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Job Stress, Burnout, and Turnover Intention of Clinical Research Associates

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Abstract: Objective: This study aimed to analyze the general characteristics, job stress, burnout, and turnover intentions of Clinical Research Associates (CRAs). Our objective was to provide a reference point for devising strategies to reduce CRA turnover and burnout rates. Methods: A descriptive, quantitative, and correlative research design was used. A total of 126 CRAs completed a questionnaire that consisted of 115 items, with 21 items on general characteristics, 60 items on occupational role, and 10 items on personal strain in job stress. The Burnout Inventory scale was used to investigate 22 items of burnout, and turnover intentions was measured using a 5-item scale. Results: Of the 126 participants, 63 (50%) answered that they intended to leave their job within 1 year & the most of participants were nurse (n = 56, 44.4%). Job stress related to the occupational role of CRA's vocational stress (r = 0.518), burnout (r = 0.406), and turnover intention (r = 0.181) of personal strain were correlated with each other. Job stress due to personal strain had an explanatory power of 18.7% as a factor influencing turnover intention. Conclusions: To reduce the turnover intention of CRAs, who play an important role in clinical research, it is necessary to find ways to reduce job stress and burnout.

Keywords: clinical research; job stress; burnout; turnover intention; nurse

1. Background

Clinical trials have been conducted in humans to demonstrate the safety and efficacy of investigational medicinal products, confirm a drug's pharmacokinetics and clinical effects, and investigate adverse reactions. According to the Korea National Enterprise for Clinical Trials (KoNECT) domestic clinical trial industry survey report, which targeted 145 pharmaceutical companies involved in clinical trials, the total workforce in 2022 included 51,174 individuals with clinical research associates (CRAs) accounting for 19.8% [1]. Among 72 clinical research organizations (CROs) [1], CRAs accounted for 27.9% of the total workforce of 6801 people. As clinical trials began in earnest in Korea, new job categories such as CRA and clinical research coordinator (CRC) emerged. Unlike CRCs, who mainly work in hospitals, CRAs are primarily affiliated with CROs and pharmaceutical companies [2].

The role of CRAs in clinical trial operations is to lead and manage all aspects of these trials. CRAs typically include professionals with a strong understanding of hospitals and drugs, such as nurses, pharmacists, clinical laboratory scientists, and other life sciences or health-related professionals [3,4]. The nature of CRA's work involves predominantly working from home and frequent field monitoring, leading to a lack of distinction between work and personal life. The frequent replacement and turnover of CRAs—who play a crucial role in clinical research—can hinder the development and negatively impact the quality of management of international clinical trials conducted in South Korea [5,6].

The more an individual experiences job stress and burnout, the more likely it is they will have lower job satisfaction and greater turnover intentions. Previous studies have examined job stress, burnout, and turnover intentions in various occupations, such as nurses, clinicians, epidemiologists, mental health facility workers, social welfare facility workers, and laboratory personnel [7–9].

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There has been little investigation into job satisfaction among CRAs in South Korea. Investigating the relationship between job stress, burnout, and turnover intentions of CRAs in South Korea compared to other occupations and other countries is highly meaningful.[10-12] It can provide multifaceted insights into reducing turnover intentions among CRAs. Based on these prior findings, we sought to identify the predictive factors influencing CRA job stress and provide a point of reference for devising strategies to reduce CRA turnover rates and burnout [13,14].

2. Participants and Methods

2.1. Research Design

A descriptive, quantitative, and correlative research design was used. This study aims to identify job stress, burnout, and turnover intention as perceived by CRA and investigate their interrelationships.

2.2. Research Participants

The study participants included CRAs working in clinical trial contract organizations and pharmaceutical companies across South Korea. All participants provided written consent to participate. Individuals deemed unable to comply with study requirements or otherwise considered unsuitable by the researcher were excluded. The participants were selected using a convenience sampling method. We visited the educational place where the CRA received job-related training and the company where the CRA was employed, distributed the questionnaire, and collected the responses.

