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Impact of Patient Safety Incidents Reported by the General Public in Korea

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Objective: The study aimed to investigate the impacts of patient safety incident (PSI) experienced by the general public.

Methods: We conducted a self-administered online survey, in which we examined the following experiences of the patients and the caregivers: the level of harm induced by PSIs, difficulties due to PSIs, posttraumatic stress disorder (PTSD), and posttraumatic embitterment disorder, etc. A χ^2 test was performed to identify differences in difficulties because of the direct and indirect experience of PSIs. A 1-way analysis of variance was performed to identify the differences in the total PTSD and posttraumatic embitterment disorder scores according to the characteristics of PSIs.

Results: Of the survey participants who indirectly experienced PSIs, 27.2% and 29.3% reported that they experienced sleep disorder and eating disorder, respectively. However, of the participants who directly experienced PSIs, 40.7% and 42.6% reported experiencing sleep disorder and eating disorder, respectively. The average PTSD scores of the participants who experienced permanent disability and death were 83.8 points for less than 6 months of elapsed time since the incident, 80.8 points for 6 months to less than 5 years, and 94.7 points for 5 years or more; they did not demonstrate a statistically significant difference ($P = 0.217$).

Conclusions: This study suggested that the general public who experienced PSIs have numerous difficulties at the time of the incident and the trauma or the resentment of the general public does not quickly regress even if time passes.

Key Words: patient safety, patient safety incident, adverse event, medical error, posttraumatic stress disorder, posttraumatic embitterment disorder

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The World Health Organization defines patient safety as “the absence of preventable harm to a patient during the process

of healthcare and reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum.”¹ Patient safety requires the collaboration of various stakeholders involved in the process of providing and receiving health services.² Teamwork and collective efforts are key to minimizing and preventing the occurrence of adverse events.³ However, complete patient safety cannot be ensured merely by reducing preventable incidents. It is also crucial for healthcare professionals to alleviate the physical suffering of the patient affected by the incident, stabilize the condition of the patient and the caregiver, and assist in resolving in any practical challenges, such as financial difficulties.⁴ Furthermore, the healthcare professionals are expected to respond promptly after the occurrence of any such patient safety incidents (PSIs), which include adverse events and medical errors.⁵

In their qualitative study, Pyo et al⁶ described how a medical accident that caused paraplegia resulted not only in physical impairment but also triggered psychological distress in the patient. In cases where the condition calls for lifetime therapy and rehabilitation treatment, the financial incapability of the patient can hinder complete recovery.⁶ Another qualitative study reveals the case of a child who became the victim of a medical accident and whose mother put her life aside and devoted herself completely to the treatment of her child.⁷ A qualitative case study of a family that lost a member in an absurd and unexplainable manner in a medical accident details the emotional journey of the affected family and how it struggled to cope with the loss of their loved one.⁸ Throughout the process of medical litigation, the victims of medical accidents experience disruption of social beliefs and frustration caused by the irrationality of bearing the burden of proof and unfair countermeasures of the medical and legal professions.^{6,8} These studies demonstrate that medical accidents affect not only the lives of the victims but also their families and their surroundings.

Although evidence in the form of qualitative research on first victims of PSIs, which include patients and their caregivers, is available, not many studies have been conducted that quantify the extent of difficulties confronted by them. The Republic of Korea has not yet established a system that can accurately examine the current status of PSIs. A study by Ock et al⁹ revealed that approximately 3.4% of the general population reported PSIs and that 5.3% reported that their family members had been victims of PSIs. The statistics on PSIs can be derived from the number of counseling cases related to medical disputes. According to the Mediation and Arbitration Statistical Yearbook of the Korea Medical Dispute Mediation and Arbitration Agency, there has been an increase in the number of consultation cases related to medical disputes in the last 3 consecutive years. In 2016, there were 46,735 cases, which increased to 54,929 in 2017 and 65,176 in 2018.¹⁰ Furthermore, the number of PSIs reported in the Patient Safety Reporting System, which was established under the Patient Safety Act of 2016 and implemented by the Medical Evaluation and Certification Service, reached 20,000 as of May 2019.¹¹ Based on the figures of voluntary reports by medical professionals, patients, and caregivers, it can be presumed that a substantial number of PSIs have occurred.

