

2-2014

# Development and Preliminary Evaluation of a Telephone-based Mindfulness Training Intervention for Survivors of Critical Illness

Christopher E. Cox

Laura S. Porter

Pamela J. Buck

Mary Hoffa

Derek Jones

*See next page for additional authors*

Follow this and additional works at: [http://rdw.rowan.edu/csm\\_facpub](http://rdw.rowan.edu/csm_facpub)



Part of the [Health Psychology Commons](#)

## Recommended Citation

Cox, Christopher E.; Porter, Laura S.; Buck, Pamela J.; Hoffa, Mary; Jones, Derek; Walton, Brenda; Hough, Catherine L.; and Greeson, Jeffrey M., "Development and Preliminary Evaluation of a Telephone-based Mindfulness Training Intervention for Survivors of Critical Illness" (2014). *Faculty Scholarship for the College of Science & Mathematics*. 79.

[http://rdw.rowan.edu/csm\\_facpub/79](http://rdw.rowan.edu/csm_facpub/79)

This Article is brought to you for free and open access by the College of Science & Mathematics at Rowan Digital Works. It has been accepted for inclusion in Faculty Scholarship for the College of Science & Mathematics by an authorized administrator of Rowan Digital Works. For more information, please contact [jiras@rowan.edu](mailto:jiras@rowan.edu), [rdw@rowan.edu](mailto:rdw@rowan.edu).

---

**Authors**

Christopher E. Cox, Laura S. Porter, Pamela J. Buck, Mary Hoffa, Derek Jones, Brenda Walton, Catherine L. Hough, and Jeffrey M. Greeson

## Development and Preliminary Evaluation of a Telephone-based Mindfulness Training Intervention for Survivors of Critical Illness

Christopher E. Cox<sup>1,2</sup>, Laura S. Porter<sup>3</sup>, Pamela J. Buck<sup>4</sup>, Mary Hoffa<sup>1</sup>, Derek Jones<sup>1,2</sup>, Brenda Walton<sup>1,2</sup>, Catherine L. Hough<sup>5</sup>, and Jeffrey M. Greeson<sup>3</sup>

<sup>1</sup>Division of Pulmonary and Critical Care Medicine, Department of Medicine, <sup>2</sup>Program to Support People and Enhance Recovery, <sup>3</sup>Division of Medical Psychology, Department of Psychiatry and Behavioral Sciences, and <sup>4</sup>Department of Psychology and Neuroscience, Duke University, Durham, North Carolina; and <sup>5</sup>Division of Pulmonary and Critical Care, Department of Medicine, University of Washington, Seattle, Washington

### Abstract

**Rationale:** Persistent symptoms of psychological distress represent an unmet need among intensive care unit (ICU) survivors.

**Objectives:** We aimed to develop and pilot test a simple telephone-based mindfulness training intervention to address this population's unique needs.

**Methods:** Open trial involving survivors of medical and surgical critical illness and their informal caregivers, using a pretest–posttest design.

**Measurements and Main Results:** We developed a six-session, telephone-delivered, ICU survivor–specific mindfulness intervention based on past focus groups, the medical literature, and the precedent of the most effective components of existing mindfulness programs. A total of 11 survivors of mechanical ventilation were enrolled, together with 2 informal caregivers for exploratory purposes. Three patients dropped out before

intervention initiation because of progressive illness or severe social stressors. Of the 10 remaining participants, 8 (80%) completed the program within 7 weeks. Among these eight patients and caregivers who completed all study procedures, six (75%) experienced improvement in symptoms of psychological distress (anxiety, depression, or post-traumatic stress disorder). Changes in distress symptoms were correlated with improvement in mindfulness qualities, adaptive coping, and emotion regulation. Participants reported high satisfaction with the program in postintervention interviews.

**Conclusions:** A new ICU survivor–specific mindfulness training intervention delivered by telephone was acceptable and feasible. Changes in symptoms of distress were correlated with changes in skills that were targeted by the mindfulness program. Controlled trials are needed to further evaluate this promising intervention.

**Keywords:** critical illness; mindfulness; behavioral therapy; depression; post-traumatic stress

(Received in original form August 23, 2013; accepted in final form October 28, 2013)

Supported by a career development award (R00AT004945) from the National Center for Complementary and Alternative Medicine (J.M.G.).

*Author Contributions:* Study design: C.E.C., L.S.P., B.W., C.L.H., J.M.G.; data analysis and interpretation: C.E.C., M.H., J.M.G., P.J.B.; writing and review: C.E.C., L.S.P., P.J.B., M.H., D.J., B.W., C.L.H., J.M.G.; supervising data collection: C.E.C., D.J.; acquisition of funding: J.M.G.

Correspondence and requests for reprints should be addressed to Christopher Cox, M.D., M.P.H., Duke University Medical Center, Division of Pulmonary and Critical Care Medicine, Box 102043, Durham, NC 27710. E-mail: christopher.cox@duke.edu

This article has an online supplement, which is accessible from this issue's table of contents online at [www.atsjournals.org](http://www.atsjournals.org)

Ann Am Thorac Soc Vol 11, No 2, pp 173–181, Feb 2014

Copyright © 2014 by the American Thoracic Society

DOI: 10.1513/AnnalsATS.201308-283OC

Internet address: [www.atsjournals.org](http://www.atsjournals.org)

Acute respiratory failure severe enough to require mechanical ventilation in an intensive care unit (ICU) affects more than 1 million persons annually (1). Although survival has improved over time, at 1 year postdischarge the majority of survivors and their informal caregivers (i.e., family members) still suffer from clinically

important symptoms of psychological distress including depression, anxiety, and post-traumatic stress (2). Few interventions have addressed this persistent postdischarge distress, its antecedents, and ICU survivors' unique barriers to face-to-face care such as distance from expert centers, physical disability, and financial stress.

Mindfulness is a self-regulatory awareness practice that uses a variety of meditative techniques to alleviate distress, illness, suffering, and pain (3, 4). Mindfulness, based on centuries-old meditation techniques, is thought to work in part by developing mindful qualities (observing, not judging, not reacting) that

help patients change the way they relate to emotional and physical symptoms, and by facilitating mindful coping that helps patients skillfully regulate difficult emotions, thoughts, and memories (5–8). We have shown previously that although ICU survivors highly value mindfulness-related skills (e.g., coping, emotional regulation, appraisal of life events), they use these skills infrequently and ineffectively—a pattern associated with prolonged distress (9). Mindfulness training is promising for ICU survivors because it has reduced distress in other populations, it can be personalized to address an individual's past and present stressors, and it can be delivered inexpensively by telephone (10–13). However, mindfulness to our knowledge has not been studied among ICU survivors or their caregivers.

