical features of nasopharyngeal carcinoma, most of the studies included in our study were published in China. Wider researches with larger sample sizes are needed to further identify the incidence and risk factors for radiotherapy-induced oral mucositis.

Implications for further research and nursing practice

The results of this study showed that almost all nasopharyngeal carcinoma patients inevitably experienced radiotherapy-induced oral mucositis, and more than half of patients even suffered from severe oral mucositis during radiotherapy. Radiotherapy-induced oral mucositis poses negative effects on patients' physical, emotional, and social dimensions and quality of life [58], which should be highly valued as an interdisciplinary problem during clinical practice. Therefore, interventions for effective management of oral mucositis should cover interdisciplinary professionals, including oncology, stomatology, psychology, and nutritional science. For instance, in addition to the symptom management of oral mucositis, it is also essential for regular clinical screening the risk of nutritional and psychological problems [59]. In addition, most risk factors for oral mucositis in our study were modifiable, including oral hygiene, oral pH, the use of oral mucosal protective agents, smoking, drinking, and overweight. Further studies and clinical practitioners should focus on the controllable risk factors and should accordingly develop targeted preventive measures for radiotherapy-induced oral mucositis among patients with nasopharyngeal carcinoma.

Conclusions

This study found that almost all patients with nasopharyngeal carcinoma have experienced radiotherapy-induced oral mucositis, and more than half of patients have suffered from severe oral mucositis during radiation therapy. Poor oral hygiene, oral pH less than 7.0, use of protective agents, smoking, drinking, overweight before radiotherapy, combined chemotherapy, and the use of antibiotics at early treatment stage are risk factors for severe radiotherapy-induced oral mucositis. Wider and larger well-designed studies are needed to explore the risk factors for radiotherapy-induced oral mucositis, and promoting oral health, especially good oral hygiene, might be the key focus of decreasing the risk and severity of radiotherapy-induced oral mucositis among patients with nasopharyngeal carcinoma.

Contributions

Study Design and writing: JJL, XLH and CMZ.
Data Collection: JJL, YZ, CG and QW.
Data Analysis and Interpretation: JJL, CMZ, YXD and XLH.
Manuscript Writing: JJL and XLH.

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Ethical statement

Informed consent and ethical approval were unnecessary, as the data used in this study came from already published studies.

Data availability statement

The authors confirm that the data supporting the findings of this study are available within the article and its supplementary materials.

Conflict of interest

No conflict of interest exists in the submission of this manuscript.

Acknowledgments

We would like to thank the Professor Mary for her support and guidance.

Appendix A Supplementary data

The following is the Supplementary data to this article.**Multimedia component 1**Multimedia component 1

Appendix A Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.anr.2023.04.002.

Study ID	Country	Study design	Sample size	Women/Men	Mean age	Cancer stage	Treatment regimen	Diagnostic criteria	Incidence of RTOM	Assessed risk factors	NOS score/risk of bias
Chen et al., 2021a	China	Case-control study	240	71/169	51.3	All stages	Chemo-radiotherapy	RTOG criteria	131/240	Concurrent chemotherapy, mean oral cavity dose, Vitamin B2, Vitamin C	6/moderate
Cheng et al., 2014	China	Prospective cohort study	85	28/57	50	Stage II-IV	Chemo-radiotherapy	RTOG criteria	83/85	Smoking, diabetes, BMI	8/low
Dong et al., 2021	China	Prospective cohort study	115	34/81	54.4	All stages	Chemo-radiotherapy	RTOG criteria	115/115	Smoking history, oral pH ≤ 6.5, concurrent chemotherapy, oral mucosa dose≥32 Gy, did not use mouthwash	8/low
Kawashita et al., 2023	Japan	Retrospective cohort study	22	NA	64.5	All stages	Radiotherapy or chemo-radiotherapy	CTCAE V5.0	22/22	/	7/low

Li &Zheng, 2011	China	Prospective cohort study	150	66/84	50	All stages	Radiotherapy	WHO OM Grading scale	150/150	/	8/low
Li et al., 2013	China	Prospective cohort study	114	36/78	49.6	All stages	Radiotherapy or chemo-radiotherapy	CTCAE V3.0	114/114	/	9/low
Li et al., 2017	China	Prospective cohort study	92	25/67	NA	Stage T3-4NxM0 or TxN2-3M0	Chemo-radiotherapy	RTOG criteria	92/92	Body weight loss, V30 ≥ 70%	9/low
Li et al., 2020a	China	Prospective cohort study	270	207/63	50	All stages	Chemo-radiotherapy	RTOG criteria	270/270	/	9/low
Li et al., 2020b	China	Case-control study	120	44/76	NA	All stages	Radiotherapy	NA	120/120	BMI>24, smoking, drinking, oral care, oral pH < 7.0, antibiotics, oral mucosal protective agents, chemotherapy	6/moderate
Liu et al., 2023	China	Retrospective cohort study	190	135/55	46.3	All stages	Chemo-radiotherapy	WHO OM grading scale	190/190	/	8/low
Luo et al., 2005	China	Prospective cohort study	102	34/68	47.9	All stages	Radiotherapy or chemo-radiotherapy	CTCAE V2.0	102/102	Chemotherapy, oral hygiene, antibiotics, smoking	9/low
Orlandi et al., 2018	Italy	Retrospective cohort study	132	40/92	49	Stage II-IVB	Chemo-radiotherapy	CTCAE V4.0	40/132	BMI ≥ 30 kg/m^2, combined parotid glands EUD	7/low

Pang &Yi, 2020	China	Prospective cohort study	120	59/61	53.8	All stages	Radiotherapy	WHO OM grading scale	120/120	Smoking, oral care, mouth PH < 7.0, antibiotics, chemotherapy, oral mucosal protective agents	9/low
Peng et al., 2016	China	Case-control study	1674	434/1240	48	All stages	Radiotherapy	RTOG criteria	1500/1674	Diabetes, prediabetes, smoking, cancer stage	6/moderate
Song et al., 2023	China	Retrospective cohort study	228	59/169	NA	All stages	Radiotherapy or chemo-radiotherapy	CTCAE V5.0	228/228	Modified nutrition index	8/low
Sun et al., 2020	China	Prospective cohort study	96	36/60	59.2	Stage II-IV	Chemo-radiotherapy	RTOG criteria	81/96	Smoking, diabetes, white blood cell	8/low
Study ID	Country	Study design	Sample size	Female/male	Mean age	Cancer stage	Treatment regimen	Diagnostic criteria	Incidence of RTOM	Assessed risk factors	NOS score/risk of bias
Wang et al., 2017	China	Prospective cohort study	92	39/53	52.4	All stages	Radiotherapy	WHO OM grading scale	92/92	Smoking, oral care, oral pH < 7.0, antibiotics, oral mucosal protective agents, chemotherapy	9/low
Wang et al., 2022	China	Case-control study	172	77/95	53.1	All stages	Radiotherapy or chemo-radiotherapy	NA	86/172	Smoking, oral hygiene, drinking, oral pH < 7.0, overweight, antibiotics, chemotherapy, oral mucosal protective agents	7/low
Wu et al., 2022	China	Prospective cohort study	88	28/60	54.4	Stage I-III	Radiotherapy or chemo-radiotherapy	RTOG criteria	88/88	Smoking, diabetes, oral pH < 7.0	7/low