Sample size calculations were executed with G-Power 3.1.9.7 using a significance level of 0.05, effect size of 0.15, and power of 0.95, which resulted in a sample size of 120. Data were collected from 20 May to 20 July 2024, from 155 participants. After excluding 29 participants with incomplete questionnaires, a total of 126 participants were included in the analysis.

2.3. Research Tools

This study used a structured self-report questionnaire that took approximately 20 min per person to complete. The reliability of job stress, burnout, and turnover intention was assessed using Cronbach's alpha. The questionnaire consisted of 115 questions.

2.4. General Characteristics of CRAs

The general characteristics of the participants were derived from previous studies [10,11], and 18 items were structured by the researcher.

2.5. Job Stress

Job stress was measured using the Occupational Stress Inventory Revised Edition™ (OSI-R™), developed by Osipow, and verified in multiple studies [15,16]. The OSI-R™ includes 60 items of job stress (labeled the Occupational Role Questionnaire (ORQ) subsection) and 10 items on vocational strain (labeled the Personal Strain Questionnaire (PSQ) subsection) to assess participant job stress levels. In this study, we focused specifically on the stress experienced by CRAs due to the job; hence, we included ORQ and PSQ but excluded Personal Resources Questionnaire, which assesses personal resources and coping strategies. The OSI-R™ was translated into Korean for use in this study. The ORQ measures the amount of stress induced by work roles, divided into the following six subscales: role overload, role insufficiency, role ambiguity, role boundary, responsibility, and the physical environment. High scores on vocational strain from the personal strain questionnaire indicated poor attitudes toward work, including dread, boredom, and lack of interest. Responses were measured on a 5-point Likert scale, with 1 indicating "rarely or never" and 5 indicating "most of the time." Higher scores indicated higher levels of stress.

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2.6. Burnout

To assess CRA burnout, we used a translated version of the Maslach Burnout Inventory (MBI) created by Maslach et al.[17] This tool consists of 22 items: nine on emotional exhaustion (a state of depletion caused by work-related stress), five on depersonalization (describes a detached and impersonal response toward the recipients of one's service), and eight on reduced personal accomplishment (feelings of competence and successful achievement in one's work). The Likert scales ranged from 0 to 6, with higher scores indicating higher levels of burnout. The Cronbach's alpha for this tool in the present study was 0.87 compared to 0.76 reported by Maslach et al. (1981).

2.7. Turnover Intention

The turnover intention scale, developed by Mobley (1977) and modified by Cha In-sung (2012), was used with permission [18,19]. This scale consists of five items measured on a 5-point Likert scale, with 1 indicating "not at all" and 5 indicating "very much so." Higher scores indicate higher turnover intention. Cronbach's alpha in Cha In-sung's (2012) study was 0.85; Cronbach's alpha in the present study was 0.81.

2.8. Statistical Analysis

Data collected in this study were analyzed using SPSS version 29.0 (IBM Corp, Armonk, NY) as follows:

1. For general characteristics, job stress, burnout, and turnover intention of the participants, categorical data are presented as frequencies and percentages, whereas continuous data are presented as means and standard deviations.
2. A t-test and ANOVA were conducted to analyze the differences in job stress, burnout, and turnover intention, which differed from the general characteristics of the subjects.
3. Correlations between job stress, burnout, and turnover intention among CRAs were analyzed using Pearson's correlation coefficients.
4. To analyze factors influencing turnover intention, multiple regression analyses were conducted.

2.9. Ethical Considerations

This study was conducted in accordance with the principles of the Declaration of Helsinki. Written informed consent was obtained from all the participants. This study was approved by the Institutional Review Board of the Health and Welfare College of Woosong University in the Republic of Korea on 16 April 2024 (IRB number: 1041549-240409-SB-183).