In this treatment development study, we aimed to develop an ICU survivor-specific mindfulness training program and then to evaluate the program's feasibility, acceptability, and impact on symptoms of psychological distress. We also aimed to examine potential mechanistic factors such as mindfulness qualities, emotion regulation, and mindful coping that might be related to outcomes.

## Methods

### Overview

This study consisted of a development phase, during which the mindfulness training intervention was derived, and an evaluation phase. All study participants were recruited from between September 2012 and February 2013 from the Duke University Hospital (an academic setting) medical ICU and Duke Regional Hospital (a community setting) mixed medical-surgical ICU. Each participant was compensated \$50 for time spent in the study.

### Development of the Mindfulness Intervention

The development of the mindfulness program was guided by an explicit conceptual model in which we hypothesized that the intervention would target foundational elements of ICU survivors' distress (14) (Table 1) by enhancing mindfulness practices, coping skills, and emotion regulation (6, 15). We aimed to include caregivers because caregiving is commonly required among ICU survivors

(14, 16, 17), caregivers have a high prevalence of distress (18–20), and caregiver involvement in similar interventions can enhance treatment effect (21, 22). We adapted common core principles of effective mindfulness-based stress reduction programs (4) to the known capabilities and concerns of ICU survivors and their caregivers through a highly structured iterative process involving experts in critical illness, palliative care, and psychology (C.E.C., J.M.G., L.S.P., M.H., P.J.B., and C.L.H.). Feedback from previous patient and caregiver focus groups was also used to highlight relevant distress triggers and promoters, to identify a need for simple telephone-based interventions (9), and to clarify relevant topics and skills. Substantive content alteration was uncommon, although some topics were chosen on the basis of our clinical experiences with this patient population (e.g., mindful breathing, body scan technique, mindful eating, loving-kindness meditation, mindful movement, and sensory awareness). More significant was the emphasis on balancing content depth with our respect for patients' time and effort limitations. That is, our goal was to provide a program that consisted of fairly short sessions (e.g., 30 min or less) delivered within a relatively narrow time frame (2 mo or less) because of patients' well-known physical, emotional, and instrumental challenges. Developments in mindfulness training suggested that this was a reasonable, feasible goal (23, 24). Informal focus group feedback led to a decision to begin each session by first querying participants about a current stressor and subsequently directing the content when appropriate toward this stressor. After multiple cycles of revision and editing, investigators produced a final ICU survivor-specific mindfulness treatment manual, an interventionist telephone script for each of the six planned topics, and participant handouts (Table 1 and see the online supplement).

### Evaluation of the Intervention

Subsequently, we performed an open pilot trial of the telephone-based mindfulness intervention to explore feasibility and acceptability, as well as to understand its possible impact on psychological distress symptoms.

**Participants.** Clinical research coordinators screened study ICUs Monday through Friday at Duke University Medical

Center and Durham Regional Hospital (both in Durham, NC) for eligible consecutive patients, defined as those who received ventilation for at least 4 days (25), were at least 18 years of age, and who possessed at least mild to moderate symptoms of distress at baseline (a total Hospital Anxiety and Depression Scale [HADS] questionnaire score of 8 or greater at the time of consent) (26, 27). Within 1 month of screening, we changed the inclusion criterion for ventilation duration to 2 days to address the study team's growing concern that many patients were being excluded unnecessarily by a 4-day cutoff that itself was largely framed by an administrative database convenience rather than the patient experience we were observing. Similarly, after the first three patients dropped out before starting the intervention, due to their illness, we changed the protocol to require the presence of full decisional capacity rather than surrogate decision-maker consent (28). Exclusions included baseline history of dementia, brain injury or acute stroke with associated cognitive disability, need for a translator because of poor English fluency, or expected survival less than 3 months per the attending ICU physician. If patients agreed, we approached their informal caregivers for consent as well, to explore the feasibility of dyadic mindfulness telephone sessions. We limited enrollment to one informal caregiver per patient, defined as the person, at least 18 years of age, who expected to provide the most postdischarge patient assistance. Caregiver exclusions included baseline history of dementia, brain injury or acute stroke, or need for a translator because of poor English fluency.

**Intervention.** The mindfulness training intervention was targeted to begin approximately 2 weeks after patients' arrival home, a proactive approach proven to be feasible in our past work (9). Patients and caregivers participated in weekly sessions together, either with a speaker phone or three-way calling, and at various times of the day or early evening when most convenient for them. The intervention was delivered by two interventionists (M.H. and P.J.B.) with experience in mindfulness and who also received additional training from investigators (J.M.G. and L.S.P.). Study investigators met with interventionists regularly to address concerns, reflect on progress, and provide feedback.

**Data collection and study variables.** We gathered clinical data from medical charts

**Table 1.** Mindfulness training session topics, core principles, and distress targets

Session and Skill	Core Principle	Mindful Coping and Qualities	ICU Distress Target <sup>(14)</sup>
1. Mindful breathing	Rationale for mindfulness training	Observe and attend to present	Feelings of distraction and poor mental and physical functioning
2. Body scan meditation	The body as a source of information and wisdom	Decentering (let be/let go) Describe sensations and emotions	Critical illness defining sense of self as ill or disabled
3. Loving-kindness meditation	Emotional balance	Nonjudgment/acceptance Not react to upsetting emotions	Patient–caregiver relationship strain and change
4. Mindful eating	Focus on awareness of the moment	Cultivate positive emotions Emotion reappraisal Observe and be aware	Sense of self as ill or disabled
5. Sensory awareness	Mindful awareness as a “container” for stress	Awareness of senses and thought	Pervasive traumatic memories
6. Mindful movement	Focus on doing	Use mindful action to address self-distraction and worry	Ability to cope with disability Sense of self as ill or disabled Day-to-day impact of disability Feeling unable to function normally

Definition of abbreviation: ICU = intensive care unit.

