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 (SAF-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 SAF-T to inform a future larger randomized controlled trial.

Methods This randomized controlled trial of SAF-T (n=5) versus a control (n=5) group was conducted at a level 1 trauma center. Participants assigned to SAF-T completed 1 session daily for 3 days. Measures included enrollment rate, data completion rate, acceptability of SAF-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 SAF-T acceptability (100% of doses completed during the ICU stay) without adverse events. Stress scores after SAF-T were significantly lower than scores before SAF-T (z=−3.5, P=.01).

Conclusions SAF-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 SAF-T in preventing PICS-F seems 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. 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). Strong evidence indicates that family member distress during the ICU stay increases the risk of PICS-F, yet effective interventions for managing family members’ stress are limited. 

Sensation Awareness Focused Training (S/uni02C9AF-T) 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. Anxiety, tension, and fear experienced when a loved one is critically ill may cause an autonomic nervous system imbalance toward sympathetic response. S/uni02C9AF-T is believed to decrease sympathetic response by exercising dual taxation of working memory, increased interhemispheric interaction, smooth pursuit eye movements, and slow deep breathing, which results in a calming response and interruption of negative thoughts, feelings, and behaviors. S/uni02C9AF-T can be administered by clinical or nonclinical staff.

This pilot study tested S/uni02C9AF-T in spousal family caregivers in the ICU. The specific aims were to assess feasibility and acceptability of a 3-day S/uni02C9AF-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 S/uni02C9AF-T in the ICU and more than 90% completing S/uni02C9AF-T without adverse events.

About the Authors
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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 S/uni02C9AF-T. Participants randomly assigned to the intervention group were instructed to complete S/uni02C9AF-T once daily for 3 days during the ICU stay. Participants randomized to the control group did not complete S/uni02C9AF-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
S/uni02C9AF-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. The S/uni02C9AF-T intervention took place inside the ICU consultation room. Immediately before and after (pretest/posttest) each S/uni02C9AF-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 S/uni02C9AF-T. An increased stress rating after the S/uni02C9AF-T intervention was defined as an adverse event. Two consecutive
adverse events of increased stress levels after the SÃ©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), the Hospital Anxiety and Depression Scale (HADS), and the Impact of Event Scale (IES). 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. These instruments have demonstrated impressive reliability, validity, sensitivity, and specificity.

Sample Size and Randomization
The sample size of 10 participants was designed to represent the target population for assessment of feasibility and acceptability of SÃ©T for a future randomized controlled trial investigating SÃ©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 SÃ©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-SÃ©T to the post-SÃ©T visual analog scale stress scores. Recruitment rates, enrollment rates, and outcome measure completion rates were calculated as frequencies and percentages.

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 SÃ©T, 100% of sessions were completed, which exceeded success criteria. Mean (SD) individual SÃ©T session time was 12.3 (1.1) minutes.

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

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.

Change in Stress Before and After the Intervention

The mean (SD) stress score on the visual-analog scale before the S/AF-T intervention was 6.3 (1.3)
S/uni02C9AF-T decreases stress in spouses of critically ill patients and has a positive effect on symptoms of post–intensive care syndrome–family.

Estimated effect size of S/uni02C9AF-T on measures of post–intensive care syndrome–family over time

