RESEARCH ARTICLE

Examining the Secondary Traumatic Stress Levels of Emergency Service Healthcare Workers in Contact and Non-Contact with Covid-19 Pandemic Patients

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Abstract

Objective: The fight against the Covid-19 pandemic has not only been limited to physical risks but has also led to profound psychological impacts. Secondary traumatic stress (STS) is an important concept reflecting the effects of traumatic experiences frequently encountered by healthcare workers. This study aims to investigate the levels of STS experienced by emergency department healthcare workers during the Covid-19 pandemic. The research aims to provide insights into the impact on the mental health of healthcare workers during and after the Covid-19 pandemic. Furthermore, the analysis of the data obtained will yield important conclusions for understanding the long-term effects of the pandemic and preparing healthcare systems for such crises.

Methods: The study population consisted of doctors, nurses, and other healthcare personnel (health officers, midwives, technicians, paramedics, aides, etc.) working in emergency departments. The study covered 239 participants from various provinces within the authors' network.

Results: The study found no significant variation in STS based on whether participants lived in a major city or not. However, significant differences were identified based on gender. Additionally, significant differences were observed in the "avoidance", "arousal" subscales, and total score of STS based on the job categories of emergency department staff. Furthermore, STS scores varied significantly based on years of service among emergency department staff. Moreover, the study identified significant differences in STS scores based on the frequency of encounters with Covid-19 patients during the pandemic.

Conclusion: According to the data obtained, factors such as gender, years of service, and professional experience need to be considered to support the mental health of emergency department staff. It is also important to develop support programs and coping strategies specifically for female employees. Moreover, in extraordinary situations like the Covid-19 pandemic, it is essential to strengthen coping strategies for traumatic experiences among emergency department staff and facilitate access to supportive resources. This approach can ensure the sustainability of healthcare services and preserve the health and well-being of emergency department staff.

Keyword: Covid-19 pandemic, healthcare worker, secondary stress level.

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INTRODUCTION

The Covid-19 pandemic has posed a formidable challenge to healthcare systems and professionals worldwide. Emergency healthcare workers, in particular, have been at the forefront of this pandemic, continuously battling for the diagnosis and treatment of patients (1,2). However, this struggle has not been limited to physical risks alone; it has also led to profound psychological effects.

Secondary traumatic stress is a type of stress experienced by individuals who empathize with and internalize the suffering of those who have experienced traumatic events, even if they have not directly experienced trauma themselves (3,4). The level of secondary traumatic stress reflects the impacts of traumatic experiences frequently encountered by healthcare workers due to the nature of their profession (5). This stress is experienced by witnessing patients' suffering or internalizing what they have experienced. Particularly for professionals like emergency healthcare workers who are constantly exposed to traumatic cases, secondary traumatic stress can have serious effects on both their occupational risks and mental health.

Therefore, investigating the level of secondary stress is a crucial traumatic in step understanding the psychological needs of healthcare workers and providing appropriate support mechanisms (6-10). This study aims to explore the level of secondary traumatic stress experienced by emergency healthcare workers during the Covid-19 pandemic. Specifically, it aims to compare the levels of secondary traumatic stress between healthcare workers who have and have not been in contact with patients. Understanding pandemic how emergency healthcare workers cope with this type of stress is essential for developing measures to safeguard their mental health and enhance service quality.

By addressing gaps in the research literature, this study aims to provide insights into the impact on the mental health of healthcare workers during and after the Covid-19 pandemic. Furthermore, the analysis of the data obtained will provide important findings for understanding the long-term effects of the pandemic and preparing healthcare systems for such crises.

METHODS

Study design, Participants and Data Collection

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The study population consisted of doctors, nurses, and other healthcare personnel (health officers, midwives, technicians, assistants, etc.) working in the emergency department. A webbased cross-sectional survey was conducted between May 19th and August 8th, 2020, during the global COVID-19 pandemic. Data for the study were collected from responses to questionnaires prepared in Google Forms. The study included 239 participants from various provinces within the authors' network.