and interviews. Research staff who were not involved in the intervention administered study questionnaires both in person (baseline interview on hospital ward) and by telephone (pre- and postintervention interviews after discharge). The preintervention interview was conducted within 2 weeks of arrival home and just before initiation of the intervention. The postintervention interview was performed within 1 week after intervention completion (~6 wk after intervention initiation). We assessed psychological distress symptoms using the 14-item, two-domain (depression and anxiety) Hospital Anxiety and Depression Scale (HADS) (26). HADS total scores can range from 0 (no distress) to 42 (high distress). HADS domain scores of 8 or more reflect a high likelihood of a mood disorder (27). An HADS change in score of about 2 units has been reported to reflect a minimal clinically important difference (29). Post-traumatic stress disorder symptoms were assessed using the 10-item Post-traumatic Symptom Scale (PTSS), on which a score of 34 or more reflects clinically significant symptoms (30). We used the Brief COPE to measure coping skill use frequency that was adaptive (self-distraction, positive reframing subscales) or maladaptive (denial subscale), summing these into a composite measure after appropriate reverse scoring (31). Mindfulness qualities were assessed using three domains (nonjudging, observation, and nonreacting) from the Five

Facet Mindfulness Questionnaire, a scale developed from a factor analysis of five other mindfulness questionnaires (32). Each domain contains eight summed items with responses ranging from 1 (lesser use of mindfulness concepts) to 5 (greater use of mindfulness concepts). Quality of life was assessed with a 100-point visual analog scale derived from the EQ-5D (33), with 0 = worst quality of life possible and 100 = best quality of life possible. Emotion regulation and control were assessed using the 6-item reappraisal domain from the Emotion Regulation Questionnaire, with responses ranging from 1 (more negative regulation) to 5 (more positive regulation) (34). Health literacy was assessed at baseline using a 3-item validated scale, with a score greater than 10 representing “low literacy” as defined previously (35). We measured hope and optimism with 5-point Likert scales (“low” defined as score of >2) adapted from other validated scales (36). We measured general satisfaction with the program using an adapted version of the Client Satisfaction Questionnaire (CSQ). The CSQ is an 8-item scale (6 items with responses ranging from 1 = not at all satisfied to 4 = extremely satisfied; 2 items with yes/no responses on “overall satisfaction” and “Would you do it again?”) (37). Illness severity was assessed with a standard metric (APACHE II) (38). Well-validated scales were used to quantify the number of limitations in activities of daily living (ADLs) and instrumental ADLs

(IADLs) (39, 40). In addition, at the final interview, participants provided feedback to open-ended questions about their use of the intervention skills, its value in their daily lives, its acceptability, and ways that the intervention could be improved. The feasibility of the mindfulness program was measured on the basis of rates of enrollment, retention, and telephone session completion.

### Statistical Analyses

We present categorical data as numbers (percent) and continuous data as means (SD) or medians (interquartile range [IQR]). We performed Pearson’s correlations between pre- and postintervention change scores on the HADS, PTSS, Brief COPE, mindfulness, and emotion regulation scales. Statistical comparisons were not done because of the small sample size and exploratory nature of this study. We used Stata, version 11 (StataCorp, College Station, TX) for all analyses. Institutional review boards at all study sites approved the study procedures and all participants provided written consent. Portions of these data have been presented previously in abstract format (41).

## Results

### Participants

Of the 67 patients who were screened for inclusion, 56 met exclusion criteria and 11 were enrolled (Figure 1). The most

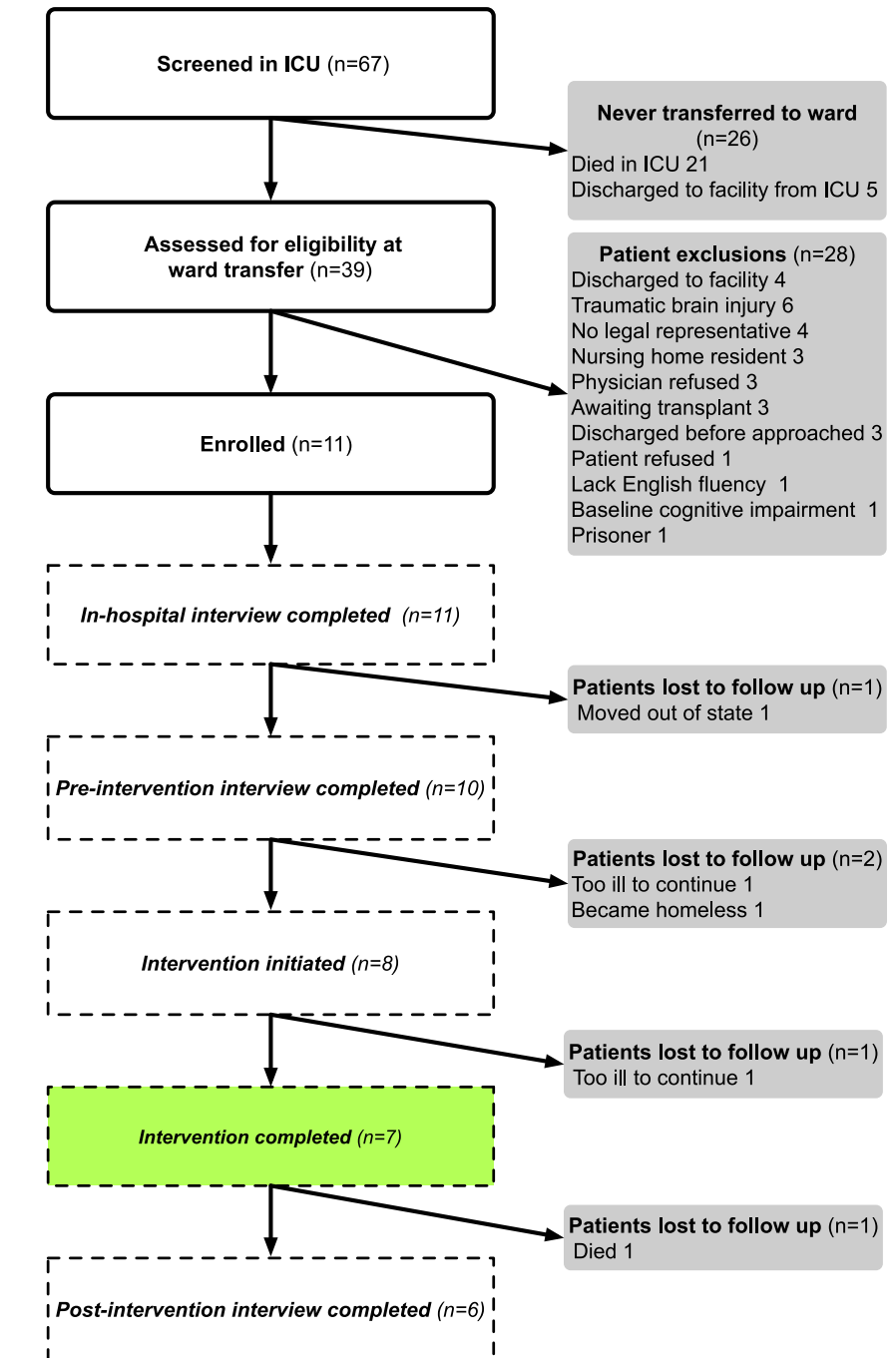
common exclusions were patient death ( $n = 21$ ), discharge to a post-acute care facility ( $n = 9$ ), and traumatic brain injury ( $n = 6$ ). For the 11 patients who enrolled, 5 had no caregiver available, 2 patients refused permission to approach family, 2 caregivers refused (both stating fatigue was reason for refusal), and 2 were enrolled. Participants were middle-aged, mostly female, and racially diverse (38% African-American, 8% Native American) (Table 2). Patients were severely ill (APACHE II median, 27 [IQR 23, 34]), required ventilation for a median of 5 days, and had long hospitalizations (median, 15 hospital d). All participants had symptoms of depression, anxiety, or PTSD at the preintervention assessment. The lowest HADS total score was 8 (range, 8–35) and the lowest PTSS score was 14 (range, 14–49).