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However, it is difficult to identify the complications experienced by first victims using these data. Identifying the physical, mental, and financial difficulties experienced by the first victims can be used as a basis for highlighting PSI as an issue that requires attention and establishing measures to support the victims. In this study, we evaluated the impact of PSIs on the physical, mental, and financial difficulties of the first victims. In particular, post-traumatic stress disorder (PTSD) and posttraumatic embitterment disorder (PTED) questionnaires were administered to measure the psychological difficulties caused by PSIs. Through this study, it is hoped that the issue of the first victims of PSIs will be recognized and specific support measures will be instituted.

METHODS

A self-administered online survey was conducted to identify the experiences of the general public (patients and the caregivers), who are defined as the first victims of the PSIs. The survey included questions on the characteristics of the PSIs and the difficulties caused by the PSIs.

Questionnaire

The questionnaires were developed based on previous studies^{9,12,13} that examined the types of PSIs experienced by the general public. Qualitative studies^{6–8} of medical accidents and the systematic literature review¹⁴ of second victims, who experienced numerous difficulties because of PSIs, helped develop questionnaire items on the consequences of PSIs on victims. After several discussions among the researchers, a draft questionnaire was developed, which was then reviewed by two people from a nonmedical field. Based on their observations in a cognitive debriefing, the items and phrases were amended.

The entire questionnaire comprised questions on (1) the characteristics of PSIs, (2) the experiences of disclosure of PSIs, (3) the impacts of PSIs, and (4) the sociodemographic characteristics of the first victims. In this study, we focused on the characteristics of the PSIs and the impacts of PSIs. Experiences of the disclosure of PSIs are described in another study.¹⁵

Characteristics of PSIs included the following items: the number of direct and indirect experiences of PSI, the elapsed time after the most memorable PSI, and the type of the most memorable PSI. Indirect experience of PSIs was limited to immediate family members, which include parents, siblings, and children. Moreover, the level of harm of the most memorable PSI and the opinions on the occurrence of medical error over the most memorable PSI were included. The impacts of the most memorable PSI were identified through occurrence of difficulties such as sleep disorders, eating disorders, and financial difficulties, and the PTSD and PTED results were also collected. Sociodemographic characteristics of the participants were collected, which included sex, age, and educational qualification. The questionnaire can be referred to in Appendix (Supplemental Digital Content 1, <http://links.lww.com/JPS/A290>.)

The PTSD and PTED

The PTSD instrument used in the study of Park¹⁶ was applied. The PTSD instrument, which measures the past and present effects of trauma, comprises 30 items and uses the following 6-point scale: 1 point for “strongly disagree,” 2 points for “disagree,” 3 points for “slightly disagree,” 4 points for “slightly agree,” and 5 points for “agree,” and 6 points for “strongly agree.” For PTED, the measure proposed by Linden et al¹⁷ was modified and revised. The instrument consists of 19 items to determine the severe adverse events in life. In this study, the phrases were adapted to identify the impacts of the most recalled PSI of the participants. The PTED instrument exercised the same 5-point scale

as the following: 1 point for “not true at all,” 2 points for “hardly true,” 3 points for “true,” 4 points for “very much true,” and 5 points for “extremely true.”

Survey and Participants

The survey was executed online over a period of 3 months, from November 2018 to January 2019. Individuals who experienced a PSI were eligible to participate in the survey. To assist the participants in completing the survey with an adequate understanding of the terms of the PSI, terms such as patient safety, medical error, adverse event, PSI, and medical accident were defined in the questionnaire, based on previous studies.^{9,18,19} Because the present study sought to determine the level of the impacts of PSIs, the first question asked whether the participants had experienced PSIs. The survey ended for those who responded that they had not experienced a PSI. We defined first victim as someone who experienced any type of PSI directly or indirectly at any time.

The survey was publicized through online blog postings, recommendations of acquaintances and nonprofit patient organizations, and word of mouth. Therefore, snowball sampling method was used. To avoid duplicate participation, the IP address was tracked and rejected if appeared more than once. To avoid incomplete responses, participants were not allowed to skip a question without providing a response.

