



STRESS MANAGEMENT INTERVENTION TO PREVENT POST-INTENSIVE CARE SYNDROME-FAMILY IN PATIENTS' SPOUSES

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Background Post-intensive care syndrome-family (PICS-F) refers to acute and chronic psychological effects of critical care on family members of patients in intensive care units (ICUs). Evidence suggests that increased distress during the ICU stay increases risk of PICS-F. Sensation Awareness Focused Training (SĀF-T) is a new, promising stress management intervention, but the feasibility of such training during the ICU stay for family caregivers who are acting as the surrogate decision-maker for patients who are undergoing mechanical ventilation is unknown. **Objectives** To assess feasibility and acceptability of SĀF-T to inform a future larger randomized controlled trial.

Methods This randomized controlled trial of SĀF-T (n=5) versus a control (n=5) group was conducted at a level 1 trauma center. Participants assigned to SĀF-T completed 1 session daily for 3 days. Measures included enrollment rate, data completion rate, acceptability of SĀF-T, and symptoms of PICS-F. Scales used included Perceived Stress, Hospital Anxiety and Depression, Impact of Event, and National Institutes of Health Toolbox Emotion Battery.

Results Mean age was 58 (SD, 12) years; 70% of participants were female. Predetermined feasibility criteria were met in enrollment rate (67%), outcome measures completion rate (>90%), and SĀF-T acceptability (100% of doses completed during the ICU stay) without adverse events. Stress scores after SĀF-T were significantly lower than scores before SĀF-T ($z = -3.5$, $P = .01$).

Conclusions SĀF-T intervention during the ICU stay is feasible, acceptable, and may improve family caregivers' post-ICU outcomes. Larger clinical trial to assess the effectiveness of SĀF-T in preventing PICS-F seem warranted. (*American Journal of Critical Care*. 2019;28:471-476)

Families suffer a great deal when a loved one is admitted to the intensive care unit (ICU). The Society of Critical Care Medicine has identified a cluster of complications that patients can experience after critical care as post-intensive care syndrome, or PICS, with an added F to represent effects on the patient's family: PICS-F.¹ Spouses who act as surrogate decision-makers for critically ill patients are more likely than other family members to suffer from PICS-F, including acute stress disorder, ongoing anxiety, depression, and posttraumatic stress disorder (PTSD).²⁻⁵ Strong evidence indicates that family member distress during the ICU stay increases the risk of PICS-F,⁶⁻¹⁴ yet effective interventions for managing family members' stress are limited.¹⁵

Family distress in the intensive care unit increases risk of post-intensive care syndrome–family.

Sensation Awareness Focused Training (SAF-T)¹⁶⁻¹⁸ is a new, innovative rapid stress management intervention adapted from Accelerated Resolution Therapy, a well-tested evidence-based psychotherapy for PTSD, depression, and complicated grief.¹⁹⁻²² Anxiety, tension, and fear experienced when a loved one is critically ill may cause an autonomic nervous system imbalance toward sympathetic response. SAF-T is believed to decrease sympathetic response by exercising dual taxation of working memory,²³ increased interhemispheric interaction,²⁴ smooth pursuit eye movements,²⁵ and slow deep breathing,²⁶ which results in a calming response and interruption of negative thoughts, feelings, and behaviors. SAF-T can be administered by clinical or nonclinical staff.

This pilot study tested SAF-T in spousal family caregivers in the ICU. The specific aims were to assess feasibility and acceptability of a 3-day SAF-T intervention on symptoms of PICS-F in spouses of patients who were undergoing mechanical ventilation in the ICU. We defined feasibility as enrollment of at least 50% of all eligible spouses and completion of all outcome measures by at least 60% of participants. Acceptability was defined as more than 90% of recruited participants randomized to receive the intervention completing at least 2 of the 3 scheduled doses of SAF-T in the ICU and more than 90% completing SAF-T without adverse events.

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Methods

Design

We used a prospective, longitudinal, randomized controlled trial design with 2 groups (intervention and control) to assess the feasibility and acceptability of SAF-T. Participants randomly assigned to the intervention group were instructed to complete SAF-T once daily for 3 days during the ICU stay. Participants randomized to the control group did not complete SAF-T.