### Feasibility of Intervention

Of the 11 patients enrolled, 8 (73%) began the intervention calls, 7 (64%) completed the intervention, and 6 (55%) completed all study procedures (Figure 1). Reasons for dropout included moving out of state and losing telephone access because of financial distress ( $n = 1$ ), disposition status changed to homeless ( $n = 1$ ), repeated episodes of critical illness related to lung transplantation ( $n = 1$ ), progressive hepatic encephalopathy ( $n = 1$ ), and a sudden cardiac death occurring days before a scheduled postintervention interview ( $n = 1$ ). The first three patients enrolled in fact accounted for all early dropout; this was remedied with a simple protocol change requiring the presence of full decisional capacity rather surrogate decision-maker consent (28). During the study period, a total of four patients were readmitted to the hospital, one received care in a post-acute care facility, and two received pharmacological treatment for depression (one for a period of 2 wk). Both caregivers who began the intervention completed all sessions, although the few available limits our ability to comment on dyadic interactions. All participants who completed the program did so within 7 weeks. Calls were 30 minutes or less in nearly all sessions. The interventionist generally made one or two telephone calls to schedule and complete each session.

### Participant Acceptability and Satisfaction with the Intervention

Participants were highly satisfied with the program as assessed by Client Satisfaction



**Figure 1.** Study patient overview. The prospective evaluation of the mindfulness intervention used an uncontrolled, preintervention–postintervention design to assess the intervention’s feasibility, acceptability, and clinical impact, using validated measures of psychological distress. The two caregivers included are not shown. ICU = intensive care unit.

Questionnaire scores (mean score, 21 [SD 3]; questionnaire maximum score, 24). All stated that they would do such a program again and would recommend it to others. When prompted by open-ended questions about good or bad points about the

program, participants mentioned general themes involving relaxation, comfort, sleep improvement, connectedness with a caregiver or partner, and stress reduction. Sessions with the most globally positive feedback were mindful breathing and

**Table 2.** Baseline characteristics of study population\*

Characteristic	Patients (n = 11)	Caregivers (n = 2)
Age, yr	54 (27, 59)	47 (43, 51)
Female	8 (73%)	2 (100%)
Race and ethnicity		
White	6 (55%)	1 (50%)
African-American	4 (36%)	1 (50%)
Native American	1 (9%)	0
Hispanic/Latino	0	0
Employment status before admission		
Employed, student, or homemaker full time	4 (36%)	1 (50%)
Retired	2 (18%)	1 (50%)
Disabled	3 (27%)	0
Unemployed	2 (18%)	0
No health insurance	3 (27%)	
Place of residence before admission		
Home	9 (82%)	2 (100%)
Home with paid care	2 (18%)	0
Low health literacy	3 (27%)	0
Low optimism	1 (9%)	0
Low hope	0	0
ADL limitations	3 (27%)	0
IADL limitations	6 (55%)	0
Financial distress	5 (45%)	1 (50%)
Charlson Comorbidity score	2 (1, 3)	0
APACHE II	27 (23, 34)	
Admission source		
ED	4 (36%)	
Ward	3 (27%)	
Transfer	2 (18%)	
OR	2 (18%)	
Diagnosis		
Medical	9 (82%)	
Surgical	2 (18%)	
Mechanical ventilation duration, d	5 (3, 5)	
Length of stay, d		
Intensive care unit	9 (5, 16)	
Hospital	15 (10, 19)	

*Definition of abbreviations:* ADL = activities of daily living; APACHE = Acute Physiology and Chronic Health Evaluation, severity of illness score; ED = emergency department; IADL = instrumental activities of daily living; OR = operating room.

\*All values represent n (%) or median (interquartile range).

mindful movement. The only negative comment was made by one participant who stated that although the program was “a little touchy-feely,” he enjoyed the program overall. All participants said that the duration of the intervention and length of calls were reasonable.