3. Results

3.1. General Characteristics of CRAs

The general characteristics of the participants are shown in Table 1. The majority of subjects were female (n = 98, 77.8%), aged 30-39 (n = 99, 78.6%), married (n = 93, 73.8%), and had a bachelor's degree (n = 90, 71.4%). The most common major among participants was nursing (n = 56, 44.4%), and most worked full time (n = 95, 75.4%) in an office-based setting (n = 86, 68.3%). Nearly half of participants (n = 57, 45.2%) worked on affiliated teams of over 20 people. Forty-two (33.5%) participants worked at a global CRO, 40 (31.7%) had more than 1 year and less than 2 years of CRA experience, and 39 (31%) had three to four business trips per month. With regard to salary, 52 (41.3%) CRAs received 30,000 to 42,000 KRW per year and were in charge of three to four clinical trial projects within the last year. Forty (31.7%) CRAs were involved with at least one anticancer drug project in the past year. Additionally, CRAs reported Phase III and Phase IV projects to be the most difficult to work on. When asked if they intended to change jobs within 3 months, 40 (31.7%) participants said yes and 63 (50%) said they intended to change jobs within a year. When asked why they wanted to change jobs, interpersonal stress was reported by 24 (19.1%).

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Table 1. General characteristics of CRAs (N = 126).

General Characteristics		Number (%)	General Characteristics		Number (%)
Sex	Male	28 (22.2)	Marriage	Married	93 (73.8)
	Female	98 (77.8)		Unmarried	33 (26.2)
Age	<30	8 (6.3)	Educational Background	Bachelor	90 (71.4)
	30–39	99 (78.6)		Master or greater	36 (28.6)
	>40	19 (15.1)			
Major	Nursing	56 (44.4)	Present position	Global PC **	17 (13.5)
	Clinical Laboratory Science	41 (32.5)		Global CRO *	42 (33.5)
	Pharmacology	8 (6.3)		Domestic PC **	18 (14.3)
	Biology	14 (11.1)		Domestic CRO *	34 (27.0)
	Others	7 (5.6)		Primary secondary hospital	4 (.3.2)
Work type	Office based	86 (68.3)			
	Home based	32 (25.4)		Tertiary Hospital	11 (8.7)
	Dedicated	8 (6.3)			
Contract type	Full time	95 (75.4)	The most difficult project	Phase 1 ****	16 (12.7)
	Temporary	27 (21.4)		Phase II ***	19 (15.1)
	Part time	4 (3.2)		Phase III **	41 (32.5)
				Phase IV & others *	50 (39.7))
Number of Affiliated team	<5	6 (4.8)			
	5–9	23 (18.3)	Turnover intention within 1 year	yes	63 (50)
	10–19	40 (31.7)		No	63 (50)
	20>	57 (45.2)			
			Turnover intention within 3 months	Yes	40 (31.7)
				No	86 (68.3)
CRA career	<1yr	16 (12.7)	Responsible projects	0–2	33 (26.2)
	1yr≤ <2yr	40 (31.7)		3–4	65 (51.6)
	2yr≤ <3yr	24 (19.0)		5–6	17 (13.5)
	3yr≤ <5yr	26 (20.6)		7≥	11 (8.7)
	5yr≤	20 (15.9)			
Monthly Business trip	0	17 (13.5)	Chemotherapy projects	0	24 (19.0)
	1–2	50 (39.7)		1	40 (31.7)
	3–4	39 (31.0)		2	33 (26.2)
	5–6	13 (10.3)		3	23 (18.3)
	7≥	7 (5.6)		4≥	6 (4.8)
Reason for turn over	Interpersonal stress	24 (19.1)	Salary (yearly contract) KRW	<30,000K	30 (23.8)
	Salary	16 (12.7)		≤30,000K<42,000K	52 (41.3)
	Company related	17 (13.5)		≤42,000K<54,000K	30 (23.8)
	Personal growth	12 (9.6)		≤54,000K	14 (11.1)
	Not applicable	57 (45.2)		(K = 1000)	

CRA: Clinical Research Associates, * CRO: Clinical Research Organization; ** G(D)PC: Global(domestic) Pharmaceutical company.