Ethics

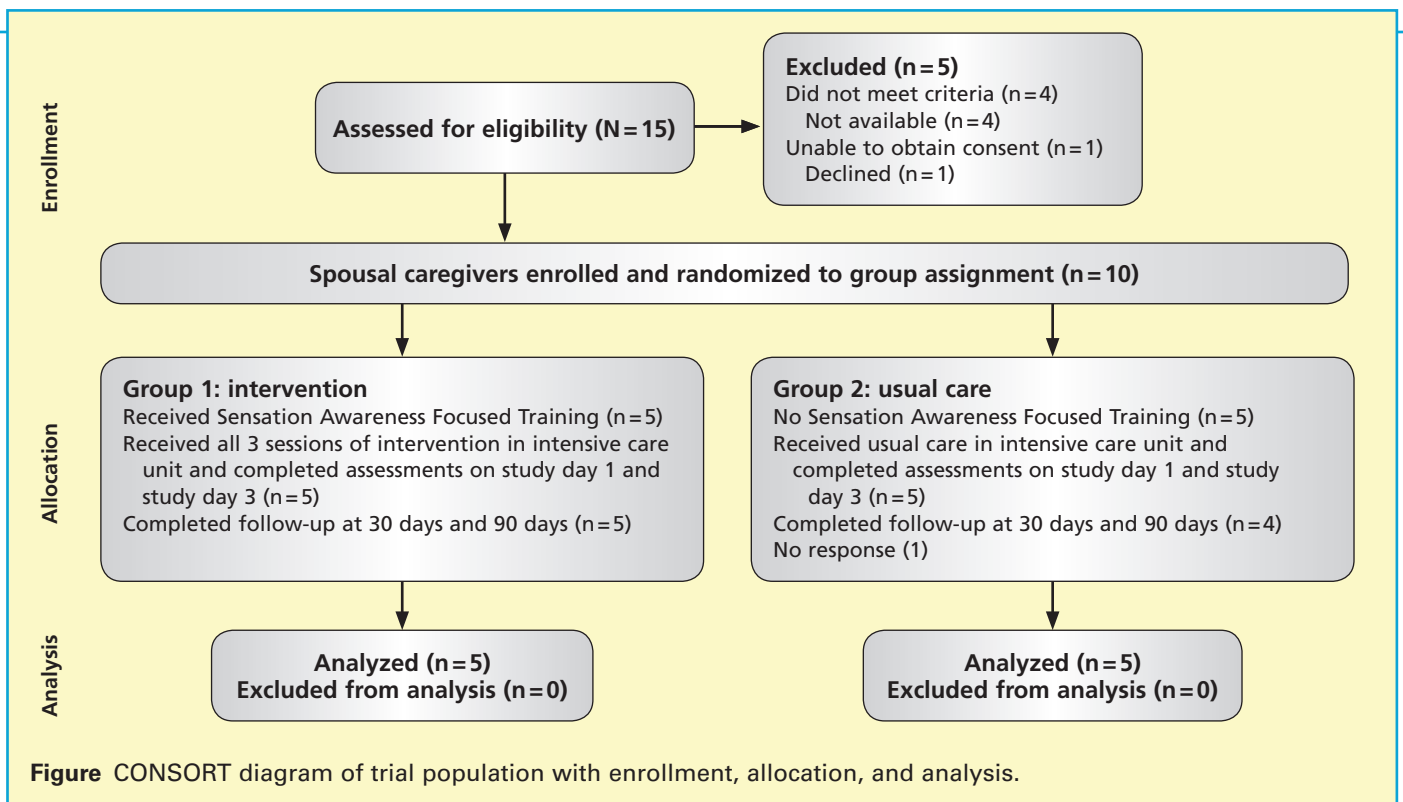
The study was approved by the university's institutional review board and carried out in alignment with the Helsinki Declaration. Written consent was obtained for study participation.

Participants

Spouses of patients undergoing mechanical ventilation in the ICU at a level I trauma center with 225 critical care beds were recruited. Spouses of patients who were intubated and admitted to the adult ICUs within the previous 36 hours were eligible if they were 18 years of age or older and able to understand English. Spouses were excluded if the clinical provider anticipated imminent patient death or if the spouse was in active treatment for a condition associated with PICS-F.

