Influencing Factors and Management of Occupational Burnout Among Clinical Research Associates in China

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Abstract

Objective We firstly assessed the extent and nature of occupational burnout among clinical research associates (CRAs) in China for the first time, and evaluated influencing factors in view of developing effective countermeasures.

Methods CRAs were evaluated using the Maslach Burnout Inventory and a self-designed questionnaire. Detected occupational burnout was used as the index. We examined possible influencing factors of burnout using wilcoxon rank test, KW rank and Spearman correlation analysis; influencing factors were screened out with multivariate ordinal logistic regression modelling.

Results Overall, 438 surveys were completed. Results indicated that 82.2% of participating CRAs had some degree of job burnout; among those, 19.9% had mild burnout, 49.8% had moderate burnout, and 12.5% had severe burnout. A total of 76.7% suffered from emotional exhaustion, 65.5% experienced depersonalization, and 15.3% felt a low sense of accomplishment. For all categories of burnout, statistically significant influencing factors were: work mode, working hours, whether the hospital provided work support and likelihood of promotion ($p < 0.05$).

Conclusion Occupational burnout was common among Chinese CRAs. To alleviate this situation and ensure the quality of clinical trials, companies and hospitals should take effective measures to establish support systems involving both hardware and software.

1. Introduction

Clinical trials are an essential stage in the development of new drugs. No new drug can be marketed for public use until it has been proven safe and effective in clinical trials. A clinical research associate (CRA) is a person with specialty knowledge who is appointed by and accountable for the sponsor in a clinical trial; they monitor and report the progress of the trial and verify the data[1–2]. CRAs' work is an important component of modern health care[3–4]. It can involve monitoring the progress of clinical trials and ensuring that they are carried out, documented, and reported in accordance with the trial protocol, standard operating procedures, and relevant laws and regulations. As of October 10, 2020, 75,677 research studies were being conducted around the world[5]. According to the Drug Clinical Trial Registration and Information Disclosure Platform in China, the number of ongoing clinical trial projects in the country was 5,607 (as of October 10, 2020)[6], and the estimated number of CRAs in China is 20,000–30,000 based on the assumption of approximately five CRAs per project. To standardize development of the clinical trial industry, a higher quality of CRAs is required in China and abroad. CRAs will then face increasing pressure from sponsors, Drug Clinical Trial Institutions, and investigators. Thus, pressure on CRAs has increased and came to be an occupational hazard[7]. Occupational burnout is considered the main response to work pressure experienced by employees[8]. Burnout has been perceived as a serious and dangerous phenomenon; it is known as the most dangerous phenomenon of the 21st century[9].

Increasingly, the attention of research groups has focused on the burnout status of various occupational groups in China and overseas.

Job burnout refers to the state of physical and mental fatigue and exhaustion experienced in response to pressure from work. The term was first proposed by Freudenberger in 1974[10] who used it to describe a state of exhaustion, experienced by people serving the helping profession, owing to excessive working hours, work volume, and work intensity. It generally includes the following three categories[11]: (1) emotional exhaustion, referring to obvious symptoms of no energy and no enthusiasm for work; (2) Depersonalization, referring to deliberately keeping a mentally distance between oneself and the work objectives, adopting a cold and neglectful attitude towards the work object and environment, perfunctory work, stagnant personal development, eccentric behavior, and applying for transfers; and (3) Low personal achievement, referring to a tendency to negatively evaluate oneself, accompanied by a decline in work ability and achievement, and believing that work is not only unable to give full play to one's abilities, but is also boring.