Analysis

Frequency analysis was performed to identify the response characteristics of each survey item. A χ^2 test was performed to identify the differences in difficulties because of the direct and indirect experience of PSIs. To analyze the responses on the PTSD and PTED instruments, the item scores were summated to obtain the total score. A one-way analysis of variance was performed to identify the differences between each sum of PTSD and PTED according to the level of harm and the elapsed time after the occurrence of the PSI. A linear regression analysis was conducted to identify the factors associated with PTSD and PTED scores. The PTSD and PTED scores were regarded as the dependent variables, and the sociodemographic characteristics of participants (sex, age group, and education), the level of harm of PSI, the experience of PSI (direct or indirect), the time elapsed since PSI, and opinions on medical error–related PSI were included as independent variables.

Data were summarized using Microsoft Excel 2007 (Microsoft Corporation, Seattle, WA), and SPSS 21.0 (IBM Corp, New York, NY) and Stata/SE13.1 (StataCorp, Texas, TX) were used in the statistical analysis. The *P* value of less than 0.05 was considered statistically significant.

Ethics Committee Approval

This study was approved by the institutional review board of the University of Ulsan Hospital (IRB Number: 2018-07-003).

RESULTS

Sociodemographic Characteristics

A total of 201 participants (79 males and 122 females) participated in the study. A majority of them were in their 20s (42.8%) and their 30s (40.3%). Of the total number of participants, 156 (79.1%) held a bachelor’s degree. Details of the sociodemographic characteristics of the participants are presented in Table 1.

Characteristics of PSIs Experiences

Most of the participants had indirect experiences of PSIs, that is, they had either witnessed or heard about incidents that had

TABLE 1. Sociodemographic Characteristics of Survey Participants

	Frequency	%
Sex		
Male	79	39.3
Female	122	60.7
Age		
20s	86	42.8
30s	81	40.3
40s	11	5.5
50s	12	6.0
>60s	11	5.5
Final education level		
Below middle school graduate	1	5.0
High school graduate	13	6.5
Bachelor's degree	156	79.1
Master's or higher degree	28	13.9
Total	201	100.0

occurred with an immediate family member (Table 2). The most frequent elapsed time was 1 to 5 years, with 73 participants (36.3%). Diagnosis-related PSIs were the most recalled type of PSIs (44.9%), which included false diagnosis, delayed diagnosis, and others. For the level of harm of PSIs, “less than a month for

recovery” accounted the most with 59 participants (29.4%), followed by “1 month to less than 6 months for recovery” with 35 participants (17.4%), and “no harm” with 34 participants (16.9%). A total of 130 participants (64.7%) believed that a medical error had caused the PSI.

Difficulties Due to the Direct or Indirect Experience of PSIs

Of the participants who indirectly experienced PSIs, 27.2% and 29.3% reported that they experienced sleep disorders and eating disorders, respectively, whereas among those who directly experienced PSIs, 40.7% and 42.6%, respectively, reported the same disorders (Fig. 1). These results were statistically significant. With regard to financial difficulties experienced by the participants, those with direct exposure to PSI experienced greater financial difficulties (31.5%) than did those with indirect exposure (22.4%). These were, however, not statistically significant.

The PTSD and PTED Instrument Scores According to the Level of Harm and Elapsed Time After PSI

Table 3 presents the PTSD and PTED instrument scores between the level of harm and the elapsed time after PSI. Most of the results did not show statistically significant differences. For example, the participants who experienced a PSI and recovered in less than a month from the injury showed an average PTSD score of 82.2 at a lapse time of less than 6 months since the incident. The average PTSD scores at more than 6 months to less than 5 years and 5 years or more of elapsed time because the accidents