Intervention

SAF-T includes scripted coaching on awareness of negative biological sensations associated with stressful ICU events while the participant performs repeated sets of lateral (left-right) eye movements.¹⁶⁻¹⁸ The SAF-T intervention took place inside the ICU consultation room. Immediately before and after (pretest/posttest) each SAF-T intervention, participants were asked to rate their current stress on a visual analog scale of 1 to 10 (1 = lowest, 10 = highest). This is the first documented study to use SAF-T. An increased stress rating after the SAF-T intervention was defined as an adverse event. Two consecutive



adverse events of increased stress levels after the SÄF-T intervention were considered a signal of harm and prompted withdrawal from the study.

Data Collection

Outcome measures were collected on study days 1, 3, 30, and 90. Symptoms of PICS-F were measured using the Perceived Stress Scale (PSS),^{27,28} the Hospital Anxiety and Depression Scale (HADS),^{29,30} and the Impact of Event Scale (IES).^{31,32} In addition, the National Institutes of Health Toolbox Emotion Battery was used to collect data on the full spectrum of emotional health in this population.³³ These instruments have demonstrated impressive reliability, validity, sensitivity, and specificity.²⁷⁻³³

Sample Size and Randomization

The sample size of 10 participants was designed to represent the target population for assessment of feasibility and acceptability of SÄF-T for a future randomized controlled trial investigating SÄF-T effectiveness. A block design randomized assignment was used to determine group assignment.

Statistical Methods

Descriptive statistics for sample demographic characteristics and baseline PICS-F measures were calculated as means and standard deviations for continuous variables and as frequencies and percentages for categorical variables. Distributions of these characteristics were compared by random

assignment by use of the Fisher exact test and the Mann-Whitney *U* test. Descriptive statistics for the SÄF-T intervention were calculated as means and standard deviations and the received doses and adverse events were calculated in frequencies and percentages. The Wilcoxon signed rank test was used to detect statistical significance of the change from the pre-SÄF-T to the post-SÄF-T visual analog scale stress scores. Recruitment rates, enrollment rates, and outcome measure completion rates were calculated as frequencies and percentages.

The National Institutes of Health Toolbox Emotion Battery was used to measure symptoms of post-intensive care syndrome-family.

Results

Recruitment, Retention, and Adherence

Recruitment, retention, and adherence data are presented in the Figure. The enrollment rate was 67%, which exceeds the success criteria for feasibility. All 10 participants (100%) completed study day 1 (pretest) and study day 3 (posttest) assessments during the ICU stay, and 9 participants (90%) completed the follow-up measures at study day 30 and study day 90; these results met success criteria. Among participants randomized to receive SÄF-T, 100% of sessions were completed, which exceeded success criteria. Mean (SD) individual SÄF-T session time was 12.3 (1.1) minutes.

Table 1
Demographic characteristics and baseline PICS-F measures by random assignment