CRA-related reports in China and abroad have included the following topics: the importance of CRAs[12], the status and tasks of CRAs[7], the rights and responsibilities of CRAs[13], the competency model of CRAs[14], the performance and obstacle factors of CRAs[15], the vocational education of CRAs[16], the management of CRAs[17], the satisfaction of CRAs[18], the occupational stress of CRAs[19], the depression of CRAs[20], and the turnover intention of CRAs[21]; however, there is a lack of research on job burnout among CRAs. As a special population in the medical and health service system, CRAs' wellbeing and job satisfaction are important. The research from Sweileh showed that little information of job burnout is available from many low- and middle-income countries might be mistakenly understood and research in this field is important in every country to determine risk factors and appropriate intervention strategies[22]. Therefore, it is necessary to understand CRAs' occupational burnout situation in China and the factors that influence it, in view of providing empirical support for psychological interventions to improve their mental health and thereby reduce job burnout and turnover, and add stability to clinical trial project teams. Thus, ultimately, effective measures can be identified to enhance the quality of clinical research.

2. Materials And Methods

2.1. Participants

The present study adopted a cross-sectional design and employed convenience sampling combined with snowball sampling. Chinese CRAs with more than 6 months monitoring experiences were eligible to be enrolled in the study. Using the WeChat, we conducted a questionnaire survey with 500 CRAs working in pharmaceutical companies or contract research organization (CRO) companies from 26 cities in China from OCT 16 to NOV 1, 2020. No incentives were provided to respondents for survey completion.

2.2 Survey tools

2.2.1 General Questionnaire

The questionnaire covered basic information about the CRAs: gender, age, educational background, educational degree, the number of managed trials, their main mode of work over the previous 5 months, and the number of hours worked per week. Additionally, the questionnaire evaluated the CRAs' support system: whether physicians cooperated with them in their work; whether the hospitals provided work support to CRAs; whether CRAs could be promoted; whether they were satisfied with their salary.

2.2.2 Job Burnout Scale

Considering the work tasks and procedures of CRAs, we applied the Chinese version of the Maslach Burnout Inventory, a scale that is widely employed in China and overseas[23–24]. The scale comprises 22 questions, which cover three categories (emotional exhaustion, low personal achievement, and depersonalization) using a 5-point Likert scale. Liu previously determined the alpha coefficient[25]. The alpha coefficient of the whole questionnaire was found to be 0.8301. The internal alpha reliability coefficients of emotional exhaustion, low personal achievement, and depersonalization were found to be 0.8227, 0.6569, and 0.9282, respectively. The correlation coefficients among the three factors were 0.4, 0.60, and 0.58, respectively. Thus, the reliability and validity of the questionnaire met measurement requirements.

(1) **Emotional exhaustion** Each of the nine items for emotional exhaustion (questions 1–8, and 22) received 1, 2, 3, 4, and 5 points in ascending order for the five answer options of 1, 2, 3, 4, and 5. We obtained the final score for this category by dividing the score by all of the above in this category.

(2) **Low personal achievement** Each of the eight items for low personal achievement (questions 9–16) was assigned points in reverse order (5, 4, 3, 2, and 1 points) for the five answer options of 1, 2, 3, 4, and 5. We obtained the final score for this category by dividing the score by all of the above in this category.

(3) **Depersonalization** Each of the five items for depersonalization (questions 17–21) received 1, 2, 3, 4, and 5 points in the order of the five answer options of 1, 2, 3, 4, and 5. We obtained the final score for this category by dividing the score by all of the above in this category.

A score of 2.5 or more indicated the presence of burnout in that category. We based the comprehensive determination of burnout on Li's method[26]: if burnout was not found in any of the three categories, no burnout occurred; burnout in one category was classified as mild burnout; burnout in two categories was regarded as moderate burnout and burnout in all three categories signified severe burnout.

2.3. Statistics

We employed SPSS Statistics Version 26.0 software (IBM Corp: Armonk, NY) for statistical analysis. The primary outcome measure was job burnout rate. Frequency and percentage descriptions were used for categorical variables. In this study, indicator variables were rank data; if the grouping variables were dichotomous variables, wilcoxon rank and test was used for inter-group comparison; if the grouping

variables were multi-categorical unordered variables, KW rank and test was used for inter-group comparison; if the grouping variables were ordered data, spearman correlation analysis was used for inter-group comparison.