Data collection tools in the study included a "Personal Information Form" consisting of 10 demographic and descriptive questions designed according to the research hypotheses, as well as the "Secondary Traumatic Stress Scale (STSS)." The Turkish adaptation of the STSS, developed by Yıldırım, Kıdak, and Yurdabakan (12), is based on the scale originally developed by Bride et al. (11). This scale, comprising 17 items rated on a five-point Likert scale (Never (1), Rarely (2), Sometimes (3), Often (4), and Very often (5)), is designed to measure the level of secondary traumatic stress developed by healthcare professionals working with traumatized individuals. Possible scores on the scale range from 17 to 85, with higher scores indicating higher levels of impact. The scale includes three subscales named "emotional intrusion." "avoidance." and "arousal." Items 2, 3, 6, 10, and 13 assess emotional intrusion symptoms, items 1, 5, 7, 9, 12, 14, and 17 assess avoidance symptoms, and items 4, 8, 11, 15, and 16 assess arousal symptoms. The internal consistency reliability coefficient (Cronbach's alpha) for the scale was found to be 0.91, and for the emotional intrusion, avoidance, and arousal subscales, the calculated internal consistency coefficients were 0.84, 0.78, and 0.82, respectively (Yıldırım et al., 2018).

Statistical analysis

All statistical analyses were performed using SPSS v26 (IBM Inc., Chicago, IL, USA) software. The assumption of homogeneity of variances was checked using Levene's test. When this assumption was met, Student's t-test or one-way ANOVA was used to compare independent groups; otherwise, Welch's t-test or Welch's ANOVA was used. Tukey's multiple comparison test was used to determine differences between groups after ANOVA, while Games-Howell's multiple comparison test was used after Welch's ANOVA. All comparisons were two-tailed, and a p-value less 0.05 than was considered statistically significant.

RESULTS

Total of 239 individuals participated in the study, comprising 46.9% males and 53.1% females. Of the participants, 51.9% were doctors, 38.1% were nurses, and 10.0% held other positions (health officers, midwives, technicians, assistants, etc.). Regarding the age distribution, 38.9% of participants were in the 18-30 age range, 41.8% were in the 31-40 age range, 15.1% were in the 41-50 age range, and 4.2% were in the 51-64 age range. Additionally,

it was determined that 77.4% of the participants resided in major cities (Table 1).

The distribution of participants' use of cigarettes, alcohol, and sedative medications, the distribution of their working hours during the COVID-19 pandemic and encounters with infected patients, and the frequencies and percentages of the responses to the questions asked in the STSS survey are provided in Tables 2-4.

Table 1. Frequencies an	nd percentages of	participant characteristics
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		n	%
Gender	Male	112	46.9
	Female	127	53.1
Age	18-30	93	38.9
	31-40	100	41.8
	41-50	36	15.1
	51-64	10	4.2
Is the city you live in a metropolitan city?	Yes	185	77.4
	No	54	22.6
Working period (years)	1-5	84	35.1
	11-15	47	19.7
	15 ↑	57	23.8
	6-10	51	21.3
Colleague	Doctor	124	51.9
	Nurse	91	38.1
	Orher	24	10.0

Table 2. Frequencies and percentages of the participant about smoking, alcohol and sedating medication uses.

	Ne	ever	R	arely	Often	
	n	%	n	%	n	%
Do you use medical or paramedical sedatives or relaxants?	211	88.3	18	7.5	10	4.2
Do you consume alcohol?	151	63.2	67	28.0	21	8.8
Do you smoke?	125	52.3	48	20.1	66	27.6

Table 3. Frequencies and percentages of the participant about Covid-19.....

		n	%
What was the frequency of encountering	Never	8	3.3
daily Covid-19 patients during the	Rarely	50	20.9
pandemic period you worked?	Mostly	131	54.8
	Always	50	20.9
What was your monthly working hours	Normal mesai süresi	90	37.7
during the Covid-19 pandemic?	Normal mesai süresinden az (esnek mesai)	80	33.5
	Normal mesai süresinden fazla	69	28.9