### Effect of Intervention on Psychological Distress

Psychological distress symptoms were reduced and quality of life improved overall among study participants over time (Figure 2 and Table 3). Of the eight participants with complete interview data, six (75%) experienced improvement in distress as assessed by reductions in scores on the HADS (5, 63%), the PTSS (5, 63%), or both (4, 50%). The magnitude of distress

scale score reduction ranged from 3 to 16 units for the HADS (five patients with a minimal clinically important difference of at least 2 units) and 2 to 16 units for the PTSS. Two of three who showed no decrease in HADS had low baseline scores (HADS < 8). The three persons who had worsened HADS scores and unchanged or worsened PTSS scores also experienced remarkable stressors during the course of the intervention: one patient who was transferred to a nursing home, one caregiver who became increasingly distressed by the demands of an increasingly ill child who required ICU care (adaptive coping score worsened as well), and one patient who experienced progression of sickle cell crises. It is noteworthy that half of the participants

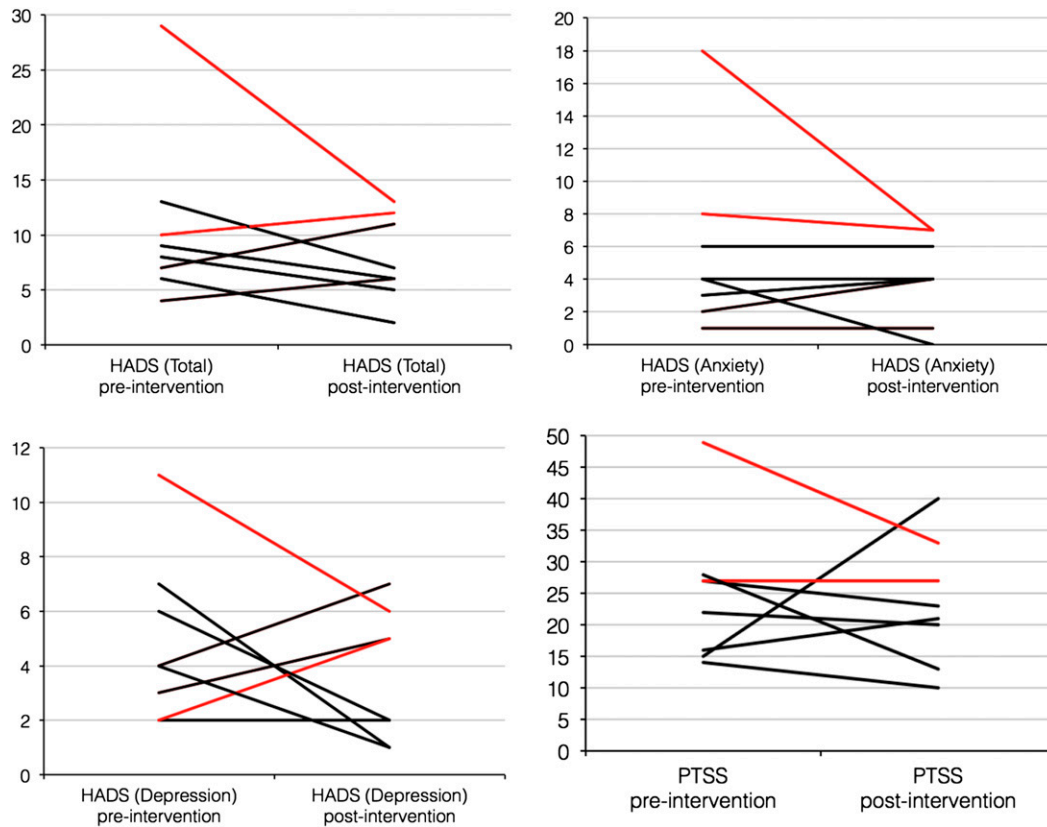
remained in self-reported serious financial distress throughout the study duration, responding at every interview that they were either “short on money and need more to pay bills” or “barely had enough to pay bills and for basic needs.”

Among patients and caregivers who completed the intervention, pre- to postintervention total HADS change scores were correlated most strongly with similar directional changes in mindful observation ( $r = -0.63$ ), mindful nonreacting ( $r = -0.49$ ), adaptive coping ( $r = -0.56$ ), and emotion reappraisal ( $r = -0.49$ ) (Table 4). Similarly, PTSS change over time was correlated with changes in mindful observation ( $r = -0.22$ ), mindful nonjudging ( $r = -0.23$ ), mindful nonreacting ( $r = -0.23$ ), and adaptive coping ( $r = -0.48$ ).

## Discussion

This exploratory pilot study demonstrates three key findings that may be useful for patients, families, providers, and researchers. First, we successfully developed a novel, brief, telephone-based mindfulness intervention for ICU survivors and their informal caregivers. To our knowledge, this is the first mindfulness study performed among survivors of critical illness and one of the few mindfulness interventions delivered by telephone. Second, we found that this intervention appears feasible, acceptable, and potentially effective. Increases in several core qualities of mindfulness were correlated with improvements in psychological distress, an observation that supports the validity of our conceptual model. Third, our experience in developing this psychosocial intervention highlights specific challenges that should be considered when studying postdischarge interventions among seriously ill patients.

The burden of psychological distress associated with critical illness is pervasive and likely a serious unmet need (42, 43). The cumulative incidence of depression and PTSD symptoms among ICU survivors is highest 3 months after discharge, although many patients' symptoms persist for more than 1 year (42, 44). In this context, our mindfulness intervention for ICU survivors and their families could be useful for many reasons. First, it targets foundational elements of this population's distress as described in quantitative and qualitative



**Figure 2.** Depression, anxiety, and post-traumatic stress disorder symptoms over the course of the mindfulness intervention. Hospital Anxiety and Depression Scale (HADS) total, HADS anxiety domain, HADS depression domain, and Post-traumatic Symptom Scale (PTSS) questionnaire mean scores are shown pre- and postintervention for the eight participants who completed all study procedures. Caregiver scores are highlighted in red.

work (9, 45). Second, the timing of mindfulness is directed toward the peak incidence of distress symptoms among a population that nevertheless has difficult-to-predict health trajectories (46, 47). The program also aims to teach skills that can be applied when needed over time. Third, mindfulness practices can be adapted by the interventionist in the moment to individuals' acute situational needs, emotional and physical stressors, social support systems, and health priorities, and can also be applied by users over the entirety of a person's life for chronic stresses (3). Such an agile and responsive intervention is uniquely appropriate for persistently stressed, heterogeneous populations such as those managed in ICUs. Nonetheless, this study also demonstrates that some acute stressors are exceedingly difficult to remedy completely. Fourth, our intervention is mobile, adaptable, and requires no direct physician input. Finally, in postintervention open-ended feedback, all participants reported

that they liked the program and actually applied its principles in their daily lives.

This study also highlights a number of challenges to the approach to psychological distress among ICU survivors and their families.