After identifing the possible influencing factors of job burnout. We then employed a multiple ordinal logistic regression model to identify the influencing factors. The correlation strength between the influencing factors and job burnout was expressed by the odds ratio (OR) and 95% confidence interval (CI); we considered $P < 0.05$ statistically significant.

This study was approved by the Ethics Committee of Beijing Cancer Hospital. The approval number is 2020YW135.

3. Results

3.1. Demographic Information and Burnout Level

438 CRAs responded and returned the completed questionnaires. The participants' demographics and the results for levels of job burnout are shown in Table 1. From the 438 completed questionnaires, we obtained the following results: female, 75.3%; age group 25–30 years, 73.1%; pharmaceutical background, 73.5%; bachelor's degree and below, 70.8%. Additionally, 72.8% were responsible for four or more managed trials, and the main (62.1%) mode of work during the previous 5 months was remote monitoring or a combination of remote and on-site monitoring. Furthermore, 33.11% of CRAs reported working more than 50 hours per week.

In terms of their support system, 53.9% of CRAs believed that the responsible physicians are "fairly likely" or "very likely" to work cooperatively; 43.8% of CRAs believed that the hospitals were "more likely to" or "very likely" supports for them; only 25.6% of CRAs believed that they could be "fairly likely" promoted or that promotion was "very likely"; and 52.1% were satisfied with the compensation provided by their company.

We found that job burnout was relatively common among the CRAs investigated, with emotional exhaustion considered the most serious. The specific data were as follows: job burnout was detected in 82.2% of participants; this included mild burnout (19.9%), moderate burnout (49.8%), and severe burnout (12.5%). Across all three categories, 76.7% had emotional exhaustion, 65.5% experienced depersonalization, and 15.3% felt a low personal achievement.

Univariate analysis showed that the four factors of main mode of work, average work hours per week, degree of work support of the hospital provided, and promotion possibilities had statistically significant differences on the degree of burnout(P-value < 0.05).

Table 1
Demographics and job burnout survey items

Project	Total	Burnout symptoms n(%)				χ2/r	P-value
		Detected	Mild	Moderate	Severe		
gender						47.110[a]	0.054
M	108	86(79.6)	27(25.0)	48(44.4)	11(10.2)		
F	330	274(83.0)	60(18.2)	170(51.5)	44(13.3)		
Age group(yrs old)						6.367[a]	0.383
< 25	45	33(73.3)	7(15.6)	23(51.1)	3(6.7)		
25–30	320	266(83.1)	65(20.3)	155(48.4)	46(14.4)		
>=31	73	61(83.6)	15(20.5)	40(18.3)	6(8.2)		
Marital status						2.003[a]	0.572
Unmarried	306	256(83.7)	64(20.9)	153(50.0)	39(12.7)		
Married childless	67	55(82.1)	15(22.4)	29(43.3)	11(16.4)		
Married with children	63	47(84.6)	8(12.7)	35(55.6)	4(6.3)		
Divorced	2	2(100)	0(0)	1(50.0)	1(50.0)		
Educational background						8.714[a]	0.121
Pharmacy	322	267(82.9)	58(18.0)	162(50.3)	47(14.6)		
Medical related	98	80(81.6)	24(24.5)	48(49.0)	8(8.2)		
Other	18	13(72.2)	5(27.8)	8(44.4)	0(0)		
Educational degree						65.376[a]	0.716
bachelor's degree and below	310	258(83.2)	64(20.6)	163(52.6)	31(10.0)		
Master's degree and above	128	102(79.7)	23(18.0)	55(43.0)	24(18.8)		
Number of managed trials						4.930 [a]	0.553
1–2	56	43(82.7)	11(19.6)	25(44.6)	7(12.5)		
3–4	135	110(81.5)	31(23.0)	67(49.6)	12(8.9)		