Characteristics/PICS-F measures	All (N = 10)	SĀF-T group (n = 5)	Control group (n = 5)	P
Race, No. (%)				.17
White	7 (70)	2 (40)	5 (100)	
Black	3 (30)	3 (60)	0 (0)	
Ethnicity, No. (%)				> .99
Non-Hispanic	7 (70)	4 (80)	3 (60)	
Hispanic	3 (30)	1 (20)	2 (40)	
Sex, No. (%)				> .99
Male	3 (30)	2 (40)	1 (20)	
Female	7 (70)	3 (60)	4 (80)	
Age, mean (SD), y	57.7 (11.9)	64.6 (9.4)	50.8 (10.7)	.05
Perceived Stress Scale score, mean (SD)	16.9 (4.2)	18.2 (2.4)	15.6 (5.5)	.35
Hospital Anxiety and Depression Scale score, mean (SD)				
Anxiety	12.6 (2.7)	13.0 (1.2)	12.2 (3.8)	.45
Depression	4.9 (2.2)	6.2 (2.1)	3.6 (1.5)	.09
Impact of Event Scale (PTSD) score, mean (SD)	26.9 (6.0)	30.4 (3.1)	23.4 (6.5)	.07
National Institutes of Health Toolbox Emotion Battery score, mean (SD)				
Positive affect	49.9 (12.4)	47.8 (11.6)	52.0 (14.1)	.35
Life satisfaction	29.2 (7.9)	24.6 (9.4)	33.8 (0.4)	.01
Meaning and purpose	30.8 (4.1)	27.6 (3.6)	34.0 (0.0)	.01
Emotional support	33.7 (6.8)	28.6 (6.0)	38.8 (1.8)	.01
Instrumental support	33.8 (6.4)	28.0 (2.7)	39.6 (0.9)	.01
Friendship	33.2 (5.7)	32.8 (7.7)	33.6 (3.6)	> .99
Loneliness	7.7 (4.1)	9.0 (5.5)	6.4 (2.0)	.64
Perceived rejection	13.2 (5.4)	17.0 (5.5)	9.4 (0.5)	.01
Perceived hostility	11.1 (3.1)	13.0 (3.5)	9.2 (0.4)	.01
Self-efficacy	30.9 (6.2)	27.4 (4.7)	34.4 (5.8)	.07
Perceived stress	27.2 (3.4)	28.4 (2.3)	26.0 (5.0)	.34
Fear affect	17.6 (4.8)	20.8 (1.1)	14.4 (5.0)	.11
Fear somatic arousal	9.7 (2.3)	8.8 (1.6)	10.6 (2.7)	.01
Sadness	13.4 (3.9)	15.0 (5.1)	11.8 (1.1)	.50
Anger affect	10.9 (2.7)	13.0 (2.4)	8.8 (0.4)	.01
Anger hostility	6.8 (2.9)	8.6 (3.4)	5.0 (0.0)	.02
Anger aggression	8.3 (2.2)	8.8 (3.0)	7.8 (1.1)	> .99

Abbreviations: PICS-F, post-intensive care syndrome–family; PTSD, posttraumatic stress disorder; SĀF-T, Sensation Awareness Focused Training.

Demographic Characteristics and Baseline PICS-F Measures

Demographic data are presented in Table 1. The intervention group participants were, on average, approximately 14 years older than control group participants (mean [SD], 64.6 [9.4] vs 50.8 [10.7]; $U = 3$; $P = .05$). Baseline data for PICS-F measures are also presented in Table 1. The PSS, HADS, and IES scores at baseline did not differ significantly between the intervention and control groups. The mean (SD) baseline PSS score was high for both groups during the first 36 hours of the patient's ICU admission at 16.9 (4.2); 90% of the participants had a PSS score of at least 14.7, the suggested cut point mean score on the norm table.²⁷ In addition, both groups at baseline scored abnormally high or borderline abnormally high in anxiety (80% in the 11 to 21 range and 20% in the 8 to 10

range) and 100% of both groups scored within the normal range (0 to 7) for depression. The mean (SD) IES score for symptoms of PTSD was high at baseline for both groups at 26.9 (6.0), and 80% of participants had an IES score of at least 26, the suggested cut point.³¹ In general, the SĀF-T group had slightly higher levels of symptoms of perceived stress, anxiety, depression, and PTSD at baseline than did the control group. The SĀF-T group also had significantly higher levels of perceived rejection and hostility, fear somatic arousal, and anger, along with significantly lower levels of life satisfaction, meaning and purpose, emotional support, and instrumental support at baseline.

Change in Stress Before and After the Intervention

The mean (SD) stress score on the visual-analog scale before the SĀF-T intervention was 6.3 (1.3)

Table 2
Estimated effect size of SĀF-T on measures of post-intensive care syndrome–family over time