Xu et al., 2019	China	Case-control study	166	74/92	NA	All stages	Radiotherapy	WHO OM grading scale	166/166	Smoking, oral hygiene, chemotherapy, oral pH, oral mucosal protective agents, antibiotics	7/low
Yuan et al., 2022	China	Retrospective cohort study	183	34/149	NA	All stages	Radiotherapy or chemo-radiotherapy	RTOG criteria	183/183	Chemotherapy, white blood cell, hemoglobin	8/low
Zhu et al., 2014	China	Prospective cohort study	56	16/40	47	All stages	Radiotherapy	RTOG criteria	56/56	White blood cell, diabetes	7/low

DETAILS

Subject:	Quality of life; Software packages; Mucositis; Citation management software; Medical prognosis; Erythema; Cross-sectional studies; Cancer therapies; Medical Subject Headings-MeSH; Risk factors; Cohort analysis; Head &neck cancer; Tumors; Radiation therapy; Chemotherapy
Identifier / keyword:	incidence; meta-analysis; nasopharyngeal carcinoma; risk factors; stomatitis
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Advanced Practice Nurses' Organization Commitment: Impact of Job Environment, Job Satisfaction, and Person-Organization Fit

Kim, Yeon Hee [1]
; Soo Il Shin [2]
; Kim, Hye-Kyung [3]
; Jun, Myunghee [4]
; Wreen, Michael [5]
[1] University of Ulsan, Republic of Korea [2] Department of Information Systems and Security, Kennesaw State University, USA [3] Department of Philosophy, University of Wisconsin-Green Bay, USA [4] Department of Nursing and Health Studies, University of Wisconsin-Green Bay, USA [5] Department of Philosophy, Marquette University, Milwaukee, USA

ABSTRACT (ENGLISH)

SummaryPurpose
The demand for advanced practice nurses (APNs) has increased globally due to a shortage of physicians and an increased demand for high-quality healthcare. Research is needed on the enhancement of advanced practice nurses' organization commitment. Organization commitment (OC) directly impacts the retention of APNs. This study aims to identify the key factors affecting the OC of advanced practice nurses.
Method
A cross-sectional survey was conducted at the largest hospital in South Korea. A total of 189 APNs answered survey questions. A partial least squares-structural equation modeling method was employed to analyze the survey responses.
Results
A pay scale of APNs is positively associated with person-organization fit (POF). However, the effect of job location and computer self-efficacy on POF is not significant. Job satisfaction plays a salient direct role in supervision and POF. Job satisfaction is also a significant moderator in the relationship between supervision and POF. POF is significantly associated with both OC and supervision. Supervision has a positive effect on organization commitment.
Conclusions
Pay scale, job satisfaction, supervision, and POF are significant factors affecting organization commitment. Establishing an intra-organization entity, such as APN steering committee, to ensure mutual consensus and transparent communication between administrators and APNs would enhance POF, the rating of supervision, and organization commitment.

FULL TEXT

DETAILS

Subject:	Research; Variables; Supervision; Job performance; Retention; Employee turnover; Work environment; Job satisfaction; Supervisors; Health care; Computer literacy; Physicians; Advanced practice nurses
Business indexing term:	Subject: Supervision Job performance Retention Employee turnover Work environment Job satisfaction Supervisors
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Performance of Early Warning Scoring Systems Regarding Adverse Events of Unanticipated Clinical Deterioration in Complementary and Alternative Medicine Hospitals

Hwang, Jee-In [1]
; Park, Jae-Woo [2]
; Kim, Jinsung [3]
; Na-Yeon Ha [4]

[1] College of Nursing Science, Kyung Hee University, Seoul, Republic of Korea [2] Department of Gastroenterology, Kyung Hee University Gangdong Korean Medicine Hospital, Seoul, Republic of Korea [3] Department of Gastroenterology, Kyung Hee University College of Korean Medicine, Kyung Hee University Medical Center, Seoul, Republic of Korea [4] Division of Digestive Diseases, Department of Internal Korean Medicine, Kyung Hee University Medical Center, Seoul, Republic of Korea

ABSTRACT (ENGLISH)

Purpose

This study aims to examine the performance of early warning scoring systems regarding adverse events of unanticipated clinical deterioration in complementary and alternative medicine hospitals.

Methods

A medical record review of 500 patients from 5-year patient data in two traditional Korean medicine hospitals was conducted. Unanticipated clinical deterioration events included unexpected in-hospital mortality, cardiac arrest, and unplanned transfers to acute-care conventional medicine hospitals. Scores of the Modified Early Warning Score (MEWS), National Early Warning Score (NEWS), and National Early Warning Score 2 (NEWS2) were calculated. Their performance was evaluated by calculating areas under the receiver-operating characteristic curve for the event occurrence. Multiple logistic regression analyses were performed to determine the factors associated with event occurrence.

Results

The incidence of unanticipated clinical deterioration events was 1.1% (225/21101). The area under the curve of MEWS, NEWS, and NEWS2 was .68, .72, and .72 at 24 hours before the events, respectively. NEWS and NEWS2, with almost the same performance, were superior to MEWS (p = .009). After adjusting for other variables, patients at low-medium risk (OR = 3.28; 95% CI = 1.02–10.55) and those at medium and high risk (OR = 25.03; 95% CI = 2.78–225.46) on NEWS2 scores were more likely to experience unanticipated clinical deterioration than those at low risk. Other factors associated with the event occurrence included frailty risk scores, clinical worry scores, primary medical diagnosis, prescribed medicine administration, acupuncture treatment, and clinical department.

Conclusions

The three early warning scores demonstrated moderate-to-fair performance for clinical deterioration events. NEWS2 can be used for early identification of patients at high risk of deterioration in complementary and alternative medicine hospitals. Additionally, patient, care, and system factors need to be considered to improve patient safety.

FULL TEXT

DETAILS

Subject:	Comorbidity; Workforce planning; Medical records; Acupuncture; Patient safety; Frailty; Blood pressure; Mortality; Research design; Medical research; Body temperature; Hospitals; Consciousness; Respiration; Alternative medicine; Coronaviruses; Intensive care; Clinical outcomes; COVID-19
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Relationship Between Trunk Control Ability and Respiratory Function in Stroke Patients: A Scoping Review and Meta-Analysis

Hsiang-Chu Pai [1]
; Chia-Chi, Li [2]
[1] Department of Nursing, Chung-Shan Medical University, Chung-Shan Medical University Hospital, Taiwan [2] Department of Nursing, Chung-Shan Medical University Hospital, Taiwan

ABSTRACT (ENGLISH)

summaryPurpose
Hemiparesis in stroke survivors has been reported to affect respiratory function. The relationship between trunk control and respiratory function, however, is not well understood. We aimed to map the state of the association between the trunk and respiratory function as well as evaluate the effect of a respiratory function training intervention on trunk control for stroke survivors.
Methods
A scoping review and meta-analysis of observational and interventional studies were performed. Cochrane Library, CINAHL with Full Text (EBSCO), Medline (Ovid), and PubMed were searched using the terms *stroke*, *respiratory*, and *trunk control*. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR) checklist was used to examine the sections of each report.
Results
A total of 102 studies were identified, of which 12, published between 2011 and 2022, were included in the meta-analysis or narrative synthesis. Three studies were included in the meta-analysis of the correlation between trunk control and respiratory function parameters (forced vital capacity [FVC], forced expiratory volume during the first breath [FEV1], maximal inspiratory pressure [MIP], and maximal expiratory pressure [MEP]) with effect sizes (Fisher's *z*) for all outcomes, which ranged from small to intermediate (between 0.21 and 0.39). Furthermore, five studies were included in the meta-analysis of the effect of respiratory function training intervention on trunk control. An overall effect size (Cohen's *d*) of 1.47 corresponds to a large effect. We also found significant improvements in MIP and MEP but not in FVC and FEV1 for stroke survivors with the interventions.
Conclusions
Respiratory training, use of diaphragmatic resistance exercise or abdominal breathing, use of a pressure threshold-loading device, and the performance of functional strengthening exercises for the trunk muscles were found to increase patients' trunk control and improve their respiratory muscle strength.