Table 4. Frequencies and percentages of STSS

	Never		ver Very little		Sametimes		Often		Very styliish		$-\overline{x}$	S .,
	n	%	n	%	n	%	n	%	n	%	Л	U _X
1. I felt emotionally numb.	56	23.4	51	21.3	80	33.5	40	16.7	12	5.0	2.6	1.2
2. My heart started racing when I thought about my sessions with clients	117	49.0	53	22.2	41	17.2	26	10.9	2	0.8	1.9	1.1
3. I felt as if I was reliving the trauma experienced by my client(s)	127	53.1	48	20.1	40	16.7	21	8.8	3	1.3	1.8	1.1
4. I had difficulty sleeping	71	29.7	47	19.7	52	21.8	38	15.9	31	13.0	2.6	1.4
5. I felt hopeless about the future.	56	23.4	50	20.9	62	25.9	35	14.6	36	15.1	2.8	1.4
6. Reminders of my sessions with clients saddened me.	85	35.6	63	26.4	53	22.2	31	13.0	7	2.9	2.2	1.1
7. I had reduced desire to be around others in social settings.	38	15.9	54	22.6	59	24.7	45	18.8	43	18.0	3.0	1.3
8. I felt nervous.	41	17.2	52	21.8	44	18.4	69	28.9	33	13.8	3.0	1.3
9. I was less active than usual.	52	21.8	41	17.2	53	22.2	55	23.0	38	15.9	2.9	1.4
10. I found myself thinking about my sessions with clients involuntarily, even when I didn't intend	71	20.7	60	25.1	66	27.6	21	12.0	11	16	2.4	1.2
to.	/1	29.1	00	23.1	00	27.0	51	15.0	11	4.0	2.4	1.2
11. I had difficulty concentrating.	66	27.6	59	24.7	62	25.9	41	17.2	11	4.6	2.5	1.2
12. I avoided people, places, or things that reminded me of my sessions with clients.	105	43.9	56	23.4	44	18.4	28	11.7	6	2.5	2.1	1.1
13. I wanted to avoid working with my clients.	137	57.3	42	17.6	38	15.9	16	6.7	6	2.5	1.8	1.1
14. I wanted to avoid working with some of my clients.	95	39.7	54	22.6	49	20.5	27	11.3	14	5.9	2.2	1.2
15. I became easily fatigued.	52	21.8	47	19.7	64	26.8	44	18.4	32	13.4	2.8	1.3
16. I felt like something bad was going to happen.	60	25.1	53	22.2	52	21.8	47	19.7	27	11.3	2.7	1.3
17. I noticed gaps in my memory regarding my sessions with clients.	95	39.7	54	22.6	59	24.7	23	9.6	8	3.3	2.1	1.1

Table 5. Descriptive statistics of STSS

	Items	n	Minimum	Maximum	Mean	SD	Cronbach's Alpha
Intrusion	2, 3, 6, 10, 13	239	5.0	25.0	10.16	4.66	0.894
Avoidance	1, 5, 7, 9, 12, 14, 17	239	7.0	35.0	17.71	6.72	0.881
Arousal	4, 8, 11, 15, 16	239	5.0	25.0	13.62	5.61	0.906
STSS-Total	1-17	239	17.0	85.0	41.48	16.18	0.957

Table 6. Descriptive statistics of STSS according to gender and living in a big city or not

	Is the city you live in a metropolitan city?												
		Yes			No		t	р					
	n	\overline{X}	S_X	n	\overline{X}	S_X	-						
Intrusion	185	10.27	4.60	54	9.78	4.90	0.682 ^a	0.496					
Avoidance	185	17.85	6.64	54	17.20	7.04	0.605 ^b	0.547					
Arousal	185	13.81	5.69	54	12.96	5.33	0.970 ^a	0.333					
STSS-Total	185	41.93	16.10	54	39.94	16.51	0.793ª	0.429					

	Gender												
		Male			Femal	e	t	р					
	n	\overline{X}	S_X	n	\overline{X}	S_X							
Intrusion	112	8.92	3.80	127	11.25	5.07	-4.049 ^b	< 0.001					
Avoidance	112	16.17	5.80	127	19.06	7.19	-3.439 ^b	< 0.001					
Arousal	112	12.03	5.05	127	15.02	5.73	-4.253ª	< 0.001					
STSS-Total	112	37.12	13.67	127	45.33	17.27	-4.099 ^b	< 0.001					

^a: Student t-test

^b: Welch's t-test

Table 7. Dese	able 7. Descriptive statistics of 5155 decording to job													
		Doctor	•		Nurse	•		Other		Б				
	n	\overline{X}	S_X	n	\overline{X}	S_X	n	\overline{X}	S_X	F	р			
Intrusion	124	10.00	4.54	91	10.78	4.91	24	8.63	4.01	2.202	0.113			
Avoidance	124	18.23 ^a	6.41	91	18.09 ^a	6.93	24	13.58 ^b	6.31	5.211	0.006^{**}			
Arousal	124	13.88ª	5.34	91	14.07 ^a	5.92	24	10.54 ^b	5.04	4.134	0.017^{*}			
STSS-Total	124	42.10 ^a	15.32	91	42.93 ª	17.10	24	32.75 ^b	14.84	4.053	0.019*			