3.2. Job Stress, Burnout and Turnover Intention of CRAs

The average score for job stress of occupational role across 126 participants was 58.6 ± 7.49 (maximum 100). Job stress of personal vocational strain was 52.02 ± 9.94 (maximum 100). Average burnout score was 60.2 ± 14.45 (maximum 100) and turnover intention was 63.9 ± 16.8 (maximum 100). Table 2 presents the average scores and standard deviations of job stress and burnout scores.

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Table 2. Job stress, burnout, and turnover intention of CRAs (N=126).

Variable			Item (number)	Likert scale [a] (Average ± SD [b])
Job Stress	Occupational role	Role overload	10	3.2 ± 1.09
		Role insufficiency	10	2.9 ± 1.03
		Role ambiguity	10	3.1 ± 1.10
		Role boundary	10	2.8 ± 1.14
		Responsibility	10	2.8 ± 1.12
		Physical environment	10	2.2 ± 1.17
		Total	60	2.8 ± 1.10
	Personal strain		10	2.6 ± 1.09
	Job stress Total		**70(A)**	
Burnout	Emotional exhaustion		9	3.1 ± 1.51
	Depersonalization		5	3.0 ± 1.58
	Reduced personal accomplishment		8	2.9 ± 1.69
	Burn out Total		**22 (B)**	3.1 ± 1.59
Turnover intention			**5 (C)**	3.2 ± 1.1
Total (A + B + C)			**97**	

[a] Likert scale ranged from 1–5 points for job stress and turnover intention, whereas it ranged from 0–6 for burnout; [b] SD: Standard deviation.

In the six sub-areas of the OSI-R™ (job stress, role overload, role sensitivity, role amplitude, role boundary, responsibility, and physical environment), role ambiguity was the highest with an average value of 3.1 (maximum 5). The overall average of the six sub-areas was 2.8, indicating that stress was felt occasionally too often among participants. The results of the MBI showed the average degree of burnout perceived by CRAs was 3.1 (maximum 6), and emotional exhaustion was the highest in each area (3.1), followed by depersonalization and reduced personal accomplishment. CRA's average turnover intention was 3.2 (maximum 5).

Job stress, burnout, and turnover intention according to the general characteristics of the participants were analyzed using a t-test and ANOVA, but there were no statistically significant differences.

3.3. The Correlation of Job Stress, Burnout, and Job Turnover Intention in CRAs

Pearson's correlation coefficient was used to understand the correlation between job stress, burnout, and turnover intention of the study subjects. The correlations among job stress, burnout, and turnover intention are presented in Table 3. The higher the stress on the occupational role, the higher the job stress of personal strain (r = 0.518), and there was a positive correlation with burnout (r = 0.406) and turnover intention (r = 0.181).

Table 3. The correlation of job stress, burnout, and job turnover intention in CRAs.(N = 126).

	Job Stress (Occupational Role)	Job Stress (Personal Strain)	Burnout	Turnover Intention
Job stress (Occupational role)	1			
Job stress (Personal strain)	0.518 **	1		
Burnout	0.406 **	0.277 **	1	
Turnover intention	0.181 *	0.422 **	0.250 **	1

* P value < 0.05; ** P value < 0.01.

3.4. Influencing Factors on Turnover Intention

To identify the factors influencing CRA turnover intention, a stepwise multiple regression analysis was performed using job stress and burnout as independent variables. The statistically

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significant variable influencing turnover intention was job stress due to personal strain, with 18.7% explanatory power for turnover intention. The predictors of turnover intention are shown in Table 4.

Table 4. Influencing factors on turnover intention (N = 126).

Variable	Unstandardized Coefficients		Standard Coefficients	t (p)	*TOL*	*VIF*
	B	SE	*β*			
Constant	6.962	2.666		2.611 (0.010)		
Job stress (Occupational role)	-0.021	0.019	-0.115	-1.153 (0.251)	0.657	1.522
Job stress (Personal strain)	0.366	0.080	0.433	4.573 (<0.001 ***)	0.726	1.377
Burnout	047	0.023	0.177	1.99 (<0.05) *	0.829	1.206
F(p)	10.576 (<0.001 ***)					
adj. R^2	0.187					
Durbin-Watson	1.915					

* p < 0.05; ** p < 0.01; *** p < 0.001.