Primary outcome measure	Effect size (95% CI)		
	Days 1-3	Days 1-30	Days 1-90
Perceived Stress Scale score	1.51 (0.15-2.87)	1.13 (–0.14-2.40)	1.26 (–0.04-2.56)
Hospital Anxiety and Depression Scale score			
Anxiety	1.58 (0.20-2.96)	0.95 (–0.28-2.19)	0.97 (–0.27-2.21)
Depression	0.15 (–1.00-1.30)	0.47 (–0.70-1.64)	0.47 (–0.70-1.64)
Impact of Event Scale (posttraumatic stress disorder) score	1.94 (0.45-3.42)	1.39 (0.06-2.72)	1.95 (0.46-3.45)
National Institutes of Health Toolbox Emotion Battery score			
Positive affect	–0.73 (–1.92-0.47)	–0.57 (–1.81-0.67)	–0.54 (–1.78-0.69)
Life satisfaction	–0.40 (–1.56-0.76)	–0.52 (–1.75-0.71)	–0.52 (–1.75-0.71)
Meaning and purpose	–0.16 (–1.30-0.99)	–0.03 (–1.24-1.17)	0.22 (–0.99-1.43)
Emotional support	–0.21 (–1.36-0.94)	–0.47 (–1.70-0.75)	–0.45 (–1.68-0.77)
Instrumental support	–0.49 (–1.66-0.68)	–1.31 (–2.69-0.08)	–1.31 (–2.69-0.08)
Friendship	0.00 (–1.14-1.14)	–0.44 (–1.66-0.78)	–0.44 (–1.66-0.78)
Loneliness	0.32 (–0.84-1.47)	–0.30 (–1.52-0.91)	–0.30 (–1.52-0.91)
Perceived rejection	0.19 (–0.96-1.33)	0.35 (–0.87-1.56)	0.41 (–0.81-0.63)
Perceived hostility	2.06 (0.53-3.58)	1.93 (0.36-3.50)	1.93 (0.36-3.50)
Self-efficacy	–1.03 (–2.28-0.22)	–0.9 (–2.19-0.39)	–0.96 (–2.26-0.35)
Perceived stress	1.50 (0.14-2.87)	1.23 (–0.13-2.59)	1.13 (–0.21-2.47)
Fear affect	2.16 (0.60-3.71)	0.81 (–0.46-2.09)	1.02 (–0.30-2.33)
Fear somatic arousal	0.28 (–0.87-1.44)	1.30 (–0.08-2.68)	0.75 (–0.52-2.01)
Sadness	0.45 (–0.71-1.61)	0.63 (–0.62-1.88)	0.58 (–0.66-1.82)
Anger affect	1.28 (–0.03-2.58)	1.14 (–0.20-2.48)	1.35 (–0.05-2.74)
Anger hostility	0.00 (–1.14-1.14)	0.09 (–1.11-1.29)	0.09 (–1.11-1.29)
Anger aggression	–0.45 (–1.61-0.72)	–0.41 (–1.63-0.81)	–0.41 (–1.63-0.81)

Abbreviation: SĀF-T, Sensation Awareness Focused Training.

and the mean (SD) stress score after SĀF-T was 3.8 (0.6), with a mean difference of 2.5 (0.4) (data not shown). Post-SĀF-T stress scores were significantly lower than pre-SĀF-T stress scores ($z = -3.5, P = .01$). No adverse events occurred. (Adverse events were defined as an increased stress score after the SĀF-T intervention.)

Estimated effect sizes of SĀF-T on PICS-F measures over time are shown in Table 2.

Discussion

After a systematic review of 238 studies involving family-centered care in the ICU environment, researchers concluded that effective strategies and interventions to support family caregivers during the crisis of critical illness are limited.¹⁵ Rigorous research testing family-centered interventions that promote caregiver health by decreasing stress during the most at-risk stressful events (eg, ICU admission of a loved one) is warranted. In this pilot study, the 3-day SĀF-T stress management intervention was feasible and acceptable to spouses of patients undergoing mechanical ventilation in the ICU, and it was not associated with adverse events. Further, the study provided preliminary data to support a positive effect of SĀF-T on symptoms of PICS-F (Table 2).

Strengths of the study include use of a highly standardized treatment protocol (SĀF-T). As limitations of the study, we recognize that the sample size was small and baseline characteristics were not equivalent between groups.

In conclusion, family-centered care in the ICU may improve outcomes for both patients and their family caregivers. The SĀF-T intervention facilitates family-centered care by allowing family members to manage their stress during the ICU experience.³⁴

This preliminary study provided data important to future large randomized controlled trials to test effectiveness of SĀF-T in preventing PICS-F.

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