FULL TEXT

Introduction
A stroke often leaves the patient with hemiparesis, a condition that can interfere with the normal postural control of the trunk [1]. A previous study has shown that 96.4% of patients with stroke have trunk impairment [2]. Hemispheric ischemic stroke has been reported to affect respiratory function to some extent due to reduced chest wall and diaphragmatic excursions contralateral to the stroke [3]. Annoni et al. [4] reported that the mechanical limitation of thoracic excursion caused by weakness, hypotonicity, and incoordination of the trunk musculature creates a restrictive respiratory syndrome. In a systematic review and meta-analysis, Pozuelo-Carrascosa et al. [5] found that respiratory muscle training improved respiratory function and walking ability in patients with stroke. However, they did not evaluate the relationship between respiratory function and trunk impairment or trunk control.
Another systematic review indicated that although diverse aspects of the clinical progression in stroke ambulation capacity or trunk stability are directly related to respiratory function, respiratory training programs fail to include ambulation and trunk stability [6]. Filha et al. [7] noted that inspiratory muscle strength is associated with functional mobility in patients with stroke. These results suggest that attention must be paid to trunk injury and respiratory function in patients with stroke.

From a nursing perspective, because of the inability to balance their bodies, in the ward, patients are often seen to be reclining when lying in bed or sitting up. Furthermore, the imbalance may result in an unsteady gait and falls [8]. In a systematic review on the care practices for patients with stroke, Clarke [9] reported that nurses' participation in poststroke patient rehabilitation is limited. Clarke further recommended that stroke-specific rehabilitation skills should be integrated into the nursing practice, which will help improve outcomes in stroke survivors. Similarly, Meng et al. [10] suggested that participation of nurses is important for the rehabilitation of patients with stroke. In addition to receiving physical therapy from a rehabilitation therapist, patients with stroke should receive relevant care from the nurses in the ward, to improve trunk control and postural stability. A preliminary understanding of the relationship between trunk damage and respiratory function may help nurses design their nursing tasks to promote trunk stabilization in patients with stroke. Therefore, we conducted a scoping review [11] to clarify the relationship between trunk control and respiratory function. A scoping review helps with the mapping of the body of literature regarding the relationship between trunk control and respiratory function and can also facilitate the presentation of an overview of a potentially large and diverse body of literature pertaining to a broad topic. Therefore, the articles found were not limited to randomized controlled trials (RCTs) or required the best available evidence [11].

Methods Aim

The present study aimed to systematically map the evidence on the relationship between trunk control and respiratory function as well as determine the effect of respiratory muscle training on trunk control for stroke survivors. The specific research questions were as follows: (1) What is the association between trunk control and respiratory function? (2) What is the effect of the respiratory function training on trunk control?'

Study design

This study, which was designed as a scoping review and meta-analysis, was conducted and reported as per the guidelines formulated by the *Joanna Briggs Institute (JBI) Manual for Scoping Reviews* [12] and the *Cochrane Handbook* for analyzing data and undertaking meta-analyses [13]. The Preferred Reporting Items for Systematic reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR) checklist was also used to guide the reporting of each section of this report [14]. The project was preregistered on the Open Science Framework (OSF) (https://osf.io/7nup6) before the data extraction to provide transparency of the process and limit the occurrence of reporting bias [12].

Search strategy

A three-step search strategy, as suggested by Peters et al. [12], was utilized. First, the first researcher (Hsiang-Chu Pai) conducted an initial limited search in Medline (Ovid) and CINAHL databases between April and May 2022 using the following terms: *stroke AND respiratory AND trunk*. From this initial search, key studies were identified and screened for other relevant search terms by title, abstract, and keywords. We also used an automation tool (Word Frequency Analyzer, https://sr-accelerator.com/#/wordfreq) to identify the relevant research terms [15]. Second, following an iterative process, authors (Hsiang-Chu Pai and Chia-Chi Li) finalized the search, using the following terms: *(stroke or cerebrovascular accident or CVA or cerebral vascular event or CVE or transient ischemic attack or TIA) AND (lung function or lung function test or pulmonary function or pulmonary function test or respiratory function or respiratory function test) AND (trunk control or postural control or core stability or trunk stability or Trunk Impairment Scale or trunk balance or trunk)*. In addition, all observational studies (e.g., correlational, cohort, case control, and cross-sectional studies) or those using experimental study design, related to respiratory function and trunk impairment or trunk control, were included. The search of the index terms were then undertaken across four major databases (Cochrane Library, CINAHL with Full Text (EBSCO), Medline (Ovid), and PubMed) from January 1990 (or inception) to May 2022. Third, we identified additional studies through other resources, including Google Scholar, and checked the reference lists of all identified sources (Appendix 1).

Screening and data extraction

The selection criteria, set to identify the studies with considerable data on the relationship between respiratory function and trunk control in patients with stroke, included the following: (1) adult patients with stroke (hemorrhage or ischemic) and (2) outcome variables were respiration muscle function parameters (including forced expiratory

volume during the first breath [FEV_1] and forced vital capacity [FVC]), parameters of respiratory muscle strength (including maximal expiratory pressure [MEP] and maximal inspiratory pressure [MIP]), as well as other parameters related to pulmonary function and functional capacity, including trunk impairment, trunk stability, and trunk control. Exclusion criteria were (1) clinical trial protocols that did not include the results and (2) any study topic that did not meet the inclusion criteria.

In a total of 102 record studies, 35 duplicate studies were removed, and the remaining 67 studies were then entered into a two-stage screening process (title/abstract and full-text). All the study selection was performed by authors (OOO and OOO). Finally, we identified 12 studies that met our review objectives and all inclusion criteria (Figure 1).

Methodological quality appraisal

Assessment for publication bias was not performed because the included studies were less than 10 for each meta-analysis [16]. However, we used the 8-item Joanna Briggs Institute (JBI) critical appraisal tool/for analytical cross-sectional studies to assess the quality of four studies [17]. Articles scoring >7, 5–7, and 18]. In addition, a 13-item checklist for RCT was used to assess the quality of eight studies [19], and a score above 7 points were considered as high quality [20].

Data syntheses and meta-analysis

A meta-analysis was conducted to examine the correlation between trunk control and respiratory function. Data synthesis was also performed when the study reported on the effects of breathing training on trunk control.