TABLE 2. Characteristics of PSIs Experiences of the Participants

	Items	Frequency	%
Experience of PSIs	Had direct experience	23	11.4
	Had indirect experience through an immediate family member, such as witnessing or hearing	147	73.1
	Had direct and indirect experience	31	15.4
Elapsed time since PSIs	<1 mo	10	5.0
	>1 mo to <6 mo	28	13.9
	>6 mo to <1 y	31	15.4
	>1 y to <5 y	73	36.3
	>5 y	59	29.4
The most recalled PSI type (multiple responses)	Diagnosis-related PSI (e.g., diagnosis error, delayed diagnosis, and more.)	105	44.9
	Medication, fluid administration and transfusion-related PSI (e.g., adverse effects of medication and transfusion, and more.)	37	15.8
	Patient care-related PSI (e.g., fall, decubitus ulcer, suicide, and more.)	21	9.0
	Surgery or procedure-related PSI (e.g., enterobrosia from an endoscope, and more.)	45	19.2
	Infection-related PSI (e.g., surgical site infection, catheterization-related urinary tract infection, and more.)	17	7.3
The level of harm of PSI	Other PSI	9	3.9
	No harm	34	16.9
	It took <1 mo to recover from the harm	59	29.4
	It took >1 mo to <6 mo to recover from the harm	35	17.4
	It took >6 mo to recover from the harm	22	10.9
Opinions on medical error–related PSI	It left permanent disability	21	10.4
	Death	30	14.9
	There was a medical error.	130	64.7
	There was not a medical error.	19	9.5
	I do not know.	52	25.9

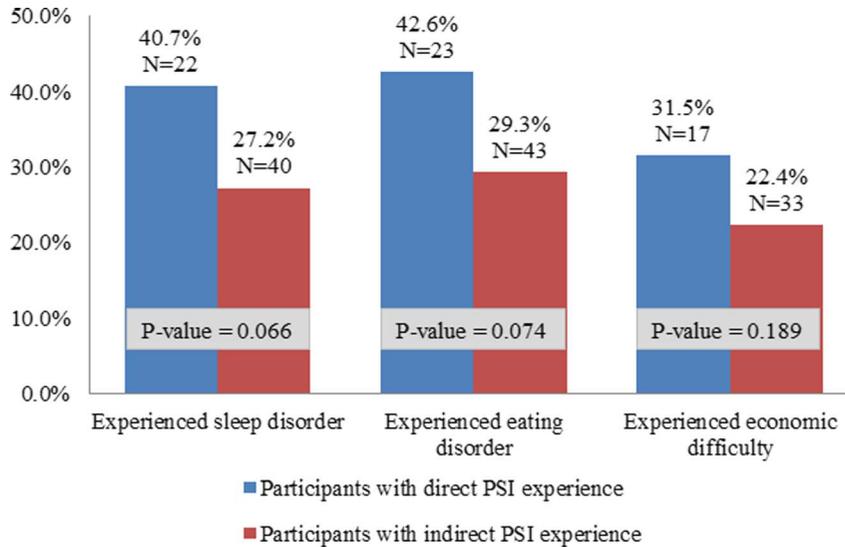


FIGURE 1. Difficulties due to PSI experiences according to the types of experiences.

were 67.9 and 69.3, respectively; these differences were statistically not significant ($P = 0.113$). Moreover, the average PTSD scores of the participants who experienced permanent disability and death were 83.8 points at less than 6 months of elapsed time since the incident, 80.8 points at 6 months to less than 5 years, and 94.7 points at 5 years or more; they did not demonstrate a statistically significant difference ($P = 0.217$).

Factors Associated With PTSD and PTED Instrument Scores

The results of linear regression revealed that PTSD scores were higher by 20.37 points (95% confidence interval [CI] = 10.23 to 30.51) when the level of harm of PSIs was more than 1 month to recover from the harm than when the level of harm of PSIs was less than 1 month to recover (Table 4). Furthermore, PTSD scores were lower by 17.27 points (95% CI = -32.02 to -2.52) when participants did not regard PSIs as medical errors than when they regarded PSIs as medical errors. Posttraumatic embitterment disorder scores were lower by 4.82 points (95% CI = -9.24 to -0.39) when experience of PSIs was indirect than when it was direct. In addition, PTED scores were lower by 7.69 points (95% CI = -13.05 to -2.33) when elapsed time since PSIs was

more than 6 months to less than 5 years than when that was less than more than 1 month to less than 6 months.

DISCUSSION

The purpose of this study was to investigate the impact of PSIs among the general public through a self-administered online questionnaire. A total of 201 participants responded and data on various aspects of the PSI experience were analyzed. There have been several studies of the experience frequency and characteristics of PSIs and the experiences of the medical professionals' countermeasures to the PSIs.^{9,12,13,20} However, no studies have quantitatively examined the physical, mental, and financial difficulties experienced by the general public because of PSIs. The significance of this study is that it establishes a basis for the necessity of supporting members of the general public who may encounter PSI and paves the way for developing content related to such support.