Table 7. Descriptive statistics of STSS according to job

F: One-way ANOVA

*:<0.05, **:<0.01

Means that do not share a common letter are significantly different at p<0.05

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rable	0.	Descri	puve	statistics	01	2122	according	ω	working p	berioù

	Working period (years)													
	<u> </u>					11-15				15↑		T		
	n	\overline{X}	S_X	n	\overline{X}	S_X	n	\overline{X}	S_X	n	\overline{X}	S_X	ľ	р
Intrusion	84	10.26 ^a	4.62	51	11.67 ^a	4.99	47	10.57 ^a	5.11	57	8.32 ^b	3.37	6.633+	< 0.001
Avoidance	84	18.73 ª	6.32	51	20.33 a	6.53	47	17.40 ª	7.11	57	14.11 ^b	5.67	9.683	< 0.001
Arousal	84	14.82 ª	5.18	51	15.53 ª	5.88	47	13.30 ª	5.70	57	10.39 ^b	4.50	10.795	< 0.001
STSS-Total	84	43.81 ª	15.04	51	47.53 a	16.56	47	41.28 ª	17.26	57	32.81 ^b	13.04	9.296	< 0.001

F: One-way ANOVA

F⁺: One-way ANOVA

Means that do not share a common letter are significantly different at p<0.05

		Never			Rarely	ý		Ofter	1	Б	n
	n	\overline{X}	S_X	n	\overline{X}	S_X	n	\overline{X}	S_X	ľ	р
		Меа	lical or p	param	nedical u	se of sec	lative	or rela	xant sub	stances	
Intrusion	211	9.95	4.68	18	11.89	3.85	10	11.40	5.27	1.813	0.165
Avoidance	211	17.42	6.78	18	19.72	5.96	10	20.10	6.23	1.642	0.196
Arousal	211	13.31	5.63	18	15.67	4.89	10	16.30	5.56	2.690	0.070
STSS-Total	211	40.69	16.32	18	47.28	13.66	10	47.80	15.14	2.193	0.114
	Alcohol use status										
Intrusion	151	10.09	4.78	67	10.30	4.53	21	10.24	4.39	0.051	0.950
Avoidance	151	17.42	6.70	67	17.97	7.08	21	18.90	5.73	0.517	0.597
Arousal	151	13.44	5.51	67	13.70	6.02	21	14.57	5.19	0.381	0.684
STSS-Total	151	40.95	16.16	67	41.97	17.06	21	43.71	13.72	0.309	0.735
					Sn	ioking S	tatus				
Intrusion	125	10.13	4.65	48	11.02	4.56	66	9.59	4.73	1.317	0.270
Avoidance	125	17.54	6.76	48	19.27	6.59	66	16.88	6.66	1.850	0.159
Arousal	125	13.62	5.52	48	14.42	5.90	66	13.03	5.59	0.847	0.430
STSS-Total	125	41.29	16.19	48	44.71	16.15	66	39.50	16.08	1.464	0.233

Table 9. Descriptive statistics of STSS according to length of service

F: One-way ANOVA

	2
Covid-19 patients during the pandemic period you worked?' in relation to STSS	

	Never			Rarely			Mostly				Alway	5	\mathbf{F}^+	р
	n	\overline{X}	S _X	n	\overline{X}	S_X	n	\overline{X}	S_X	n	\overline{X}	S_X		
Intrusion	8	6.38 ^b	2.07	50	9.50ª	3.86	131	11.04 ª	4.77	50	9.12ª	4.87	10.254	< 0.001
Avoidance	8	9.50 °	2.73	50	16.22 ^b	5.85	131	19.34 ^a	6.20	50	16.24 ^b	7.71	25.761	< 0.001
Arousal	8	7.00 °	2.27	50	11.54 ^b	4.97	131	15.33 ª	5.01	50	12.26 ^b	6.32	28.732	< 0.001
STSS-Total	8	22.88 °	6.42	50	37.26 ^b	14.08	131	45.70 ^a	14.98	50	37.62 ^b	18.30	25.017	< 0.001

F⁺: Welch's ANOVA

Means that do not share a common letter are significantly different at p<0.05

Table 11. The variation based on responses to the question	'What was your monthly working hours during
the Covid-19 pandemic?' in relation to STSS.	