All the effect sizes (ES), Fisher's *z*, and Cohen's *d* were calculated. Before combining the findings, a fixed or random model was developed, based on the heterogeneity test. The *I*-squared (I^2) statistic and the Cochran chi-squared (Cochran *Q*) test were used to examine heterogeneity. As a guide, if the I^2 value was 75% to 100%, it indicated considerable heterogeneity, calling for the use of random-effects estimation. In addition, a *p*-value of .10 (rather than .05) was used to determine statistically significant heterogeneity in the Cochran chi-squared test [13,21]. All data arrangement for the meta-analysis was performed using the Review Manager (RevMan; The Cochrane Collaboration) software, version 5.4.

Ethical consideration

This scoping review and meta-analysis included only summary data or statistics from previously published studies; therefore, this study did not require a review or an approval by an institutional review board (IRB).

Results Study demographics and characteristics

Following the JBI framework for scoping review [12] and the inclusion criteria listed above, a total of 12 studies were identified. Four of the 12 studies were observational (Table 1), and the other eight were interventional (Table 2). All 12 studies were published between 2011 and 2022. The mean age of the participants reported in these studies ranged from 55.20 to 56.30 years. The geographic and ethnic representation of these studies included South Korea (*k* = 7), Brazil (*k* = 2), Spain (*k* = 1), China (*k* = 1), and Turkey (*k* = 1). Fewer studies from Western settings were found in this scoping review.

Quality of included studies

The JBI appraisal checklist for the four cross-sectional studies revealed that two studies [22,23] did not describe whether there were confounding factors or discuss whether confounding factors affected the results. Their risks of bias scores were 5 and 6, respectively, which indicated a moderate risk of bias [18]. For two other studies [24,25], the score of the risk of bias was 8 (low risk of bias) [18]. The results of the quality assessment are presented in a supplementary document (Appendix 2).

Additionally, the JBI appraisal checklist for the eight RCTs studies show that the risk of bias ranged from 8 to 12 (a low risk of bias) [18]. In two studies [26,27], all the assessors were blinded. In only one study [28], both those who provided the treatment and the participants were blinded. Although another study stated that it was single-blind, the text only reads “All the evaluations and trainings were performed by separate …, ” and it was impossible to confirm whether the therapist or the evaluator was blinded [29]. Four studies [30–33] did not clearly state whether the participants, assessors, or those providing treatment, were blinded. The results of the quality assessment are presented in a supplementary document (Appendix 3).

Correlations across different respiratory function indices and trunk control

Four studies examined the relationship between trunk control and respiratory function (Table 2). Participants in three studies were in the presubacute stage—the mean time since stroke ranged from 14.90 to 64.83 days [23–25]. In only one study, the mean time since stroke was 36.6 months [22]. Most studies used the Trunk Impairment Scale (TIS) [34] to measure the patients' trunk control ability. In addition, four indices, two each of respiratory muscle function (FVC, FEV_1) and respiratory muscle strength (MIP, MEP), were included in the assessments in all four studies. Lee et al. [25], however, did not perform a correlation analysis of TIS with respiratory muscle function (FVC, FEV_1) or strength (MIP, MEP) but presented the predictive value of TIS on VO_2max. Thus, in the present study, three studies were included in the meta-analysis [22–24].

Of the three studies included, the total number of participants included in the meta-analysis was 117. The sample size of studies ranged from 21 to 52. As shown in Figure 2, there was a significant positive correlation between trunk control and FVC and FEV_1; the pooled Fisher's *z* was 0.39 (95% confidence interval [CI] = 0.21, 0.58) and 0.32 (95% CI = 0.13, 0.51), with no significant heterogeneity (I^2 = 0%). There was also a significant positive correlation between trunk control andMIP_1; the pooled Fisher's *z* was 0.21 (95% CI = 0.02, 0.40), with no significant heterogeneity (I^2 = 49.0%). The pooled Fisher's *z* between trunk control and MEP was 0.52 (95% CI = 0.17, 0.87) with significant heterogeneity (I^2 = 79.0%).

Assessment of the effect of respiratory function training on trunk control, pulmonary function, and pulmonary strength

Among the 12 studies included, seven examined the effects of respiratory function training on trunk control [26–32], together with respiratory muscle function (FVC, FEV_1) and respiratory muscle strength (MIP, MEP). Therefore, we conducted a meta-analysis for these outcome variables separately. Another interventional study [33], which also focused on trunk control, was not included in the meta-analysis because it used different respiratory function assessment tools (maximal voluntary ventilation [MVV]), so we additionally performed a narrative synthesis. The length of the interventions ranged from 3 to 8 weeks. Most participants were in the subacute stage of stroke recovery, about 1 week to several months after the stroke.

Four of the 8 studies used TIS as a measurement tool and as a trunk control variable [26,29–31]. Tovar-Alcaraz et al. [28] used the trunk control test (TCT) measure as the trunk control variable. We calculated the results of these five studies as effect size (Cohen's *d*) and performed the meta-analysis. The total number of participants included in the analysis was 81 in the experimental group and 80 in the control group. The meta-analysis revealed an overall effect size (Cohen's *d*) of 1.47 (95% CI: 0.46–2.48; I^2 = 86.0%, p = .004), corresponding to a large effect, significantly different from 0 (Figure 3a).

We also examined the effect of respiratory function training on pulmonary function (FVC, FEV_1) and pulmonary strength (MIP, MEP). As some studies used different units of the parameters (e.g., %, liter, cmH_2O), we converted these results to effect size (Cohen's *d*). The FVC was analyzed in six studies [20,22–26], and the total number of participants included in the analysis was 97 in the experimental group and 95 in the control group. The pool effect size (Cohen's *d*) was 0.39 (95% CI: −0.30 to 1.09; I^2 = 80.0%, p = .27) (Figure 3b). The analysis did not show significant differences between the ES of the groups in regard to FVC. In addition, FEV_1 was analyzed in seven studies [26–32], with a total number of participants of 110 in the experimental group and 107 in the control group. The pooled effect size (Cohen's *d*) was 0.27 (95% CI: −0.00 to 0.54; I^2 = 58.0%, p = .05) (Figure 3c). The analysis again did not show significant differences between the ES of the groups in regard to FEV_1.

Other respiratory muscle strength parameters (MIP, MEP) were analyzed in four studies [20,21,25,26], and the total number of participants included in the analysis was 70 in the experimental group and 67 in the control group. The pooled estimated ES on MIP was 0.54 (95% CI: 0.20 to 0.88; I^2 = 0%, p = .002), and the pooled estimated ES on MEP was 0.63 (95% CI: 0.28 to 0.97; I^2 = 0%, p

Finally, only one study reported on the performing neck stabilization exercises with breathing retraining and evaluation of the MVV [33]. This study found that the corresponding intervention can increase trunk stability while improving postural control and activity of the trunk's respiratory muscles in stroke patients.

Discussion

We conducted a scoping review to map the body of literature on the relationship between trunk control and respiratory function, and the included studies were observational or RCTs in design. For eligible studies, study appraisal and meta-analysis were performed. However, one study data could not be integrated into the analysis; therefore, it was reported in the discussions as a narrative synthesis. Overall, the results of the present study show a significant positive relationship of trunk control with respiratory muscle function (FVC, FEV_1) and respiratory muscle strength (MIP and MEP). We also found significant effects of specific respiratory function training on trunk control, MIP, and MEP but not on FVC and FEV_1.