4. Discussion

There have been few studies on CRAs across the globe, and the general characteristics of the CRAs investigated in previous studies differed from those of the CRAs participating in this study [11].

The first, second, and third strongest factors that influenced turnover consideration were low salary, workload, and career advancement in a prior study,[11] but in this study, interpersonal stress, company-related stress, and low salary were the three strongest factors influencing turnover intention among CRAs. In a 2016 Bares study, the total turnover of all industry workers in the United States was 17.8, and the total turnover rate of health care workers was 19.9% [20]. In this study, 31.7% of CRAs reported high turnover intention within three months, and 50% reported turnover intention within a year. This is also different from a prior report which reported CRA's reasons for turnover as salary (74%, n = 23), growth opportunities (45%, n = 14), and burnout (29%, n = 9) [3]. It is very necessary to retain the qualified CRA, who plays an important role in the research team conducting clinical trials.

Consistent with the results of previous studies, the positive correlation between job stress, burnout, and turnover intention was statistically significant (p < 0.01) [8,14]. In Ughulu's "Clinical research monitor burnout" study, which studied job stress and burnout, they concluded it is important to detect CRA's job-related stress early to prevent irreparable sufferings, and recommended that managers diagnose CRA's burnout.[21] In this study, there was no significant difference in job stress, as it was the same across six sub-areas. This is similar to the results of a prior study that analyzed nurse's occult stress and resilience [22].

The factors influencing CRA turnover intent were burnout and stress in previous studies [12,14]; in this study, the same results were found for vocational stress presenting in the sub-area of personal strain.

Job stress and burnout among CRAs is a significant problem that impacts turnover intention. Organizations may prevent burnout and turnover by taking action to control job stress, prevent burnout, and monitor stress levels. Organizations can support CRAs in carrying out their responsibilities efficiently and retaining their wellbeing by preventing burnout [21].

5. Conclusions

This study analyzed the general characteristics, job stress, burnout, and turnover intention among CRAs (Clinical Research Associates) and examined the factors influencing turnover intention.

The results of this study are as follows:

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1. The factors influencing turnover intention were interpersonal stress, company-related stress, and low salary, in that order. Among the CRAs, 31.7% had a high intention to leave within three months, and 50% had an intention to leave within one year.
2. The degree of stress across six subdomains of job stress was found to be consistent, with no significant differences in job stress across these areas. The average job stress score related to professional roles among the 126 participants was 58.6 ± 7.49 (out of a maximum of 100 points).
3. The average level of burnout perceived by CRAs was 3.1 (out of a maximum of 6 points), and the average turnover intention score was 3.2 (out of a maximum of 5 points).
4. There was a significant positive correlation between job stress, burnout, and turnover intention ($p < 0.01$).
5. The variable that significantly influenced turnover intention was job stress caused by personal tension, with an explanatory power of 18.7% for turnover intention.

Given these results, it is crucial to reduce job stress and burnout among CRAs, who play a vital role in the clinical research industry, to decrease turnover intention and retain CRAs, thereby improving occupational health as a part of the public health.

Author Contributions: Y.K.: literature review, methodology, data collection, statistical analysis. E.K.: research design, supervision, writing-reviewing and editing, discussion.

Ethical considerations: This study was approved by the Institutional Review Board of the Health and Welfare College of Woosung University in the Republic of Korea on 16 April 2024 (IRB number: 1041549-240409-SB-183).

Consent to participate: Written informed consent was obtained from all the participants.

Consent for publication: All participants provided written consent for publication.

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Data availability: The datasets generated during and/or analyzed during the current study are not publicly available as they contain sensitive information but are available from the corresponding author on reasonable request.

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