Project	Total	Burnout symptoms n(%)				χ2/r	P-value
>=5	247	207(83.8)	45(18.2)	126(51.0)	36(14.6)		
Hours worked per week						80.422[a]	0.0428
<=50	293	56(19.1)	63(21.5)	143(48.8)	31(10.6)		
>=51	145	22(15.2)	24(16.6)	75(51.7)	24(16.6)		
Main working mode over the past 5 months			)				0.010
Unable to monitor	142	122(85.9)	22(15.5)	72(50.7)	28(19.7)		
Remote monitoring	30	18(60.0)	5(16.7)	11(36.7)	2(6.7)		
On-site monitoring after suspension of monitoring	36	30(83.3)	9(25.0)	18(50.0)	3(8.3)		
Combination of remote and on-site monitoring	230	190(82.6)	51(22.2)	117(50.9)	22(9.6)		
The physician is very cooperative with me						12.672[a]	0.393
Very unlikely	14	2(14.3)	1(7.1)	7(50.0)	4(28.6)		
Somewhat unlikely	83	15(18.1)	12(14.5)	42(50.6)	14(16.9)		
Somewhat likely	105	20(19.0)	25(23.8)	48(45.7)	12(11.4)		
Fairly likely	181	28(15.5)	35(19.3)	98(54.1)	20(11.0)		
Very likely	55	13(23.6)	14(25.5)	23(41.8)	5(9.1)		
The hospital I am involved in supports me						29.461[a]	0.003
Very unlikely	37	32(86.5)	5(13.5)	17(45.9)	10(27.0)		
Somewhat unlikely	90	76(84.4)	9(10.0)	51(56.7)	16(17.8)		
Somewhat likely	128	110(85.9)	25(19.5)	71(55.5)	14(10.9)		
Fairly likely	122	97(79.5)	30(24.6)	57(46.7)	10(8.2)		
Very likely	61	45(73.8)	18(29.5)	22(36.1)	5(8.2)		
I might get a promotion						24.704[a]	0.016

Project	Total	Burnout symptoms n(%)				χ2/r	P-value
Very unlikely	63	55(87.3)	9(14.3)	35(55.6)	11(17.5)		
Somewhat unlikely	101	87(86.1)	18(17.8)	51(50.5)	18(17.8)		
Somewhat likely	98	85(86.7)	17(17.3)	60(61.2)	8(8.2)		
Fairly likely	162	124(76.5)	39(24.1)	67(41.4)	18(11.1)		
Very likely	14	9(64.3)	4(28.6)	5(35.7)	0(0)		
I'm satisfied with the company's salary						14.198[a]	0.288
Very unlikely	85	76(89.4)	13(15.3)	47(55.3)	16(18.8)		
Somewhat unlikely	125	102(81.6)	22(17.6)	64(51.2)	16(12.8)		
Somewhat likely	82	66(80.5)	20(24.4)	40(48.8)	6(7.3)		
Fairly likely	125	100(80.0)	25(20.0)	59(47.2)	16(12.8)		
Very likely	21	16(76.2)	7(33.3)	8(38.1)	1(4.8)		

3.2. CRA burnout: multiple factor analysis

To further examine the factors that associated with burnout among CRAs and to reduce the impact of confounding factors, we used the self-rated burnout grade as the dependent variable and assigned the degree of burnout as follows: 0, no burnout; 1, mild burnout; 2, moderate burnout, and 3, severe burnout (0 was the reference group). Following a review of the literature, we identified the following factors in our univariate analysis that associated with CRAs' burnout grade: the average number of hours worked per week, main work mode, degree of work support of the hospitals provided, the probability of being promoted. These four factors were used as the independent variables to which values were assigned. These factors passed the parallelism test (P = 0.373). A multiple ordinal logistic regression model (backward method) showed that work hours, main work mode, the degree of work support of the hospital provided to CRA and the probability of being promoted had statistically significant impact on burnout grades (Table 2).