A previously published study summarizes the evidence in regard to respiratory impairments in major neurological diseases and reports that trunk motor control impairment shows an association with pulmonary function in stroke survivors [6]. Our study extended the findings of Valenza et al. [6] and focused on the search strategies for trunk control and respiratory function. We included three studies with a total of 117 stroke patients, and we performed a meta-analysis based on different lung function indices. Our results show that patients who have better trunk control present better FVC, FEV_1, MIP, and MEP. All three indicators, FVC, FEV_1, and MEP are related to the expiratory function or expiratory muscle. Our results appear consistent with a previous report, which indicated that trunk paresis can lead to postural dysfunction, which promotes a decrease in the activation of the abdominal muscles and leads to a decrease in the values of the maximum pulmonary pressures related to respiration. Thus, these changes promote a decrease in expiratory pressure and FEV [35,36]. In addition, Harik-Khan et al. [37] report that MIP is an indicator of inspiratory muscle strength, determined by having the subject expire to a residual volume and then perform a maximum inspiratory maneuver. Clearly, that MIP is indirectly related to the amount of exhalation and explains the correlation between trunk control and MIP. Our findings also confirm those of Lee et al. [25], who indicated that VO_2max, which reflects cardiopulmonary function, is significantly associated with poststroke trunk control. These findings suggest that the stability of the trunk in stroke patients is related to their respiratory function and respiratory muscle strength. Therefore, we suggest that nurses should be able to assess the extent of trunk damage in a timely manner to promote the care of stroke patients. They should also pay more attention to the assessment and care of the respiratory function of such patients.

Regarding the effects of specific respiratory function training on trunk control, our results showed the effectiveness of respiratory interventions to improve trunk control in patients with stroke. It is worth noting that we found that the interventions in the studies were diverse and included inspiratory muscle training (IMT) [28,29], chest resistance exercise [30], respiratory exercise using respiratory exercise equipment (i.e., Lung Boost Respiratory Trainer MD8000) [31], and conventional rehabilitation training combined with Liuzijue exercise [26]. These studies, however, use trunk control as the outcome variable. In addition, common to these interventions is that breathing training involves (a) the use of diaphragmatic resistance exercise or abdominal breathing; (b) the use of a pressure threshold-loading device; and (c) the performance of functional strengthening exercises for the trunk muscles. It is important to promote stroke survivors' respiratory function, by stretching the latissimus dorsi muscle and using the functional strengthening exercises for the trunk muscles [29]. These results also echo our findings in regard to three other studies that show that respiratory muscle training with trunk stabilization exercises [27], dynamic core-postural chain stabilization exercises [32], and neck stabilization exercises with breathing retraining can increase trunk stability [33], while improving postural control and the activity of the trunk's respiratory muscles in stroke patients. These findings are also in keeping with the findings of Hodges and Gandevia [1], indicating that the diaphragm, which is a primary inspiratory muscle, is also among the trunk stabilizer muscles. This also illustrates the importance of abdominal or diaphragmatic breathing in stabilizing the trunk and promoting respiratory function in stroke patients. We found that these interventions resulted in significant improvements in MIP and MEP. However, the interventions in the experimental groups were not better than those in the control groups in improving FVC and FEV_1. This may be related to the duration of the intervention because the intervention period for the eight studies included in this study was between 3 and 8 weeks [26–33]. This finding shows that the promotion effect of intervention on MIP and MEP can be seen within this short period; however, the effects of FVC and FEV1 may require longer intervention time. This

also indicates that the combined effect of improving respiratory function and trunk control in stroke patients requires further research. However, it is worth noting that nurses can provide bedside care in clinical settings to assist the stroke survivors in stabilizing their trunks, including abdominal breathing training, guidance on sitting posture stability, and the correct posture when lying in bed. These will promote the stability of the trunk and improve the respiratory function.

Limitations

Because the number of relevant studies and the number of participants were small, we recommend that more studies focusing on interventional trunk control be analyzed in future. We also suggest that increasing the number of participants can strengthen the findings. In addition, due to the small number of studies, we could not conduct a meta-analysis of subgroups (e.g., age, gender, hemiplegic limbs). Therefore, we also suggest that future research select samples based on patients of different ages or different hemiplegic limbs, which will be able to provide more specific clinical care applications.

Conclusion

Our study was the first to map the positive relationship between trunk control and respiratory function in stroke patients. We also found that respiratory function training combined with abdominal movement of the diaphragm can improve trunk control and further strengthen the patient's MIP and MEP. Our research extends the findings of Pozuelo-Carrascosa et al. [5], who found that respiratory muscle training can promote stroke survivors' respiratory function. However, their study did not focus on the relationship between respiratory function and trunk impairment or trunk control. Our findings provide further insight into the positive relationship between trunk control and respiratory function.

Conflict of interest

The authors declare no conflicts of interest in this study.

Appendix A Supplementary data

The following are the supplementary data to this article.**Multimedia component 1**Multimedia component 1

Appendix A Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.anr.2023.04.001.

Study/country	Time since stroke/Participants	Study design	Assessment measure	Major findings
Jandt et al., 2011 [22] Brazil	Mean time since stroke was 36.60 (SD = 23.90) months 21 stroke patients: 9 women, 12 men; mean age = 58.90 (SD = 13.50) years	Observational	TIS MIP MEP FVC FEV1 PEF TIFF	Trunk control had a significant positive correlation with PEF (r = .489, p = .024) and MEP (r = .517, p = .016). No relation was found between FVC, FEV1, TIFF, MIP, and TIS (r = .38, .34, .39, .43, p > .5).

Santos et al., 2019 [23] Brazil	Mean time since stroke was 14.90 (SD = 26.30) days 44 stroke patients: 25 women, 19 men; mean age = 59.40 (SD = 12.20)	Cross-sectional	TIS MIP MEP FVC FEV1 TIFF FEV1/FVC FIM	Trunk control had a significant positive correlation with MIP, FVC, FEV1, and FIM (r = .26, .28, .29, .77, p < .05) Mean of MEP was 36.1 (SD = 18.6), and TIS was 14.4 (SD = 5.8).
Jeong et al., 2020 [24] Korea	Mean time since stroke was 68.83 (15–167) days 52 stroke patients: 34 men, 18 women; mean age 57.46 (range from 29 to 84) years	Observational	TIS MIP MEP FEV1 FVC PCF	PCF, FVC, and FEV1 were significantly correlated with poststroke trunk balance (r = .65, p < .001, .45: p < .001, 0.32: p = .026). MIP and MEP, however, were not significantly correlated with poststroke trunk balance (r = .01, p = .96, .17; p = .239).
Lee et al., 2022 [25] Korea	Mean time since stroke was 64.83 (SD = 45.62) days 71 stroke patients: 46 men, 25 women; mean age 58.72 (SD = 13.96)	Observational, longitudinal follow-up study	TIS MIP MEP FEV1 FVC FEV1/FVC VO2max.	MIP, MEP, FVC, FEV1, and FEV1/FVC were not associated with maximum oxygen consumption (VO2max). VO2max was significantly associated with the post-stroke Trunk Impairment Scale (β = 0.31, p = .006).