#### Who Should Be Included in Future Studies of Psychological Distress?

Very simplistically, one wishes to include as broad a population of patients who are sick enough to have a high risk of distress, while excluding those who are too ill to receive benefit or to follow through multiple postdischarge care venues (46). Yet, the unclear natural history of some ICU-acquired conditions (e.g., delirium, cognitive deficits) as well as the uncertain validity of including symptoms-based inclusion criteria are challenges to capturing such an ideal cohort (48). Avoiding screening symptom scores could enhance enrollment, address the relatively common phenomenon of emerging postdischarge stressors (42), and improve

generalizability among a population in which symptoms of depression, anxiety, and PTSD are the norm. We chose a low burden of baseline distress symptoms as an inclusion criterion for our exploratory sample, and perhaps as a result, enrolled a cohort with relatively modest baseline psychological distress. It seems likely that requiring demonstration of even higher (but not prohibitive) levels of distress could avert a "floor effect" treatment limitation and increase effect sizes (49).

#### How to Optimize Value and Choice for Patients and Systems?

- We need to define the optimal dose of behavioral therapy for ICU survivors that balances effect with burden. Higher doses of standard behavioral therapy, defined as the product of session time and session number, are generally thought to lead to greater effect. However, longer mindfulness interventions are not



**Table 3.** Study outcomes among participants who completed study procedures\*

	Preintervention	Postintervention
HADS total	11 (8)	8 (4)
HADS anxiety	6 (5)	4 (3)
HADS depression	5 (4)	4 (2)
PTSS	25 (11)	23 (10)
QOL VAS	69 (16)	73 (18)
Mindfulness: Observing	27 (8)	32 (5)
Mindfulness: Nonjudging	29 (5)	29 (5)
Mindfulness: Nonreacting	23 (4)	26 (7)
Coping	22 (3)	21 (2)
Emotional Response Scale	35 (9)	38 (3)
CSQ	N/A	21 (3)

*Definition of abbreviations:* CSQ = Client Satisfaction Questionnaire; HADS = Hospital Anxiety and Depression Scale; N/A = not applicable; PTSS = Post-traumatic Symptoms Scale; QOL = quality of life; VAS = visual analog scale.

\*Values are displayed as means (SD).

consistently more effective than shorter programs (50), can increase costs, and may not be feasible for seriously ill participants. It would be helpful to better understand the minimum amount of therapist contact required to achieve a clinically relevant treatment effect, and to determine whether web-based adaptations of these programs deliver comparable treatment.

- We must improve access and connectedness for this stressed population. In this study, two participants lost to follow-up early in the study had very unstable social situations, including new homelessness, and half of participants remained in self-reported serious financial distress throughout the study duration. Our experience suggests

that improving patients' access to postdischarge resources in general is needed (51).

- We need to explore study designs that are flexible, adaptable, and include self-management. For populations as heterogeneous as ICU survivors, it makes sense to consider using adaptive study designs such as multiphase optimization studies, sequential multiple assignment randomized trials, and continuous quality refinement. These designs could advance the field faster and safeguard against technological obsolescence in the process. They could also provide needs-based effect thresholds and stepped-down self-management components that patients value and that could reduce intervention costs (52).

**Table 4.** Correlations between study outcome measures and potential mechanistic factors\*

	HADS Total	HADS Anxiety	HADS Depression	PTSS
HADS total	1.00			
HADS anxiety	0.85	1.00		
HADS depression	0.79	0.35	1.00	
PTSS	0.66	0.56	0.57	1.00
Observing <sup>†</sup>	-0.63	-0.69	-0.29	-0.22
Nonjudging <sup>†</sup>	-0.04	-0.01	-0.01	-0.23
Nonreacting <sup>†</sup>	-0.49	-0.22	-0.58	-0.23
Coping	-0.56	-0.29	-0.67	-0.48
Emotion regulation	-0.49	-0.77	-0.06	-0.04

*Definition of abbreviations:* HADS = Hospital Anxiety and Depression Scale; PTSS = Post-traumatic Symptoms Scale.

\*Pearson's correlations between change scores (pre- to postintervention) among participants who completed the intervention. For example, the correlation between the pre- and postintervention HADS depression score and the pre- and postintervention coping score was -0.67.

<sup>†</sup>Mindfulness domains from Five Facet Mindfulness Questionnaire.

- We need to consider scale and technological enhancements when considering costs associated with behavioral interventions. A general concern about therapist-driven interventions is the direct cost. However, we estimate that a course of telephone-based mindfulness training could be provided to 100–150 patients for the same incremental cost as a single episode of extracorporeal membrane oxygenation (53). Also, as populations become increasingly connected to the Web, Internet-based therapy modules could reduce therapist time and mobile patient reported outcomes processes could streamline monitoring costs (54).
- We need to consider choice and personalization. Conceptually, we believe that it is helpful to think of distress interventions more as targeted tools rather than as broad “blockbuster drugs.” We also foresee that combinations of decision supports, clinical profiles, preferences, and other factors will drive postdischarge treatment modality choice (mindfulness, coping skills training, cognitive behavioral therapy, medication). Mindfulness addresses patients' general preference for nonpharmacological treatments and represents a diversification of possible future treatment choices. In fact, ICU survivor mindfulness could represent one way to target therapy to personal neural connectedness, as the treatment response in depression (medication vs. behavioral therapy) has been shown to be associated with baseline differences in functional brain imaging (55).

There are clearly a number of notable limitations in this open exploratory pilot study. It was an uncontrolled treatment development study, and as such, is not explanatory, generalizable, or definitive. The population was predominantly female, a factor that will require consideration during recruitment for future related studies. Some elements of our conceptual model, including nonjudging and coping, did not change appreciably with the intervention. Although most likely related to the sample size, more study of the intervention's mechanisms of effect is needed. Our use of two interventionists could have

resulted in differential response, although there was no such measurable effect. Because we did not include long-term follow-up, the duration of any treatment effect is unknown. Although there was notable dropout early in the study, a simple protocol change regarding capacity determination reduced this to a negligible rate thereafter. Nonetheless, enrolling and retaining ICU survivors remains a high-intensity task (51). Overall, ICU survivor mindfulness training requires further thoughtful study

to address these specific limitations and the general challenges outlined previously.