First of all, it is perceptible that diagnosis-related PSI, such as diagnostic error or delayed diagnosis, represented a majority of PSI (105 cases, 44.9%). Among the precedent studies conducted in Korea, diagnosis-related PSI was identified as the primary incident type.⁹ Despite numerous methods to verify PSIs, such as medical record review, administrative data analysis, medical

TABLE 3. Comparison of PTSD and PTED Instrument Scores Between the Level of Harm and the Elapsed Time After PSIs

			Elapsed Time Since PSI									P
			<6 mo			>6 mo to <5 y			>5 y			
			CI			CI			CI			
			Avg.	Min	Max	Avg.	Min	Max	Avg.	Min	Max	
The level of harm (recovery period)	<1 mo	PTSD	82.2	74.1	90.3	67.9	58.4	77.3	69.3	56.3	82.3	0.113
		PTED	44.7	39.0	50.3	34.0	29.7	38.2	36.8	31.3	42.3	0.009
	>1 mo	PTSD	83.9	48.0	119.7	93.4	83.3	103.5	91.0	67.3	114.7	0.769
		PTED	39.1	25.3	52.9	42.9	38.7	47.2	44.2	32.0	56.3	0.740
Permanent disability and death		PTSD	83.8	33.9	133.6	80.8	69.9	91.7	94.7	83.2	106.2	0.217
		PTED	40.0	21.8	58.2	38.1	33.2	43.1	43.8	38.0	49.6	0.310

TABLE 4. Regression Analysis of Factors Related to PTSD and PTED Instrument Scores

	PTSD			PTED		
	Coefficient	95% CI		Coefficient	95% CI	
Lower		Upper	Lower		Upper	
Sex						
Men	Ref			Ref		
Women	3.20	-5.56	11.96	-1.62	-5.69	2.45
Age, y						
19-29	Ref			Ref		
30-39	4.66	-4.46	13.79	1.69	-2.55	5.94
40-49	2.02	-16.46	20.49	4.97	-3.62	13.56
50-59	-13.58	-32.63	5.48	-7.07	-15.93	1.80
≥60	-3.15	-22.53	16.24	-0.01	-9.02	9.01
Education level						
Below middle school graduate	Ref			Ref		
High school graduate	10.24	-51.24	71.71	-14.24	-42.83	14.35
Junior college graduate	-4.53	-65.18	56.11	-17.25	-45.45	10.95
Senior college graduate	-13.31	-72.31	45.68	-23.70	-23.70	3.73
Master's or higher degree	-12.67	-77.31	47.10	-23.72	-23.72	4.08
Level of harm						
<1 mo to recover from the harm	Ref			Ref		
> 1 mo to recover from the harm	20.37	10.23	30.51	5.73	1.02	10.45
Permanent disability or death	16.18	5.55	26.80	4.64	-0.30	9.58
Experience of PSIs						
Direct experience	Ref			Ref		
Indirect experience	-8.91	-18.42	0.60	-4.82	-9.24	-0.39
Elapsed time since PSIs						
>1 mo to <6 mo	Ref			Ref		
>6 mo to <5 y	-11.09	-22.62	0.45	-7.69	-13.05	-2.33
>5 y	-5.11	-17.56	7.33	-3.84	-9.53	2.04
Opinions on medical error-related PSI						
There was a medical error.	Ref			Ref		
There was not a medical error.	-17.27	-32.02	-2.52	-5.83	-12.69	1.03
I do not know.	-11.94	-21.77	-2.11	-2.71	-7.28	1.86

Bolded items are statistically significant results.

litigation analysis, and patient safety reporting system analysis, the cause of the incident being diagnostic-related is revealed clearly in the responses of the participants who were affected directly or indirectly. It is unlikely that the medical professionals would leave any information related to diagnosis-related PSI in the medical records.²¹ Consequently, to confirm the magnitude of the diagnosis-related PSI, it is necessary to develop a strategy that enables effective incident reporting of patients or the general public. There is an urgent need to implement evidence-based strategies to reduce the diagnosis-related PSI.²²