Study/country	Time since stroke/Participants/Study design	Intervention/Control	Measure	Major findings
Song &Park, 2015 [30] Korea	Mean time (months) since stroke was TG = 4.70 (SD = 1.69); CG = 3.95 (SD = 1.63) 40 stroke patients: TG = 20, mean age 55.50 (SD = 11.43) years; CG = 20 mean age = 58.30 (SD = 11.10) years Randomized-controlled study	Intervention: Chest resistance exercise group (CREG). Control: Chest expansion exercise group (CEEG). Time: 30 min a day, 5 times a week, for 8 weeks.	TIS FVC FEV1	Post-intervention TIS mean score: TG = 14.13 (SD = 0.92); CG = 12.07 (SD = 1.17) Both groups were effective in improving respiratory function and trunk control ability.

Lee &Kim, 2018 [31] Korea	Mean time (months) since stroke: N/A 24 stroke patients: TG = 12, mean age 61.7 (SD = 6.20) years; CG = 12, mean age = 59.20 (SD = 4.60) years Randomized-controlled study	Intervention: Neurodevelopmental treatment + respiratory exercise using respiratory exercise equipment Control: Neurodevelopmental treatment Time: 30 min a day, 5 times a week, for 4 weeks.	TIS FVC FEV1	Post-intervention TIS mean score: TG = 16.60 (SD = 1.10); CG = 12.80 (SD = 0.80) The respiratory exercise using respiratory exercise equipment was effective in improving trunk control and pulmonary function.
Tovar-Alcaraz et al., 2021 [28] Spain	Mean time (months) since stroke: N/A 16 stroke patients: TG = 8, mean age = 58 (SD = 12.90) years; CG = 8, mean age 56 (SD = 9.20) years Randomized, double-blind, controlled clinical trial	Intervention: IMT program + progressive intensity Control: IMT program Time: 5 days a week, once a day, for 8 weeks	Trunk control test (TCT) FVC FEV1 PEF VMV PImax	Post-intervention TCT mean score: TG = 77.50 (SD = 32.70); CG = 84.20 (SD = 12.60) IMT, although low intensity, is effective in improving inspiratory muscle strength; however, the effects on postural control and balance remain uncertain.
Zheng et al., 2021 [26] China	Mean time (days) since stroke was TG = 26.23 (SD = 15.59); CG = 30.97 (SD = 14.19) 60 stroke patients: TG = 30, mean age = 63.50 (SD = 10.36) years; CG = 30, mean age = 67.23 (SD = 9.15) years Single-blind randomized controlled trial	Intervention: Liuzijue exercise Control: Conventional respiration training Time: 25 min a day, 5 times a week, for 3 weeks.	TIS MIP MEP FEV1 FVC PEF BBS	Post-intervention TIS mean score: TG = 18.00 (IQR = 16.75–19.0); CG = 15.00 (IQR = 12.75–16.25) Liuzijue exercise improves trunk control ability, respiratory muscle functions, and activities of daily living ability.

Aydoğan Arslan et al., 2022 [29] Turkey	Mean time (months) since stroke was TG = 14.27 (8.37); CG = 20.20 (15.36) 21 stroke patients: TG = 11, mean age = 61.72 (SD = 10.77) years; CG = 10, mean age = 66.10 (SD = 8.87) years Single-blinded randomized-controlled study	Intervention: Neurodevelopmental BOBATH Treatment (NDT) + IMT Control: Neurodevelopmental BOBATH treatment approach (NDT) Time: 30 min a day, 5 days a week, for 6 weeks	TIS MIP MEP Timed Up and Go Test (TUG) BBS Six-Minute Walk Test (6MWT)	Post-intervention, there was a significant difference in the change in TIS between groups (p = .006). IMT improved inspiratory muscle strength and trunk control.
Lee et al., 2019 [27] Korea	The mean time (months) since stroke was TG = 11.15 (2.38); CG = 11.00 (2.17) 25 stroke patients: TG = 13, mean age = 58.62 (SD = 12.38) years; CG = 1, mean age = 59.75 (SD = 13.38) years Randomized-controlled trial	Intervention: Respiratory muscle training with trunk stabilization exercise group Control: Trunk stabilization Time: 40 min a day, 3 times a week, for 6 weeks.	MEP MIP PEF Vital capacity (VC) peak inspiratory flow (PIF)	Trunk stability was significantly increased in the intervention group. In the intervention group, respiratory muscle thickness was significantly increased.
Yoon et al., 2020 [32] Korea	The mean time (weeks) since stroke was TG = 7.43 (2.25); CG = 7.00 (2.23) 31 stroke patients: TG = 16, mean age = 62.93 (SD = 12.19) years; CG = 15, mean age = 58.06 (SD = 16.44) years Randomized-controlled trial	Intervention: Dynamic core-postural chain stabilization (DCS) Control: Neurodevelopmental treatment (NDT) Time: 30 min each session, 3 times a week, for 4 weeks.	FVC FEV1 MIP MEP.	DCS is effective in improving core stability, postural control, and respiratory function via increased diaphragm movement.

Lee &Jang, 2019 [33] Korea	The mean time (months) since stroke was TG = 17.33 (7.13); CG = 20.33 (8.52) 30 stroke patients: TG = 15, mean age = 66.20 (SD = 11.07) years; CG = 15, mean age = 69.67 (SD = 9.74) years Randomized-controlled trial	Intervention: Neck stabilization exercise + breathing retraining exercise Control: Breathing retraining exercise Time: 30 min a day, 5 times a week, for 6 weeks.	Maximal voluntary ventilation (MVV)	The intervention group showed significantly larger change in the activity of the trunk's respiratory muscles and MVV.

DETAILS

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Fatigue and Quality of Life Among Patients with Diabetes and Non-diabetes Receiving Primary Percutaneous Coronary Interventions

Su, Shu-Fen [1]
; Wen-Ting Yeh [2]
[1] Department of Nursing, National Taichung University of Science and Technology, Taiwan [2] Department of Nursing, Taichung Veterans General Hospital, Taiwan

ProQuest document link

ABSTRACT (ENGLISH)

s u m m a r yPurpose

Few studies have examined the effect of diabetes mellitus (DM) on patients with coronary artery disease. The relationships between quality of life (QoL), risk factors, and DM of patients receiving percutaneous coronary interventions (PCIs) are poorly understood. We investigated the influence of DM on fatigue and QoL over time among patients receiving PCIs.

Methods

An observational cohort study with a longitudinal, repeated-measures design was used to investigate fatigue and QoL among 161 Taiwanese patients with coronary artery disease with/without DM who received primary PCIs between February and December 2018. Participants provided demographic information and their Dutch Exertion

Fatigue Scale and the 12-Item Short-Form Health Survey scores before the PCI and two weeks, three months, and six months post-discharge.