## Conclusions

Mindfulness training delivered by telephone appears to be a feasible and acceptable strategy for reducing psychological distress among ICU survivors during the postdischarge period. Given the promising findings from the treatment development

phase, a randomized controlled study is needed to determine efficacy, to better understand potential mediating mechanisms, and to identify which populations may be best served by behavioral interventions such as mindfulness training. ■

**Author disclosures** are available with the text of this article at [www.atsjournals.org](http://www.atsjournals.org).

**Acknowledgment:** The authors thank Charles McCormick, M.D., M.P.H., for conducting study interviews.

## References

- Society of Critical Care Medicine. Critical care statistics in the United States [Accessed December 2013]. Available from: [http://www.sccm.org/SiteCollectionDocuments/StatisticsBroch\\_d4.pdf](http://www.sccm.org/SiteCollectionDocuments/StatisticsBroch_d4.pdf).
- Davydow DS, Desai SV, Needham DM, Bienvenu OJ. Psychiatric morbidity in survivors of the acute respiratory distress syndrome: a systematic review. *Psychosom Med* 2008;70:512–519.
- Ludwig DS, Kabat-Zinn J. Mindfulness in medicine. *JAMA* 2008;300:1350–1352.
- Kabat-Zinn J. Full catastrophe living. New York: Delta Publishing; 1990.
- Chambers RH, Lo BCY, Allen NA. The impact of intensive mindfulness training on attentional control, cognitive style, and affect. *Cognit Ther Res* 2008;32:303–322.
- Garland E, Gaylord S, Park J. The role of mindfulness in positive reappraisal. *Explore (NY)* 2009;5:37–44.
- Ochsner KN, Gross JJ. The neural architecture of emotion regulation. In: Gross JJ, editor. Handbook of emotion regulation. New York: Guilford Press; 2007.
- Snyder CR. Coping: the psychology of what works. New York: Oxford University Press; 1999.
- Cox CE, Porter LS, Hough CL, White DB, Kahn JM, Carson SS, Tulsy JA, Keefe FJ. Development and preliminary evaluation of a telephone-based coping skills training intervention for survivors of acute lung injury and their informal caregivers. *Intensive Care Med* 2012;38:1289–1297.
- Fjorback LO, Arendt M, Ornbol E, Fink P, Walach H. Mindfulness-based stress reduction and mindfulness-based cognitive therapy: a systematic review of randomized controlled trials. *Acta Psychiatr Scand* 2011;124:102–119.
- Vollestad J, Nielsen MB, Nielson GH. Mindfulness- and acceptance-based interventions for anxiety disorders: a systematic review and meta-analysis. *Br J Clin Psychol* 2012;51:239–260.
- Thompson NJ, Walker ER, Obolensky N, Winning A, Barmon C, Diiorio C, Compton MT. Distance delivery of mindfulness-based cognitive therapy for depression: project UPLIFT. *Epilepsy Behav* 2010;19:247–254.
- Salmoirago-Blotcher E, Crawford SL, Carmody J, Rosenthal L, Yeh G, Stanley M, Rose K, Browning C, Ockene IS. Phone-delivered mindfulness training for patients with implantable cardioverter defibrillators: results of a pilot randomized controlled trial. *Ann Behav Med* 2013;46:243–250.
- Cox CE, Docherty SL, Brandon DH, Whaley C, Attix DK, Clay AS, Dore DV, Hough CL, White DB, Tulsy JA. Surviving critical illness: acute respiratory distress syndrome as experienced by patients and their caregivers. *Crit Care Med* 2009;37:2702–2708.
- Chambers R, Gullone E, Allen NB. Mindful emotion regulation: an integrative review. *Clin Psychol Rev* 2009;29:560–572.
- Cox CE, Martinu T, Sathy SJ, Clay AS, Chia J, Gray AL, Olsen MK, Govert JA, Carson SS, Tulsy JA. Expectations and outcomes of prolonged mechanical ventilation. *Crit Care Med* 2009;37:2888–2894.
- Im K, Belle SH, Schulz R, Mendelsohn AB, Chelluri L. Prevalence and outcomes of caregiving after prolonged mechanical ventilation in the ICU. *Chest* 2004;125:597–606.
- Pochard F, Azoulay E, Chevret S, Lemaire F, Hubert P, Canoui P, Grassin M, Zittoun R, le Gall JR, Dhainaut JF, et al. Symptoms of anxiety and depression in family members of intensive care unit patients: ethical hypothesis regarding decision making capacity. *Crit Care Med* 2001;29:1893–1897.
- Novaes MA, Knobel E, Bork AM, Pavao OF, Nogueira-Martins LA, Ferraz MB. Stressors in ICU: perception of the patient, relatives and health care team. *Intensive Care Med* 1999;25:1421–1426.
- Davidson JE, Jones C, Bienvenu OJ. Family response to critical illness: postintensive care syndrome-family. *Crit Care Med* 2012;40:618–624.
- Monson CM, Fredman SJ, Macdonald A, Pukay-Martin ND, Resick PA, Schnurr PP. Effect of cognitive-behavioral couple therapy for PTSD: a randomized controlled trial. *JAMA* 2012;308:700–709.
- Porter LS, Keefe FJ, Garst J, McBride CM, Baucom D. Self-efficacy for managing pain, symptoms, and function in patients with lung cancer and their informal caregivers: associations with symptoms and distress. *Pain* 2008;137:306–315.
- Hoffman CJ, Ersser SJ, Hopkinson JB, Nicholls PG, Harrington JE, Thomas PW. Effectiveness of mindfulness-based stress reduction in mood, breast- and endocrine-related quality of life, and well-being in stage 0 to III breast cancer: a randomized, controlled trial. *J Clin Oncol* 2012;30:1335–1342.
- Pbert L, Madison JM, Druker S, Olendzki N, Magner R, Reed G, Allison J, Carmody J. Effect of mindfulness training on asthma quality of life and lung function: a randomised controlled trial. *Thorax* 2012;67:769–776.
- Wunsch H, Linde-Zwirble WT, Angus DC, Hartman ME, Milbrandt EB, Kahn JM. The epidemiology of mechanical ventilation use in the United States. *Crit Care Med* 2010;38:1947–1953.
- Zigmond AS, Snaith RP. The Hospital Anxiety and Depression Scale. *Acta Psychiatr Scand* 1983;67:361–370.
- Bjelland I, Dahl AA, Haug TT, Neckelmann D. The validity of the Hospital Anxiety and Depression Scale: an updated literature review. *J Psychosom Res* 2002;52:69–77.
- Appelbaum PS. Clinical practice: assessment of patients' competence to consent to treatment. *N Engl J Med* 2007;357:1834–1840.
- Puhan MA, Frey M, Buchi S, Schunemann HJ. The minimal important difference of the Hospital Anxiety and Depression Scale in patients with chronic obstructive pulmonary disease. *Health Qual Life Outcomes* 2008;6:46.
- Schelling G, Stoll C, Haller M, Briegel J, Manert W, Hummel T, Lenhart A, Heyduck M, Polasek J, Meier M, et al. Health-related quality of life and posttraumatic stress disorder in survivors of the acute respiratory distress syndrome. *Crit Care Med* 1998;26:651–659.
- Carver CS. You want to measure coping but your protocol's too long: consider the Brief COPE. *Int J Behav Med* 1997;4:92–100.
- Baer RA, Smith GT, Hopkins J, Krietemeyer J, Toney L. Using self-report assessment methods to explore facets of mindfulness. *Assessment* 2006;13:27–45.