The results showed that those who cannot monitor were more likely to report burnout than those whose work involved a combination of remote and on-site monitoring (OR = 1.561, 95%CI 1.040–2.344). Working hours had an impact on burnout levels. Those CRAs who worked less than 50 hours per week were less likely to report burnout than those who worked more than 50 hours per week (OR = 0.596, 95%CI 0.406–0.876). There were differences in the level of burnout caused by the level of work support given to CRA from the hospitals. Compared with " very likely ", " fairly unlikely " and " somewhat unlikely " have work support are risk factors for job burnout (OR = 3.134,95%CI1.406 ~ 6.985), (OR = 2.571,95%CI1.366 ~

4.837). Promotion opportunities have an important influence on the burnout of CRA. "very unlikely promoted" “Somewhat unlikely” “Somewhat likely” versus "very likely " promotion is a risk factor for job burnout, OR = 4.050 (95%CI 1.342 ~ 12.220), OR = 3.822(95%CI 1.324 ~ 11.031), OR = 3.255(95%CI 1.120 ~ 9.463).

The association between the probability of prediction and the observations was strong, showing the regression model had strong predictive ability (Table 3).

Table 2
Results of multivariate regression analysis of occupational burnout symptoms

Factor	B - value	S.E.	P- value	OR (95%CI)
Constant 1	-3.39	0.57	< .0001	
Constant 2	-0.72	0.55	0.189	
Constant 3	0.39	0.55	0.473	
Work hours per week				
<=50	-0.52	0.20	0.008	0.596(0.406–0.876)
>=50	-	-	-	1.00
Main working mode over the past 5 months				
Unable to monitor	0.45	0.21	0.032	1.561(1.040–2.344)
Remote monitoring	-0.70	0.37	0.030	0.495(0.241–1.017)
On-site monitoring after suspension of monitoring	-0.17	0.34	0.617	0.842 (0.428–1.654)
Combination of remote monitoring and on-site monitoring	-	-	-	1.00
The degree of work support of the hospital provides for me				
Very unlikely	1.14	0.41	0.005	3.134 (1.406 ~ 6.985)
Somewhat unlikely	0.94	0.32	0.003	2.571(1.366 ~ 4.837)
Somewhat likely	0.58	0.30	0.054	1.780(0.991 ~ 3.196)
Fairly likely	0.28	0.30	0.344	1.327 (0.739 ~ 2.383)
Very likely	-	-	-	1.00
I might get a promotion				
Very unlikely	1.40	0.56	0.013	4.050(1.342 ~ 12.220)
Somewhat unlikely	1.34	0.54	0.013	3.822(1.324 ~ 11.031)

Factor	B - value	S.E.	P- value	OR (95%CI)
Somewhat likely	1.18	0.54	0.030	3.255(1.120 ~ 9.463)
Fairly likely	0.64	0.52	0.217	1.907(0.684 ~ 5.311)
Very likely	-	-	-	1.00

Table 3
Associations between the probability of prediction and the observations

Project	Observed N(%)
Percent Concordant	64.2
Percent Discordant	34.2
Percent Junction	1.5
C-statistics	0.650

4. Discussion

Our study investigated the occupational status of CRAs in China and the prevalence and causes of their occupational burnout. We found that female CRAs accounted for 75.3% of respondents. Individuals under the age of 30 years constituted 97.7% of participants, and those with a bachelor's degree or below accounted for70.8% of participants, both of which are consistent with previous studies[7, 20]. Because of the particularity of their work, CRAs must have substantial pharmaceutical and/or medical knowledge. Additionally, they must carefully check clinical trial data, be able to coordinate among all involved parties, and have meticulous and strong communication skills; thus, the overall education level among CRAs tends to be high. Recent years have seen younger groups of CRAs emerging in China, owing to the high demand for CRAs and the relatively single-career development path for CRAs in the country.