This study observed that approximately 40% of the participants who reported any direct experience of a PSI and 30% of those who had an indirect exposure of a PSI complained of sleep disorders and eating disorders. Although the comparability is limited because of differences in data collection methods, it can be assumed that the members of the general public who encountered PSI face huge challenges from the time the incident took place, as approximately 7% to 10% of adults in Korea are known to experience insomnia.²³ Furthermore, approximately 30% of the participants with direct exposure and 20% with indirect exposure reported facing financial difficulties. A person who has experienced a PSI is more likely to have faced financial difficulties if he or she had

to go through medical litigation for an extended period.⁸ Besides, financial difficulties can be amplified if any disability that led to obstruction in earning one's livelihood was caused.⁶ Hence, it is essential to have measures in place to support patients encountering PSI and their caregivers in facing the physical, mental, and financial difficulties.

Extensive discussions on the countermeasures taken by the medical community in PSIs that occurred in the past are available in literature.⁴ Support for the second victims who experience emotional suffering and adverse events have also been the subject of comprehensive discussions.^{14,24-26} However, relatively insufficient attention has been paid regarding the subject of specific measures to support patients and their caregivers. Although some results of regression showed a decrease in PTED scores over time, it could be inferred that the victims do not overcome the trauma or resentment quickly even with the passage of time, regardless of the level of harm caused. The phrase "Time heals all wounds" cannot be applied to patients and their caregivers who have encountered PSIs.

It is, therefore, indispensable that a plan be prepared to support the possible physical, psychological, and financial difficulties of patients and their caregivers in the event of a PSI. In particular, it is necessary to have psychological support programs for the first

victims, such as the second victim's psychological support program. In this context, given the high scores on PTSD and PTED when the level of harm due to PSIs is high in the regression analysis, priority should be given to those who have experienced a high level of harm. Furthermore, as in the case of the second victims,²⁷ it is crucial to monitor the psychological condition of the first victims or to regularly conduct a PSI or medical error experience survey for the entire population. Moreover, it is difficult for patients and their caregivers to prove the negligence of a medical professional due to the uncertainty of the medicine when they decide to take legal action on the grounds of medical negligence based on suspicion. It is recommended that the no-fault compensation system, which does not require the victim to prove the medical negligence to be compensated for the harm or damage occurred during medical practice, be implemented. It is also essential to develop a strategy for establishing an alternative dispute resolution system that would overcome the disadvantages of medical dispute resolution through litigation.⁴

This study has a number of limitations. First, as cross-sectional questionnaires were administered to those among the general public who had encountered a PSI, there were limitations in accurately measuring the impact on the psychological conditions of the patients or their caregivers following the PSI. Therefore, there could have been a recall bias. Future research should conduct a longitudinal study on the impacts and difficulties of the general public with PSI experiences at the institutional level using data from sources such as the Mediation and Arbitration Statistical Yearbook of the Korea Medical Dispute Mediation and Arbitration Agency and the Korea Institute for Healthcare Accreditation. Second, as the data for this study were collected through an online survey, the study participants are not completely representative of the general public with PSI experience. It is proposed that another study of PSI be conducted using a larger sample that represents the general population with experience of PSI and the results of the study be compared with the results of the present study. Investigating the experience of PSIs on a larger sample would also enable detailed analyses of each type of PSI. Third, as in other studies,^{19,28} this study is also challenged by the limitation of verification failure for the validity of the reported PSI through additional methods. Therefore, estimating the magnitude of PSIs experienced by the general public from the study results should be undertaken with caution. Fourth, although we used PTSD and PTED instruments to identify the symptoms of PTSD and PTED and compare them according with the characteristics of participants, these instruments were not used to clinically diagnose PTSD and PTED. Therefore, it is not possible to determine the prevalence rates of PTSD and PTED from this study. In future studies, clinical diagnoses of PTSD and PTED are needed to determine prevalence rates PTSD and PTED among first victims.

CONCLUSIONS

Despite these limitations, this study is meaningful as it offers a quantitative analysis of the difficulties experienced by the general public who have experienced PSIs. It is hoped that the findings of this study would draw attention to the various difficulties faced by the first victims of the PSI and their caregivers. It is especially crucial to escalate the discussion on the development and application of the counseling support program that can support the psychological difficulties of the general public with the PSI experience, especially. Furthermore, we recommend that future studies investigate the experiences and impacts of PSIs on more representative public samples at a national level on a regular basis.

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