	No	Normal working hours			ss than r orking l exible wo hours	ormal nours orking	Mor wo	e than no orking ho	ormal ours	F	р
	n	\overline{X}	S_X	n	\overline{X}	S_X	n	\overline{X}	S_X		
Intrusion	90	10.89	4.99	80	9.89	4.53	69	9.52	4.29	1.898	0.152
Avoidance	90	18.86	6.52	80	17.26	7.00	69	16.72	6.53	2.249	0.108
Arousal	90	14.56	5.39	80	13.43	5.90	69	12.61	5.45	2.448	0.089
STSS-Total	90	44.30	15.96	80	40.58	16.70	69	38.86	15.51	2.428	0.090

F: One-way ANOVA

The Cronbach's alpha coefficient of this scale and all dimensions is 0.88–0.96, with good reliability (Table 5).

Neither the total nor the sub-dimension scores of the STSS showed significant differences based on whether the city of residence was a major city or not (p>0.05). However, a significant difference was observed in STSS scores based on gender, with women having higher averages in both the total and subdimension scores (p<0.001) (Table 6).

The 'Intrusion' sub-dimension of the STSS did not differ significantly according to the task groups of the participants (p>0.05). However, the 'Avoidance' and 'Arousal' sub-dimensions and the total score of the scale showed significant differences according to the task groups of emergency service workers (p<0.01, p<0.05, p<0.05, respectively). While there was no significant difference in the 'Avoidance', 'Arousal', and 'Total' scores between doctors and nurses working in emergency services (p>0.05), the 'Avoidance', 'Arousal', and 'Total' scores of other emergency service workers were statistically significantly lower than those of both doctors and nurses (p<0.05) (Table 7).

STSS scores showed significant differences according to the years of service of emergency service workers (p<0.001) (Table 8). While there was no significant difference among those with years of service of '1-5 years,' '6-10 years,' and '11-15 years' (p>0.05), the scores of those

with '15 years and over' of service were significantly lower (p<0.05).

STSS scores did not show significant differences based on the use of medical or paramedical sedatives or relaxants, alcohol, and smoking among emergency service workers (p>0.05) (Table 9).

Significant differences were found in STSS scores based on the responses of emergency service workers to the question, 'How often do you encounter COVID-19 patients on the days you work during the pandemic?' (p<0.001) (Table 10). The 'Intrusion' sub-dimension of the scale was found to be significantly lower among those who never encountered COVID-19 patients compared to those who did encounter them daily (p<0.05). There was no significant difference between those who encountered COVID-19 patients daily and those who answered 'rarely,' 'mostly,' and 'always' (p>0.05). For the 'Avoidance' subdimension, those who encountered COVID-19 patients daily had significantly lower scores compared to those who never encountered them (p<0.05). While there was no significant difference between those who encountered COVID-19 patients 'rarely' and 'always' 'Avoidance' (p>0.05), the scores were significantly higher among those who answered 'mostly' (p<0.05). The same pattern was observed for both the 'Arousal' sub-dimension and the total score of the scale.

STSS scores did not show significant differences based on the responses of emergency service workers to the question, 'What is your monthly working hours during the COVID-19 pandemic?' (p>0.05) (Table 11).

DISCUSSION

In the study, neither the total nor the subdimensions of the STSS showed significant changes based on whether the city of residence was a large city or not. However, it was determined that the STSS significantly varied by gender. It was found that women had higher averages in both the total and sub-dimensions. This suggests that the size of the city is not a determining factor for secondary traumatic stress levels among healthcare workers. In the study, women had higher averages in both total STSS scores and sub-dimensions. This finding can be interpreted as female healthcare workers experiencing secondary traumatic stress more intensely than their male colleagues. Similarly, Derya et al. (10) found a significant relationship between gender and STSS. Orrù et al. also found that STSS scores were higher in women than in men (13). Other studies have yielded similar results (14, 15). However, Ilhan and Küpeli (9) did not find a difference between gender and STSS.