The fundamental requirements for ensuring the quality of drug clinical trials, protecting the rights and interests of participants, and protecting their safety to the maximum extent are: compliance with Good Clinical Practice (GCP) and with relevant laws and regulations, and the implementation of drug clinical trials in accordance with scientific standards [27–28]. Our study showed that 53.9% of the CRAs believed that the physicians in charge were fairly likely or very likely cooperative, indicating that with the popularization and strengthening of relevant laws and regulations for GCP in China, the trial personnel (e.g., researchers and CRCs) are experiencing a greater degree of cooperation within their clinical trial work. Responsible investigators who enhance communication and coordination among all parties involved in clinical trials, and responsible CRCs can reduce the workload of CRAs. The present study

showed that 52.1% of CRAs were satisfied with the compensation offered by their company, indicating that in China, CRAs' remuneration has generally increased with the development of the social economy and with people's awareness of the importance of clinical trials.

Overall, the study showed that CRAs' job burnout was very serious, and was dominated by emotional exhaustion and depersonalization (76.7% and 65.5%, respectively, of those surveyed), both of which were higher than that reported for jobs in any other field[29–30], but similar with the job burnout survey in the clinicians[31–33].

Working hours had an impact on burnout levels. Some studies have also shown a correlation between work environment and workload, and job burnout[34–35]. Recently, the demand for CRAs has increased dramatically, owing to the vigorous development of domestic clinical trials (all of which require CRAs), which has resulted in a greater proportion of CRAs with insufficient experience. Since the 722 Clinical Trials Reform Event in 2015 in China, new regulations have been issued continuously at the regulatory level to speed up the clinical trial process and standardize the clinical trial operation. More rigorous requirements have been put forward for all parties involved in the smooth communication and coordination of clinical trials, which presents a greater challenge for CRAs with less experience. In addition to the time they spend monitoring at the institution in which they work, CRAs typically expend substantial energy and physical strength on their business trips, which causes disturbances in their life rhythms. Furthermore, CRAs are often required to undertake a lot of work in addition to their role as CRA. Because of the high-intensity nature of clinical research work, its complex environment, long working hours, and high occupational pressure, CRA job burnout is becoming increasingly serious, leading to job performance obstacles[15] and an increase in CRA turnover[21].

Our analysis showed that working mode affected CRAs' burnout levels: those who couldn't work (monitoring) were more likely to report burnout than those whose work involved a combination of remote and on-site monitoring. The 2019 novel coronavirus pneumonia outbreak (Coronavirus Disease 2019, COVID-19) was deemed to constitute a global pandemic on March 11, 2020 [36–38]. Implementation of isolation measures and travel restrictions during outbreaks around the world have a significant impact on clinical trials of new drugs [39–41]. many CRA on-site monitoring could not be carried out due to the requirements of epidemic prevention and control, and tasks could not be completed. As a result, CRA_S in China and abroad are jointly facing arduous challenges. Medical institutions can use new technologies brought about by advances in information technology to cope with the impact of the outbreak on clinical trials. Several hospitals had already launched remote monitoring systems by the time of the outbreak, so monitoring has been unaffected by the pandemic situation. The remote monitoring system integrates all the medical treatment data of subjects in the hospital according to the authority, and organizes the panoramic data view of subjects according to such dimensions as medical treatment, examination, examination, medical records and medical orders for CRAs to monitoring. No matter which region the pandemic hit or in which time zone the work was located, monitoring was unaffected. The trial problems

could, therefore, be detected in a timely manner, and monitoring efficiency has improved. Furthermore, the health and safety of all parties involved in the clinical trials and the quality of the trials has been ensured.