- 33 EuroQol Group. EuroQol—a new facility for the measurement of health-related quality of life. *Health Policy* 1990;16:199–208.
- 34 Gross JJ, John OP. Individual differences in two emotion regulation processes: implications for affect, relationships, and well-being. *J Pers Soc Psychol* 2003;85:348–362.
- 35 Peterson PN, Shetterly SM, Clarke CL, Bekelman DB, Chan PS, Allen LA, Matlock DD, Magid DJ, Masoudi FA. Health literacy and outcomes among patients with heart failure. *JAMA* 2011;305:1695–1701.
- 36 Scheier MF, Carver CS, Bridges MW. Distinguishing optimism from neuroticism (and trait anxiety, self-mastery, and self-esteem): a reevaluation of the Life Orientation Test. *J Pers Soc Psychol* 1994; 67:1063–1078.
- 37 Attkisson CC, Zwick R. The Client Satisfaction Questionnaire: psychometric properties and correlations with service utilization and psychotherapy outcome. *Eval Program Plann* 1982;5:233–237.
- 38 Knaus WA, Draper EA, Wagner DP, Zimmerman JE. APACHE II: a severity of disease classification system. *Crit Care Med* 1985;13: 818–829.
- 39 Katz S, Ford AB, Moskowitz RW, Jackson BA, Jaffe MW. Studies of illness in the aged: the index of ADL: a standardized measure of biological and physiological function. *JAMA* 1963;185:914–919.
- 40 Lawton MP, Brody EM. Assessment of older people: self-maintaining and instrumental activities of daily living. *Gerontologist* 1969;9: 179–186.
- 41 Cox CE, Porter LP, Hough CL, Hoffa M, Buck P, Greeson JG. Mindfulness based training by telephone: development and preliminary testing among survivors of critical illness and their families [abstract]. American Thoracic Society International Meeting, Philadelphia, PA, May 2013.
- 42 Bienvenu OJ, Colantuoni E, Mendez-Tellez PA, Dinglas VD, Shanholtz C, Husain N, Dennison CR, Herridge MS, Pronovost PJ, Needham DM. Depressive symptoms and impaired physical function after acute lung injury: a 2-year longitudinal study. *Am J Respir Crit Care Med* 2012;185:517–524.
- 43 Davydow DS, Gifford JM, Desai SV, Bienvenu OJ, Needham DM. Depression in general intensive care unit survivors: a systematic review. *Intensive Care Med* 2009;35:796–809.
- 44 Bienvenu OJ, Gellar J, Althouse BM, Colantuoni E, Sricharoenchai T, Mendez-Tellez PA, Shanholtz C, Dennison CR, Pronovost PJ, Needham DM. Post-traumatic stress disorder symptoms after acute lung injury: a 2-year prospective longitudinal study. *Psychol Med* 2013;43:2657–2671.
- 45 Hough CL, Curtis JR. Long-term sequelae of critical illness: memories and health-related quality of life. *Crit Care* 2005;9:145–146.
- 46 Unroe M, Kahn JM, Carson SS, Govert JA, Martinu T, Sathy SJ, Clay AS, Chia J, Gray A, Tulskey JA, et al. One-year trajectories of care and resource utilization for recipients of prolonged mechanical ventilation: a cohort study. *Ann Intern Med* 2010;153:167–175.
- 47 Iwashyna TJ. Trajectories of recovery and dysfunction after acute illness, with implications for clinical trial design. *Am J Respir Crit Care Med* 2012;186:302–304.
- 48 Woon FL, Dunn CB, Hopkins RO. Predicting cognitive sequelae in survivors of critical illness with cognitive screening tests. *Am J Respir Crit Care Med* 2012;186:333–340.
- 49 Hofmann SG, Sawyer AT, Witt AA, Oh D. The effect of mindfulness-based therapy on anxiety and depression: a meta-analytic review. *J Consult Clin Psychol* 2010;78:169–183.
- 50 Carmody J, Baer RA. How long does a mindfulness-based stress reduction program need to be? A review of class contact hours and effect sizes for psychological distress. *J Clin Psychol* 2009;65: 627–638.
- 51 Herridge M, Cox C. Linking ICU practice to long-term outcome: fostering a longitudinal vision for ICU-acquired morbidity. *Am J Respir Crit Care Med* 2012;186:299–300.
- 52 Topol EJ. The creative destruction of medicine: how the digital revolution will create better health care. New York: Basic Books; 2012.
- 53 Peek GJ, Mugford M, Tiruvoipati R, Wilson A, Allen E, Thalanany MM, Hibbert CL, Truesdale A, Clemens F, Cooper N, et al.; CESAR Trial Collaboration. Efficacy and economic assessment of conventional ventilatory support versus extracorporeal membrane oxygenation for severe adult respiratory failure (CESAR): a multicentre randomised controlled trial. *Lancet* 2009;374:1351–1363.
- 54 Abernethy AP, Ahmad A, Zafar SY, Wheeler JL, Reese JB, Lyerly HK. Electronic patient-reported data capture as a foundation of rapid learning cancer care. *Med Care* 2010;48:S32–S38.
- 55 McGrath CL, Kelley ME, Holtzheimer PE, Dunlop BW, Craighead WE, Franco AR, Craddock RC, Mayberg HS. Toward a neuroimaging treatment selection biomarker for major depressive disorder. *JAMA Psychiatry* 2013;70:821–829.