<table>
<thead>
<tr>
<th>Primary outcome measure</th>
<th>Days 1-3</th>
<th>Days 1-30</th>
<th>Days 1-90</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perceived Stress Scale score</td>
<td>1.51 (0.15-2.87)</td>
<td>1.13 (-0.14-2.40)</td>
<td>1.26 (-0.04-2.56)</td>
</tr>
<tr>
<td>Hospital Anxiety and Depression Scale score</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anxiety</td>
<td>1.58 (0.20-2.96)</td>
<td>0.95 (-0.28-2.19)</td>
<td>0.97 (-0.27-2.21)</td>
</tr>
<tr>
<td>Depression</td>
<td>0.15 (-1.00-1.30)</td>
<td>0.47 (-0.70-1.64)</td>
<td>0.47 (-0.70-1.64)</td>
</tr>
<tr>
<td>Impact of Event Scale (posttraumatic stress disorder) score</td>
<td>1.94 (0.45-3.42)</td>
<td>1.39 (0.06-2.72)</td>
<td>1.95 (0.46-3.45)</td>
</tr>
<tr>
<td>National Institutes of Health Toolbox Emotion Battery score</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive affect</td>
<td>-0.73 (-1.92-0.47)</td>
<td>-0.57 (-1.81-0.67)</td>
<td>-0.54 (-1.78-0.69)</td>
</tr>
<tr>
<td>Life satisfaction</td>
<td>-0.40 (-1.56-0.76)</td>
<td>-0.52 (-1.75-0.71)</td>
<td>-0.52 (-1.75-0.71)</td>
</tr>
<tr>
<td>Meaning and purpose</td>
<td>-0.16 (-1.30-0.99)</td>
<td>-0.03 (-1.24-1.17)</td>
<td>0.22 (-0.99-1.43)</td>
</tr>
<tr>
<td>Emotional support</td>
<td>-0.21 (-1.36-0.94)</td>
<td>-0.47 (-1.70-0.75)</td>
<td>-0.45 (-1.68-0.77)</td>
</tr>
<tr>
<td>Instrumental support</td>
<td>-0.49 (-1.66-0.68)</td>
<td>-1.31 (-2.69-0.08)</td>
<td>-1.31 (-2.69-0.08)</td>
</tr>
<tr>
<td>Friendship</td>
<td>0.00 (-1.14-1.14)</td>
<td>-0.44 (-1.66-0.78)</td>
<td>-0.44 (-1.66-0.78)</td>
</tr>
<tr>
<td>Loneliness</td>
<td>0.32 (-0.84-1.47)</td>
<td>-0.30 (-1.52-0.91)</td>
<td>-0.30 (-1.52-0.91)</td>
</tr>
<tr>
<td>Perceived rejection</td>
<td>0.19 (-0.96-1.33)</td>
<td>0.35 (-0.87-1.56)</td>
<td>0.41 (-0.81-0.63)</td>
</tr>
<tr>
<td>Perceived hostility</td>
<td>2.06 (0.53-3.58)</td>
<td>1.93 (0.36-3.50)</td>
<td>1.93 (0.36-3.50)</td>
</tr>
<tr>
<td>Self-efficacy</td>
<td>-1.03 (-2.28-0.22)</td>
<td>-0.9 (-2.19-0.39)</td>
<td>-0.96 (-2.26-0.35)</td>
</tr>
<tr>
<td>Perceived stress</td>
<td>1.50 (0.14-2.87)</td>
<td>1.23 (-0.13-2.59)</td>
<td>1.13 (-0.21-2.47)</td>
</tr>
<tr>
<td>Fear affect</td>
<td>2.16 (0.60-3.71)</td>
<td>0.81 (-0.46-2.09)</td>
<td>1.02 (3-0-2.33)</td>
</tr>
<tr>
<td>Fear somatic arousal</td>
<td>0.28 (-0.87-1.44)</td>
<td>1.30 (-0.08-2.68)</td>
<td>0.75 (-0.52-2.01)</td>
</tr>
<tr>
<td>Sadness</td>
<td>0.45 (-0.71-1.61)</td>
<td>0.63 (-0.62-1.88)</td>
<td>0.58 (-0.66-1.82)</td>
</tr>
<tr>
<td>Anger affect</td>
<td>1.28 (-0.03-2.58)</td>
<td>1.14 (-0.20-2.48)</td>
<td>1.35 (-0.05-2.74)</td>
</tr>
<tr>
<td>Anger hostility</td>
<td>0.00 (-1.14-1.14)</td>
<td>0.09 (-1.11-1.29)</td>
<td>0.09 (-1.11-1.29)</td>
</tr>
<tr>
<td>Anger aggression</td>
<td>-0.45 (-1.61-0.72)</td>
<td>-0.41 (-1.63-0.81)</td>
<td>-0.41 (-1.63-0.81)</td>
</tr>
</tbody>
</table>

Effect size (95% CI)

Abbreviation: S/uni02C9AF-T, Sensation Awareness Focused Training.

and the mean (SD) stress score after S/uni02C9AF-T was 3.8 (0.6), with a mean difference of 2.5 (0.4) (data not shown). Post-S/uni02C9AF-T stress scores were significantly lower than pre-S/uni02C9AF-T stress scores (z = −3.5, P = .01). No adverse events occurred. (Adverse events were defined as an increased stress score after the S/uni02C9AF-T intervention.)

Estimated effect sizes of S/uni02C9AF-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. 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 S/uni02C9AF-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 S/uni02C9AF-T on symptoms of PICS-F (Table 2).

Strengths of the study include use of a highly standardized treatment protocol (S/uni02C9AF-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 S/uni02C9AF-T intervention facilitates family-centered care by allowing family members to manage their stress during the ICU experience. This preliminary study provided data important to future large randomized controlled trials to test effectiveness of S/uni02C9AF-T in preventing PICS-F.

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REFERENCES


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