Results

Seventy-seven PCI patients were in the DM group (47.8%; mean age = 67.7 [SD = 10.4] years). The mean scores of fatigue, physical component scale (PCS), and mental component scale (MCS) were 7.88 (SD = 6.74), 40.74 (SD = 10.05), and 49.44 (SD = 10.57), respectively. DM did not affect the magnitude of change in fatigue or QoL over time. Patients with DM perceived similar fatigue as those without DM before PCI and two weeks, three and six months post-discharge. Patients with DM perceived lower psychological QoL than those without DM two weeks post-discharge. Compared to pre-surgery scores, patients without DM perceived lower fatigue at two weeks, three months, and six months post-discharge, and higher physical QoL at three- and six-months post-discharge.

Conclusions

Compared with DM patients, patients without DM had higher pre-intervention QoL and better psychological QoL two weeks post-discharge, and DM did not influence fatigue or QoL of patients receiving PCIs over six months. DM may affect patients in the long term; therefore, nurses should educate patients to regularly take medication, maintain proper habits, notice comorbidities, and follow rehabilitation regimes after PCIs to improve prognosis.

FULL TEXT

DETAILS

Subject:	Quality of life; Marital status; Insulin resistance; Diabetes; Fatigue; Validity; Pilot projects; Health surveys; Demographics; Coronary vessels; Hypertension; Questionnaires; Cardiovascular disease; Hospitals; Heart; Cell growth; Smooth muscle
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Sunpapoa, C., Na-Ek, N., Sommai, A., Boonpattharatthiti, K., Huynh, N. S., & Kanchanasurakit, S. (2023). Impact of nursing interventions on hospital readmissions in patients with pulmonary tuberculosis: A quasi-experimental study. Asian Nursing Research, 17(3), 167-173. doi:https://doi.org/10.1016/j.anr.2023.06.002

SummaryPurposeOur study aimed to evaluate the effectiveness of the nursing care program on the incidence and rate of 28-day hospital readmissions among pulmonary tuberculosis (TB) patients.MethodsWe conducted a quasi-experimental study using a historical control (usual care) group. Patients diagnosed with pulmonary TB who received nursing interventions between January 28, 2021, and May 31, 2021, were categorized as an intervention group, whereas historical controls were selected from January 1, 2020, to December 31, 2020. The primary outcomes were the incidence and rates of hospital readmissions within 28 days due to TB-related complications. The secondary outcome was the change in knowledge and self-care behavior scores at discharge and 28 days postdischarge. Cox models were used to assess the intervention's impact on the incidence of hospital readmission. Rates of readmission were compared by the Poisson model. Both Cox and Poisson models were adjusted for age, sex, sputum smears at diagnosis, serum albumin level, and diabetes mellitus at baseline.ResultsAmong 104 pulmonary TB patients included in the analysis (68 were in a historical control group and 36 were in an intervention group), 20 patients were readmitted due to TB-related complications. We found that our nursing care program resulted in a significant reduction in the incidence (adjusted hazard ratio was 0.16 95% CI 0.03, 0.87]) and the rate of hospital readmissions (adjusted incidence rate ratio was 0.22 95% CI 0.06, 0.85]). Furthermore, nursing interventions significantly improved knowledge and self-care behavior scores with significant score retention at 28 days postdischarge.ConclusionsThe nursing care program can significantly decrease the incidence and rate of 28-day hospital readmission and improve knowledge and self-care behavior scores in pulmonary TB patients.

Mei, S. C., Janet Wing, H. S., Kai, C. C., Suhaimi, A., & Sek, Y. C. (2023). A theory-based, technology-assisted intervention in a hybrid cardiac rehabilitation program for patients with coronary heart disease: A feasibility study. Asian Nursing Research, 17(3), 180-190. doi:https://doi.org/10.1016/j.anr.2023.06.004

SummaryPurposeTo assess the feasibility of a technology-assisted intervention in a hybrid cardiac rehabilitation program among patients with coronary heart disease.MethodsThis study was a two-arm parallel randomized controlled trial. Twenty-eight patients with coronary heart disease were randomly assigned to either the intervention group, receiving a 12-week technology-assisted intervention (n = 14), or the control group (n = 14), receiving usual care. Guided by the Health Belief Model, the intervention group received three center-based, supervised exercise training sessions, a fitness watch that served as a cue to action, six educational videos, and a weekly video call. The Self-efficacy for Exercise, exercise capacity, and Health Promoting Lifestyle Profile II were assessed at baseline and immediately post-intervention (12-weeks).ResultsAmong the 28 patients who participated in this study, 85.7% completed the program, with a relatively low attrition rate (14.3%). The number of exercise training sessions accomplished by the participants in the intervention group was 51.27 ± 19.41 out of 60 sessions (85.5%) compared to 36.46 ± 23.05 (60.8%) in the control group. No cardiac adverse events or hospitalizations were reported throughout the study. Participants in the intervention group showed greater improvement in health-promoting behaviors when compared with the control group at 12 weeks. Within-group effects demonstrated improvement in exercise self-efficacy and exercise capacity among participants in the intervention group. A participant satisfaction survey conducted immediately post-intervention revealed that participants were “very satisfied” (23.1%) and “satisfied” (76.9%) with the technology-assisted intervention.ConclusionsThe findings demonstrated that technology-assisted intervention in a hybrid cardiac rehabilitation program was feasible and suggested to be beneficial in improving exercise self-efficacy, exercise capacity, and health promoting behavior among patients with coronary heart disease. A full-scale study is needed to determine its effectiveness in the long term.Trial and protocol registrationClinicalTrials.gov NCT04862351.https://clinicaltrials.gov/ct2/show/NCT04862351.

Tam, L., Wong, E. M. L., & Cheung, K. (2023). Educational program with text messaging for community-dwelling patients with hypertension: A pilot randomized controlled trial. Asian Nursing Research, 17(3), 158-166.

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SummaryPurposeControlling blood pressure minimizes the risk of cardiovascular events among patients with hypertension. Despite regular follow-ups, the hypertension management for patients aged ≥45 years is limited as evidenced from a decreased control rate. This pilot study aimed to test a theory-guided educational program for community-dwelling patients with hypertension.MethodsSixty-nine patients with hypertension aged ≥45 years and having high blood pressure (>130/80 mmHg) were recruited in this two-arm pilot randomized controlled trial. Participants in the intervention group underwent a program guided by the Health Promotion Model, whereas those in the control group received usual care. Data were collected at baseline, week 8, and week 12 and used to assess the blood pressure, pulse pressure, self-efficacy, and adherence to hypertension management. Data were analyzed using a generalized estimating equation based on the intention-to-treat principle. Process evaluation was conducted to assess the feasibility and acceptability of the educational program.ResultsThe results obtained using the generalized estimating equation revealed that the educational program led to reduction in the systolic blood pressure (β = −7.12, p = .086) and pulse pressure (β = −8.20, p = .007) and to improve self-efficacy (β = 2.61, p = .269) at week 12. The program had a small-to-moderate effect on the reduction of systolic blood pressure (effect size = −0.45) and pulse pressure (effect size = −0.66) and self-efficacy (effect size = 0.23). The participants were highly satisfied with the educational program.ConclusionsThe educational program was found to be feasible and acceptable and may be incorporated into current hypertension management practices at the community level.Trial registrationClinicalTrials.gov with identifier: NCT04565548.