This study showed that some differences in the level of burnout were caused by the degree of work support of the hospital provides for CRAs. Compared with those who were “very likely” to receive good work support, those “very unlikely” and “somewhat unlikely” to receive good work support were more likely to experience job burnout. The result[42] from 154 university faculty members on two occasions revealed that perceived organizational support buffered the mediated effect of negative rumination and job satisfaction. It is suggested that hospitals should more fully understand and appreciate the importance of the CRA role, and establish a support system for CRAs in terms of hardware and software, and humanized, innovative management of CRAs. Moreover, Bugla survey 200 CRAs[43], indicated that 36.07% CRAs were not satisfied with quality control and work efficiency of the hospitals. These hospitals must pay more attention to quality control of CRAs’ work, and should take scientific and appropriate measures to solve monitoring problems. Hospitals can help CRAs formulate clear and standard operating procedures, provide them with monitoring offices and Hospital Information System computers to check participants’ medical records, and regularly hold CRA training courses. With the help of modern tools such as WeChat, relevant procedures and systems may be issued and kept up to date. The telephone, WeChat, and online platforms may be used to increase communication with CRAs. Institutional staff should follow up efficiently on existing problems delineated in CRAs’ monitoring reports, or communicate directly with the CRA, so problems in the clinical trials can be solved in a timely manner and management efficiency can be improved. Informatization and AI intelligence can also been adopted for clinical trial management and digital quality control to ease the work of CRAs.

Promotion opportunities have an important influence on CRAs’ burnout rate. Our multiple factor analysis modelling showed that there were reciprocal, positive relationships between promotion and burnout. For example, “Fairly likely promoted” versus “very unlikely promoted” is a protective factor for job burnout. This finding is consistent with those of other studies[44–45]. Influenced by the general promotion pattern in China, there is a lack of vertical promotions and salary settings for the CRA position in China at present. Only 25.6% of the CRAs surveyed in the present study think they can be promoted fairly likely. Enterprises should establish a more equitable promotion system and make the established promotion standards open and transparent. Furthermore, they could consider appointing CRA managers and other positions at the same level as the project manager, so employees who enjoy or prefer the front-line CRA work can continue to develop in that field. Additionally, enterprises should accurately evaluate employees’ personal characteristics and work abilities, and adopt different incentive measures to motivate and guide employees according to their differences. Their work-related training and vocational education can also be strengthened to improve their work abilities[16]. Because CRA work requires exceptional communication ability, companies should provide sufficient support for communication-based soft skills while cultivating ‘hard’ skills to assist CRAs’ career development.

Some limitations in the present investigation should be noted. The sample size was 438, which is a little small to represent the whole CRA population. We look forward to expanding the sample size in future

research. Because our study was survey-based, our results may also be limited by both recall and selection biases.

5. Conclusion

The degree of job burnout among CRAs is extreme. Work modes, amount of guidance offered by involved clinical research institutions, the probability of being promoted, and the level of anxiety experienced during the pandemic are factors that affected the occurrence of burnout. Companies and institutions should pay close attention to the emotions of CRAs, regularly understand their work-related difficulties and psychological demands, reasonably divide their work responsibilities and scope, and strengthen the quality of mental health evaluations for CRAs. Corresponding measures should be actively taken to establish a CRA support system involving both hardware and software, to reduce CRA job burnout, to stabilize their working environment, and ultimately ensure the quality of clinical trials.

Declarations

Ethics approval and consent to participate

This study was approved by the Ethics Committee of Beijing Cancer Hospital. The approval number is 2020YW135.

The questionnaire displayed a written informed consent for CRAs to read and voluntarily accept before they could more to the question items.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and/or analyzed in this study will be made available by the corresponding author upon reasonable request.

Competing interests

All authors declare no competing interests

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None

Authors' contributions

Zhiying Fu: performed data collection and analysis, reviewed the literature and contributed to drafting the manuscript. Yannan Yuan: performed data analysis, reviewed the literature, contributed to interpreting the data, and assisted in drafting the manuscript. Min Jiang: conceptualized and designed the study; supervised, coordinated, and was responsible for the integrity of the data and the accuracy of its analysis; she critically reviewed the results' interpretation, and assisted in the final write-up. All authors read the final manuscript and approved it.

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