In the study, the 'Avoidance' and 'Arousal' subdimensions and total scores of the scale showed significant differences according to the task groups of emergency service workers. While there was no significant difference between the

'Arousal', 'Avoidance', and 'Total' scores of doctors and nurses, it was observed that the 'Avoidance', 'Arousal', and 'Total' scores of other emergency service workers were statistically significantly lower than those of both doctors and nurses. These findings demonstrate differences in secondary traumatic stress levels among emergency service workers according to their task groups. While no significant difference was found between doctors and nurses, other emergency service workers were found to have lower levels of these stress symptoms. This may suggest that the different tasks of emergency service workers affect their levels of secondary traumatic stress and that these professional groups may have different coping mechanisms. In similar studies, Salameh et al. found higher percentages of STSS in nurses (16). Other studies have also yielded similar results (4, 7, 14, 17). No studies were found in the literature comparing the sub-dimensions of the STSS scale used in this study.

In the study, STSS scores showed significant differences according to the years of service of emergency service workers. However, no significant difference was found among those with '1-5 years', '6-10 years', and '11-15 years' of service, while the scores of those with '15 years and over' were found to be significantly lower. This can be explained by the fact that those who have worked in the emergency environment for many years' experiences less secondary traumatic stress. The results suggest that the professional experience of emergency service workers may have a significant impact on secondary traumatic stress. Long-term service may allow emergency service workers to develop coping mechanisms for occupational stress and better adapt to traumatic experiences. From another perspective, the professional experience of emergency service workers can be considered an important factor in supporting the sustainability of healthcare services.

In the study, significant differences were found in STSS scores based on the responses of emergency service workers to the question, 'How often do you encounter COVID-19 patients on the days you work during the pandemic?'. The 'Intrusion' sub-dimension of the scale was found to be significantly lower among those who never encountered COVID-19 patients compared to those who encountered them daily. No significant difference was found between those who encountered COVID-19 patients daily and those who answered 'rarely,' 'mostly,' and 'always'. However, the 'Avoidance' sub-dimension was found to be significantly lower among those who never COVID-19 encountered patients. The 'Avoidance' found to scores were be significantly higher among those who answered 'mostly'. The same pattern was observed for both the 'Arousal' sub-dimension and the total score of the scale. The 'Intrusion' subdimension of the STSS scale was found to be

significantly lower among emergency service workers who never encountered COVID-19 patients daily. This can be interpreted as those who did not have contact with COVID-19 patients experiencing fewer symptoms of intrusion caused by such traumatic experiences. The lack of significant differences in the 'Intrusion', 'Avoidance', and 'Arousal' subdimensions and the total score between those who encountered COVID-19 patients 'rarely', 'mostly', and 'always' suggests that the frequency of encountering COVID-19 patients does not affect the secondary traumatic stress levels of emergency service workers. However, a significant difference was found in the 'Avoidance' sub-dimension between those who never encountered COVID-19 patients and encountered those who mostly them. Additionally, the 'Avoidance' sub-dimension scores were found to be higher among emergency service workers who mostly encountered COVID-19 patients. This indicates that the frequency of encountering COVID-19 patients daily has a significant impact on avoidance and arousal symptoms. The traumatic experiences faced by workers during the COVID-19 pandemic may have influenced their stress symptoms and caused functional impairments.

CONCLUSION

The study found that gender, years of service, task groups, and the frequency of encountering COVID-19 patients daily had a significant impact on STSS scores. Women generally had higher STSS scores, with a notable difference in the 'Avoidance' sub-dimension. Additionally, those with long-term service and those who did not encounter COVID-19 patients daily had lower STSS scores.

In this context, it is important to consider factors such as gender, years of service, and professional experience to support the mental health of emergency service workers. Developing support programs and stress management strategies for female workers is crucial. Furthermore, training and guidance programs to enhance the coping skills of new emergency service workers should be established. Given the impact of daily encounters with COVID-19 patients on STSS levels during the pandemic, providing psychosocial support to healthcare workers during such periods is essential. Strengthening coping strategies and facilitating access to supportive resources for emergency service workers in extraordinary situations like the COVID-19 pandemic will help maintain the sustainability of healthcare services and protect the health and well-being of emergency service workers.

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Ethics Committee Approval: Ethical approval

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