Ho, Y. L., Nam, E. S., Chai, G. J., & Doo, M. K. (2023). Benefits of music intervention on anxiety, pain, and physiologic response in adults undergoing surgery: A systematic review and meta-analysis. Asian Nursing Research, 17(3), 138-149. doi:https://doi.org/10.1016/j.anr.2023.05.002

SUMMARYPurposeEvidence on factors influencing the variations of music's effect on anxiety and pain in surgical patients is unclear. We aimed to elucidate the effects of music intervention on anxiety and pain throughstudy characteristics.MethodsWe conducted a search on the PubMed, CINAHL, Embase, Cochrane, and Web of Science databases from March 7 to April 21, 2022, for randomized controlled trials (RCTs) for the effect of music intervention on anxiety, pain, and physiological responses in surgical patients. We included studies published within the last 10 years. We assessed the risk of bias in the study using the Cochrane risk of bias tool for randomized trials and performed meta-analyses using a random-effects model for all outcomes. We used change-from-baseline scores as summary statistics and computed bias-corrected standardized mean differences (Hedges'g) for anxiety and pain outcomes and mean differences (MD) for blood pressure and heart rate.ResultsOf the 454 records retrieved, 30 RCTs involving 2280 participants were found to be eligible. Music intervention was found to be superior to standard care in reducing anxiety (Hedges' g = −1.48, 95% confidence interval: −1.97 to −0.98), pain (Hedges's g = −0.67, −1.11 to −0.23), systolic blood pressure (MD = −4.62, −7.38 to −1.86), and heart rate (MD = −3.37, −6.65 to −0.10) in surgical patients. The impact of music on anxiety and pain relief varied significantly depending on the duration of the intervention. The largest effect was observed in interventions lasting between 30 and 60 minutes, with a decrease in anxiety and pain.ConclusionsMusic intervention is an effective way to reduce anxiety, pain, and physiological responses in surgical patients. Future reviews examining the influence of different types of surgery on the effects of music would add to the body of knowledge in this field. This study has been registered on the International Prospective Register of Systematic Reviews (PROSPERO) under the number CRD42022340203, with a registration date of July 4, 2022.

Hasanah, I., Nursalam, N., Krisnana, I., Ramdani, W. F., Haikal, Z., & Rohita, T. (2023). Psychoneuroimmunological markers of psychological intervention in pediatric cancer: A systematic review and new integrative model. Asian Nursing Research, 17(3), 119-137. doi:https://doi.org/10.1016/j.anr.2023.07.001

SUMMARYPurposePediatric cancer is a serious problem and still becomes a global challenge today. Various complex stressors due to diagnosis, disease symptoms, and various side-effects from the treatment that children with cancer undergo will cause problems in the child's psychoneuroimmunological aspects. Psychological interventions designed to modulate the stress response include psychoneuroimmunological markers. Unfortunately,

there is little evidence to support the effect of psychological interventions on psychoneuroimmunological markers. This systematic review aims to assess the effectiveness of psychological interventions on psychoneuroimmunological markers in children with cancer and to provide a new integrative model for further research.MethodsThis systematic review uses four main databases (Scopus, PubMed, ScienceDirect, and ProQuest). The guideline used Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA). Selecting articles used the Rayyan application. The quality study was conducted using Joanna Briggs Institute (JBI)'s critical appraisal tools. The data were analyzed using the population, intervention, comparison, outcome, and study design (PICO) Synthesis based on similarities and differences in study characteristics to interpret the results.ResultsThe search results in this systematic review found 1653 articles, 21 of which matched the predetermined inclusion and exclusion criteria. Most of the designs used were randomized controlled trials (57.1%). Massage therapy was the most common type of psychological intervention (14.2%). Almost half of the studies measured psychological responses (38.0%), and psycho-physiological responses (42.9%), and only a small proportion assessed the effectiveness of psychological interventions on neuroimmunological markers in pediatric cancer.ConclusionsWe recommend the use of psychological interventions as an additional intervention in managing psychoneuroimmunological markers of pediatric cancer. This study offers a new integrative model demonstrating the interaction between stress and psychological intervention involving neuroendocrine and immune mechanisms. However, future researchers need to test all domains of these new integrative models. This will reveal the complex interactions among these components and understand their relevance to health outcomes.

Suh, M. (2023). Increased parasympathetic activity as a fall risk factor beyond conventional factors in institutionalized older adults with mild cognitive impairment. Asian Nursing Research, 17(3), 150-157. doi:https://doi.org/10.1016/j.anr.2023.05.001

SummaryPurposeThis study aimed to investigate autonomic nervous function during the orthostatic challenge and its relationship with depression and fall, and to elucidate fall-associated factors, including autonomic function, executive function, and depression among institutionalized older adults with mild cognitive impairment (MCI).MethodsThis study employed a descriptive cross-sectional design. Fall experiences in the current institutions were researched. Heart rate variability (HRV) during the orthostatic challenge was measured. Executive function was evaluated using the semantic verbal fluency test and clock drawing test. Depression was assessed using the Geriatric Depression Scale.ResultsOf the 115 older adults, 17 (14.8%) experienced falls in the current institution. None of the HRV indices during the orthostatic challenge showed any significant changes except for the standard deviation of normal RR intervals ($p = .037$) in the institutionalized older adults with MCI. None of the HRV indices was significantly related to the depressive symptoms. Multivariate logistic regression analysis showed that normalized high frequency on lying was independently associated with falls (OR = 1.027, $p = .049$) after adjusting for other conventional fall risk factors although executive function and depressive symptoms were not significant factors for falls.ConclusionsInstitutionalized older adults with MCI were vulnerable to autonomic nervous modulation, especially to sympathetic modulation, during the orthostatic challenge, which was not associated with depressive symptoms. As increased resting parasympathetic activity seemed to play a key role in association with falls, autonomic nervous function assessment should be considered for fall risk evaluation.

Pearkao, C., Potisopha, W., Wonggom, P., Jumpamool, A., Apiratwarakul, K., & Lenghong, K. (2023). Outcomes of emergency trauma patients after the implementation of web application operating systems. Asian Nursing Research, 17(3), 174-179. doi:https://doi.org/10.1016/j.anr.2023.06.003

SUMMARYPurposeTrauma has significant impacts on the livelihoods and well-being of patients. Prompt emergency, medical, and nursing care is the key to reducing mortality rates. Digital platforms have become important for patient care. This research aimed to evaluate patient outcomes after implementing a novel web application operating system in trauma care.MethodsA descriptive comparative study was conducted on trauma patients. The patients were divided into two groups: those who used the developed application (n = 70) and those who did not (n = 70). The patients' characteristics, the time of the trauma team's arrival at the emergency department (ED) and the length of stay in the ED, and patients' outcomes were collected from electronic medical records and the application database. A statistical analysis was performed to evaluate this data. Sixty registered nurses who used the

application completed the survey on the feasibility of the application.ResultsThe activated trauma intervals for the non-application-used group and the application-used group were 5.0 ± 1.1 and 3.1 ± 0.4 minutes, respectively (p = .010). The length of stay in the ED for the non-application-used group and the application-used group were 30.1 ± 5.1 and 18.3 ± 6.2 minutes, respectively. A high level of agreement confirms the feasibility of the application.ConclusionsThis application improves patient outcomes in terms of length of stay. This mobile application can improve the cooperation and communication and efficacy of the trauma care team.